REPORT OF THE SPECIAL TASK FORCE
STUDYING THE PRACTICE OF THERAPEUTIC
INTERCHANGE

A STUDY OF THE PRACTICE OF THERAPEUTIC INTERCHANGE OF CHEMICALLY DISSIMILAR DRUGS IN VIRGINIA

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 57

COMMONWEALTH OF VIRGINIA
RICHMOND
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COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

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January 7, 1998

TO: The Honorable George Allen

and

The General Assembly of Virginia

This report contained herein is pursuant to House Joint Resolution 630, passed by the 1997 General Assembly.

I am submitting this report on behalf of the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drug Products. The report contains the discussions and recommendations of the Task Force.

Respectfully submitted,

Joseph M. Teefey, Director
Department of Medical Assistance Services

Report of the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drugs in the Commonwealth of Virginia Pursuant to HJR 630 (1997)

Submitted to the General Assembly of Virginia
by Joseph M. Teefey, Task Force Chair
on behalf of the Task Force

December 1997

AUTHORIZATION

The work of the Special Task Force Studying the Practice of Therapeutic Interchange was completed pursuant to House Joint Resolution 630 passed by the General Assembly of Virginia during its 1997 Session. The full text of HJR 630 can be found in Appendix A of this report. A summary of the provisions of HJR 630 is provided below.

RESOLUTION SUMMARY

HJR 630 established a special task force to study the practice of therapeutic interchange of chemically dissimilar drug products. The special task force was directed to:

1. State the practice of therapeutic interchange to reach consensus on its incidence and prevalence.

2. Determine the impact of the practice of therapeutic interchange on health care, the affected professions, the overall costs of health care products and services, and patients.

3. Identify the components of the cost of the practice.

The resolution defined the membership of the Task Force and directed that the Department of Medical Assistance Services provide staff support to the Task Force. The Department contracted with the Virginia Commonwealth University School of Pharmacy to facilitate the Task Force meetings and provide documentation.*

* This report was written by Dr. Michael A. Pyles of the Virginia Commonwealth University School of Pharmacy, in his role of facilitator for the Task Force under contractual arrangements with the Department, and does not contain the personal views, opinions, positions or perspectives of Dr. Pyles or the School of Pharmacy.

TASK FORCE MEMBERS

Mr. Michael J. Ayotte
Pharmacist (Richmond)
Virginia Assn. Of Chain Drug Stores

Dr. Lawrence E. Blanchard, III
Physician (Richmond)
Medical Society of Virginia

Dr. Randall E. Dalton
Physician (Richmond)
Old Dominion Medical Society

Mr. Charles E. James, Sr.
Director (Richmond)
Virginia Dept. Personnel & Training

Dr. Thomas L. Moffatt
Physician (Richmond)
Medical Society of Virginia

Ms. Cynthia J. Pigg
Pharmacist (Glen Allen)
Academy of Managed Care Pharmacy

Mr. Mark A. Szalwinski
Pharmacist (Norfolk)
Virginia Society of Health Systems Pharmacists

Mr. William A. Towler
Pharmacist (Highland Springs)
Virginia Pharmacists Association

The Honorable I. Vincent Behm, Jr.
Democrat, District 91 (Hampton)
Virginia House of Delegates

Mr. James G. Council
Attorney (Glen Allen)
Pharmaceutical Care Mgt. Assn.

Dr. Douglas R. Hadley
Physician (Glen Allen)
Virginia Association of HMOs

Dr. Karen E. Knapp
Physician (Richmond)
Virginia Board of Medicine

The Honorable Stephen D. Newman
Republican, District 23 (Lynchburg)
Senate of Virginia

Ms. Marjorie E. Powell
Attorney (Washington, DC)
Pharmaceutical & Research Mfrs. Of America

Mr. Joseph M. Teefey [Chair]
Director (Richmond)
Virginia Dept. Of Medical Assistance Services

Mr. W. Tommy Walker
Pharmacist (Lawrenceville)
Virginia Board of Pharmacy

TASK FORCE MEETINGS

The first meeting of the Special Task Force was held on June 19, 1997, in Richmond. Subsequent meetings were held on July 16, 1997, August 20, 1997, and September 17, 1997. All meetings were held in House Room D of the Virginia General Assembly Building except the September 17 meeting, which was held in House Room C. Mr. Joseph M. Teefey, Director of the Department of Medical Assistance Services, and a member of the Task Force, served as chair of the Task Force and presided over all of its meetings.

Agendas and transcripts for each meeting can be found in Appendices B and C, respectively. Each meeting included a public comment period so that Task Force members could hear from interested parties concerning the practice of therapeutic interchange of chemically dissimilar drugs.

In an effort to ensure that Task Force members had access to as much pertinent information as possible, and to ensure that they would be able to make informed decisions concerning the practice of therapeutic interchange of chemically dissimilar drugs in the Commonwealth, several speakers were invited to make presentations and give comments on the topic.

INVITED SPEAKERS

Kenneth D. McArthur, Jr., Esq.
Durrette, Irvin, Bradshaw, P.C.
Richmond

Mr. McArthur's firm represents independent pharmacies throughout the Commonwealth of Virginia. In his remarks, Mr. McArthur noted that there are some very important issues that the Task Force needs to consider. He identified himself as one of the drafters of the failed Bill that was introduced last year to outlaw the practice of switching chemically dissimilar drugs where a monetary incentive is present. Mr. McArthur urged the Task Force to look at hard evidence produced by all interested parties and to make an informed decision on that basis.

Stephen Rosenthal, Esq.
Mays and Valentine
Richmond

According to Mr. Rosenthal, he was speaking on behalf of a large coalition that was involved in the previous legislation that generated this study and the Task Force. Mr. Rosenthal advised the Task Force to look closely at what is happening today in the health care market and warned them that anecdotal evidence was not sufficient to warrant any large scale, legislative action. Like Mr. McArthur, Mr. Rosenthal urged the Task Force to consider the facts and data presented by the staff and interested parties and identify whether there are any specific aspects of the practice that pose a risk to the public and, if so, to determine if the practice outweighs any associated benefits to the public.

Mr. David Shepherd, R.Ph.
DMAS, Pharmacy Supervisor
Richmond

Mr. Shepherd served as staff to the Task Force and was asked to give an overview of the Virginia Medicaid Pharmacy Program. Mr. Shepherd noted that prescribed drugs are among the 35 services available to eligible Medicaid recipients and one of 19 optional services provided by the program. According to Mr. Shepherd, prescribed drugs have been a part of Virginia's Medicaid

Program since its inception. In his overview Mr. Shepherd advised the Task Force that the operation of Virginia's Medicaid Program, and the prescription drug benefit, are under the oversight of the federal Health Care Financing Administration. Mr. Shepherd provided a great deal of information about the program and how it operates in the Commonwealth of Virginia.

Carol Pugh, Pharm.D.
Virginia Commonwealth University, School of Pharmacy
Richmond

Dr. Pugh was invited to share information about drug utilization review within DMAS. In her remarks Dr. Pugh informed the Task Force that she was a DUR consultant working under an Inter-agency Agreement between DMAS and Virginia Commonwealth University from January 1992 through January 1995. According to Dr. Pugh, DMAS is currently performing DUR using the program that she developed and implemented. Virginia's DUR program has both retrospective and prospective components and allows DMAS to monitor service utilization under its prescription drug program. Dr. Pugh noted that DUR is required by the federal government and that Virginia actually implemented its program before the required date.

Mr. Michael Worthington
Agency Management Lead Analyst, DMAS
Richmond

Mr. Worthington served as staff to the Task Force and provided a summary of the literature pertaining to therapeutic substitution and therapeutic interchange. Mr. Worthington acknowledged the assistance of Ms. Julie Sisler, who was a summer research fellow in the School of Pharmacy at VCU, in conducting the review of the literature. In his remarks, Mr. Worthington defined two key terms that are relevant to the work of the Task Force: Therapeutic Substitution and Therapeutic Interchange. In the case of the former, no physician approval is sought as opposed to the latter where the physician's approval is sought.

Norman V. Carroll, Ph.D.
Virginia Commonwealth University, School of Pharmacy
Richmond

Dr. Carroll was asked to share some of his insight regarding the practice of therapeutic interchange. Dr. Carroll is a professor of Pharmacy Administration in the School of Pharmacy at VCU and has conducted research in this area. In his opening remarks Dr. Carroll advised the Task Force that he was speaking as a researcher and individual and not as an official representative of VCU's School of Pharmacy. Dr. Carroll stated that there is a lack of empirical research on therapeutic interchange, specifically on drug switching. He cited three reasons for the situation: 1) a pharmacy regulation preventing pharmacists from sharing patient data with any one other than the physician or the pharmacist, 2) the common practice of PBMs and managed care organizations of making pharmacists sign confidentiality statements, and 3) a reluctance on the part of a lot of pharmacists and physicians to do anything which they think might antagonize or might criticize managed care organizations.

Howard Casway, Esq.
Asst. Attorney General
Richmond

Ms. Scotti Russell, R.Ph.
Virginia Board of Pharmacy
Richmond

Mr. Casway and Ms. Russell were invited to answer specific questions related to the practice of pharmacy in the Commonwealth raised by Task Force members. They provided answers and responses to questions such as "What are other states doing with regard to therapeutic interchange?", "Does state law prohibit the practice of therapeutic interchange/substitution?", "Does state law say anything about switching drugs based on rebates?", and "Does the Virginia Board of Pharmacy have the statutory or regulatory authority to regulate the practice of therapeutic interchange/substitution?"; among others. Mr. Casway and Ms. Russell assisted the Task Force in understanding the scope of practice of pharmacists in the Commonwealth and the extent to which the Board of Pharmacy has oversight for pharmacists and pharmacies. Ms. Russell, in a later presentation, also shared with the Task Force some of the legislative actions that the Board of Pharmacy will be pursuing during the 1998 session of the General Assembly.

DISCUSSION

The Task Force believed that it was very important to clearly define the term "therapeutic interchange of chemically dissimilar drugs." The following definition was unanimously adopted by the Task Force on August 20, 1997.

> **Therapeutic interchange is the dispensing of a drug, by any person authorized by law to dispense drugs, that is a chemically dissimilar alternative for the drug initially prescribed. The alternative drug is expected to have the same clinical results and similar safety profile, when administered to patients in therapeutically equivalent doses, as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug, or their lawful designee.**

The adoption of this definition was crucial to the work of the Task Force as it attempted to describe the practice of therapeutic interchange of chemically dissimilar drugs and identify the impact of the practice in the Commonwealth. Prior to the adoption of this definition, the Task Force had an in depth discussion centering around this issue.

Two important questions emerged from Task Force deliberations.

1) Is the practice of therapeutic interchange harmful to Virginia residents?

2) How many Virginians are affected by this practice?

Is therapeutic interchange harmful?

The first question was addressed by interested parties representing two points of view. Interested parties who expressed concern that the practice is harmful and dangerous articulated the first point of view. Many of the comments made by speakers holding this point of view called attention to a piece of legislation that failed during the 1997 session of the Virginia General Assembly (SB 1114, see Appendix A) which sought to outlaw the practice of Drug Switching in the Commonwealth. The consensus of those persons holding this point of view is that the practice of therapeutic interchange is indeed harmful and dangerous and that we do not have sufficient empirical data to suggest otherwise

The other point of view contends that accounts of the harmful and dangerous nature of the practice are inaccurate and rely solely on anecdotal evidence. The consensus of persons holding this point of view is that the practice must be allowed to continue because it makes good economic sense and any attempt to make the practice unlawful in Virginia, or otherwise restrict it, would result in substantial increases in health care costs for the residents of the Commonwealth as well as employers whose health care benefits include prescription drug coverage.

How many Virginians are affected by therapeutic interchange?

In an attempt to understand the potential impact of this practice in the Commonwealth, a Task Force member raised the question on the number of Virginians affected by the practice. The Task Force staff concluded that there is no exact answer to this question. At best, the number of Virginians covered by prescription benefit programs could only be estimated, since such data are not routinely or uniformly collected and reported. The staff estimates that over 5,000,000 Virginians are covered by such plans. Current population data indicate that 87% of Virginia's population is covered by health insurance. National health insurance data indicate that between 42% and 94% of persons who are covered by a health plan have coverage for their prescription drugs under those plans.

One issue that engendered a lengthy discussion by the Task Force was the statutory and regulatory authority of the Board of Pharmacy to oversee out-of-state pharmacies. Members of the Task Force raised questions about the dispensing of prescription drugs to Virginia residents by pharmacies operating in other states, especially by means of mail order. According to information that it received, the Task Force acknowledges that the Virginia Board of Pharmacy has limited regulatory authority over these out-of-state pharmacies and their dispensing operations.

CONCLUSIONS

The chair of the Task Force solicited policy options and recommendations from Task Force members and interested parties regarding the practice of therapeutic interchange of chemically dissimilar drugs in the Commonwealth. During the last meeting of the Task Force, members heard from the Executive Director of the Board of Pharmacy and considered policy options from a Task Force member and interested parties.

In the course of its deliberations, the Task Force came to the conclusion that additional information is needed before any specific recommendations regarding the practice of therapeutic interchange can be made. Although an abundance of information was disseminated to Task Force members, and despite the impassioned testimony of invited speakers and interested parties on both sides, it is the collective opinion of the Task Force that final recommendations about the practice of therapeutic interchange of chemically dissimilar drugs in the Commonwealth of Virginia be deferred.

RECOMMENDATIONS

After a lengthy discussion, and in light of its deliberations, the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drugs made the following recommendations.

1. The addition of the following to the *Code of Virginia*, §54.1-3434.4, as subsection B thereof.

   It is unlawful for any nonresident pharmacy to dispense a drug that is chemically dissimilar from the drug initially prescribed without the approval of the prescriber or his lawful designee.

   This is a part of a policy option submitted by Matthew Jenkins in a letter to Mr. Joseph M. Teefey dated September 12, 1997.

2. The introduction of a joint resolution during the 1998 session of the General Assembly to continue the Task Force for another year so that the Task Force will have the opportunity to consider the findings of a study to be performed by the Virginia Commonwealth University School of Pharmacy pursuant to House Joint Resolution 574 from the 1997 session of the General Assembly.

   These recommendations were adopted by a unanimous vote of the Task Force.

APPENDIX A

BILLS AND RESOLUTIONS (1997)

House Joint Resolution 630
House Joint Resolution 574
Senate Bill 1114
House Bill 2714

HOUSE JOINT RESOLUTION NO. 630

Establishing a special task force to study the practice of therapeutic interchange of chemically dissimilar drug products.

Agreed to by the House of Delegates, February 22, 1997
Agreed to by the Senate, February 22, 1997

WHEREAS, issues have arisen regarding the practice of therapeutic interchange of chemically dissimilar drug products; and

WHEREAS, legislation has been proposed addressing this practice; and

WHEREAS, whether or not the legislation is enacted, further study of this practice is desirable; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That a special task force be established to study the practice of therapeutic interchange of chemically dissimilar drug products. During the course of this study, the special task force shall examine all aspects and effects of the practice of therapeutic interchange of chemically dissimilar drug products throughout the health care delivery system, including, but not limited to, its impact on health care, the affected professions, the overall costs of health care products and services, and patients.

The special task force shall be composed of 16 members, as follows: 1 member of the House of Delegates; 1 physician, upon the recommendation of the Old Dominion Medical Society; 1 practicing pharmacist, upon the recommendation of the Virginia Association of Chain Drug Stores; 1 representati of a manufacturer of brand name prescription drug products, which does not own a Pharmacy Benefits Manager (PBM) or have a strategic alliance with a PBM, upon the recommendation of the Pharmaceutical Research and Manufacturers Association; 1 pharmacist, upon the recommendation of the Virginia Society of Health System Pharmacists; and 1 representative of a health maintenance organization, upon the recommendation of the Virginia Association of Health Maintenance Organizations, all to be appointed by the Speaker of the House; 1 member of the Senate; 2 licensed physicians, upon the recommendation of the Medical Society of Virginia; 1 practicing independent pharmacist, upon the recommendation of the Virginia Pharmacists Association; 1 pharmacist, upon the recommendation of the Academy of Managed Care Pharmacy; and 1 representative of a PBM, upon the recommendation of the Pharmaceutical Care Management Association, all to be appointed by the Senate Committee on Privileges and Elections; the Director of the Department of Medical Assistance Services; the Director of the Department of Personnel and Training; and 1 representative of the Board of Pharmacy, upon the recommendation of the Executive Director of the Board of Pharmacy, to be appointed by the Speaker of the House; and 1 representative of the Board of Medicine, upon the recommendation of the Executive Director of the Board of Medicine, to be appointed by the Senate Committee on Privileges and Elections, both to serve ex officio without voting privileges. Nonlegislative members shall serve in a voluntary capacity and shall not be entitled to compensation or reimbursement for their expenses for participation in this study.

The Department of Medical Assistance Services shall provide staff support for the study. Technical assistance shall be provided to the special task force by the Board of Medicine and the Board of Pharmacy.

All agencies of the Commonwealth shall provide assistance to the special task force for this study, upon request.

The special task force shall complete its work in time to submit its findings and recommendations to the Governor and the 1998 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

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HOUSE JOINT RESOLUTION NO. 574

Requesting the Department of Medical Assistance Services to examine the impact of the practices of pharmacy benefits manager firms on the Commonwealth's citizens and upon the health care market.

Agreed to by the House of Delegates, February 20, 1997
Agreed to by the Senate, February 19, 1997

WHEREAS, as the health insurance industry reconfigures and managed care programs become pervasive, the effects on patient care and small businesses delivering health services are far-reaching; and

WHEREAS, a recent development in managed care approaches is the implementation of or contracting for pharmacy benefits management; and

WHEREAS, pharmacy services are essential to the well-being of many elderly and disabled persons for the maintenance of their health; and

WHEREAS, appropriate pharmacy services can prevent hospital admissions and the need for emergency care -- expensive services placing greater demands on society's resources; and

WHEREAS, the present management techniques practiced by some pharmacy benefits managers may interfere in the statutorily required physician-patient-pharmacist relationship; and

WHEREAS, personal consultation and direct knowledge of the patient's conditions and medications are an important part of handling many chronic conditions; and

WHEREAS, so-called "desk audits" are allegedly being conducted many months after the dispensing of prescriptions; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Medical Assistance Services be requested to examine the practices of pharmacy benefits manager firms on the Commonwealth's citizens and upon the health care market. In conducting its study, the Department shall coordinate its efforts with any similar studies undertaken during the interim by the Department or by other state entities. In addition, the Department shall solicit input from such experts and interested parties as may be appointed to a special task force established pursuant to House Joint Resolution No. 630 (1997), relating to the practice of therapeutic interchange.

Technical assistance shall be provided by the Bureau of Insurance within the Virginia State Corporation Commission. All agencies of the Commonwealth shall provide assistance to the Department for this study, upon request.

The Department of Medical Assistance Services shall complete its work in time to submit its findings and recommendations to the Governor and the 1999 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

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HOUSE BILL NO. 2714

Offered January 20, 1997

A BILL to amend the Code of Virginia by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, relating to the Virginia Anti-Drug Switching Patient Protection Act; penalties.

Patrons-- Davies, Baker, Bloxom, Cooper, Councill, Cranwell, Crouch, Dickinson, Hall, Hargrove, Jackson, Johnson, Keating, McEachin, Melvin, Moran, Morgan, Nelms, Orrock, Plum, Spruill, Stump, Tate, Van Yahres, Wagner and Woodrum; Senators: Couric, Edwards, Gartlan, Hawkins and Trumbo

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Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, as follows:

CHAPTER 34.1.
VIRGINIA ANTI-DRUG SWITCHING PATIENT PROTECTION ACT.

§54.1-3480. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Advertisement" means a representation disseminated in any manner or means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of a prescription drug. The term does not include any act prohibited by the chapter.

"Attorney" means the Attorney General of Virginia, and the attorney for any city, county or town.

"Caregiver" means (i) a parent or guardian of a minor patient, (ii) a relative, close friend or employee of a patient who provides in-person physical assistance to the patient, or (iii) a person employed by another to care for a patient who provides in-person physical assistance to the patient.

"Chemically dissimilar" means a prescription drug which possesses one or more active ingredients that are different from those of another prescription drug.

"Deliver" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Dispense" or "dispensing" means to deliver a prescription drug to a patient by or pursuant to the lawful order of a prescribing practitioner.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or

prevention of disease in an individual; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of an individual; or (iv) articles or substances intended for use as a component of any article specified in (i), (ii), or (iii). "Drug" does not include devices or their components, parts or accessories.

"Employer" means a person who provides monetary or other compensation to another person for goods or services, whether the one receiving monetary or other compensation is an employee, agent, partner, independent contractor or other.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means or chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Manufacturer" means any person who manufactures and all agents of that person.

"Monetary incentive" means any rebate, discount, kick-back, fee, special charge or other financial incentive received directly or indirectly from a manufacturer.

"Patient" means an ultimate consumer of a prescription drug who obtains the prescription drug from a licensed pharmacist or practitioner who is authorized by law to prescribe or dispense prescription drugs.

"Pharmacists" means a person duly licensed by the Virginia Board of Pharmacy to practice pharmacy or a person duly licensed by any other state or U.S. territory to practice pharmacy.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, dentist, osteopath, podiatrist, nurse practitioner, TPA-certified optometrist, or physician's assistant.

"Prescribing practitioner" means a practitioner who (i) prescribes a prescription drug for a patient and (ii) is authorized by applicable law to prescribe or administer such drugs.

"Prescription drug" or "prescribed drug" means any drug required by federal law of regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the Federal Food, Drug, and Cosmetic Act.

"Sells" or "selling" includes barter, exchange, transfer, or gift, or offer therefor.

§54.1-3481. Exceptions to applicability of chapter; no exemption from other provisions of title.

A. The provisions of this chapter shall not apply to any prescription drug prescribed by a scientific investigator for purposes of research or prescribed by a veterinarian. Where the solicitation or encouragement prohibited herein is directed to a practitioner, this chapter shall only apply to a solicitation or encouragement where the practitioner has a bona fide practitioner-patient relationship with a specific patient for whom a specific drug has been prescribed from which a substitution is sought.

B. This chapter shall not be construed as exempting any person from the requirements of Chapter 33

(§54.1-3300 et seq.) or Chapter 34 (§54.1-3400 et seq.) of this title.

§54.1-3482. Unlawful actions.

A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug which the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug, unless the person is the patient, another practitioner, or a caregiver of the patient. The foregoing shall in no way limit the ability of any person to contact a patient's prescribing practitioner to warn of a contraindication, precaution or adverse reaction

B. No practitioner shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug where a purpose of the substitution is to assist the practitioner, or an employer of the practitioner, in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

C. No pharmacist shall sell or dispense a prescription drug to a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, if the pharmacist possesses actual knowledge that (i) a person solicited or encouraged the patient's prescribing practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug, and (ii) that a purpose of the substitution is to assist such person or any employer of that person in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

D. No person shall solicit or encourage (i) a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, (ii) a caregiver of the patient, or (iii) a practitioner of the patient to request the patient's prescribing practitioner to substitute a prescription drug the prescribing practitioner originally prescribed with a chemically dissimilar prescription drug where a purpose of the substitution is to assist such person or an employer of that person in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

§54.1-3483. Presumption of violation.

For purposes of this chapter, where a person or a person's employer receives a monetary incentive from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar, it shall be presumed to be a violation of this chapter.

§54.1-3484. Violators entitled to bring suit.

A. Any person entitled to bring an action pursuant to this chapter as set forth herein may do so regardless of whether that person has violated a provision of this chapter himself.

B. Any practitioner who violates any provision of this chapter shall pay for each violation a civil penalty of not more than ten dollars, plus attorney fees and costs. However, if a practitioner or his employer receives in violation of this chapter any monetary incentive from another person for his assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed i. violation of this chapter, each practitioner or employer shall pay a civil penalty of not more than $100, plus attorney fees and costs. Any person other than a practitioner who violates any provision of this chapter shall, for each violation, pay a civil penalty of not more than $5,000, plus attorney fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person and shall be paid into the Literary Fund.

C. Notwithstanding any other provisions of law to the contrary, the attorney may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, the city, county, or town, the Virginia Board of Pharmacy, or the Virginia Board of Medicine, respectively, to enjoin any violation of this chapter, to impose civil penalties as prescribed herein and to recover reasonable attorney fees and costs. Any circuit court having jurisdiction is authorized to issue temporary and permanent injunctions to restrain and prevent violations of this chapter notwithstanding the existence of an adequate remedy at law. In any action under this chapter, it shall not be necessary that damages be proven.

§54.1-3485. Investigative orders.

A. Whenever the attorney has reasonable cause to believe that any person has engaged in, or is engaging in, or is about to engage in any violation of this chapter, the attorney, if after making a good faith effort to obtain such information, is unable to obtain the data and information necessary to determine whether such violation has occurred, or believes that it is impractical for him to do so, he may apply to the circuit court within whose jurisdiction the person having the information resides, the person has a principal place of business in the Commonwealth, or where any part of the alleged violation occurred in the Commonwealth, which includes without limitation, the jurisdiction of the practitioner's place of business, the jurisdiction in which the patient resides, and the jurisdiction in which the patient's caregiver resides, for an investigative order requiring such person to furnish to the attorney such data and information as is relevant to the subject matter of the investigation.

B. The circuit courts are empowered to issue investigative orders, authorizing discovery by the same methods and procedures as set forth for civil actions in the Rules of the Supreme Court of Virginia, in connection with investigations of violations of this chapter by the attorney. An application for an investigative order shall identify:

1. The specific act or practice alleged to be in violation of this chapter;

2. The grounds which shall demonstrate reasonable cause to believe that a violation of this chapter may have occurred, may be occurring, or may be about to occur;

3. The category or class of data or information requested in the investigative order; and

4. The reasons why the attorney is unable to obtain such data and information, or the reason why it is impractical to do so, without a court order.

C. Within twenty-one days after the service upon a person of an investigative order, or at any time before the return date specified in such order, whichever is later, such person may file a motion to modify or set aside such investigative order or to seek a protective order as provided by the Rules of th.

Supreme Court of Virginia. Such motion shall specify the grounds for modifying or setting aside the order, and may be based upon the failure of the application or the order to comply with the requirements of this chapter, or upon any constitutional or other legal basis or privilege of such person.

D. Where the information requested by an investigative order may be derived or ascertained from the business records of the person upon whom the order is served, or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the information is substantially the same for the attorney as for the person from whom such information is requested, it shall be sufficient for that person to specify the records from which the requested information may be derived or ascertained, and to afford the attorney reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries thereof.

E. It shall be the duty of the attorney, his assistants, employees and agents, to maintain the secrecy of all evidence, documents, data and information obtained through the use of investigative orders or obtained as a result of the voluntary act of the person under investigations and it shall be unlawful for any person participating in such investigations to disclose to any other person not participating in such investigation any information so obtained. Any person violating this subsection shall be subject to a civil penalty not to exceed $25,000 and contempt of court. Notwithstanding the foregoing, this section shall not preclude the presentation and disclosure of any information obtained pursuant to this section in any suit or action in any court of this Commonwealth wherein it is alleged that a violation of this chapter has occurred, is occurring or may occur, nor shall this section prevent the disclosure of any such information by the attorney to any federal or state law-enforcement authority that has restrictions governing confidentiality and the use of such information similar to those contained in this subsection.

F. Upon the failure of a person without lawful excuse to obey an investigative order under this section, the attorney may initiate contempt proceedings in the circuit court that issued the order to hold such person in contempt.

G. No information, facts or data obtained through an investigative order shall be admissible in any civil or criminal proceedings other than for the enforcement of this chapter and the remedies provided herein.

§54.1-3486. Tolling of limitation.

When any of the authorized government agencies file suit under this chapter, the time during which such governmental suit and all appeals therefrom are pending shall not be counted as any part of the period within which a private cause of action under this chapter shall be brought.

§54.1-3487. Individual action for damages or penalty; statute of limitations.

A. If a person who is not a practitioner solicits or encourages a patient, a caregiver of the patient or a practitioner of the patient in violation of any provision of this chapter or if a person who is not a practitioner violates any other provision of this chapter, the patient shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter.

B. If any practitioner solicits or encourages a patient in violation of any provision of this chapter or if

any practitioner violates any other provision of this chapter, the patient shall be entitled to initiate an action against such practitioner to recover actual damages, if any, or liquidated damages of ten dollars per violation whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter; however, if the practitioner or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the patient may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

C. Any caregiver or practitioner who is solicited or encouraged in violation of any provision of this chapter by a person who is not a practitioner shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs.

D. Any caregiver or practitioner who is solicited or encouraged in violation of any provision of this chapter by a practitioner shall be entitled to initiate an action against such practitioner to recover actual damages, if any, or liquidated damages of ten dollars per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs; however, if the practitioner or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the caregiver or practitioner may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

E. Except as provided in §54.1-3486, any claim arising under this chapter shall be brought within tw years of the wrongful act or discovery of the act, whichever is later.

Go to (General Assembly Home)

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SENATE BILL NO. 1114
AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Education and Health
on January 30, 1997)
(Patron Prior to Substitute--Senator Hawkins)

A BILL to amend the Code of Virginia by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, relating to the Virginia Anti-Drug Switching Patient Protection Act; penalties.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, as follows:

CHAPTER 34.1.
VIRGINIA ANTI-DRUG SWITCHING PATIENT PROTECTION ACT.

§54.1-3480. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Advertisement" means a representation disseminated in any manner or means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of a prescription drug. The term does not include any act prohibited by the chapter.

"Caregiver" means (i) a parent or guardian of a minor patient, (ii) a relative, close friend or employee of a patient who provides in-person physical assistance to the patient, or (iii) a person employed by another to care for a patient who provides in-person physical assistance to the patient.

"Chemically dissimilar" means a prescription drug which possesses one or more active ingredients that are different from those of another prescription drug.

"Deliver" means the actual, constructive, or attempted transfer of any item regulated by Chapter 34 of this title, whether or not there exists an agency relationship.

"Dispense" or "dispensing" means to deliver a prescription drug to a patient by or pursuant to the lawful order of a prescribing practitioner.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in an individual; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of an individual; or (iv) articles or substances intended for use as a component of any article specified in (i), (ii), or (iii). "Drug" does not include devices or their components, parts or accessories.

"Employer" means a person who provides monetary or other compensation to another person for goods or services, whether the one receiving monetary or other compensation is an employee, agent, partner,

independent contractor or other.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by Chapter 34 of this title, either directly or indirectly by extraction from substances of natural origin, or independently by means or chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Manufacturer" means any person who manufactures and all agents of that person.

"Monetary incentive" means any rebate, discount, kick-back, fee, special charge or other financial incentive.

"Patient" means an ultimate consumer of a prescription drug who obtains the prescription drug from a licensed pharmacist or practitioner who is authorized by law to prescribe or dispense prescription drugs.

"Person" means any individual, corporation, partnership, association, company, business, trust, joint venture, governmental agency, or other institution or legal entity.

"Pharmacist" means a person duly licensed by the Virginia Board of Pharmacy to practice pharmacy or a person duly licensed by any other state or U.S. territory to practice pharmacy.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, dentist, osteopath, podiatrist, nurse practitioner, TPA-certified optometrist, or physician's assistant.

"Prescribing practitioner" means a practitioner who (i) prescribes a prescription drug for a patient and (ii) is authorized by applicable law to prescribe or administer such drugs.

"Prescription drug" means any drug required by federal law of regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the Federal Food, Drug, and Cosmetic Act.

"Sells" or "selling" includes barter, exchange, transfer, or gift, or offer therefor.

§54.1-3481. Exceptions to applicability of chapter; no exemption from other provisions of title; advertisements.

A. The provisions of this chapter shall not apply to any prescription drug prescribed by a scientific investigator for purposes of research or prescribed by a veterinarian. Where the solicitation or encouragement prohibited herein is directed to a practitioner or pharmacist, this chapter shall only apply to a solicitation or encouragement where the practitioner or pharmacist has a bona fide practitioner-patient or pharmacist-patient relationship with a specific patient for whom a specific drug has been prescribed from which a substitution is sought.

B. This chapter shall not be construed as exempting any person from the requirements of Chapter 33 (§54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.) of this title.

C. The provisions of this chapter shall have no application to advertisements for prescription drugs.

D. The provisions of this chapter shall also not apply to: (i) the Department of Medical Assistance Services, (ii) any health care provider while rendering services pursuant to a provider agreement with the Department of Medical Assistance Services, and (iii) any program implemented by the Department of Medical Assistance Services through a contract with an insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical, and surgical or major medical coverage on an expense-incurred basis, any corporation providing individual or group accident and sickness subscription contracts, and any health maintenance organization providing a health care plan for health care services.

§54.1-3482. Unlawful actions.

A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug which the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug, unless the person is the patient, another practitioner or pharmacist, or a caregiver of the patient. The foregoing shall in no way limit the ability of any person to contact a patient's prescribing practitioner to warn of a contraindication, precaution or adverse reaction.

B. No practitioner or pharmacist shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug where a purpose of the substitution is to assist the practitioner or pharmacist, or an employer of the practitioner or pharmacist, in receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

C. No pharmacist shall sell or dispense a prescription drug to a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, if the pharmacist possesses actual knowledge that (i) a person solicited or encouraged the patient's prescribing practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug, and (ii) that a purpose of the substitution is to assist such person or any employer of that person in receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

D. No person shall solicit or encourage (i) a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, (ii) a caregiver of the patient, (iii) a pharmacist of the patient or (iv) a practitioner of the patient to request the patient's prescribing practitioner to substitute a prescription drug the prescribing practitioner originally prescribed with a chemically dissimilar prescription drug where a purpose of the substitution is to assist such person or an employer of that person in receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

§54.1-3483. Presumption of violation.

For purposes of this chapter, where a person or a person's employer receives a monetary incentive from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the plac of another prescription drug which is chemically dissimilar, it shall be presumed to be a violation of this chapter.

§54.1-3484. Violators entitled to bring suit; civil penalties.

A. Any person entitled to bring an action pursuant to this chapter as set forth herein may do so regardless of whether that person has violated a provision of this chapter himself.

B. Any practitioner or pharmacist who violates any provision of this chapter shall pay for each violation a civil penalty of not more than ten dollars, plus attorney fees and costs. However, if a practitioner or his employer or pharmacist or his employer receives in violation of this chapter any monetary incentive from another person for his assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed in violation of this chapter, the practitioner or pharmacist shall pay a civil penalty of not more than $100, plus attorney fees and costs. Any person other than a practitioner or pharmacist who violates any provision of this chapter shall, for each violation, pay a civil penalty of not more than $5,000, plus attorney fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person and shall be paid into the Literary Fund.

C. Notwithstanding any other provisions of law to the contrary, the Attorney General or the attorney for any city, county or town may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, the city, county, or town, the Virginia Board of Pharmacy, or the Virginia Board of Medicine, respectively, to enjoin any violation of this chapter, to impose civil penalties as prescribed herein and to recover reasonable attorney fees and costs. Any circuit court having jurisdiction is authorized to issue temporary and permanent injunctions to restrain and prevent violations of this chapter notwithstanding the existence of an adequate remedy at law. In any action under this chapter, it shall not be necessary that damages be proven.

§54.1-3485. Investigative orders.

A. Whenever the Attorney General or the attorney for any city, county or town has reasonable cause to believe that any person has engaged in, or is engaging in, or is about to engage in any violation of this chapter, the attorney, if after making a good faith effort to obtain such information, is unable to obtain the data and information necessary to determine whether such violation has occurred, or believes that it is impractical for him to do so, he may apply to the circuit court within whose jurisdiction the person having the information resides, the person has a principal place of business in the Commonwealth, or where any part of the alleged violation occurred in the Commonwealth, which includes without limitation, the jurisdiction of the practitioner's or pharmcist's place of business, the jurisdiction in which the patient resides, and the jurisdiction in which the patient's caregiver resides, for an investigative order requiring such person to furnish to the attorney such data and information as is relevant to the subject matter of the investigation.

B. The circuit courts are empowered to issue investigative orders, authorizing discovery by the same methods and procedures as set forth for civil actions in the Rules of the Supreme Court of Virginia, in connection with investigations of violations of this chapter by the Attorney General or the attorney for any city, county or town. An application for an investigative order shall identify:

1. The specific act or practice alleged to be in violation of this chapter;

2. The grounds which shall demonstrate reasonable cause to believe that a violation of this chapter may have occurred, may be occurring, or may be about to occur;

3. The category or class of data or information requested in the investigative order; and

4. The reasons why the Attorney General or the attorney for any city, county or town is unable to obtain such data and information, or the reason why it is impractical to do so, without a court order.

C. Within twenty-one days after the service upon a person of an investigative order, or at any time before the return date specified in such order, whichever is later, such person may file a motion to modify or set aside such investigative order or to seek a protective order as provided by the Rules of the Supreme Court of Virginia. Such motion shall specify the grounds for modifying or setting aside the order, and may be based upon the failure of the application or the order to comply with the requirements of this chapter, or upon any constitutional or other legal basis or privilege of such person.

D. Where the information requested by an investigative order may be derived or ascertained from the business records of the person upon whom the order is served, or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the information is substantially the same for the Attorney General or the attorney for any city, county, or town as for the person from whom such information is requested, it shall be sufficient for that person to specify the records from which the requested information may be derived or ascertained, and to afford the Attorney General or the attorney for any city, county, or town reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries thereof.

E. It shall be the duty of the Attorney General or the attorney for any city, county or town, his assistants, employees and agents, to maintain the secrecy of all evidence, documents, data and information obtained through the use of investigative orders or obtained as a result of the voluntary act of the person under investigations and it shall be unlawful for any person participating in such investigations to disclose to any other person not participating in such investigation any information so obtained. Any person violating this subsection shall be subject to a civil penalty not to exceed $25,000 and contempt of court. Notwithstanding the foregoing, this section shall not preclude the presentation and disclosure of any information obtained pursuant to this section in any suit or action in any court of this Commonwealth wherein it is alleged that a violation of this chapter has occurred, is occurring or may occur, nor shall this section prevent the disclosure of any such information by the Attorney General or the attorney for any city, county or town to any federal or state law-enforcement authority that has restrictions governing confidentiality and the use of such information similar to those contained in this subsection.

F. Upon the failure of a person without lawful excuse to obey an investigative order under this section, the Attorney General or the attorney for any city, county or town may initiate contempt proceedings in the circuit court that issued the order to hold such person in contempt.

G. No information, facts or data obtained through an investigative order shall be admissible in any civil or criminal proceedings other than for the enforcement of this chapter and the remedies provided herein.

§54.1-3486. Tolling of limitation.

When any of the authorized government agencies file suit under this chapter, the time during which such governmental suit and all appeals therefrom are pending shall not be counted as any part of the period within which a private cause of action under this chapter shall be brought.

§54.1-3487. Individual action for damages or penalty; statute of limitations.

A. If a person who is not a practitioner or pharmacist solicits or encourages a patient, a caregiver of the patient, a practitioner of the patient, or pharmacist of the patient, in violation of any provision of this chapter or if a person who is not a practitioner or pharmacist violates any other provision of this chapter, the patient shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter.

B. If any practitioner or pharmacist solicits or encourages a patient in violation of any provision of this chapter or if any practitioner or pharmacist violates any other provision of this chapter, the patient shall be entitled to initiate an action against such practitioner or pharmacist to recover actual damages, if any, or liquidated damages of ten dollars per violation whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter; however, if the practitioner or his employer or the pharmacist or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the patient may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

C. Any caregiver, practitioner or pharmacist who is solicited or encouraged in violation of any provision of this chapter by a person who is not a practitioner or pharmacist shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs.

D. Any caregiver, practitioner or pharmacist who is solicited or encouraged in violation of any provision of this chapter by a practitioner or pharmacist shall be entitled to initiate an action against such practitioner or pharmacist to recover actual damages, if any, or liquidated damages of ten dollars per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs; however, if the practitioner or his employer or the pharmacist or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the caregiver, practitioner or pharmacist may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

E. Except as provided in §54.1-3486, any claim arising under this chapter shall be brought within two years of the wrongful act or discovery of the act, whichever is later.

APPENDIX B

TASK FORCE MEETING AGENDAS

HJR 630 SPECIAL TASK FORCE

Initial Meeting

Thursday, June 19, 1997
House Room D

9:30 - 11:30 a.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Introductions and Statement of Purpose ..... **Mr. Joseph M. Teefey**

Task Force Operations ..... **Dr. Michael A. Pyles**
Task Force Facilitator

- **Membership Roster**
- **Meeting Schedule**

Presentations on Therapeutic Substitution (30 minutes each)

Mr. Kenneth D. McArthur, Jr.
Associate
Durrette, Irvin, Bradshaw, PC
Richmond, Virginia

Mr. Stephen D. Rosenthal
Partner
Mays & Valentine
Richmond, Virginia

Discussion ..... **Task Force Members**

Adjournment

HJR 630 SPECIAL TASK FORCE

Second Meeting

Wednesday, July 16, 1997
House Room D

8:30 a.m. - 12:30 p.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Public Comments ..... **Mr. Joseph M. Teefey**

Overview of Virginia Medicaid Pharmacy Program ..... **Mr. David Shepherd, R.Ph.**
DMAS Pharmacy Supervisor

Overview of Drug Utilization ..... **Carol Pugh, Pharm.D.**
Assoc. Prof., VCU School of Pharmacy

BREAK

Summary of Literature ..... **Mr. Michael Worthington**
DMAS Lead Management Analyst

Comments on Availability of Empirical Data on Drug Switching ..... **Norman Carroll, Ph.D.**
Professor, VCU School of Pharmacy

Review of Materials Sent to Task Force ..... **Mr. Kenneth McArthur, Esq.**
Durrette, Irvin, Bradshaw, PC

Mr. Stephen Rosenthal, Esq.
Mays & Valentine

Discussion of Drug Switching ..... **Mr. Michael Worthington**

Development of Task Force Consensus Statement on Drug Switching ..... **Dr. Michael A. Pyles**
Task Force Facilitator

Adjournment

HJR 630 SPECIAL TASK FORCE

Third Meeting

Wednesday, August 20, 1997
House Room D

8:30 a.m. - 12:30 p.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Review of Materials & Update ..... **Dr. Michael A. Pyles**
Task Force Facilitator

Public Comments ..... **Mr. Joseph M. Teefey**

Responses to Questions Raised
in July 16th Meeting ..... **Mr. Michael Worthington**
Lead Agency Management Analyst
Department of Medical Assistance Services

Mr. Howard Casway
Assistant Attorney General
Commonwealth of Virginia

Ms. Scotti Russell
Executive Director
Virginia Board of Pharmacy

Discussion and Adoption of
Consensus Statement ..... **Dr. Michael A. Pyles**

Initial Discussion of Outline for Task Force
Report and Recommendations ..... **Mr. Joseph M. Teefey**

Adjournment

HJR 630 SPECIAL TASK FORCE

Fourth Meeting

Wednesday, September 17, 1997
House Room C

8:30 a.m. - 12:30 p.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Public Comments ..... **Mr. Joseph M. Teefey**

Policy Options from the Virginia Board of Pharmacy ..... **Ms. Scotti Russell**
Executive Director
Virginia Board of Pharmacy

Discussion to Reach Consensus on Recommendations and Report to General Assembly ..... **Mr. Michael Worthington**
Lead Agency Management Analyst
Department of Medical Assistance Services

Dr. Michael A. Pyles
Task Force Facilitator

Further Business Before Task Force ..... **Mr. Joseph M. Teefey**

Adjournment

APPENDIX C

TRANSCRIPTS OF MEETINGS

VIRGINIA:

DEPARTMENT OF MEDICAL ASSISTANCE

IN RE: HJR 630 SPECIAL TASK FORCE

Meeting of the Special Task Force held on June 19, 1997, General Assembly Building, House Room D, at 9:30 a.m.

CRANE-SNEAD & ASSOCIATES, INC.
4914 Fitzhugh Avenue
Richmond, Virginia 23230
(804) 355-4335

ORIGINAL

DR. PYLES: We're going to go ahead and get started. It's 9:30 and we have a business agenda. To start off with I would like for the people on the Task Force to introduce themselves.

SPEAKER: I'm Dr. Karen Knapp from the Board of Medicine.

SPEAKER: I'm Dr. Doug Hadley. I am the Medical Director for Signa Health Care of Virginia.

SPEAKER: Marjorie Powell from the Pharmaceutical Research and Manufacturers of America.

SPEAKER: I'm Joe Teefey and I am the Director of the Medicaid program.

SPEAKER: I'm Mark Swenski. I'm President of Virginia Society of Health Systems.

SPEAKER: Cindy Pigg and I work for Signa Health Care, but I'm here representing the Academy of Managed Care Pharmaceuticals.

SPEAKER: I'm Larry Blanchard. I'm a practicing dermatologist. I'm here representing providers.

SPEAKER: Jim Counsel. I'm the general counsel for First Health Services in Richmond. I'm here on behalf of Pharmaceutical Care Management Association.

MR. TEEFEY: I have three people that will help staff this: David Sheppard, who is the pharmacist for the Department will be one the staff members. I have Mike Worthington, who is in the policy division at Medicaid will be working with us, and Dr. Mike Pyles.

We've contacted with the Pharmacy School. We have 29 studies to do this summer. We don't have quite enough people to do them. So I contracted some of the studies out. And the four studies dealing with pharmacy, we will use the Pharmacy School at MCV. Mike will be facilitator for the group here. And you'll hear from all those people a little bit later.

I just want to make some general remarks before we get started. The reason we're here is because there were two bills--House Bill 2714 and Senate Bill 1114--that were introduced during the Session. They were talking about the Virginia Anti-Drug Switching

Patient Protection Act.

During the arguments--and I know it was a rather discussed subject during the General Assembly--there were three main things that came out of it.

The first one, I think I'll refer to Dr. Blanchard and one of the arguments he used about physicians' concerned about being away and being in another environment, being in another place when you have a call for anti-switching. And I think he expressed himself extremely well. So that's one of the concerns we had.

The other concern was the discounts and rebates to the pharmacies. There was some discussion how that would be handled. I think there was a lot of confusion on that.

The last thing was basically the effect of the formulary. I tried to sit through as many of the meetings and discussions as possible. I think it got to be such a discussed area that the House and the Senate both felt a need to study it further. That's why HJR-630 came about and that's the reason we're here today.

We've got to define what the similar therapeutic class drugs are, the affects and the effect it will have on the deliberate health care. We have to find out the impact it will have on D-Mass with our rebate, probe and retro-DUR programs and the limited pre-authorization we do.

We have a big task in front of us. I'm going to get Mike to review the Legislation with you and talk about coming up to some type of statement as far as the Committee is concerned.

DR. PYLES: Good morning. First of all, I'd like to just go through a few quick housekeeping things if I could. Many of you I did fax or Federal Express to you about two days ago to you a form. I didn't have some information that I think we'll be needing from you. Before the end of day if you did not get the form to me or never received it, please see me before you leave so I can compile the official roster of members for this Task Force.

Next, you should see a blue page up there that has our meeting schedule. Let me say that we're working with a very short

period of time as you know. We have basically only about three months of work here.

We initially scheduled these meetings for two hours. I've spoken to Mr. Teefey and at this time we need to talk a little bit about the future meetings. The Thursday, August 14th meeting, if you would note, we're going to change that to the following Wednesday, which will be August 20th, instead of August 14th. The other meetings I think are okay as they are.

The future meetings at this point are going to be in the Library of Virginia. This one was originally put in the Register to be there but it was confirmed at this room. We will give you the exact locations of those future meetings.

Mr. Teefey, I think at this time it might be wise for us to talk about with the work had ahead of us-- Maybe before we do that, let me give you an outline of some of the things that we have to accomplish.

What the Legislation has asked this Task Force to do is to study is the practice of therapeutic substitution and come up with a

statement about the extent to which it is going on presently and also to assess it's impact on various interested parties including the pharmacists, prescribers as well as the patient, to look at the cost associated with the practice itself. So the work ahead of the Task Force is quite ambitious for the time that we have. And I really don't think that two-hour meetings will suffice.

What I'm proposing is that we think about longer meetings on the days that have been indicated there. Perhaps maybe at least three--at least four- to five-hour meetings depending on what the Task Force wishes to accomplish in each meeting.

Today's meeting is going to be relatively straightforward. Following this brief introductory period, we will hear from two persons today. We will hear from Mr. Kenneth McArthur, who is with Durrette, Irvin, Bradshaw. We will also hear from Mr. Steven Rosenthal, who is with Mays & Valentine. What we will do is hear from them and plan our future meetings and come up with an agenda for the next meeting.

I thought it would be

important for us to at least begin by getting a grip on what we mean my therapeutic substitution. It is used in various ways in the literature and everyday language. I think that one of the things we need to do is at least establish what we mean by it, particularly the part dealing with chemically dissimilar drug products and changing classes. That's what we need to accomplish.

My proposal is that, for instance, looking at the July 16th meeting, I think a 9:30 start time is good, but I think we need to go beyond 11:30, which will give us enough time to discuss the issues more thoroughly.

If we decide to bring in other speakers or whatever, it will give us a chance to hear them and have a chance to discuss among ourselves what it is we would like to go on record.

Our products at the end of this whole process--what the Legislation asks for is actually a document that will talk about, one, the impact of the practice. And that is a statement or what have you--whatever the Task Force deems would be an appropriate way to do

that.

Then also we need to identify what the components of the cost of the practice are. To do that I suspect it means we would need to have some idea, for instance, what it costs the pharmacists, who often in terms of time is the one there making phone calls, what have you.

They've also asked us to draft legislation or what have you related to this practice that could come before the General Assembly in the next session for review.

As we get further along in the process that will also be up to us with the help of Division of Legislative Services to come up with some draft legislation. That pretty much is what we have before us.

My proposal, Mr. Teefey, is that we might look at meeting from about 9:30 to 1:30 for the next meeting at least.

MR. TEEFEY: Okay.

MS. KNAPP: Is it inappropriate to ask if we start earlier.

MR. TEEFEY: Is anybody coming in from out of town? I think Ms. Powell is.

MS. POWELL: But I can be here

earlier.

MR. TEEFEY: That would be great. We could start earlier.

DR. PYLES: What's a good time?

MR. TEEFEY: 8:30.

DR. PYLES: At least for a meeting, we can get in there any time.

SPEAKER: This room is available and so is House Room 4.

DR. PYLES: I don't have any preference. Do you, Mr. Teefey?

MR. TEEFEY: Either one would be okay. Let's see which one would be the easiest to get.

DR. PYLES: Was this building pretty accessible to everyone?

TASK FORCE MEMBERS: Yes.

DR. PYLES: So we could look at the future meetings being held in House Room D.

MR. TEEFEY: Then we could change the starting time to 8:30 in the morning.

DR. PYLES: The starting time will be 8:30 at future meetings and continue to

meet in House Room D unless there is a problem with availability. If that is the case, I will let you know.

8:30 until what time?

MR. TEEFEY: Let's say 12:00, 12:30.

DR. PYLES: All right. Let's go ahead then and say for the future meetings; July 16th, August 20th and September 17th we will begin at 8:30 in this room and go until 12:30. And if something changes, I'll get back with you.

One last little piece: What I'm going to try to do to expedite our meetings is get information to you in a timely manner so that if there are documents you've asked for, et cetera-- The reason I Federal Expressed you that form is so that I can get things to you either E-mail-- We will use E-mail but also use overnight delivery when that's necessary to expedite things. That's why I need that information from you. I think that's all in terms of housekeeping details.

At this time, Mr. Teefey, if it's okay with you, the first speaker we have for this morning is Mr. Kenneth McArthur from

Durrette, Irvin and Bradshaw.

MR. TEEFEY: Before Kenneth gets started-- This is a real important subject and we have people in the audience-- After we have the two presentations if anybody wants to give--to be fair to the Task Force, if anybody wants to give any type of two-minute statement, we'll let you do that.

We just feel that this is an important subject, and I want the Task Force to have the benefit of any opinions that come out of the audience.

MR. MCARTHUR: Good morning. As Dr. Pyles said I'm Ken McArthur and I'm with the Richmond based law firm of Durrette, Irvin and Bradshaw.

The reason I'm here today, I think, is because I was one of the drafters of the Bill which was introduce dollars last year which sought to outlaw the practice of switching chemically dissimilar drugs where a monetary incentive is present. That is a gross oversimplification of the Bill but because of time and that bill is not currently in front of us I'm got not going to waste your time and waste

the limited amount of time I have here to present our perspective on this issue to you by going through the Bill from last year line by line.

Let me say at the outset that I am not going to try to make every single argument that I think could be made to criticize the practice of switching chemically dissimilar drugs for money. I don't think I have time in 30 minutes to do that, nor do I think that I need to do that because I think most of the people who are present here today already know them.

I'm also not going to try to set forth specific terms of any Bill for next year and suggest any language of any Bill that would outlaw such practices. Again, because of concerns with time and because I think that the purpose of this Task Force is to work through this issue and come up with language of such a Bill and that's not my job.

So what I am going to do is raise, what I hope, are some issues which I think are critical for this Task Force to address. And if they are not addressed, in my opinion and in my humble opinion, this Task Force will not have done its job.

Before I get into those issues what I would like to do-- And I apologize to those of you who are more knowledgeable perhaps of some of the terms used in the health careen industry even than I am. I have to modestly say I have spent approximately 7,000 hours of my life now over the past three years studying the pharmaceutical industry. In fact, spending a substantial majority of that time focussing on this very issue which is before this Task Force.

Even though many of you already know what many of these terms mean, just to clarify for my purposes of raising this issue, I would like to good ahead and define these terms as I'm going to use them. I'm not going to try to convince everybody that we should reach a consensus on the definition of these terms. I just want to define them so everybody knows what I'm talking about when I raise these issues.

The first definition that I would like to give is one of generic substitution. My definition of generic substitution is switching from a chemically similar drug--from one drug to a chemically similar drug. When I use the term chemically

similar, I'm using the language that I believe is used by the Food and Drug Administration and is reflected in its annual publication, which is supplemented from time to time throughout the year, which is known throughout the industry as the Orange Book.

When the active ingredients in a prescription drug are the same--there may be one or more active ingredients--then the switch from one drug to that other drug where the active ingredients are the same is, in my definition, a generic substitution.

It doesn't necessarily have to be from a brand name drug to a generic drug. It could be from a generic drug to a branded generic by another manufacturer. It could be from a branded generic to another branded generic from another manufacturer. There are several permitations but the thought is the same. Generic substitution for purposes of my issues that I'm going to raise today is switching among chemically similar drugs.

In the industry there is some confusion, I think, at last there appears to be among people, of what the definition of

therapeutic substitution is. My definition of that for purposes of raising issues today is switching from one drug to another drug and for purposes of my discussion today, will be a chemically dissimilar drug, which simply means that one are or more active ingredient are different in the switched to drug from the original drug.

The switching, however, is done without consulting the prescriber on each individual switch. There may be some protocol whereby the prescriber, group of prescribers has given advance permission, if you will, are or authorization to certain individuals, usually pharmacists, to make switches from one drug to a chemically dissimilar drug.

Therapeutic interchange, however, is something a little different. Therapeutic interchange is switching among chemically dissimilar drugs. So its like therapeutic substitution in that sense. However, in therapeutic interchange the prescriber is consulted. There is a telephone call or some other contact with the prescriber and the person who is seeking the switch--seeking the solicitor

to encourage the switch asks the prescriber to rewrite a brand new prescription for a chemically dissimilar drug.

It is my understanding that in the hospital in-patient setting the kind of drug switching that goes on when there is drug switching is therapeutic substitution. In the ambulatory setting, which is virtually everywhere else, if not everywhere else outside the in-patient hospital setting, we're talking about therapeutic interchange. Because it is unlawful in those ambulatory settings to switch a patient's drug to a chemically dissimilar drug without consulting with the prescriber and having a brand new prescription written for the drug.

Now, having clarified that, let me say when I talk about the drug switching, when I raise some issues with the Task Force over the next couple of minutes, what I'm talking about is therapeutic interchange.

The first point that I would like to make--it really is not just a point. It's eight points and a request of the Task Force. The point is that I am concerned that I have never seen any studies published anywhere

that show me that someone has conducted clinical scientifically-based peer-reviewed research on what risks are involved in switching from one drug to a chemically dissimilar drug. I just haven't seen any published studies.

Now, I have made an effort and I have a network of co-counsel, and clients around the country, and we have all made an effort to seek out this information. So far, I haven't found any studies that have been published that fit that description that assess the risk of switching from any drug to any chemically dissimilar drug.

However, what I have seen and what I think every member of this Task Force would agree to is that health care providers seem to me at least to agree throughout the industry that there is a risk involved when you switch from one drug to another drug.

There is a risk involved to the patient's health. By the way, that risk includes even when you are making a generic substitution. You are switching among chemically similar products. And I think certain state legislatures have had the wisdom to recognize

that even chemically similar switching can be dangerous and involves a risk, particularly when it involves a class of drugs that is commonly called the narrow therapeutic index drugs.

Despite the existence of this risk and agreement among all health care providers with whom I've ever spoken or publications that I have ever read that there is a risk involved, I have seen no risk assessment studies. That's my point.

My question is: The Task Force needs to ask whether such studies exist. If they exist, they need to be produced so that the Task Force can critique these and analyze them and determine whether they're scientifically based and whether they're valid and should be considered in whatever the initiative the Task Force may want to adopt.

The second point I would like to make is that I have heard asserted by a lot of--and I'm not going to pick on any particular company or any particular individual, but I have heard asserted and read in statements which have been created by a lot of different people and entities that there is a public policy reason

underlying switching chemically dissimilar drugs. That public policy reason is that it is a managed care cost containment tool. It is a way to enforce a restricted drug formulary. It is a way to affect cost savings for a plant and that is desirable to third party plan sponsors, whether they be government entities or private entities or individuals.

I would like to make the point and again make a request that I'd like to make the point that I have never seen a published scientifically peer-reviewed study anywhere in the United States that shows that there is any cost savings to any plan resulting from chemically dissimilar switching of prescription drugs. I have heard a lot of claims. I have heard a lot of statements, but I have never seen any evidence.

So my request is that if there is such evidence, the Task Force should request it and whoever has it should bring it forward and it should be properly considered as part of putting together any kind of initiative the Task Force may choose to put together.

My third point, which is

somewhat related to the second point--I guess all three points are related--is that I have also seen in the marketplace a lot of studies and a lot of articles published in scientific publications that conclude that switching chemically dissimilar drugs on patients, in fact, increases overall health care costs.

Just to explain, although I don't think it's necessary among this group, but just for record to explain what I mean by that: Health care costs are typically looked at in components. There's a cost component analysis approach to looking at the cost of health care. There would be a drug component, how much you spend on prescription drugs. There might be an emergency room visit component. There might be a doctor's visit component, a hospital stay component. It doesn't matter how you cut it up. There are different types of components of costs within any given health care plan.

The Overwhelming majority--in fact, not just the overwhelming majority, but all of the studies published in scientific literature that have read indicates that when you engage in the switching of chemically dissimilar drugs, you

increase the cost in other components of the health care plan.

To illustrate: A patient is titrated on a particular blood pressure medication. It's working well for the patient. The patient is in a private health care plan. The patient goes to the patient's physician and sees the physician. The physician writes a refill or an original prescription for a blood pressure medication for this patient. The patient goes into the patient's pharmacy.

The patient discovers from the pharmacist that the pharmacist has received when the pharmacist has submitted a claim across his on-line claims adjudication system he or she received a message from that plan--from that insurance plan that this particular drug is not going to be covered by that plan or that that drug is not preferred by that plan. And therefore, that pharmacist should talk to the patient perhaps, talk to the doctor perhaps and persuade the physician or original prescriber to rewrite a new prescription for a chemically dissimilar drug.

When that happens, the patient

may have to be retitrated on the new drug, which may require additional visits to the doctor that otherwise would not have been required had the patient's drug not been switched.

In such a case, the five or six additional doctor's visits that may go along with retitrating that patient will cost enough money that even if there were a cost savings produced by switching the drug in the drug component, it would be more than offset by the additional cost of going to see the physician that many times. That is a simple what I consider relatively benign example.

There is a risk to the patient. There is an additional increase in cost to other health care components, but it may or may not be life threatening. One of the reasons we are so concerned about this issue is because this is not the only kind of example that we have seen in the Commonwealth of Virginia. There are many, many examples that we have seen that are life-threatening examples.

I would like to point out that any statements that I make today I'm going to produce--and I'm going to state this on the

record, I'm going to produce all the evidence that I have alluded to to support the statements that I make. I didn't bring it with me today but I will be happy to submit it to the Task Force before its next meeting.

We would urge the Task Force to demand accountability from those entities which are engaged in the practice of switching chemically dissimilar drugs. We would ask the Task Force to ask those engaged in this practice or wish to be engaged in this practice, and therefore oppose any legislative initiative which would outlaw it to produce the evidence to support their position.

We believe that the burden of proof falls squarely on those who wish to engage in the practice. There is a consensus among the health care--among the people in the health care community that this practice is risky. We don't know how risky it is and don't have any evidence that it is saving anybody any money, so there's not even any public policy reason for it.

Therefore, we ask that those would seek to engage in the practice the burden of proof be placed on them to justify why they

should be allowed to engage that the practice. And should they fail to meet their burden of proof or should those who oppose the practice sufficiently rebut the evidence they put forward that this practice be outlaw until such time as someone, if ever, can figure out a way to engage in this practice that is safe and has some benefit to society.

Before I end I want to address a couple of points that I think need to be addressed here in the outset while we're framing this issue. I heard a lot of criticism of the Bill that was introduced last year. I would like to just very quickly go through and address some of those criticisms.

One of the criticisms that I heard was that we don't need to legislate this problem because the private market place will take care of it. I would like to address that argument.

First of all, I'm not sure that the private market place can address this problem. What we have found is that third-party plan sponsors are largely uninformed about this issue. We actually went around and talked to

some employee benefits managers and some of the Fortune 500 hundred companies here in Richmond. When we started talking about the switching of chemically dissimilar drugs and entities like PBMs and that sort of thing, we were met with glazed eyes and responses and questions like what's a PBM.

In a study that was performed a little over a year ago, six of the nation's largest HMOs on condition of anonymity gave a team of research scientists access to their confidential proprietary competitively sensitive documents and allowed them to have at it and attempt to lay to rest criticisms of restrictive drug formularies and any practice associated with those including prescription drug switching.

I have talked to the person who led that team, Dr. Susan Horn. She informed me that when she began that study she was a big believer in things like prescription drug switching programs. But that after conducting that study she became a convert and decided that prescription drug switching was not a good idea. And she informed the six HMOs of this after she produced to them results from that study which

indicated that the more these kind of programs were used, the higher the overall health care cost in their health care plans.

She has informed me that as a result of that study those 6 HMOs at least have actually taken steps toward stopping some of these practices.

The second criticism that I heard most often was that this Bill was going to negatively impact pharmaceutical care. Now I find that very interesting because I think what we have is a problem here again on definitions.

I think that most managed care organizations define pharmaceutical care as pharmacists engaging in prescription drug switching programs. The managed care organization enters into contracts with drug manufacturers pursuant to which they get paid money to attempt to affect what prescriptions get prescribed for their plan participants. And to the extent that a pharmacist is valued as a tool in for in that process they might be paid to do it.

That's my understanding of many managed care entities definition of

pharmaceutical care, cognitive services, disease state management and the like.

My clients, who are mostly community pharmacists, define pharmaceutical care in a very different way. They define pharmaceutical care as an educated, trained, experienced, licensed pharmacist making decisions which in his or her professional judgment on a patient-by-patient basis, that are in best overall short and long term interest of that patient. And hopefully when the information is available to them in the market place, decisions which will be cost effective for the plan.

I think that the dispute over how to define pharmaceutical care is one that should be addressed by this Task Force, as well as the other points I've already mentioned.

A third criticism that I heard about this Bill was that if this Bill were enacted in law, it would cause health care costs to rise. Together with that was the statement that it would do away with drug formularies and that those were supposed to somehow be linked to each other.

Now, I've already made the

statement earlier so I won't repeat myself that I have not seen any evidence that any cost results, either in the drug component or in the overall health care plan from drug switching practices. So I'm not sure exactly what the statement that this is going to increase costs means.

In fact, I've seen ample evidence that it will decrease cost in the overall health care plan. So in my view, passing the Bill would decrease costs, not increase costs.

Again, if there are those that have information that is contrary to my belief, I would encourage them to present it to the Task Force and as Jerry McGuire says, "Show us the money." Let's see it. Because I think it's important that the Task Force members understand that there is a flow of money from drug manufacturers to managed care organizations of all kinds.

But that flow of money needs to be differentiated. It needs to be broken out so that everyone understands that some of that money has to do with generic substitution. Some of that money has to do with certain educational

things that the managed care organization might do. Some of that money has to do with other things the managed care organization might do.

I think if anybody is going to make a claim that this Bill is going to increase the health care cost, they need to show to what extent and how much.

The last point I would like to make is that I hope that the Task Force members will keep in mind as they go through this process that the most important consideration that should be made here is what kind of impact do these practices have on patients in the Commonwealth of Virginia. What does this do to Virginians? Are we being penny wise and pound foolish? In this process let's not forget that the patients are the most important.

I hope also that as the Task Force goes forward that the Task Force will be sure to remember to look at hard evidence in making its decisions. I don't expect to make any more statements in front of the Task Force unless I'm called upon to do so.

I hope that the Task Force will not waste its time by listening to a lot of

statements from a lot of different people who have opinions on the subject.

I hope instead what they will do is look at the hard evidence that is produced by all interested parties and make an informed decision on that basis. Thank you very much for this opportunity.

MR. TEEFEY: Thank you, Ken. Can you make sure as soon as possible that you get us all that information so we can get it to the Task Force because I'm sure it will be a lot of reading?

MR. MCARTHUR: Yes, sir, I will.

MR. TEEFEY: If we could get it as soon as possible.

MR. MCARTHUR: I would be happy to. Thank you.

MR. TEEFEY: Mr. Rosenthal.

MR. ROSENTHAL: Members of the special Task Force, thank you for the opportunity to be here. I listened to Ken's comments with interest because I think you're going to find a lot of what I have to say is the same thing. We may define terms different ways but in terms of

how this Task Force moves forward and the types of things it looks at. Ken and I seem to be on the same wavelength although we have not discussed what our comments would be before today.

Let me tell you who I am. I'm Steve Rosenthal. I'm an attorney with Mays & Valentine here in Richmond. I represent a large coalition that was involved in the previous legislation that generated this study and special Task Force.

I don't know how many of you saw last month's Money magazine. Did any of you see that? I hope so because I may be showing you something I shouldn't be. I want to read an article. Those of you who were not in the General Assembly last year will not recognize this piece out of the article. Those who were, like Dr. Blanchard and a few others, will remember a woman who testified at a number of committees about "drug switching." And I use that term in quotes.

The lead article-- I just want to read a couple of paragraphs. The lead article says that Marie Williams, a 56-year-old

school bus driver and resident of Richmond. For five years she had been using Zestril to control her high blood pressure.

But when she went to her local pharmacy on January 4th to get a refill, her pharmacist had disturbing news. He would give her Zestril, which successfully lowered her blood pressure with no side effects only if she paid the full cost of the drug because her health insurance did not cover it any more.

On New Year's Day, Williams' employer had switched health plans. And its new insurer, Signa, preferred that certain blood pressure patients take a different version of the drug called Prinivil.

Without consulting Williams' physician, who was Dr. Annette Reed, the pharmacist switched her to Prinivil.

The article goes onto say that a few days after taking the new drug, Ms. Williams knew something was wrong. She was lightheaded. She had headaches and her ears were popping as though she were high up in the mountains. She was a school bus driver for children and this rightly concerned her.

This same testimony was given to at least two committees that I know of on the issue of drug switching, on the component side of legislation.

If you look in the Physicians' Desk Reference in fact what you find is that Zestril and Prinivil are identical drugs. They are both Lisinopril. There is no difference. One is produced by Merck and the other is produced by Zeneca.

Merck is the only company that has the patent on Lisinopril and it has licensed Zeneca to also produce it. I have copies if you want them--and I'll pass them out later after the meeting--to show you that the chemical make-up is identical. It's not just similar, it's identical.

Where am I going with this? There was no drug switching. There was no therapeutic interchange of chemically dissimilar. There was no chemical dissimilarity. There was literally no chemical change at all.

Yet, during the General Assembly this poor woman, Marie Williams, who apparently did have a problem and her husband,

were paraded through the Assembly, through the committees as prime examples of the evils of switching chemically dissimilar drugs.

Now why do I go through this? It's for the same reason that Ken said to you what he said earlier. It is this kind of misinformation and this kind of hyperbole that has generated this Task Force and this study.

You're not here to watch a propaganda war. I can tell you from the coalition that I represent that we're not here to wage one. The whole problem with legislative session was a total lack of reason, debate that was grounded in fact.

Antidotal evidence won't suffice. And we encourage this Task Force to demand nothing short of objective data to support any particular course of action.

As you can see from the Money magazine article, and as we found during the General Assembly, there has to be a careful use of terminology as we discuss these issues. A broadside condemnation of so-called drug switching is not helpful, and it doesn't advance any particularized understanding of the issues

that this body needs consider.

You as a Task Force were constituted to bring to a complex issue diverse expertise, background, training and experience and to have the time to apply those qualities in an environment free from the severe constraints of a General Assembly session that tries to look at thousands of Bills within a few week's time.

You are tasked to use that expertise and the time to find out what those facts are and how those facts impact a large number of state holders. Not just independent pharmacies and not just a large employer and not just large coalitions, but also the Commonwealth, Medicaid, HMO, managed care organizations, the mental health community and most importantly the Commonwealth citizens.

There has been talk-- In fact, I even mentioned about the previous legislation. Let me say very clearly that our understanding is that--and we encourage you to start with a clean slate, that failed legislation is not the starting point. There are no presumptions. Either the legislation is needed or the legislation is not needed. Either way,

you should demand that the need or lack of need be proven from the ground up before you.

You should not simply accept antidotal evidence. It's not fair to you and it's not fair to all those that will be impacted by your decision. Any such antidotes, like the one I mentioned earlier, must be carefully examined and investigated by the State and this Task Force. Without that kind of scrutiny, you will fall victim to the same emotional appeal as Money magazine.

The starting point is facts and data. Facts and data to be gathered by your staff and presented to you. Facts and data so that you can make an informed and meaningful policy recommendations.

We, too, like Ken, have requests and ask that you look at certain things. As you are studying this issue look and see--identify what is going on in the market today and why is it happening. Are there specific practices that pose risks to the public that outweigh any associated benefit to the public? Who is doing what and why? Does the identity or interest of the party engaged in a

particular practice matter?

This study raises important questions about the physician, patient, pharmacist relationship. As you work through this complex area, before you decide on any course of action, I encourage you to consider these types of questions. Will it harm the overall quality of care that is provided to Virginians? Will it prevent pharmacists from informing physicians of significant price differences among alternative drug sources, such as the two identical drugs I mentioned in the beginning?

Will it cause the Commonwealth to spend more on drugs for Medicaid beneficiaries than necessary? Would it disadvantage the competitive posture of Virginia businesses? Would it eliminate practices Virginia would want to encourage? Would it force employers to restructure benefit plans to the detriment of our citizens? What is the overall financial impact to Virginia?

On this issue there's been almost no consideration of a factor as important as this. We say to you if there is something

wrong and a need to fix it by legislation, then you have an obligation to identify the problem and an obligation to suggest appropriate solutions and report that to the General Assembly.

But by the same token, if there are no problems or none that call for a legislative fix, then you need tell the General Assembly that also.

All of these things: The need to avoid allegations not grounded in fact, starting with a clean slate, making sure that all points of view are heard and considered, all of those are really just another way of saying what your enabling resolution says.

That resolution is that special Task Force be established to study the practice of therapeutic interchange of chemically dissimilar drug products. The special Task Force shall examine all aspects and effects of the practice of therapeutic interchange of chemically dissimilar products throughout the health care system, including, but not limited to its impact on health care, the affected professions, the overall cost of health care products and services

and patients.

The coalition that I represent, we are here honestly to assist in any way we can. Our goal is to provide you and your staff any information that's not confidential and can't be released, any information otherwise that will be helpful in attacking these issues.

We appreciate the time and I know a lot of effort will be put into this. We stand ready to help.

MR. TEEFEY: Again, Steve, we have to sort through a lot of information. Whatever information you have, if you could get it to us as soon as possible.

MR. ROSENTHAL: Thank you.

MR. TEEFEY: Before we get into the statements, would anybody in the audience like to make a statement?

DR. PYLES: I would just ask a identified yourself.

SPEAKER: My name is Cindy Warner. I just wanted to make a statement just to clarify one point so there would be no misunderstanding. One of the things that Ken McArthur stated was trying to differentiate

between different versions of what pharmaceutical care is.

I think it's very important and clarify that pharmaceutical care from the pharmacist's perspective is meant to a collaborative practice. They are there to aid and assist, to provide information, to optimize the drug therapy for that patient and that's done in conjunction with the physicians.

The other point is--and I don't think anybody really hit this on the head and this is something that the Task Force I hope they would really seriously consider would be who is initiating the change or the request for the change for that patient. I think the bottom line for that is is it coming from a business decision or is it coming from a patient-oriented decision from the health care provider that best knows that patient.

Thank you very much.

DR. PYLES: If have those written, could I have a copy?

SPEAKER: Sure.

MR. TEEFEY: Would anyone else like to make a statement?

From the statements that we have now to look at, we have a pretty good job in front of us.

DR. PYLES: Mr. Teefey, that is pretty much what we had on the agenda for today. If the Task Force members would like to make comments at this point or requests of us, you can do so at this time in terms of our next meeting and what you would like to see for the next meeting. If you could identify yourself for me.

SPEAKER: My name is Cindy Pigg. I'm just curious as to what our framework will be so I can be prepared at our next meeting on how do we begin to tackle this issue.

DR. PYLES: One of the first things we would like to do is have the Task Force on record with the statement of the practice of therapeutic interchange and what it means in terms of the Task Force's view. That is a statement--a cogent statement that says this and it involves this. So that's something that we will probably be drafting and putting out to each of you for your input so we can come to a consensus of what we mean by that, and any other

issue or any other thing that needs to be defined that the Task Force deems necessary to define.

MR. TEEFEY: Cindy, I had kind of the same feeling you had. I go back to Ken;s comment. Ken has really laid out a pretty good sequence in here. He's got the definitions of the two. And I think we've got to decide on a definition.

I think the second thing is he talks about particular studies. One of the studies is there are no studies anywhere that shows that this is a cost savings. I think we have to look at the risks that he stated there. He's laid out quite a few things.

I think what we've got to do when we get in between the next two is to come up with an agenda. Take Ken's and Steve's two talks and lay out some of those things that they brought out and get supportive information from both of them so that we can start deciphering it and coming up--

I think its real important we come up with some statement. We know what the legislation says but I think the statement is the next thing.

SPEAKER: With all due respect to Mr. Rosenthal and Mr. McArthur, both of whom I had the opportunity to meet before, when they give us their information, I'm not going to assume that's all the information that is out there. Do we have somebody that has the time to dig through the literature for us?

DR. PYLES: Some of that is going on Mr. Worthington who is the other staff member of D-Mass and has done some of that. We have identified I think an Inspector General report that addressed this issue, looking at a study I think of several states. So we do have some things. Between now and the next meeting perhaps we'll put together what we do have already and get it to you.

SPEAKER: The other thing I would ask is are there any other states that have addressed this from a statutory--

DR. PYLES: Not to my knowledge but we can check.

MR. TEEFEY: Ken, during the General Assembly, I think you said a couple of other states were looking at it and that--

SPEAKER: Could we see that

legislation?

MR. MCARTHUR: Yes. I'll be happy to provide that for you. There are at least three other states that I know of that have either introduced legislation or planning to introduce legislation.

MR. TEEFEY: I know Missouri was one of them. What we can do is call those states and get the legislation and whatever Ken has. We'll look at the federal study that was done and pull out study pieces out of that also.

SPEAKER: One other request: Mr. McArthur, does that study where the HMO formularies were examined, is that published anywhere?

MR. MCARTHUR: It is.

SPEAKER: So you'll provide us with that?

MR. MCARTHUR: Absolutely.

MR. ROSENTHAL: There are a number of responses to that study that criticize that. I assume you want those.

SPEAKER: Absolutely.

SPEAKER: I'm Doug Hadley. I would just like to also comment on the article

that Mr. Rosenthal quoted from Money magazine. Obviously, we're sensitive about that issue. I think that's a good example of how we've got to begin to, again, be objective and look at what is the actual published evidence out there and not be swayed by an antidote that comes up, which was obviously used for purposes which really weren't for what it was intended.

As you rightly pointed out, that particular substitution was a generic substitution and had nothing to do with therapeutically dissimilar drugs and was portrayed both in that article and I think when she testified before the Assembly as if it were a therapeutically dissimilar drug.

I have spoken with the physician about this particular episode, Dr. Annette Reed. In fact, she had been consulted about the whole situation. She was also interviewed by Money magazine and tried to convince them that this was, in fact, a particular kind of reaction that made no sense, that it was probably some type of placebo or psychological reaction. Despite telling them that on several occasions, they proceeded to

publish it in that manner.

I agree that we can't accept antidotal evidence. If there are such things, they have to be presented in writing and thoroughly let us evaluate them so we can separate some of these things. Because there is a lot of hysteria and hyperbole that is going on in the media. I think if we're not careful we can be dissuade. We know patients will, on occasions individual patients will have very unusual things that can be can't be explained by normal means of science.

I agree with the statement to not use antidotal evidence and that type of testimony.

MR. TEEFEY: All right.

Dr. Blanchard.

SPEAKER: One additional piece of information I think might be useful is make sure we are armed with the current state regulations that apply to bona fide patient pharmacy relationship, ones dealing with kickbacks.

There's been some talk--I don't understand it--about Jane Woods recent

legislation of last year and how that may impact this discussion.

The bottom line of what I've been hearing up here is that the responsibility taken on by the members of this Committee is to be willing to take the time, the effort to sift through a fairly voluminous set of data facts and try to sort out antidote from factual statistically significant and insignificant and come up with a responsible recommendation to the Commonwealth of Virginia.

I appreciate being given a 30-minute presentation as opposed to what seems to me like a legislative process or two-minute soundbite which do oversimplify things. So I hope these lengthier meetings will produce the kind of the results we want.

DR. PYLES: Dr. Blanchard, are you asking for the particulars of the scope of practice of the prescribers and pharmacists?

SPEAKER: Yes, that's correct. I have some Virginia State title things that I've been made aware that affects this, as well.

MR. TEEFEY: I think truthfully and I've always held that our

legislature has a lot of good sense. I think after we have seen what's happened here today, I think having this Task Force put together assures me that our legislature is using its good sense. Because just getting the definitions I'm confused.

SPEAKER: I would like us to make sure we talk about these definitions. The one definition Ken started talking about but was not alluded to specifically was the difference between switching a patient who is already on a medication--is titrated on that medication, what do they cost in (inaudible) of forcing or encouraging that patient to switch to another drug as opposed to the doctor switching before the patient ever starts taking it.

SPEAKER: Mark Swenski. Perhaps just enlarging the scope a tad, I think there are some valid points about therapeutic switching. But there was a time when I started in pharmacy practice not too long ago that 20 percent or less of the business was managed care business. When a patient came to the pharmacy to pick up a $50 or $60 prescription, that they could not afford, there was no coverage at all.

Many times the patient went without medication because they could not afford that medicine.

In looking at this, I would suggest that we try and understand what the role of insurance is in financing the delivery of pharmaceutical care and how throwing that piece in has allowed more people access to drugs. It's not quite as simple as: If I have insurance, I ought to be able to pick the drug I want. It seems like it should be that way, but it's not that simple.

The insurance vehicle has provided a lot of people coverage to prescription medicines that they didn't used to have. I think that there's a piece that we shouldn't neglect.

SPEAKER: Marjorie Powell. As perhaps the only non-Virginian on this Task Force it would be helpful to me to have an understanding of what the Medicaid DUR program is. Because I understand that Virginia has a very effective DUR program. And I know there are instances when a pharmacist would, under a DUR program, call a physician to switch a patient for what would be medically appropriate reasons.

I think because that's an

important distinction that Ken did point out, we need to keep that in mind and it would help me to have a sense of the kinds of things that pharmacists look at within the DUR program.

MR. TEEFEY: For the next meeting we'll have somebody come and go over our DUR program. As a matter of fact, we'll go over our whole pharmacy program.

DR. PYLES: Any other comments from the Task Force members?

If not, Mr. Teefey, it appears that what we will do between now and the next meeting is to put together some information and get it to you for your review. I encourage you to be thinking very seriously about the statement--the definition. I think that is the most pressing thing at the moment in terms of getting started and moving on with the rest of our work.

Again, what we're looking for--what was called for in the legislation was that this Task Force come up with a statement of the extent to which this practice occurs. But it seems to me before we can make a statement about the extent to which something occurs, we need to

agree that we're talking about the same thing. So the definition and the description of what we're talking about is perhaps one of the most pressing things before us.

At the next meeting we should be prepared to have some discussion on that and reach consensus on that, among other things. I will make sure that we get with the staff at Medicaid and make available to you some of the things you ask for today.

MR. TEEFEY: Ken and Steve, can you all make sure you have some representatives at each one of these meetings because you're giving us supportive information. We are probably going to have some questions, if that's all okay.

MR. ROSENTHAL: Yes, sir.

SPEAKER: I think The Board of Pharmacy and Board of Medicine is supposed to offer assistance, too.

MR. TEEFEY: That would be great.

I thank everybody for coming. The main thing we wanted to do was surface both sides of the argument and make sure that you

understand where we are. And we will have a lot of information and we'll try to summarize some of the information that we have to get to you so that you don't have to labor through.

DR. PYLES: Before you all leave, I did not have phone numbers for most of you. Please make sure that if you did not get the form that I sent to you, make sure that you circle your name on the tentative roster and fill in that information for me and give it back to me. Thank you.

(CONCLUDED AT 10:40 A.M.)

STATE OF VIRGINIA

COUNTY OF CHESTERFIELD, TO WIT:

I, Therese A. Rothchild, certify I reported and transcribed the foregoing, which is complete and accurate, to the best of my ability.

I am not related to nor employed by any counsel, party or witness, and have no interest in this matter.

Given under my hand this 1st day of July, 1997.

Therese A. Rothchild

1 ! RGINIA:
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6 HOUSE JOINT RESOLUTION 630
SPECIAL TASK FORCE
7 Studying Practice of Therapeutic Interchange
of Chemically Dissimilar Drugs
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12 Second Meeting
13
14 July 16, 1997
15
16
17
18 When heard at:
8:30 a.m.
19 General Assembly Building
House Room D
20 Richmond, Virginia 23219
21
22
23
24 CRANE-SNEAD & ASSOCIATES, INC.
4914 Fitzhugh Avenue, Suite 203
25 Richmond, Virginia 23230
Tel. No. (804) 355-4335

1 APPEARANCES:
2 Mr. Joseph M. Teefey, Chairman;
3 Mr. Michael J. Ayotte;
4 Dr. Lawrence E. Blanchard, III;
5 Dr. Randall E. Dalton;
6 Mr. James G. Council;
7 Dr. Karen E. Knapp;
8 Dr. Thomas L. Moffatt;
9 Ms. Cynthia J. Pigg;
10 Mr. Mark A. Szalwinski;
11 Mr. William Alan Towler;
12 The Honorable Senator Stephen D. Newman;
13 Ms. Marjorie E. Powell;
14 Mr. W. Tommy Walker.
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4 SPEAKERS: PAGE
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1 July 16, 1997
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3 NOTE: The following hearing was called to be
4 heard at 8:44 a.m., viz:
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6 CHAIRMAN TEEFEY: We're going to go ahead and
7 get started. It's a little past 8:30.
8 I'd like to thank everybody for coming. I'd
9 like to welcome everybody in the audience for coming.
10 I passed out some things when I came in.
11 Somebody asked for a little bit of information about
12 the Department of Medical Assistance Services, so I
13 passed out a little bit of information. That's in
14 your information and that's about our eligibility,
15 about our budget, some of the initiatives that we're
16 working on.
17 Mike Pyles will cover the notebook. He's put
18 together a notebook, and he wants to cover what's in
19 the notebook and the information that you'll be
20 getting.
21 We had a little bit of a mix-up last time.
22 We're going to have another whole big batch of
23 information coming to you today. Mr. Durrette was kind
24 enough to give us all of the backup information he had
25 when you made your presentation, and we're sending it

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out to the Task Force. We didn't get it from the other side, and they brought it in today and we will FAX it out to everybody, or we will get it out to you tonight as soon as we copy it.

So, have you got copies?

DR. PYLES: We have copies for them.

CHAIRMAN TEEFEY: Oh, good. We've got copies for everyone.

DR. PYLES: We'll pass them out in a moment.

CHAIRMAN TEEFEY: I wouldn't want you to read it now, because I think it would take most of the day to do that.

We tried to put on the agenda today the information -- Some of the Task Force members asked for specific information, and we're going to start off today with that specific information that you asked for, and then we're going to start expanding into what we are here for.

But, to start off with, Mike, do you want to go over the notebook first?

DR. PYLES: Yes, if you don't mind.

Good morning to everyone. What I would like to do is just walk you through the notebooks. What I have tried to do was to put together a notebook and put some order to it so that, as we go along in our

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deliberations and meetings, as things come, you can add it to specific sections, and I will walk through those with you real quickly.

The very first page there should be a Table of Contents which roughly corresponds to each of the tabbed sections of the notebook, and I will walk you through that.

Behind Tab Number 1, you should find a current listing, updated listing, of the Roster of Members. Again, I ask you to look over it and make sure that that information is correct and let me know if it's not.

I did send -- I put together a list server for the Task Force, and I sent a message, oh, I guess about the 7th or so. I think I got seven responses. What I will do between now and the next meeting is to continue to send information. If you have reason to believe that you're not getting E-mail from me and we do have your address, of course, let me know. But, you will find that listing behind Tab Number 1.

And, then, behind Tab Number 2, what you will find is a copy or you should find a copy of House Joint Resolution Number 630, as well as Senate Bill Number 1114. And, in the future, if we need to add additional legislative documents, they will go behind

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Tab Number 2, and I will try to direct you, as we mail things out or what have you, where things go. If you don't like my particular order of things, of course, you are welcome to make adjustments.

Behind Tab Number 3, this is where I thought you could keep up with E-mail correspondence and other internal documents. What you should have there right now is a Revised Meeting Schedule. You will note that the times for the August 20th and the September 17th meetings we left at 8:30, and, at this point, unless we change, we will continue to have them from 8:30 to 12:30 in this room, House Room D. So that's an updated meeting schedule.

Behind Tab Number 4, you should find, today you should find two Agendas, today's Agenda and the Agenda for the initial meeting and the transcript from the first meeting. As we get the transcripts following a meeting, they will go behind Tab Number 4. What I had hoped is that we would have the agenda/transcript, agenda/transcript, in that order, from the most recent meeting to the earlier meetings. That will be behind Tab Number 4.

The Agenda, I think, is pretty straightforward today, as you can see there. And, if you would like, you can take it out, if you would like

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to reference it as we go through the meeting today.

Behind Tab Number 5, you will find letters that the Task Force Chair may receive from other parties or even from among yourselves and copies of that will be there. I believe that you already may have received some of that, but any letters that are addressed to the Chair and enclosures that come with those letters, you can place behind Tab Number 5.

Behind Tab Number 6, you will find the handouts from invited speakers, those persons that addressed the Task Force during our meetings. And what I will be doing is, as you get,-- What I suggest is that as you get information, just add it on top there. So that kind of keeps it current and you will know approximately the order in which you received it by just doing it in reverse chronological order there. And, for today, you should have in there already comments about the Virginia Medicaid Pharmacy Program, which we'll hear from David Shepherd of DMAS. Also, a literature review, we will hear from Michael Worthington of DMAS. Then, also, the information that you received in the mail prior to this meeting you can place behind Tab Number 6, as well, and there was an enclosures list with that mailing, and that information should go behind Tab Number 6.

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I apologize if some of the pages seemed not to be hole punched quite properly, but we did the best we could.

Behind Tab Number 7, you will find materials and handouts from other interested parties. These persons may not have addressed the Task Force, but, as we get the information, we will make it available to you, and you can put it behind Tab Number 7.

Then, Tab Number 8, there is nothing back there. You can use that to accumulate your own notes and what have you. If there is anything that was promised or that you have asked for that we don't cover today, I ask that you give us a chance to go through the meeting today, and if there has been something omitted, an oversight on my part or what have you, please let me know and I will make sure that anything that you've requested either we have attempted to get the information or we've just neglected by an oversight to put it in the binders or to get it to you. So I just ask at the end of the day you let me know if there is an oversight.

I would also ask, when you have a moment, to go back to the transcript from the first meeting and look through that, and if you find any errors there or what have you, names misspelled, misspelled words or

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what have you, please let me know by E-mail or giving me a call. On the new updated roster, I think on the second page of that roster, you will find the staff, and my name is listed there with my E-mail address and phone numbers.

Okay. Any questions from anyone?

NOTE: (No response.)

DR. PYLES: If not, Joe, then back to you.

CHAIRMAN TEEFEY: Okay. We're going to start off every meeting with a public comments portion.

Is there anybody in the audience that wants to make a comment?

DR. PYLES: Just for the record, I'd ask that you state your name real clearly for the Reporter. Thank you.

MS. WARRINER: Yes. My name is Cindy Warriner, and I'm a licensed pharmacist practicing in the State of Virginia, and my comments will be very brief today.

Since this is an opportunity to submit documents, I have five documents that I would like to submit to you as a Task Force for your review. I will briefly describe each one and then summarize why they are important for this particular study.

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The first document submitted is a form or physician statement relating to an issue that was addressed during the General Assembly a couple of years ago. The Department of Medical Assistance Services was attempting to contract its pharmacy services through a PBM and opposed the initiative based, in part, on the practices involving PBM-developed formularies and how these formularies were managed.

The second letter is from the National Association of Chain Drug Stores highlighting their disappointment of the Federal Trade Commission's Consent Agreement with respect to Lilly's acquisition of PCS. Specifically mentioned were some of the practices engaged by PBMs and other manufacturers as it relates to drug switching.

The third is a letter from Medco and Trigon in response to the Department of Personnel Training's RFP. Medco is one of the largest PBMs, and Trigon is currently Virginia's largest single insurer and HMO.

Contained within the response is their opinion and, in my opinion, criticism of drug switching. The first is an editorial comment in response from the June published issue of Money Magazine sent in by the American Society of Health

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System Pharmacists. I would like to directly quote from this letter the following statements:

"Unfortunately, the formulary system which our organization helped pioneer in hospitals over the past four decades is perverted by some managed care plans. Rather than basing formulary selection based on the best judgment of the physicians and pharmacists who are involved in treating the patients locally, some managed care plans are prone to design national formularies with their large populations of patients in ways that give individual practitioners little or no input or volume. When combined with inflexible rules for enforcing formulary restrictions this approach has the potential of subverting good patient care."

In addition to these documents, I know the Board of Pharmacy has discussed concern regarding drug switching practices and both the Medical Society of Virginia and the Virginia Pharmacists Association supported the previously-proposed legislation that would have outlawed the practice. Therefore, my premise in mentioning all of these is, in my opinion, there seems to be already somewhat of a consensus by a large number of the groups represented on the Task Force that there is a problem with the practice of

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switching chemically dissimilar drugs, contingent upon a rebate or a kickback.

The final document in the packet that has been provided is an example of the potential negative outcome which will probably become more prevalent if this issue is not addressed. The document is a copy of the recent amendment to a group policy contract. It states that "The Company...," referring to the insurance company, "... will determine whether a particular generic prescription drug is equivalent to a brand prescription drug." While the specific example refers only to generic substitutions, which is different from the specifics of what this Task Force is addressing, in my opinion, the message is loud and clear, "the Company" will make the final professional medical decision.

The question I would like to raise is, I realize that the Company may legally determine whose product it will and will not pay for. But, it seems to me this contract language usurps the pharmacist's and a physician's professional judgment, as well as the Virginia Voluntary Formularies' expertise in dealing with equivalent drugs.

Is this appropriate and is this what we want for Virginia's citizens and patients?

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Finally, as a licensed practicing Virginia pharmacist, I would like to close with a quote, once again, from the American Society of Health System Pharmacists' letter. It is one of the best statements I have read regarding this particular issue. "The safe, effective and appropriate use of medications requires the active partnership of the patient, the physician and the pharmacist. All three players must resist having their options dictated strictly on economic grounds. Prescription drug products are powerful therapeutic tools that should not be selected for a patient by individuals who are not involved in the patient's direct care."

Thank you.

CHAIRMAN TEEFEY: Thank you, Cindy.

Does anybody have any questions of Cindy?

NOTE: (No response.)

CHAIRMAN TEEFEY: Is there anyone else that wants to speak?

NOTE: (No response.)

CHAIRMAN TEEFEY: Okay. David? David is going

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to give an overview of the Medicaid Program. Somebody asked last week to give an overview of what we did in Medicaid as far as pharmacists are concerned.

MR. SHEPHERD: Good morning, ladies and gentlemen. My name is David Shepherd. I'm the Pharmacy Supervisor for Virginia Medicaid. I also serve as Staff for this Task Force, and we'll work with Michael Worthington and Michael Pyles to facilitate anything that you might need from the Department.

There should be a handout in your notebook under Section 6. It's my intent this morning to give you some insight into the Virginia Medicaid Pharmacy Program.

The first page is an outline of the topics I'll try to briefly or quickly go over. Actually, the first two sections are just some definitions, acronyms, a Glossary of Terms. Since both the Federal and the State Government like to use acronyms, it may be helpful as a reference to you when I get to referring to things such as AWP or NDC, et cetera.

The background of the Virginia Medicaid and Pharmacy Program. Under the approximately 35 services provided by the Virginia Medicaid Program, prescribed drugs are provided to eligible recipients as an

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optional service, along with 18 other optional services. Prescribed drugs have been a service since the inception of the Program and fundamental to appropriate health care of the patients.

Prescribed drugs are simple compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance, which are prescribed by a physician or other licensed practitioner of the Healing Arts, within the scope of their professional, practice as defined and limited by Federal and State law.

The drugs must be dispensed by licensed, authorized practitioners on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

Excuse me. I need to get my glasses. I forgot.

Federal Medicaid Regulations dictate the method for reimbursement under the Prescription Drug Program. Reimbursement is made on a retrospective fee-for-service basis, with payments limited to the lower of pharmacy's usual and customary charge or estimated acquisition cost of the drug plus, as established, dispensing fee to cover the pharmacy's

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overhead and profit. (Some states have experimented with enrolling Medicaid eligibles in Health Maintenance Organizations under capitated payment contracts, which is gaining favor throughout the United States.) In 1976, using authority to set an upper limit for services available under Medicaid programs, as provided under Section 1902 of the Social Security Act, the HCFA or the Health Care Financing Administration of HHS implemented drug reimbursement rules pertaining to upper limits for Medicaid and other programs.

Specifically, these regulations provided that the amounts the Department recognized for drug reimbursement or payment was not to exceed the lowest of: The maximum allowable cost of the drug as established by HCFA's Pharmaceutical Reimbursement Board for certain multi-source drugs. (Specifically generic drugs), plus a reasonable dispensing fee.

It might be good if I explain to you that our funds come both from the Federal Government and the State Government--approximately 50 percent from each. So, we have to comply not only with Federal regulations, but we have to comply with State regulations and sometimes they conflict. We have to be very careful that, as we carry out our Program, that

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we comply in both areas. This is a very controversial area, reimbursement, and that's why I'm spending quite a bit of time on it.

The estimated acquisition cost or EAC of the price, (the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers for a particular drug in the package size most frequently purchased) as determined by the Program Agency, plus a reasonable dispensing fee.

Third, the Provider's usual and customary charge to the public for the drug. Usual and customary usually defines what the cash paying customer would pay, would actually pay for the prescription should they not have any type of supplemental reimbursement.

The Regulations at 45 CFR established within HCFA a pharmaceutical reimbursement board. The PRB as it was identified, also identified multi-source drugs for which significant amounts of Federal funds were expended and was responsible for establishing the MAC for these drugs.

During its decade of implementation, a number of problems and concerns were voiced about the MAC Program by the pharmacies and the pharmaceutical industry. Specific concerns included: The quality of

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the multi-source drugs; two, the interpretation of "widely and consistently available" as related to the process used by the PRB in setting MAC limits; three, the adequacy of drug reimbursement; and, four, problems in administering the MAC and EAC Programs.

In 1983, a departmental task force was established to review the Department's drug reimbursement regulations at 45 CFR. Subsequent to the Department's review process, a Notice of Proposed Rule-Making was established August 19th, 1986.

The proposed rule was to remove the Department's rule that limited drug reimbursement under certain Federal programs, including Medicaid. In 1987, HCFA ruled again on the payment limits or upper limits.

On July 31st, 1987, the Health Care Financing Administration published a notice of the final rule for limits on payments for drugs in the Medicaid Program. In this final rule, they were attempting to respond to public comments; two, provide maximum flexibility to the states in their administration of the Medicaid Program; three, provide responsible but not burdensome Federal oversight of the Medicaid Program; and, four, take advantage of savings in the marketplace for multi-source drugs.

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To accomplish this, HCFA adopted a Federal upper limit standard for certain multiple-source drugs, based on application of a specific formula. The upper limit for other drugs is similar, in that it retains the EAC as the upper limit standard that state agencies must meet. However, this standard is applied only on an aggregate basis rather than on a prescription-specific basis. State agencies are, therefore, encouraged to exercise maximum flexibility in establishing their own payment methods.

A multi-source drug is one that is marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or under a proprietary name and without such a name.

A specific upper limit for a multi-source drug may be established if the following requirements are met: All of the formulations of the drug approved by the Food and Drug Administration have been evaluated as therapeutically equivalent in the current edition of the publication, "Approved Drug Products with Therapeutically Equivalent Evaluations," which are known as the Orange Book. Some of you are probably familiar with it. This is all the published approved drugs in the United States that the FDA --

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They make that available on a yearly basis with supplements on a monthly basis.

At least three suppliers list a drug (which is classified by the FDA as Category A in its publication) in the current edition of published compendia of cost information for drugs available for sale nationally.

The upper limit for multi-source drugs for which a specific limit has been established does not apply if a physician certifies in his or her own handwriting that a specific brand is "medically necessary" for a particular recipient. This is unique to Medicaid. I believe all the other programs that employ Federal upper limits or use some type of maximum allowable cost allow other types of overrides. But Medicaid is specific. It is required that the physician write "medically necessary" in his own handwriting on the prescription.

If it's a phoned-in prescription, they must send an actual handwritten copy to the pharmacy for documentation. This is an audit process and it's very important that the rules are followed with this. We do recoup monies as a result of this particular issue not being followed.

The handwritten phrase "medically necessary"

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must appear on the face of the prescription, but it does not address the use of a two-line prescription form. HCFA never has addressed a two-line prescription form, so we still are operating under the 1987 upper-limit rules.

The formula used to calculate the aggregate upper limit of payment for certain multi-source drugs is 150 percent of the least costly therapeutic equivalent that can be purchased by pharmacies in quantities of a hundred tablets or capsules or, in the case of liquids, the commonly listed size, plus a reasonable dispensing fee.

The other drugs issued deals with all of the drugs: A brand name drug certified as medically necessary by the physician; two, a multi-source drug not subject to the 150 percent formula; or, three, a single-source drug. This is where the EAC determination comes in, estimated acquisition cost.

I also handed out a sheet of all 50 states relating to their pharmacy payment and patient cost sharing. And, as you can see, it varies from state to state as to what they define their EAC to be. HCFA was very strict about making all states at least come to some form of what they determine to be actual acquisition costs or estimated acquisition costs.

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And, upon the threat, of course, of not allowing the states to have their State Plan, thus, not having Federal funds.

States may continue to use this existing EAC Program or adopt another method, as long as their aggregate expenditures do not exceed what would have been paid under EAC principles. HCFA publishes a list of multi-source drugs to which the upper Federal limit formula applies, which is revised every six months under the present rules and published, to my knowledge, probably in most of the compendia or is available through wholesalers.

The rule does not prescribe a preferred payment method for the states, but gives states the flexibility to determine how they will pay for prescription drugs under Medicaid. As long as the state's aggregate spending is at or below the amount derived from the formula, the state is free to maintain its current payment program or adopt other methods. States can alter payment rates for individual drugs, balancing payment increases for certain products with payment decreases for other drugs so that, in the aggregate, the program does not exceed the established limits.

The next piece of legislation that impacted

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pharmacy and Medicaid was something known as OBRA Now, this was a very important piece of legislation on the Federal level. It actually involved some rewriting of pharmacy issues. Virginia, prior to this legislation being enacted, had passed two pieces of legislation. One was a drug formulary, a restricted formulary and the other was a new drug review. With the passage of those two Bills, we had negotiated, with certain manufacturers, rebates related to the formulary. Actually, Merck Pharmaceutical had already signed a contract with us, and we had several other pharmaceutical companies negotiating for individual rebate contracts.

As a result of OBRA '90, these two Bills were repealed, subsequent to OBRA '90's enactment because of the conflict in the legislation between Federal and State.

OBRA '90 was very inclusive of several areas, not only dealing with reimbursement, but also dealing with the practice of pharmacy.

Rebate calculation, which was an important part of this, was a very involved, complicated issue and has been changed twice since its inception under OBRA '90. There were approximately 450 manufacturers that signed an agreement with HHS as a result of the

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rebate program. And, of those 450 manufacturers, most of them are still under the rebate program, which has been in place for approximately six years.

I don't think it's necessary that I go into the actual calculations of the rebate percentages. They are in my handout, and they were graduated from calendar year '91 through '94, initially. They built in the cap that, if there was a price increase, that it could not exceed the Consumer Price Index-Urban or CPI-U, from '91 to '93.

Another issue that was addressed under OBRA '90 was prior authorization. Under OBRA '90, State Medicaid formularies must include all prescription products of manufacturers who have signed rebate agreements. States may have or require physicians to request and received official permission before a particular product can be dispensed. But states could not operate prior approval plans unless the state providers had a response time of 24 hours or unless the program had a response time of 24 hours of a request and provided for a 72-hour emergency supply of the medication. States could not restrict a newly-approved pharmaceutical product until six months after approval. States may restrict all drugs in the therapeutic class, quantities per prescription and

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refills as necessary to discourage waste.

The Congressional intent of the prior authorization provision was not to encourage the use of such programs, but rather to make available to the states for the purpose of controlling utilization of products that have narrow indications or high abuse potential.

OBRA '90 did not provide any set-aside monies or allocations to increase pharmacy reimbursement. But, until 1995, the Federal Government could not modify the formula on reimbursement limits to reduce reimbursement to pharmacies, as the result of a moratorium for that time period. The purpose there was to study the reimbursement levels nationwide in the Medicaid Program. The moratorium was lifted and subsequently there have been changes in reimbursement structures.

Drug Utilization Review was a very important piece.

Do you want me to go faster?

CHAIRMAN TEEFEY: We've got to go a little bit faster because we have a lot to cover.

MR. SHEPHERD: Okay. I think Carol is going to cover most of the DUR anyway, so I don't need to worry about that.

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Another important piece of OBRA '90 was electronic claims management, which Virginia implemented in June of 1994 after a pilot program and went statewide by August of 1994. Today we have 95 percent of our claims, in the Medicaid Programs, submitted in the outpatient population on-line point of sale.

Not only does that adjudicate the claim, it tells the provider that the patient is or the recipient is eligible, it tells them how much they're going to get paid, and it carries with it the Pro-DUR enhancement, which is a very important piece for quality assurance. There are at least ten to eleven Pro-DUR areas that are addressed that were initially called alerts. We now have implemented three areas in over-utilization known as early refill, therapeutic duplication and dose duration and allowed a prior authorization number or medical necessity to be entered into the computer without having to go through a paper process. This has proved to be a very cost savings initiative and we are still gathering data as to how effective that has been. That has happened within the last two years.

OBRA '90 was subsequently amended at least twice. In the Veterans' Health Care Act in '92, it was

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determined that the prices were being raised in the Federal programs under the VA, Public Health. So they had to amend OBRA '90 to allow the prices to be reduced back to those particular entities. It also in '93 allowed back or brought in an anti-formulary provision. Formularies were not allowed under OBRA '90. But, as of '93, states could initiate a formulary, and a six-month window for new drugs was changed.

Now, specifically, Virginia Medicaid Pharmacy Program-- With our agreement with the Health Care Financing Administration, under our State Plan, we basically follow or comply with Federal guidelines. We have some flexibility in certain areas, but we primarily do not cover DESI drugs, drugs that have been recalled, experimental or non-FDA approved drugs, drugs used to promote fertility, drugs used for cosmetic purposes such as hair growth and skin pigmentation and vaccines for routine immunizations; that's pharmacy specific pigmentation. Vaccines are covered in one of the other programs.

We have complied with the Federal upper limits since its inception and we also have Virginia Maximum Allowable Drugs that go outside of the Federal upper limits, but have their own criteria as far as

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determining whether or not we set a MAC on that particular drug and that is subject to the Virginia Voluntary Formulary.

Prior to 1990 reimbursement for prescriptions were AWP plus $3.40 per prescription.

October, 1990 reimbursement changed to AWP minus 9% plus $4.40.

During 1989 to 1990 the fee was also reduced to allow only one prescription per drug for a specific patient per calendar month.

In 1995, the dispensing fee was reduced to $4.25 as a result of the moratorium sunset clause in OBRA '90.

The rebate program was initiated in 1991. And, as I spoke earlier, Virginia had already implemented a state-specific rebate program, and that was repealed.

Retrospective DUR was initiated in 1991 to comply with Federal statutes.

The Virginia Health Outcomes Partnership, also known as VHOP, was initiated initially to facilitate voluntary prior authorization and has evolved to a prototype disease management/outcomes based program.

The Department is presently under request for

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proposal for a Disease Management and Outcomes Management.

Other legislative initiatives have included formation of a Pharmacy Liaison Committee made up of representatives from the pharmacy community to address pharmacy-related issues pertaining to DMAS. This committee meets and has met approximately every month for the last two years as a result of budget language two years ago.

As of this year, we're participating in four studies as a result of the '97 legislative session. These studies include: HJR 630 of which you are a part; two, budget item 322 representing the feasibility of payments for cognitive services; three, HJR-574 to study impact of the practices of PBMs on the Commonwealth's citizens and upon the health care market; four, HJR-623 Compliance with Pharmacy Freedom of Choice.

All four of these studies have been through a sister-agency agreement with the School of Pharmacy, MCV. They are performing the studies, of which Michael has this particular study.

Quickly over Pharmacy Expenditures. In the back of your handout, there is a spread sheet that gives you eight years of expenditures in the Pharmacy

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Program starting in 1989 through 1996. The headings: Number of claims; expenditures in dollars; rebate dollars collected starting in 1992; expenditures le: rebates; total Virginia Medicaid expenditures; and, percent of total Medicaid expenditures attributable to pharmacy.

As you can see, the trend has been over the eight years for the cost to go up, increasing practically every year, from 4.7 million in 1989, excuse me, expenditures 71 million in 1989 to 220.5 million in 1996. The numbers of claims have also increased almost double since 1989. 4.7 million claims in 1989 and 7.9 million claims in 1996. There are many reasons for this, one being our eligibility base has increased tremendously due to Federal programs, primarily.

OBRA '90 was a big impact in that, is that correct, Joe?

CHAIRMAN TEEFEY: Correct.

MR. SHEPHERD: What has stayed consistent, though, is that the percent of the pharmacy total has remained around eight to seven percent of the total budget. Pharmacy claims are the highest claim volume service within the Agency, and we deal with an extremely large data base. There are over two hundr

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thousand national drug codes in our file. We have a monthly upload from First Data Bank, which is also known as Blue Book, one of the national compendia for AWP that lists all the drugs. This is a national compendia book. This is the Red Book. There is another one known as Medi-Span. Most states under the Medicaid Program do subscribe to the Blue Book or First Data Bank.

This is a highly intensive program that requires monitoring or exclusive monitoring, not only from compliance issues, but we're fortunate enough that we have a good DUR Program, not only retrospectively but prospectively that helps us in that respect.

When OBRA '90 was initiated or implemented in this State and the DUR Program came about, we contracted with Carol Pugh to actually initiate the program for us, and I will let her have the stage, unless there are any questions.

CHAIRMAN TEEFEY: I think the important thing I want you to remember is Medicaid does not have formulary, so everything in that Orange Book, ever drug in that Orange Book is eligible to Medicaid recipients.

I think that's the first most important

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thing.
Yes, ma'am.
MS. PIGG: Can I ask you a question? The way the rebate structure works in Medicaid, if a manufacturer elected to not give you a rebate, would their drug be covered?
MR. SHEPHERD: No.
CHAIRMAN TEEFEY: We have the option not to cover it.
MR. SHEPHERD: Right.
MS. PIGG: Right.
So, can you describe for me the clinical process around the whole rebate structure? I mean, you don't use formularies, per se, but I think your goals were to make sure the quality of care was good for our citizens of Virginia, our eligibles, and also to contain the costs. So, what is the clinical process around the whole rebate structure? I don't quite understand where the clinical piece comes into play. If the information we have says that if they, basically, agree to give you a rebate, you'll cover their drug.
MR. SHEPHERD: Actually, there is no clinical aspect related to the rebate portion of the statute. The clinical aspect would be a result of the DUR or

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Compliance Review. Should there be a problem in a particular therapeutic class, we would not allow our recipients to be endangered. And, from the standpoint of what the Federal Government requires, they do make exceptions and you can make an exception with HHS through the Secretary of HHS, should it be necessary. So, they may not rebate, but if it's an essential drug that's needed, then an exception could be made.
MS. PIGG: How about if it's a class like a--
MR. SHEPHERD: A total therapeutic class? A total therapeutic class could be excluded. I'm sorry, H2s?
MS. PIGG: Well, I am just using that as an example. But, if Zantac came in and said, we will rebate you in the absence of any clinical review, which it doesn't seem like there is, but Zantac says, we will rebate you; Pepcid says, we will not rebate you. In that case, would Pepcid not be a covered drug?
MR. SHEPHERD: Correct. There was a conscientious decision made by certain manufacturers--Roche being one--that certain drugs would not be rebatable. One happened to be Valium, and Valium is not covered in the Medicaid Program, as a result of that.

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CHAIRMAN TEEFEY: The contract of rebate is between HCFA and the drug manufacturers.
MR. SHEPHERD: Right. Which makes it very problematic, because we actually administer the program. The states administer the program, collect the monies, do all the record gathering and send that to HCFA. But the agreement is with the Health Care Financing or through HHS.
MS. PIGG: But because they're rebate contracts, even though they are with HCFA, that ultimately determines what drugs the citizens of Virginia can and cannot get, is that correct?
MR. SHEPHERD: Not in totality. I mean, you can make the exception, should it be necessary. We have means to do that.
Does that answer your question?
MS. PIGG: Yes.
DR. HADLEY: I have a question. I have a question.
MR. SHEPHERD: Oh.
DR. HADLEY: What happens if a Medicaid patient presents a prescription from their physician for Valium. You just said it's not covered.
MR. SHEPHERD: It's not reimbursed.
DR. HADLEY: Okay. So there is no process for

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exception; that basically the patient would have to, under that, whether it would be a therapeutic substitution--
MR. SHEPHERD: We have had an appeal related to Valium not being covered, since the inception of OBRA '90. And those appeals actually were voted or we did not cover it even with the appeal.
DR. HADLEY: So, in essence, in those cases, the Medicaid patient either must find the means to pay that out of pocket or agree upon its therapeutic substitution--
MR. SHEPHERD: Correct.
DR. HADLEY: --with their physician.
MR. SHEPHERD: Correct.
DR. HADLEY: Another drug in that category.
MR. SHEPHERD: Correct.
DR. HADLEY: Okay.
MR. SHEPHERD: Diazepam is available generically from numerous manufacturers.
DR. HADLEY: Oh, okay.
MR. SHEPHERD: There's a whole list of them in the Virginia Voluntary Formula and Valium is Diazepam, chemically.
DR. HADLEY: Okay. So its generic substitution?

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MR. SHEPHERD: Yes.
DR. HADLEY: Okay.
CHAIRMAN TEEFEY: Yes, Larry.
DR. BLANCHARD: Yes. This is Larry Blanchard. Is the mechanism for rebate just a strict numerical rebate percentage that applies to everybody? It's not based on the volume or market share?
MR. SHEPHERD: No. The differentiation is between generics and brand name or sole-source drugs.
DR. BLANCHARD: Right.
MR. SHEPHERD: It can go up as high as 50 percent on the sole-source, based on the best price that that particular manufacturer sells that product for.
DR. BLANCHARD: But it's not a negotiated amount. It's pretty much set, according to what their--
MR. SHEPHERD: Correct.
DR. BLANCHARD: --basic price in the marketplace is.
MR. SHEPHERD: Correct. And this has been audited by the OIG extensively--extensively.
DR. BLANCHARD: There's another comment in your presentation that states, "... may not restrict

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a newly-approved pharmaceutical product until six months after approval." That's still in incentives for OBRA '90, is that true?
MR. SHEPHERD: Initially, the six-month limitation under OBRA '90 did not allow us to restrict any new product coming on the market, FDA approved, for six months. In 1993, that was changed as a result of an amendment to OBRA '90.
DR. BLANCHARD: So that restriction has been completely eliminated?
MR. SHEPHERD: Right. Correct.
DR. BLANCHARD: Is the practice of your drug program to evaluate those drugs promptly or, in general, if the drug is released and you don't know anything bad about it, it's approved until--
MR. SHEPHERD: Unless it meets one of the criteria of a drug that may be an abusable drug or something of that nature.
DR. BLANCHARD: Short of that--
MR. SHEPHERD: Right.
DR. BLANCHARD: --it's available to the citizens once it's approved?
MR. SHEPHERD: Yes. As soon as we can get it in the file.
MS. PIGG: What preempted your,-- Well, anyone

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connected with HCFA said you couldn't have a formulary. But prior to OBRA '90 you we're going down a path of a closed formulary in negotiating rebates with the manufacturers. What was with your thoug... process there? Were you going to have a clinical review--
MR. SHEPHERD: Yes.
MS. PIGG: --to restrict drugs in order to get--
MR. SHEPHERD: Yes. There was a committee. There was a committee.
CHAIRMAN TEEFEY: Yes, sir.
SENATOR NEWMAN: I think you have calculated what the lost impact would be to Medicaid that would affect you. Have you guys looked into the cost that that would affect you by?
CHAIRMAN TEEFEY: It would be hard to do that since a recipient can appeal to us, and they have to have that drug filled. We don't have a formulary and that's why we have the presentation by Medicaid. The thing I want to emphasize is Medicaid does not have a formulary, and, if a drug is switched or is forced to switch and the recipient appeals it, then they have to get the drug that the physician prescribes for them.
SENATOR NEWMAN: Maybe I can ask you, then.

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When we start presenting information in the General Assembly, it seems to me one of the vital pieces is, one, how much is this going to cost the State,--
CHAIRMAN TEEFEY: Right.
SENATOR NEWMAN: --and I don't know how we're going to calculate it, but I think we have to find some way to try to calculate that. And, then, the other question is, what's the medical implication of what we're doing now and have there been ramifications that have been detrimental to patients.
CHAIRMAN TEEFEY: You're exactly right. It came on so fast during the General Assembly, we didn't know how the rebate portion would be affected and that's what our main argument was. If we discriminate against the manufacturer and say, you can't switch or you can switch to that drug, does it affect our rebate--ability to get those rebates. And, since the General Assembly, we have given it a lot of thought and that person can get that drug anyway. If that person appeals to Medicaid, then the pharmacy has to fill the original drug that was prescribed for that patient, because we don't have a formulary.
MR. COUNCIL: If it's not rebatable, it's not covered?
CHAIRMAN TEEFEY: If it's not rebatable, we

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have the option not to pay for it, that's right. But most of the drugs we have, most of the manufacturers have a rebate agreement to protect them.

SENATOR NEWMAN: So, on a de facto basis, there is no drug switching program in Medicaid now, other than those few that are not covered?

CHAIRMAN TEEFEY: There might be drug switching, but the individual recipient can get that drug that was prescribed for them, if they appeal.

Yes, sir?

MR. AYOTTE: Do you grant all of your appeals for drugs? Your Department has the ultimate say whether or not a drug will be covered?

CHAIRMAN TEEFEY: Yes, sir. Any appeal that comes in from a recipient has to be heard by Medicaid, and it has to be ruled on within a 90-day period.

MR. AYOTTE: My question was, do you grant all drug appeals or you have the ultimate say? I'm just remembering that thing that Cindy passed out earlier that said the Company has the determination. That sounds very similar where there would be an appeal process to be able to get the drug. But, you need to appeal.

CHAIRMAN TEEFEY: Any appeal that is registered with Medicaid has to be heard by Appeals

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Division.

MR. SHEPHERD: Right. Yes, and even to go to an Administrative Law Judgment.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: Maybe I'm not quite getting it. Can you help me? If someone comes in and has a prescription for whatever it is, and they are told that that is not covered, do they get that noncovered drug immediately or are they rejected to get that noncovered drug? What is the process for appeals and how many of these people know about the appeals process? Therefore, just take the other drug, and what is the effect of that in the 90 days? Do they then get the other drug and pay for it and be reimbursed?

CHAIRMAN TEEFEY: Let me go back to the first thing. If they bring a script in and they want that script, under our HMO contracts and all of our contracts, that pharmacist has to fill that script, because we don't have a formulary. Most HMOs and most insurance companies have a formulary.

And, if that drug is not on that formulary, that means that the insurance company is not going to pay for it. In our agreements we have with the HMOs,

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anything that is covered under our State Plan has to be covered by that HMO. So, even though HMOs have formularies, it doesn't take -- Medicaid is not ruled by that formulary, because we have an open formulary. And that's specified in the contract we have with the HMOs.

MR. COUNCIL: But, she said, excuse me, "Anything covered by the State Plan."

CHAIRMAN TEEFEY: The State Plan, there's a State Plan. It's all of those pharmaceuticals that are covered by the rebate program.

MR. COUNCIL: Okay.

MR. SZALWINSKI: Are there drugs that are not covered by the rebate program?

CHAIRMAN TEEFEY: Valium.

MR. SZALWINSKI: Are there other drugs?

MR. SHEPHERD: Yes.

MR. SZALWINSKI: Are there any--

MR. SHEPHERD: Primarily generic companies that really aren't--they don't have Nationwide distribution. There have been companies that have been, and primarily the generics again, that have been dismissed from the rebate program for various reasons.

MR. SZALWINSKI: So there is a formulary and

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there is a prior authorization program for things such as drugs for cosmetic purposes and other things that are exclusions that you do not cover?

CHAIRMAN TEEFEY: There are exclusions we don't cover, right.

MR. SHEPHERD: Right.

MR. SZALWINSKI: So,--

CHAIRMAN TEEFEY: But it's not a formulary. They're exclusions that the State has decided not to cover.

MR. SHEPHERD: If we get into a definition of formulary, it could be restrictive, open, closed, et cetera, et cetera. We really considered having an open formulary. That's what--

DR. BLANCHARD: 99 percent.

MR. SHEPHERD: Yes, probably 99 percent of the drugs are covered. It's open.

Yes, ma'am?

DR. KNAPP: If somebody comes in with a prescription for a drug that is not on the State Plan, but there is a generic equivalent for it on the State Plan, they will get the generic equivalent. But if there is not a generic equivalent for it on the State Plan, they will not get the drug?

MR. SHEPHERD: That is a possibility.

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DR. KNAPP: Unless they pay for it.
MR. SHEPHERD: That is a possibility.
DR. KNAPP: So there are medications that patients could come with a prescription for--and excuse the grammar, but there is no generic equivalent for it, so they will not be able to get it, unless they pay for it themselves or they appeal?
MR. SHEPHERD: Right.
CHAIRMAN TEEFEY: Right. That, I can tell you that would probably happen once in a million times.
DR. KNAPP: Well, that was going to be my next question, too.
MR. SHEPHERD: Yes.
CHAIRMAN TEEFEY: Because we have rebate agreements with all the major manufacturers. And, if they rebate, if those manufacturers rebate, we have to have their drug on our Plan.
MS. PIGG: But the bottom line is your list of things that are covered or the eligibles, call it a formulary, call it not a formulary, is totally economically driven by the rebate structure from the manufacturers?
CHAIRMAN TEEFEY: Because HCFA says it has to be that way.
SENATOR NEWMAN: Mr. Chairman?

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CHAIRMAN TEEFEY: Yes, sir.
SENATOR NEWMAN: Given that, if we did have a Bill in Virginia that says that you cannot switch drugs based on a rebate, would that do detriment to your current agreements if all of them then started pulling back from the rebate saying, we don't have to give the rebates? And what would be the effect of that on the Commonwealth of Virginia, as far as Medicaid goes? Or, can we calculate that?
CHAIRMAN TEEFEY: I think when you put rebates in there, I think you're asking for it. I would have to get an opinion on that, Senator. I think you're asking me something that I really can't answer right now. But I will get you an answer on it. But I think when you tie rebates in there, I think you're really--you're really eliminating the program from anything.
MR. SHEPHERD: May I say something?
CHAIRMAN TEEFEY: Yes, ma'am?
MS. POWELL: I think it's important to remember, however, that the rebate contract is a national contract. So, if you decide not to offer, not to pay the rebate in Virginia, as a manufacturer, your drugs would not be reimbursed in any Medicaid program around the country. So, that a manufacturer making a decision about whether to sign a rebate contract needs

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to look at the entire contract.
SENATOR NEWMAN: But that raises a question about whether, Mr. Chairman, we could possibly pass the law to make Virginia required to break the law to where you would be required to take a rebate; that we would say, it would be unlawful for you to take.
MR. SHEPHERD: To my knowledge, Federal statute would take precedence.
MS. PIGG: But do you want to treat your Medicaid eligibles differently than the other citizens of the Commonwealth?
MR. SHEPHERD: That was a primary reason that we asked to be exempted from the legislation that was introduced last year.
CHAIRMAN TEEFEY: Yes, ma'am?
DR. KNAPP: I mean, after listening to this, I think the Medicaid citizens of the Commonwealth are being treated differently. They have a bigger, more open formulary. So, in that respect, it's advantageous.
CHAIRMAN TEEFEY: We have a bigger and we have an open formulary because the General Assembly has decided that's the way it is going to be. I mean, when we came over for a formulary a couple of years ago, the General Assembly decided it was not in the

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best interests of the Medicaid recipients to do that.
MS. PIGG: But, did the General Assembly, I mean, then you've got this HCFA, I mean, it's just too many things that's going around. You have HCFA saying, you pay us, you get covered; you don't pay us, you don't get covered.
CHAIRMAN TEEFEY: But there are so few drugs that are not covered by the rebate program. The example that we use would be once in a million that somebody would come in with that drug. If it's in that book, it has an NDC number on it and that company rebates us, then that drug is covered.
Just like David said, you have a few small generic companies that are not in the book, that they don't have contracts with.
MS. PIGG: But the issue is there is no clinical basis to what is covered or not covered? It is simply a monetary arrangement?
CHAIRMAN TEEFEY: It's a monetary arrangement with HCFA and the drug manufacturers, you're exactly right.
DR. BLANCHARD: But, Mr. Chairman, the one exception that there is, is that the clinical basis is FDA approval. So, there has been a clinical assessment of safety and efficacy.

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But, the point is, at the end, and the other gentleman, I think, is well taken, that one of the reasons we're here is to see if any legislation that would be recommended uses the word "rebate" appropriately, so that we're not talking apples and oranges when we're prohibiting "rebates," and I think that's a good point.

MR. AYOTTE: Mr. Chairman, I also think it's important that we talk about whether or not legislation is needed. You know, looking at the current Board of Pharmacy Regulations and things that currently exist, it may not be a need for this, you know, any other additional legislation that would burden everybody.

CHAIRMAN TEEFEY: Well, I think before the day is over, we're going to get a definition of exactly what we're talking about. And I think that's what we're leading up to. Because, you know, we have done a lot of reading between the last meeting and this meeting, and we have talked to hospitals, we have talked to pharmacists, we have talked to physicians, and it's all different. And, when Mike gets up there he's going to point out some of these things.

MR. SZALWINSKI: Mr. Shepherd?

MR. SHEPHERD: Yes.

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MR. SZALWINSKI: Can I just make one request? On your Sheet Number 1, your excel spread sheet in the back, is there a way that we could get added in there the number of covered people for the denial?

MR. SHEPHERD: Recipients?

MR. SZALWINSKI: Recipients--

MR. SHEPHERD: Sure.

MR. SZALWINSKI: --on an annual basis so there is a denominator in there.

MR. SHEPHERD: Be glad to.

MR. SZALWINSKI: Would be helpful.

MR. SHEPHERD: Be glad to.

Any other request that I can help with?

NOTE: (No response.)

MR. SHEPHERD: Thank you.

CHAIRMAN TEEFEY: All right. We have Carol Pugh, and Carol is a Doctor of Pharmacy, and she set up our DUR Program, and it's been the model around the Country. We get feedback from all of the Country that they're using Virginia's Program, and we owe a great deal to Carol. She did a marvelous job of this and that's why we asked her to take time out of her busy schedule to talk about DUR.

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DR. PUGH: Good morning. I'm a pharmacist in Virginia, and I am also on the faculty at the MCV School of Pharmacy, or, excuse me, the VCU School of Pharmacy. And, I think you'll tell from my handout material that I'm used to talking to people and giving lectures, and so forth.

This morning I'm going to try to be very brief. I have prepared a fairly comprehensive handout for you so that I don't need to go through every little detail. You will have it for your reference. I didn't realize that you were going to have three-ring binders or else I would have brought it with three holes in it, but I apologize for that oversight.

You have already heard about OBRA '90. David has talked about it. What I'm here to talk to you about is the DUR portion of OBRA '90. And, it basically, has three major components related to DUR-type activities. One was that it mandated the creation of a retrospect and prospective DUR Program. There were a number of items that had to be included in this. There is a list of nine different types of drug-related problems that are supposed to be included in the program and they're listed for you on the handout. I know you all can read, so I won't read

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through them all.

It also mandated that patient counseling be offered to Medicaid outpatients. And, again, it mandated a number of items that needed to be included in the counseling. And, for those of you who are pharmacists, there are things that are very obviously things that we would want to include in counseling anyway.

Then, finally, with respect to the DUR portion of OBRA '90, it mandated that pharmacists keep a profile. And, in Virginia, this is a little bit redundant, because we already had a requirement within the State to keep a profile. But, in OBRA '90 it specified certain items that needed to be kept in that profile for every Medicaid recipient.

Now, the thing to remember is that OBRA '90 was specifically for Medicaid recipients. And many states, including Virginia, passed legislation or regulations that made OBRA '90 generalizable to the entire population. So the incentives for OBRA '90 compliance within Medicaid, as David has previously mentioned, for the Agency, for DMAS, if they didn't play along with this, HCFA had a pretty big stick. It said, if you don't have this program in place by January 1st, 1993, we're going to remove our funding

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for your drug budget, which, in this State, is about 50 percent of the money spent on drugs. So the Agency had a very strong incentive to want to do this. Even if it was the right thing, they had a really strong incentive to want to do it, anyway.

For pharmacists, their incentive was certainly not monetary, but, as I mentioned, Virginia also has a, basically, OBRA '90 requirement that applies to all citizens. And this actually went into effect six months before the required OBRA '90 day. So, there were incentives all the way round for this program to occur.

If you will turn to the next page, I will give you a little bit of history and explain what's involved in the various components of the Program.

Now, I'm not a native Virginian, I will admit that. All of my higher education is here in Virginia. But, I have been told that in order to be a true Virginian you have to give a history of what's going on. So, I will give you a brief history of how I became involved in this process.

I was hired as a DUR consultant by an inter-Agency Agreement between DMAS and the VCU School of Pharmacy. I started in 1992, in January, and my job was to develop, implement, and manage the Program,

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with the idea that once it was up and running, Medicaid would take over its management. And that, indeed, happened three years later in January of 1995.

So, for the last two and a half years, Medicaid has been running the Program that I helped them develop.

Now, the DUR Program has two major components. It has a retrospective component and a prospective component, and I will first go through the retrospective component.

Obviously, by the name, it is something that occurs after a drug has been dispensed. And its main purpose and utility is in identifying patterns of prescribing, dispensing, and patient use of medications. It uses claims that have already been filed, and the Program in Virginia uses both pharmacy and medical claims. Now a number of the states use only pharmacy claims and there are some commercial DUR programs that only use pharmacy claims. I think one of the strengths of the Virginia program is that it also factors in inpatient and outpatient claims for hospitals, practitioner office visits, and laboratory claims, along with all the pharmacy claims. So it allows for developing a much better picture of what's going on in service utilization.

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Initially, the criteria development process used was, we identified therapeutic categories and types of drug problems that were of concern. A DUR board was named. It consisted of and still consists of, to my knowledge, physicians, pharmacists, representatives from the Schools of Medicine and Pharmacy, various professional associations within the State, and so forth. So, they're all practicing physicians and pharmacists, and I believe nurse practitioners are represented now on it, as well.

And, we also, when we did the first go round with the criteria, because it was such a hot topic and there was a lot of anxiety all over the place, we also accepted input from representatives of the pharmaceutical industry and various other people that were interested in the process. In general, we did get, almost on every set of criteria that were developed for every therapeutic class, we did get input from the industry. Generally, it was fairly minimal because, as I tried to show them, and until they saw it I guess they didn't believe it, we really weren't out to get anybody. We were really interested in picking out the most therapeutically appropriate problems to look at and to try to solve.

Now, the way a retrospective DUR Program

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works is you need a really big computer, and it doesn't work on a PC. Well, there are some programs that work on PCs, but, basically, you need a really big mainframe computer. And what happens is, six months worth of the pharmacy and medical claims are combined into one large file, and then they're sorted by the recipient ID number so that you put all the claims for one person together, and then again by the date of service, so that you can look at things chronologically. And this listing of claims for an individual recipient is called a patient profile. So we have for a six-month period all the medical claims, all the pharmacy claims arranged in chronological order for every recipient in the Medicaid Program.

Then, these profiles are checked against the entire DUR criteria catalogue. I lost track of how many criteria we had. It was up into the several thousands when I left the Program. I'm not sure how many are there now. I'm sure some have been added and deleted and changed, and so forth, but it's a lot.

Any patient profile that has one or more, the terminology is a criteria violation. In essence, a drug interaction, a dose that's too high, a duration of therapy that's too long, is known as an exception. And when these profiles are marked electronically by

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the computer system and now, instead of just being called a patient profile, we now call it an exception profile, because it contains an exception to the criteria.

Each month about a thousand exception profiles for one or more therapeutic categories are randomly selected for review. The reason we used a random, or they used a random selection right now is that there just would be too many profiles to be reviewed if we looked at all of them. The exception profiles contain all of the exceptions that have been found. So, say the particular profile run was to look at antibiotics. Well, if there were some other problems that were noted with cardiovascular drugs or pulmonary drugs or any other type of drug that was noted for that patient, it will show up on the profile, as well.

Over the course of the year, though, all the therapeutic categories are covered through this DUR process. So once a whole year is over, we've gone through the entire criteria catalogue, run profiles for them, and, basically, evaluated everything that goes on.

Now, these profiles, these exception profiles, are then reviewed by a group of pharmacists

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and physicians known as a DUR Committee, and it's their job to take this computer sifting process, which is clumsy at best, and really look at what's going on with this particular patient. And, if, in their judgment, the problem looks like it's been solved, it may have been something that happened at the beginning of the six months and looking through all of the claims for the patient, you can tell that the problem has been resolved, then they will say, this provider does not need to receive a letter saying there is a problem. The problem has been fixed.

The DUR Committee members then decide whether or not an intervention letter needs to be sent. And, they send the profiles back to Medicaid and the DUR pharmacist reviews it one more time as a QA check of sorts.

One of the problems I noted when I first worked with the Program is, we had some really zealous reviewers and some more reasonable reviewers, and what we tried to do, the QA check step is an attempt to make sure that we're sending letters out to the same degree of problem. So, if somebody has a little bit higher level or lower level or lower threshold of concern, we make sure that we are not sending letters out willy-nilly to people that we -- When we send

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letters, that they're worth looking at. And, when the Program first began, I received a lot of feedback from providers that said that we were, indeed, making that happen because we were not getting a lot of letters coming back or responses coming back saying, this is dumb, this is a waste of my time, and so forth. Most of them were very positive or at least neutral in terms-- in their response.

Along with the letter is a response form, and the provider is asked to send back some feedback as to whether or not this is really a problem, what's going to be done, then fix it, and so forth. When the response form is received by Medicaid, it is then posted onto the DUR data base. Then, six months later a review profile is generated to check and make sure that any of the other problems that were noted have been fixed. This is another one of the reasons why not every category is looked at every month, because, if you did that, you'd be constantly dealing with the same people over and over and over again. You need to allow a little bit of time for the process to work for changes to occur, and so forth. So, that's what's involved in the retrospective DUR process.

Now, this process is not perfect, like most things in the world. It has some advantages and

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disadvantages. I have listed those for you on the top of Page 3. The major advantage is that it allows for the determination of the trends of drug use across the whole patient population. So, you can look at the prescribing, the dispensing, utilization. It also allows and serves as a backup for the prospective DUR Program, which I'll talk about in just a minute. Because of the nature of prospective DUR, we can't always find everything right up front, and so we have to allow for things that fall through the cracks and that's what retrospective DUR is good at.

Its major disadvantage, and I will be the first one to admit it, is that it occurs well after the fact. The proverbial horse has left the barn and now we're closing the door. The problem may have already been solved and an intervention letter may have gotten sent.

Another problem is that the profiles are patient based rather than provider based. And, what this means is that you can have a physician or a pharmacist that has a patient, one patient that has one problem and they will get a letter. A much more efficient way of dealing with this would be to use a provider profiling-type situation where you can send letters to pharmacists or physicians that have

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multiple problem patients, rather than sending one person one letter and then they don't hear from you for another six months. Right now, because of this all being based on the mainframe, the technology is a little bit behind the times. Actually, when I asked Medicaid to write the RFP, I asked for this, and it's now just beginning to be offered by the vendor who is providing the retrospective DUR services.

And, as I have mentioned, the process is inefficient. Again, I'll admit this. The intervention letters are generally sent out to only about ten percent of the exception profiles. And part of this is due to the nature of the mainframe computer and the way the criteria work, and part of it is just due to the fact that you're looking at a big time period and problems often get resolved and letters don't need to be sent out.

So that's sort of the quick view of what goes on with retrospective DUR. Before I move on to prospective, are there any questions?

DR. BLANCHARD: Can you give me an idea of the number of prescriptions or the number of recipients that receive prescriptions, compared to the number of exceptions you find that might deserve a letter? Do you know how many letters you sent out that's ten

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percent?

DR. PUGH: Well, roughly a thousand profiles are generated each month, and roughly ten percent of those result in letters, so that would be about a hundred. I know the enrollment numbers have changed since I was at Medicaid two and a half years ago. I'm not sure what the number of recipients that receive the drug benefits are.

CHAIRMAN TEEFEY: Do you know? We just, we have a DUR report that we've done, and I can get you a copy of that.

DR. PUGH: Yes, because the annual report to HCFA is due June 30th each year.

CHAIRMAN TEEFEY: As a matter of fact, we just signed off on it. I will get you a copy of it.

DR. PUGH: And that would have all the denominator numbers for the Program and what all is involved.

Other questions?

NOTE: (No response.)

DR. PUGH: Okay. The more exciting and interesting are the--

CHAIRMAN TEEFEY: Can I ask you a question?

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Could you pick up drug switching in the retro DUR?

DR. PUGH: It would be difficult. You would have to write -- I'm not sure the logic behind the DUR system has a pattern that would enable you to find that. Would it work as a therapeutic duplication-type problem?

MS. PIGG: I think it would have to do with the logic--

DR. PUGH: It would be very difficult.

MS. PIGG: – but what we could sort out was, was it a switch, just a switch made because the first drug wasn't working or was it a switch made due to the intervention? We may have to figure that out.

DR. PUGH: Yes, that's one -- That's another big drawback that I probably should have put on here is that you're dealing with the claims data, and those of you that are practitioners know, the numbers don't tell you everything. The administrative data set we're using for clinical purposes, and it's putting a square peg in a round hole, and it somewhat fits but it's not a perfect fit. So, that's another one of the reasons for having a DUR Committee review the profiles. Because, what the computer finds, once you have a practitioner look at it, they will say, well, this is nuts, this is not, you know, this is really not a

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problem in this patient given the fact, for example, if it was a drug interaction that could cause toxicity because of a decrease in the metabolism of another drug, and you see evidence from the lab claims that that drug level is being monitored, then you can assume that the practitioner is aware that this is a problem. They're taking care of it, and so you wouldn't send a letter.

So that is, one of the problems is, is that you don't know what's going on. It could have been an honest switch because, for therapeutic reasons. It could have been a switch because of, you know, other reasons. But you can't tell, you can't assign it that, as such.

DR. PUGH: Okay. Any other questions?

NOTE: (No response.)

DR. PUGH: Okay. On to prospective. Obviously, from the name, this happens before the prescription is dispensed, and it can be used to prevent problems from happening. And, just to make things complicated, there's not just one type of prospective DUR, there's two types. The first type is what's known as on-site prospective DUR. This occurs

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in the dispensing pharmacy before the claim is submitted. It involves the pharmacy's computer system and the patient profile that's on that system and any system DUR criteria. Now, depending upon what software the pharmacy is using, if they're using Computer RX, I know that they use the First Data Bank as their source of information for drug interactions and other types of criteria. Other programs use Medi-Span or the Red Book, as David referred to.

So, depending upon who the software vendor is, it's kind of like whether you're talking about MS Office versus Corell, versus a MAC or whatever. With PCs you have a lot of different variations of ways of doing word processing. There's also a lot of different software programs available for pharmacies to process the prescription dispensing process. And what ends up happening is, depending upon the system that's there, you may see slightly different types of messages come across. But any pharmacy that's computerized, I didn't want to state every one of them does have this, but they all should have it and it all should be turned on. And, one of the big problems that practicing pharmacists run into is that some of these programs have every interaction known to man, even the most insignificant ones. But, most of the

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programs do allow for a switch to turn on or off different levels of significance.

The majority of pharmacies do end up keeping on with the major significant interactions and problems and turning off the minor ones. So, otherwise, almost every prescription would probably end up with some kind of alert and nothing would ever get done. So computers are nice, but they also kind of mess things up sometimes. One of the important things to remember about the on-site prospective DUR is that it is the only way to screen for drug allergy interactions. Because of the information that's available in the claims file for the on-line perspective DUR, which we'll talk about in a minute, allergy is not part of that information, because remember, we're dealing with claims that are submitted to pay providers for the activities that they perform for a patient.

Local pharmacies have allergy information and their software can actually check for drug allergy problems. The other nice thing about these systems is, because it's locally within the pharmacy, generally, they can use several months to even years' worth of data so that you can look at a much longer period of time to look for potential problems. So that it allows

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for you to go way far back into the history of the patient.

On-line prospective DUR, on the other hand, occurs at the claims processor after the claim has been submitted, and it involves the claims processor's computer, which is usually a large mainframe, and the criteria that have been specified by DMAS, so that the DMAS/DUR Board has determined the prospective DUR criteria that are to be used for Medicaid recipients and that's what's used. It's not somebody else's idea of what's important. It's the DMAS/DUR Board's idea of what's important.

Now, the nice thing about this system is that it allows for the detection of problems regardless of where the prescription has been filled. So, if you have somebody that's going to 16 different pharmacies, and we did have some cases like this, and there's drug interactions, you can find them. If they're going to 16 different pharmacies and one is a Ukrop's, one is a Rite-Aid, one is an independent, one is some other chain, their systems don't talk to each other, and you wouldn't be able to find that. This is important therapeutically, but it's also important for abuse issues, as well.

The only other problem or the other criteria

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to remember with this type of DUR is that because of the system requirements, and by that I mean the amount of time that's available for this whole electronic transaction to occur, you can only use about two to three months' worth of prescription data in the screening process. Otherwise, it just takes too long and the whole--the world, as we know it, will grind to a halt, or maybe not quite that, but it's along those lines. It's a pretty bad mess. If you talk to any pharmacist who has ever had problems with a switch or has had the system go down on them, it's close to the end of the world.

So, what I'm now going to do is give you a generic overview of the prospective DUR process. And the reason I'm calling it a generic overview is because I've added a few steps in there that aren't necessarily things that Medicaid does, but I think will help you with the overall picture and in getting at some of the issues that you're dealing with as a Task Force.

So, the first step is, is that a prescription is presented to a pharmacist in a pharmacy and the prescription information, the patient information are entered into the computer. At this point, screening goes on to look for potential DUR problems, and this

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is the on-site prospective DUR that we've just recently talked about. Now, if problems are found, the issues are clarified with the patient and/or prescriber, depending upon the nature of the problem. Often the physician needs to be called and there may need to be a correction to the prescription or it may be that a replacement prescription is needed, and this is entered into the system.

If a new prescription is put in, it's again screened. So, you can just keep doing this several times. Usually, it doesn't take more than one go around in that loop before you can move on.

If you're lucky and there are no problems found, you can go to Step B, which is at the bottom of Page 3. This is where the claim is submitted electronically. Now, those of you that are familiar with using the Internet know you have to dial up and then wait and all of this kind of stuff goes on. The same kind of thing happens, more or less, when an electronic pharmacy claim is sent. The pharmacy needs to use their modem to dial into a switch, which then converts their information electronically to something that the computer that's processing the claims can understand. Now, the whole process for submitting a claim and receiving a reply back from the processor

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can take more than about 30 seconds. It just won't work. The switch is time out. It just -- The whole process just takes too long, because it takes more than 30 seconds. And the vast majority of this 30 seconds is involved in this transaction with the switch to the processor and then the processor back to switch, back to the pharmacy.

So, what I'm going to describe to you now, on the top of Page 4, which are the various edits or checks, this all takes place in probably less than five seconds. The eligibility edits is first because, obviously, if a patient is not eligible, there is no sense going any further with trying to process the claim. If the patient is not eligible, a denial message is sent, and usually this is a denial that can't be overridden, for obvious reasons. If the patient is eligible, we can proceed to Step D.

This is where things may differ from what Medicaid does. Is a number of programs now have some other administrative edits, and these may be things such as, is this drug on the formulary, is this a prior authorization drug, and so forth. So there are things that administratively deal with other programs that are being used.

Again, if there is a problem, a denial

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message will be sent and, depending upon what the health plan has decided it may be overridable; it may not be overridable. It may require a phone call in order to be overridable. There's all kinds of variations out there as to what can be done. Hopefully, the edits are passed, and we can proceed to Step E. This is where the actual on-line prospective DUR occurs. And, as is the case, we can have, either you pass the edits or you don't. If the edits aren't passed, the pharmacy is sent what's known as a DUR alert message, and, depending upon the setup that the plan has, it may or may not include a claim denial. And, again, depending upon what the plan has decided, this may or may not be overridable. And, if there is a problem, then the pharmacist will have to deal with it on the other end.

But, hopefully, we see Situation 2, which is that the edits are passed and the pharmacy gets the message that the claim has been approved, there are no problems. So, basically, there are two major outcomes from this process: One, is that--the one that we all like to see--is that the claim passes all the edits without any denials and the pharmacist may dispense prescription. The other one is that you may have a denial message or a DUR alert message, and then the

Page

pharmacist has to work to either override it and explain the rationale for why they overrode it; they have to make a phone call to do it; they may have to confer with the prescriber if it's a drug interaction problem, and if there's two different prescribers involved, they need to talk with two different people sometimes, and so this can be a fairly time-consuming process.

So, that's sort of the generic overview of what happens with that. I spoke with Mary Ann Rollins on Friday to ask about what was being done now with on-line prospective DUR since things have changed since I was at Medicaid. Originally, DMAS was not denying for any kind of on-line prospective DUR alert. This is mainly because we were new at it. We didn't want to overburden people with messages, and so we decided to take a cautious route and kind of phase things in.

My understanding is that now denials are being issued for therapeutic duplications, which generally means that's two or more drugs for the same pharmacologic class, so if two drugs can do the same thing, the patient really doesn't need to be on both of them. One of them should take care of their needs. Now, an important thing to remember about

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those denials that are being used by DMAS right now is that they can be overridden by pharmacists, and the pharmacists are asked to send a DUR response indicating the rationale for their override. This is a very reasonable approach compared to some other private health plans. So, it's a very conservative but very safe approach.

Another area that gets a denial message is an early refill. I don't know. Are you using 75 percent? David, is it 75 percent that you're using?

MR. SHEPHERD: 75 percent.

DR. PUGH: Most plans use 75 percent. If the prescription, for example, if it's before three weeks of a one-month supply that should have been consumed by the patient, then you'll get an early refill message. This doesn't mean that the patient can't get the drug. There are obviously reasons why people would need it. You know, they may have lost it. They be going out of town and need it. There's a number of very good reasons for early refills. The instructions may have changed, and they're using more drug than was originally planned. So, this is, again, overridable by the local pharmacist.

Another initiative is the excessive dose or duration of anti-ulcer medications. And this is mainly

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for clinical reasons, which also has a very big economic component to it, as well. If a patient's ulcer hasn't been cured within three months of using these medications, they require reevaluation and may require a totally different kind of therapy. So, there's monetary reasons, but the more overriding reason is the therapeutic reason. So, in a nutshell, that's some of the specifics for Medicaid DUR, for the on-line.

Now, like with the retrospective, there are advantages and disadvantages. The major advantage is that you can solve problems before they occur. It's a very proactive process. It can also be used as a direct abuse prevention tool, if the appropriate administrative criteria are written. And, that's something that requires a fair amount of criteria, because there are so many different drugs that can be used and some of them, it's not just you're looking at one particular drug, you want to find, are people getting a whole range of drugs, and so forth, but it is possible to use this system by writing administrative edits to do that sort of thing.

The disadvantage is listed at the top of Page 5. You can only address the tip of the iceberg because of the system's time requirements. So,

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although you might think that, well, prospective DUR gets things before they happen, it's great, it's wonderful. The problem is, because of the volume that's involved, you can't find or send back messages about every single problem or else the dispensing world would grind to a halt and nobody would get their prescriptions. So, because of the time requirements, we can only go for the tip of the iceberg. So in reality, you also need both the on-site and the on-line DUR in order to catch most of the significant problems. So, just running it on the processor's machine isn't enough. It also has to be run at the local pharmacy.

Now, are there any questions about the prospective DUR?

CHAIRMAN TEEFEY: Yes.

DR. PUGH: Yes.

CHAIRMAN TEEFEY: Under D up there, under the administrative edits,--

DR. PUGH: Yes.

CHAIRMAN TEEFEY: --this is where the formulary comes in?

DR. PUGH: Exactly.

CHAIRMAN TEEFEY: Is this, and I'm going back to the General Assembly now, and let's say a druggist

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has an agreement with the pharmacy or manufacturer where they get a rebate for a drug. I think that's one of the examples you-all used.

DR. PUGH: Okay.

CHAIRMAN TEEFEY: This wouldn't pick up that, would it, the administrative fees? It would just pick up the formularies that come from the actual insurance entity?

DR. PUGH: Yes. But, this is going on, on the health plans or the Agency's processor's computer. So it would only know what's going on, like what your rules are, or if this was for an HMO or for Key Advantage, one of the plans that State employees use. It would only know what they have said is on their formulary or whatever. It is only -- It's specific for that particular plan.

CHAIRMAN TEEFEY: All right. Let's go down to E, and let's have the clinical edits.

DR. PUGH: Uh-huh.

CHAIRMAN TEEFEY: Would the clinical edits pick up the chemical differences if they switched the drug?

DR. PUGH: You would have to write specific criteria for that and that is not a type of criteria that's generally used in the clinical edits. It's

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similar to what you find with the retrospective DUR.
CHAIRMAN TEEFEY: Okay.
SENATOR NEWMAN: Mr. Chairman?
CHAIRMAN TEEFEY: Yes, sir.
SENATOR NEWMAN: That raises the question, since we're here about drug switching, do your computers, as strong as they are, can they determine whether or not there has been a clinical problem with a switch? And, if so, what is that evidence or are your computers not doing that or able to do that?
DR. PUGH: The computers really are not able to do that, especially with prospective because problems usually develop after a patient has been taking the drug. There have, in the hospital environment, they have used some surrogate measures that show that there has been a problem with the drug. For example, dispensing Benadryl, which would indicate that somebody may have had an allergic reaction, and they needed that to help quell the allergic reaction. And there's a few other things we used in the hospital environment, but they're not perfect measures.
In the outpatient arena, which is what we're talking about here, I just don't see how it can be done, given the current state of technology, and, at

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least, especially with the Medicaid program with what is available to them, when maybe some other programs that have much better data bases that can do things better, but I kind of doubt it at this stage of the game.
MS. PIGG: Would that get at that--I'm asking Bill because it's been a while--where you can--
MR. TOWLER: On the claim.
MS. PIGG: Yes, on the claim.
MR. TOWLER: I don't believe that information can be transmitted.
DR. PUGH: Yes. There's a whole series of codes that have been put together by the National Council for Prescription Drug Plan, NCPDP, that allows pharmacists to respond back to DUR messages with a coded message that would indicate different things that could have happened; their reasons for things that have been changed, and so forth. But, unless the pharmacist submits that stuff, which is a separate transaction, which costs them money to send it in, that's probably, that would be the closest thing you could do.
I was reminded by one of the observers here that one thing you can also do, especially in the Medicaid program, since you do have integrated claims,

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is you can look for certain types of hospitalizations. So, if somebody stops using their inhaler and all of a sudden needs to go to the emergency room because they're in status hypnoticus, then you end up with a situation where you can say, umm, they didn't use their drug. Then this may have been the cause of the hospitalization. But you're still kind of out on limb because there may be some other things going on. They may have received a sample from their physician and there's all sorts of other things that can explain that. So there is no really good way to pin it, even with the computers that we have.
Yes?
MR. AYOTTE: I just want to make sure that the DUR Program which you're discussing and the people that service DUR, and it does mirror your managed care process, do they have the same formulary in their data banks when the claim bounces up against it?
CHAIRMAN TEEFEY: The-- Ask that again.
MR. AYOTTE: Earlier we talked about open formulary--no formulary or open formulary, whatever it was, that goes in against the First Health Data Banks. When a claim goes out in your capitated program, is that bouncing against that same formulary

Page

or is that bouncing against--
CHAIRMAN TEEFEY: No, it's not.
DR. PUGH: Because they're not submitted claims, are they?
CHAIRMAN TEEFEY: No.
DR. PUGH: So, that would be right. So the ones that are in the managed care plans would not be subject to this same DUR system. One would hope they'd be -- They'd be subject to another one, though.
MR. AYOTTE: They would be subject to the DUR system that is involved with the capitated process?
DR. PUGH: Whatever the plan is using.
DR. BLANCHARD: If we use this discussion as an attempt to educate us in the process, not just for Medicaid, but how the computer systems work in pharmacies with, under managed care hands, am I correct in assuming under D, that would be sort of the point where a message might appear that, A, this drug is not under the formulary; you need to talk to the patient, Doctor, and get another medication? Here are some recommended substitutions. Or, this drug is on formulary but our plan prefers a cheaper or better drug.
DR. PUGH: Exactly.
DR. BLANCHARD: This is the time to start

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asking. This is where that would pop up?
DR. PUGH: That's exactly correct. That's one of the reasons for doing it this way.
MR. BLANCHARD: All sorts of messages could be written in there to the pharmacist, at that stage, depending on the incentives or whatever it might be.
DR. PUGH: Yes. Yes, depending on what the plan was, yes.
MR. AYOTTE: Excuse me, Carol. You also have to remember it's depending on the system that you have, the capability to take those messages back. Once again, in all these things, you have to have the capacity to review that whole message.
DR. PUGH: But, that can be a problem, and the other problem can be, sometimes the messages are on more than one screen, and, you know, in a busy pharmacy, they don't always have time to read through all that stuff--
DR. BLANCHARD: Chaos.
DR. PUGH: --or don't want to or whatever. And, I can remember when I was a Pharm.D. student at MCV Hospital, that they have a physician order entry computer system and the P and T Committee thought it would be a great idea to educate House Staff about formulary choices, and so forth. And they had all

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these nice educational screens as to why you wanted to do this and why you didn't want to do this. And, it didn't take most of the House very long to figure how many clicks of that light pen it took to bypass all those screens and get to where they needed to go. So, is it five for this drug and two for this drug? And, so, the same thing happens with pharmacists, as well, when they get all these messages back. And, that's one of the important things to remember, especially with these prospective DUR systems, the on-line ones, is that you get message overload.
So while they're wonderful tools, they can just absolutely snow pharmacists with, you know, just information overload that can't be assimilated. And, in a very fast-paced pharmacy, it can be very difficult to keep up with all of that stuff.
MR. AYOTTE: Mr. Chairman, you also, you amended your earlier, you amended your number of responses to return, correct? So, that they don't receive that. Your high level interactions were the only ones that get it.
DR. PUGH: Yes. The level of significance was set at a high level in order to minimize false positives.
MR. AYOTTE: I can see that throughout the

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industry.
DR. PUGH: Yes. And, we were very, very careful about that when we first started out, and, again, the feedback from the folks in the field was that we were doing a reasonably good job and that most messages we sent out were worth reading, so that was encouraging.
MR. COUNCIL: Could there not be a lot of--I'm referring to your outline again, Page 4.
DR. PUGH: Uh-huh.
MR. COUNCIL: Are there a lot of clinical edits that the prescription may not pass that would flip you back into D? Also, in which case it would be necessary to call the prescriber?
DR. PUGH: Well, if there are clinical edits that aren't passed, it would be under Item E, and it would be Number 1. They'll send a DUR Message alert, or alert message will be sent back to the pharmacy. And, then, depending upon what needs to be done, if a whole new drug needs to be prescribed, then you go all the way back to the beginning and start at Step A and go through all this again. And, you know, if it happens to be a nonformulary drug this time, you will hit up against those edits, and it would be a very time consuming.

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But, by itself,--
DR. BLANCHARD: But, it's not an administrative edit, the results of clinical edits, which will throw you back into the loop.
DR. PUGH: No. Clinical edits would result in either, yes, this will be a paid claim, there are no problems; or, there are some problems, here they are, and you decide what to do about it. And some plans, as an example, here with Medicaid, there are a few therapeutic edits or clinical edits that are denied. But, the vast majority of the marks, so, for example, a drug interaction wouldn't be denied. The pharmacists would have used their judgment as to whether something needed to be fixed or, for example, it may be that the patient was taking two interacting drugs, and because the other drug had been filled recently, the computer says, oops, there's a big drug interaction here. But, it could be that their physician had instructed them, while you're taking this medicine, stop taking your old drug. So, the computer would think that there is a problem. But, in reality, there wouldn't be.
But, the pharmacist would then need to talk with the patient and say, well, the computer says we have this drug interaction here. Is that the patient

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could say, well, you know, the doctor said, don't take this other drug while I'm taking this, because of the drug interaction. So, it just further enforces that it's a situation that something may slip through the cracks that can be taken care of. So it's an educational kind of thing, rather than an administrative kind of thing.

Other questions?

NOTE: (No response.)

DR. PUGH: I'd like to finish up very briefly with what DUR is not.

This area is really confusing to people that are in pharmacy practice, and I'm sure to physicians, as well. It's, I'm sure, even more confusing to people that don't deal with all these acronyms and all these different kinds of systems all the time. So, what I have attempted to do is to list out three things that are commonly confused or mixed in with DUR programs and talk about them very briefly. They have already been touched upon by some other folks, so I will be brief. But these are not the same thing as a DUR Program.

The first thing is a formulary or rebate

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system. And you all know what a formulary is by now, I think, based on the definitions and I have my version of the definition down there for you. Basically, it's a list of drugs that are going to be covered by the health plan. And, depending upon the health plan, it may be, in the best of all worlds, there's a formal Pharmacy and Therapeutics Committee, also known as the P and T Committee that's composed of practitioners. They're involved in the drug selection process. And, in the idle situation, the drugs that are selected are selected because of therapeutic concerns, comparative efficacy and safety and then cost comes in third. That's the ideal situation. You have the whole extreme there. There are some people that put the cost stuff first. There's some people that definitely do put the therapeutic stuff first.

So, it's important to find out how that plan is operated, because you just can't say that because it's being run by a PBM that automatically cost is no one's concern. There are some PBMs in the health plans that that is true for. There are also some plans that that is not true for. Somebody once said, once you've seen one formulary, you've seen one formulary.

Once a formulary has been determined, the

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health plan generally tries to get its best price, and that may or may not involve rebates. And, again, rebates have been discussed here, so I won't go into them any further.

One of the big problems with formularies is adherence to them. It's variable and it requires a lot of effort on everybody's part but, most notably, the practitioners in the field. One thing and one reason why DUR gets mixed in with formularies and rebates is that you can use the administrative edits of an on-line system to monitor and police and maintain your system. So, some people think of that as DUR. It is not DUR. It is an administrative edit on the computer. DUR is really just the clinical edit.

Then, we have the famous prior authorization, the thing that gets everybody all up in a tizzy every time it's mentioned. Basically, this is a cost controlling strategy. And, again, it varies from program to program. An amount of kneecap breaking is involved in the process. Some programs are very reasonable. Others make you jump through all kinds of hoops and it just makes it not even worth even wanting to try. So, again, if you have seen one prior authorization program, you have seen one prior

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authorization program.

Generally, cost is a major concern. And, again, one of the reasons why we end up getting into problems with people thinking that this is the same thing as DUR is, in the on-line system you can use the administrative edit to make this system run as well.

Then, finally, Disease State Management Programs, and since this is a newer term and the definitions really haven't settled down quite as nicely as they have for rebates, excuse me, for formularies and prior authorization, I decided to use a recent reference that I have found that provides very nice, clear definitions of what exactly, at least, one author's idea of the Disease State Management Program, and this comes from the Annals of Internal Medicine from last year. The basic premise is that "there is a more optimal way to manage patients, which results in lower costs and improved health outcomes." I have listed for you the assumptions and really what's going on here is this is beyond DUR. It's a population-based approach and it intervenes, as does DUR, but it measures outcomes and it sort of involves--it's involved in a continuous quality improvement cycle. So that DUR does have some continuous quality improvement to it, but Disease

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State Management goes much further beyond this and is a much, in my opinion, to be a preferred way of doing things. As I mentioned, there's a lot of different definitions out there and a lot of different variations on programs. So, it's still kind of being figured out right now.

And, again, one of the reasons why Disease State Management might possibly be confused with DUR is that the use of identifying a patient and looking at their utilization can sort of be confused with retrospective DUR and, indeed, you can use a retrospective DUR system to kind of begin to build profiles for what you're working with, but it's not the same thing.

So, if you have any other questions?

MR. TOWLER: Yes. Have you ever served on, in the past or currently, serve on any P and T committees?

DR. PUGH: I served as Staff for P and T committees in the hospital setting.

MR. TOWLER: Was that, basically, a closed or an open system?

DR. PUGH: Well, in one hospital it was very much a closed system. And, in another hospital, we used to joke and say that our formulary was the PDR.

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So, I've been involved in the more rigorous ones, and I have also been involved in ones that are just P and T committees by name.

MR. TOWLER: Are those predominantly in the hospital setting?

DR. PUGH: And predominantly in a hospital setting.

MR. TOWLER: Would you say in a closed formulary environment, are there any problems that you think came out from that in a hospital setting?

DR. PUGH: Well, there's problems with everything. One of the issues that, when I think of the most rigorously closed formulary that I worked with, would be an issue of when a nonformulary drug was wanted and didn't happen to be readily available and it might take as long as 24 hours in order to get it. But rarely was there not another therapeutic alternative that could be used in the interim or maybe in place of, totally, that particular agent that was wanted. So, in terms of harm to patients, I don't hink I ever saw that occur. In terms of people not getting what they wanted, that occurred fairly frequently.

DR. BLANCHARD: I have a question. In that same hospital, closed formulary, was there also a box

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to check when the doctor wrote the order so that he could check off his preference that the closed formulary preferred drug not be used, and that the drug actually written for be used?

DR. PUGH: No, because the physicians entered all the orders by computer, and if the drug wasn't on the computer, they knew it wasn't on the formulary.

MR. BLANCHARD: But, then, if it wasn't on the formulary, what did they to do?

DR. PUGH: They had to fill in a nonformulary request.

DR. BLANCHARD: And, what percentage of the time was that, was that allowed, assuming it was available in the formulary?

DR. PUGH: I wasn't involved in fulfillment of those requirements, so I don't know. You know, I do know that when there were reasonable requests, they were accommodated. When there were things that were -- A person wanted a particular brand name, and it was generically available, that wasn't necessarily accommodated.

DR. BLANCHARD: Sure.

DR. PUGH: So I can't tell you, you know, what was done in all cases. But, there was a procedure for determining whether or not this was something that was

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necessary, to the patient's care and that was overseen by the Pharmacy and Therapeutics Committee.

DR. BLANCHARD: Presumably, that appeal process and decision was usually made on the basis of hours or a day?

DR. PUGH: Oh, it's made, yeah, within--very shortly after the request is made.

DR. BLANCHARD: It's a period of a 90-day appeals process?

DR. PUGH: Well, no, because it was the Hospital.

DR. BLANCHARD: I understand that.

DR. PUGH: Yeah, it's just a little bit different situation.

DR. BLANCHARD: But not necessarily to a sick person who is standing at the counter of a drugstore.

DR. PUGH: Well, I guess it depends on-- When I think of the situations I've had being enrolled in a health plan that has a formulary, there have been times when a prescription was written and that drug wasn't covered. So you just used another drug. And very rarely do formularies, that I'm familiar with anyway, there may be some out there, but the vast majority of formularies that I'm familiar with, usually have enough variety of different types of

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therapeutic classes of drugs so that pretty much every situation can be covered. And, if something is not covered and it is absolutely necessary, it's usually done for the patient.

Now, with Medicaid, my guess is that the patient--the pharmacist and the physician that are taking care of that patient, aren't going to say, well, go home, you can wait 90 days to get a drug. They're going to come up with some other alternative that can be used by that patient in the interim. Or, else, I have known of situations where pharmacists have "eaten" it. They have given a drug to the patient and they have paid for it out of their packet, because, maybe in their opinion and the opinion of the prescriber, the alternatives were not acceptable.

So, I mean there's some pro bono care out there, too. These days it's a lot less common. But, when I was first starting in practice 15 years ago, I know I did it a number of times. Because, when I was Pharm.D. School, I worked retail relief.

DR. BLANCHARD: And, in the hospital setting, you talked about that a formulary was decided upon and agreed upon by the--

DR. PUGH: Pharmacy and Therapeutics Committee.

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DR. BLANCHARD: --who reported back to the Health Staff? Was this an academic center or--

DR. PUGH: Yes, academic center.

DR. BLANCHARD: That would be a little different from a private hospital.

DR. PUGH: Yes. I have worked with a Pharmacy and Therapeutics Committee in a private hospital and it was a committee of the medical staff, and they reported back to--I'm not sure who the Chairman of the P and T Committee reported to.

DR. BLANCHARD: Generally, there's a pretty good consensus, among the practicing physicians there, that if a formulary is developed by the P and T Committee themselves, and would buy into that and they'd prove formulary, that's something that they should feel comfortable practicing?

DR. PUGH: Right. And then with some of the plans they also have, for example, looking at some of--Kaiser-Permanente and some of those plans, they have P and T Committees that are made of practitioners, and so forth. It's just when you end up contracting out that sometimes you don't know what you're getting. They may have a nationally renowned P and T Committee. But, if you down line, don't know who is involved, it's the same thing as, you know,

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some green eyeshade accountant deciding what's going to be done. So, unless you really know what the process is involved in, you can't really tell.

MR. AYOTTE: Is there a quality assurance for P and T Committees anywhere nationally? Is there a national P and T Board?

DR. PUGH: Well, let's see. For health plans, would it be NCQA? For hospitals, I guess the Joint Commission on Accreditation of Healthcare Organizations.

MR. AYOTTE: So, there is a body that semi-regulates or monitors the qualify of the P and T Committees?

DR. PUGH: Oh, yeah, from the hospital setting, man, JCAHO has reams and reams and reams of things that you have to comply with. I'm not quite as familiar with what the NCQA standards are. But,--

MS. PIGG: NCQA is as rigorous as the Joint Commission is. Thank you.

MR. TOWLER: One other question. Just in your experience with formularies and drug selection in the hospital setting, are they, basically, similar in the drugs that are included, or do you find a lot of differences from settings?

DR. PUGH: I think it depends on the nature of

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the setting. The needs of an academic teaching hospital are going to be very different from those of a community hospital. And then you can't even call community hospitals community hospitals any more, because we have places like Henrico Doctors that do transplants. So, you know, it depends upon the nature of the type of patients that are being cared for in that facility.

Back in the good old days when we had university teaching hospitals and everybody else, there were very different types of formularies. And, quite frequently, in the community setting, they were a lot less loosely defined than they were in the academic teaching centers.

MR. TOWLER: Could you tell, from the formulary that you worked with, whether there was maybe more preponderance of a cost factor in the decision-making?

DR. PUGH: The only way one would be able to determine that would be to look at the minutes of the Pharmacy and Therapeutics Committee and see what kind of discussions went on, what kind of materials were prepared. When I served as Staff to the two P and T Committees that I have worked with--actually, I have worked with three of them now--my job was to write

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reviews, monographs, of the drugs that were being considered for addition to the formulary and to look for all the articles that talked about the safety and efficacy of the drug, and also to look into the cost issues. But, it was always, here's is the drug and if it doesn't work, then you don't want to have it and who cares what it costs.

So you deal with those issues first and then you deal with cost.

MR. TOWLER: Was rebate information furnished to you in those instances?

DR. PUGH: Back then, no. I know hospitals used to get a lot better break than they do now. I would work with whoever was responsible for pricing in a hospital to find out what our price would be for that drug if we put it on the formulary. So, I wasn't familiar with all the behind-the-scenes of that.

Other questions?

MR. COUNCIL: Yes, follow-up for you.

DR. PUGH: Okay.

MR. COUNCIL: Back to my clinical edits question, if a prescription failed a clinical edit because of contraindications with another dosage,--.

DR. PUGH: Right.

MR. COUNCIL: --what would-- Would the

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pharmacist recommend an alternative there?

DR. PUGH: It would depend upon the nature of the conflict. Again, if it's a situation where an adjustment has already been made, no problem. If it's something where the drug needs to be changed, the pharmacist would have to confer with the prescriber and ask, you know, let them know what was going on, and they might recommend that a particular drug be used, but it would be prescriber's decision as to what would be prescribed in place of the conflicting drug.

MR. COUNCIL: So the pharmacist may well have to go back to the prescriber?

DR. PUGH: Oh, always. Even if you want to change dosage form, you have to go back to the prescriber. You cannot -- A pharmacist cannot change anything about a prescription without conferring with the prescriber.

MR. COUNCIL: And, if they agreed upon a change neither one of them would necessarily know if the first prescription were rebatable or not or the second prescription, the substitute were rebatable, would they?

DR. PUGH: Probably not, given the fact that most pharmacies cover 30 different health plans and those physicians work with equally as many different

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groups, and it's virtually impossible to keep track in your mind what's going on with whom. That's why we use these computers.

CHAIRMAN TEEFEY: So you might have to call twice?

DR. PUGH: Oh, for sure. I mean, that's not unusual. So, and then, often you can't get through or you talk to the nurse, and they won't let you talk to the doctor.

MR. COUNCIL: But you could have had a clinical switch, presumably, from a nonrebatable to a rebatable drug.

DR. PUGH: No. Yes, that is possible. But it wouldn't necessarily -- That might not have been the intent, but that may be the outcome.

MR. COUNCIL: Right. Yes. You may not even know.

DR. PUGH: You may not even know, exactly.

DR. BLANCHARD: In your experiences with hospital formularies, have you ever seen a system where the hospital pharmacist was aware of and incentivized by a rebate or a kickback system to try to shift market share from one drug company's drugs to another drug company's drugs so that part of that decision was --

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DR. PUGH: Only in the sense of-- I can think of one very clear example from, when I was working at a community teaching hospital outside of Philadelphia where we would get a much better price if we used the IV form of Pepcid as opposed to Zantac. And, so we initiated a campaign and said, basically, you know, the drugs are the same kind of thing. They really don't have any advantages one over the other, and it costs the hospital less if we use Pepcid. So, please, use Pepcid.

DR. BLANCHARD: But, to your knowledge,--

DR. PUGH: The pharmacist didn't benefit from it.

DR. BLANCHARD: The price had been proven by a market share percentage? It was just that the price, to start with, was a lot cheaper.

DR. PUGH: It was, yes. And, it may be different now, although I've been out of hospital practice for about five years, now. So, I don't know what the current state of things is, but my guess is the individual pharmacist that's working with that, is not usually privy to that kind of information and does not receive any kind of incentives from that.

MS. PIGG: From my hospital days, the pricing there was not explicit, but it was definitely implicit

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in that when they knew, in your hospital setting, you were going to use IV Pepcid, you weren't going to stock IV Zantac. So there wasn't an explicit market share component to the price, but they knew that they were going to get the market with very little.

DR. PUGH: And they kind of knew how much you used on average, so they kind of knew what they were going to get from it.

MR. SZALWINSKI: Maybe, if I can add a little bit to that, there are different levels of buying groups in hospitals right now and different levels of whether you are a voluntary or committed buying group. And, in the committed buying group, specifically, there are market-share-driven discounts, and those are made available at Pharmacy and Therapeutics Committee meetings, generally, that I have been involved with, in order to help everyone understand the economic incentives secondary to the clinical facts surrounding the drugs. It's a total decision that needs to be made, not a singular decision. And so there are those kinds of situations happening and there are Pharmacy and Therapeutics Committees, well run Pharmacy and Therapeutics Committees that I am aware of, and I participate in that, take into account the clinical knowledge and

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facts about the drugs, as well as the economics. Because, in today's market, you need to do both of those. You can't do just one or the other. It's a decision that cannot be made effectively in a vacuum.

MS. PIGG: Would you make a decision in your P and Ts in your hospital that says, here are two drugs, they both treat hypertension. We believe one drug treats it more efficiently or better, whatever you want to call it, but this drug that doesn't work as well, we can get it a lot cheaper.

Would you make that decision?

MR. SZALWINSKI: No. No, we wouldn't make that diagnosis. I was a little bit of a straw man. I don't think that. But, no, our decisions are -- I mean, we, in order of variables, we take safety first, efficacy second, and economics third. And that's in well-run Pharmacy and Therapeutics Committees that I have had experience with and have served on, that is the order you take the data. And, if it fails at any one of those steps or specific agents are shown to be safer or more effective, then that's the screening process. And, in many situations, that screening process makes it easier for physicians to deliver better care, because a group of experts that they respect has sat down and done the clinical review for

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them. And, in many situations where it's well-run, well done, that process functions very effectively to insure patients get the best therapy that's on the market.

MS. PIGG: Where does the comparison to alternative agents that treat the same conditions come in? Because the FDA says this drug is safe and this drug isn't effective before it gets on the market. So there is another component, I believe, to your analysis.

MR. SZALWINSKI: Well, it's the-- I've reviewed clinical literature that's out there. You know, we go to the clinical literature, do literature reviews, have pharmacists and physicians who review those reviews, and, where there are comparisons, direct comparisons that are good comparisons, we use those.

SENATOR NEWMAN: Mr. Chairman, if I could ask a question.

I imagine that good medicine always makes good policy because of our tort laws in Virginia, which says, if you practice bad medicine, we'll sue you. However, have you received any information in your position on where drug switching has caused clinical problems and what the effect of drug

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switching has been? Are you aware of any studies that deal with it?

DR. PUGH: I have not reviewed the literature on that subject. I know that there are, and I remember hearing last summer some folks reporting on their individual experiences. I'm sure there are some people out there that have had problems. But, the vast majority I do not think have. And, what often ends up happening is you hear from those few that have had the problems, and you don't hear from this multitude that have not.

I can remember one person in particular that--I can't recall which drug she was talking about that she had been switched on and was concerned, because she was having problems with it. Well, she was switched to another generic brand, I mean another brand of the same chemical entity. And so, you know, when you get people like that out there in the news and getting national press and stuff, it kind of makes those people who really know what's going on, you know, wonder about the quality of some of the testimony.

SENATOR NEWMAN: But is it not true that if you have chemically-similar drugs, that are different bioavailabilities that allow, that is--

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DR. PUGH: Chemically-similar drugs are considered to be distinct chemical entities and so they are not considered to be the same. I think-- You were talking about the same--different formulations of the same medication, perhaps?

SENATOR NEWMAN: If you have a generic to a brand, the generic manufacturer has to comply with bioequivalency data?

DR. PUGH: Yes.

SENATOR NEWMAN: And they all comply to different degrees.

DR. PUGH: Yes.

SENATOR NEWMAN: And there's a 20 percent tolerance, I understand?

DR. PUGH: Yes.

SENATOR NEWMAN: So, if it's not or is more available than the brand's standard, you can see some toxicities, can you not?

DR. PUGH: Or some lack of efficacy. And, there are certain drug classes that most pharmacists, any good pharmacist and any good physician would agree that you don't want to go switching around willy-nilly on.

There are a lot of other drug classes, diuretics, where it doesn't matter. You know, it's

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just not that big a deal. So, I think it's-- If you talk about it as putting all drugs into one big box and saying, we're going to allow willy-nilly substitution, then that is problematic, but it's problematic because there is a small subset of drugs that have a very narrow index that, you know, if you have a little bit less, patients start having problems because of a lack of efficacy. If you have a little bit more, then they develop toxicity problems. Those are the drugs that you need to be careful about and do not use generic substitution on or make sure that, if you're going to switch, that you're not switching back different brands every month; that you make the switch and you stick with it.

MR. TOWLER: But, with the same chemicals, you could possibly see some of these anecdotal reports coming from people that are experiencing some sort of problem, and it may ally itself in the bioavailability question of the products that are consumed.

DR. PUGH: Well, that may possibly be the case. But, again, for the vast majority of drugs, that's not the situation. It's a very limited handful and most pharmacists and physicians can probably tick them off for you.

SENATOR NEWMAN: Mr. Chairman?

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CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: If I could, I want to play off that point, because I suspect that the neurotherapeutic drugs are possibly what is being discussed here. However, the FDA has made it very clear, especially in letters that have come to us recently that I'll provide the committee that they go to extraordinary lengths on their therapeutic drugs to make sure that the percent is only five percent, plus or minus, which is the very same, that one tablet that's made right in front of the other can be of the same manufacture.

So, if we're talking about neurotherapeutic, which may be the most sensitive of all of these, the FDA requires a much higher hurdle because of the sensitivity of those drugs.

DR. PUGH: But, even so, I think most practitioners, just because of the potential for problems, usually shy away from it.

It's better to be safe than sorry, speaking of torts.

MR. TEEFEY: Yes, sir.

MR. WALKER: Mr. Chairman, I have a question on the hospital formulary. If a patient comes in to the hospital, and they are controlled hypertensive on

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Drug X. Drug X is not covered by the hospital formulary. Is that patient switched to the formulary drug or is he put on the drug that he's been controlled on.

DR. PUGH: It depend on the hospital. Some hospitals will allow patients to bring in their own medication and let it be administered. Some hospitals will not, and they will assist on another formulary alternative to be dispensed. So, it really depends. It varies from institution to institution.

CHAIRMAN TEEFEY: Carol, we want to thank you.

DR. PUGH: You're welcome.

CHAIRMAN TEEFEY: The reason we got Carol up here is to make it more complicated.

DR. PUGH: I do a good job of that.

CHAIRMAN TEEFEY: Thank you so much, Carol.

DR. PUGH: You're welcome.

CHAIRMAN TEEFEY: Do you-all want to take about a five-minute break before we get into the next level?

NOTE: (Affirmative response.)

CHAIRMAN TEEFEY: All right. We'll take a five-minute break and be back then.

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NOTE: At this point a recess was had from 10:52 a.m. to 11:06 a.m., whereupon the hearing proceeded, viz:

CHAIRMAN TEEFEY: The Pharmacy School at MCV did a very, very, very in-depth literature search, and Mike Worthington is going to cover what we came up with, and then we will get Mr. McArthur and Mr. Rosenthal to cover the information they sent us.

MR. WORTHINGTON: Thank you, Mr. Chairman, Members of the Committee. My name is Michael Worthington. I am Lead Management Analyst with the Department of Medical Assistance Services, and my task is to review selected literature. Although it's not exhaustive, I think it's fairly representative of the literature that's out there on therapeutic substitution and interchange.

I would like to acknowledge Ms. Julie Sisler in front of me from the,-- What's your title or--

DR. PYLES: She's the Summer Research Fellow--

MR. WORTHINGTON: Summer Research Fellow--

DR. PYLES: --at the School of Pharmacy.

MR. WORTHINGTON: --at the School of Pharmacy. She assisted me very much in pulling all of

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this together. Thank you, Julie.

Also, I did my part to keep your notebooks small--I copied on both sides. So, if I get extra credit for that, I would appreciate it.

When I looked at the literature, and I started asking myself some questions. Maybe I can formulate the literature review in terms of questions, but I decided, instead, to go up with the large headings that you will see in front of you. It's in Tab 6, I believe, my remarks.

So, let's start off, first, with definitions. According to the several sources that I have looked at, I think I could first define therapeutic substitution. And, as indicated here, it's defined as the practice by pharmacists of dispensing an alternate chemical entity from the same therapeutic class for the drug product prescribed by a physician. Substitution is often authorized for classes of drugs commonly believed to have similar pharmacologic and therapeutic properties, such as antacids, antibiotics, anticholinergics, antihistamines, thiazide diuretcis, and so forth.

Some HMOs and third-party payers have advocated substitution as a way to control pharmacy costs. I think that's very clear in our deliberations

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here. And, interestingly enough, while some require pharmacists to consult the patient's physician before substitution, many do not. That was very clear in literature.

I think Mr. McArthur, in the first meeting that you all had --

MR. AYOTTE: Mike, can I ask you a question?

MR. WORTHINGTON: Sure.

MR. AYOTTE: I'm not sure that that is right. Can you describe for me what you mean by an alternate chemical entity? Are you looking at a substitution from the Virginia Voluntary Formulary? Because you've--

MR. WORTHINGTON: I'm sorry, Michael. I think we'll get into that as I illustrate in some of the research that's going on here.

MR. AYOTTE: You said that it alludes that pharmacists are doing this on their own to change drugs and not with other physicians' consult for either.

MR. WORTHINGTON: Right.

MR. AYOTTE: Unless you're talking about a substitution from within the voluntary formulary. And, I would think that that needed to be added into the definition.

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MR. WORTHINGTON: We could do that. I think as I go a little further, some of that will come out. If not, we'll come back to that.

Mr. McArthur, in the first meeting you-all had, I think it was indicated that the definition of therapeutic interchange is pretty much the same as substitution. However, it's substitution with physician approval. And I think that's what I found in the literature, also.

Generic substitution, I know that's not your concern, necessarily. However, I went ahead and put a definition for generic substitution in here for you. I think that's pretty much accepted.

Okay. What I call prevalence or where does substitution occur. A couple of sources clearly indicated that at least 30 percent of HMOs in the United States currently permit substitution. Some other research has indicated that it occurs in more than 52 percent of the Nation's acute care hospitals.

Under the first bullet, I indicate there, that the majority of HMOs practicing therapeutic substitution report that physicians are not notified when a substitution has been made.

Okay. Let's look a little bit at the risks associated with therapeutic substitution, with

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therapeutic interchange. Within a particular class of medications, there are often many drugs available to physicians for their patients. In one patient, only one of these medications may be tolerated and be of benefit, while another patient may only tolerate and benefit from another of the drugs available. With a well-recognized individual variability in response to medications there is no way of knowing, other than through a systematic approach to each person's particular circumstances, which drug or drugs will be of benefit to an individual patient, or which will not have deleterious side effects. The authors of this research allege that physicians must choose appropriately from the various drugs available.

There's further research on beta blockers as in the occurrence of therapeutic substitution in their case. Beta blockers are currently used for over 20 medical conditions. When the dosage of any available beta blocker is titrated properly, it can be effective in patients with arrhythmia, hypertension, or angina pectoris.

(Addressing Ms. Sisler) Is that correct? That term is pectoris?

MS. SISLER: Yes.

MR. WORTHINGTON: However, these drugs are not

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interchangeable, according to this research, since a given agent may be more appropriate for some patients in clinical situations. Moreover, the clinical studies upon which the safety and efficacy profiles of individual drugs are based excluded many patients with underlying conditions that would make them more prone to adverse reactions.

Then, that next bullet, I point out the three classifications, if you will, on the basis of pharmacokinetic properties for beta blockers. And, based on those three classifications there, the author alleges that retitration and careful patient monitoring following therapeutic substitution is essential.

The American College of Physicians has taken a position that therapeutic substitution is appropriate only in hospitals with an effectively functioning formulary system and a P and T Committee. We heard a little bit about that this morning.

The College of Physicians also states that ıbstitution jeopardizes patient management when ımmediate prior consent is not obtained from the authorize prescriber, and when documentation at substitutions is untimely or improper. The College further states that practices such as that must not be

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permitted.

The next bullet, I think, is very critical. It says, the practice of therapeutic substitution may be acceptable in ambulatory settings that meet standards comparable to those of institutional settings.

However, the challenge is associated with therapeutic substitution and the limited mechanisms to monitor its practice and effects when done outside the institutional setting make its practice unsafe in most ambulatory settings.

Although no reports of adverse outcomes associated with therapeutic substitution done on an ambulatory basis have been published--I think this may be getting into Senator Newman's question of a little earlier--the American College of Physicians believes that even when therapeutic substitution is done with physician supervision, under strict protocols, therapeutic inequivalence may be high for those already stabilized on a drug, for patients taking several medicines, for children, for patients with a compromised capacity to absorb, metabolize or eliminate drugs.

Therapeutic substitution is of particular concern in outpatients since adverse or suboptimal

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effects may not be easily detected.

Let's get into NSAID. There was a good deal of literature on therapeutic substitution in the NSAID class, Nonsteroidal Antiinflammatories.

The next bullet, the second one on the top of Page 3, I think, is very important to this group. It says, during one two-year study, 49 percent of patients were switched to another NSAID. Twenty percent were switched two or more times and seven percent were switched three times. Seven percent received four or more different NSAID. So, that's roughly 14 percent receiving three or more.

The data showed a very high prevalence of product switching, indicating some level of dissatisfaction with therapy on the part of the patient or the physician or both. This process of tailoring and individualizing the drug-regimen-to-patient response may be negated if therapeutic substitution occurs without detailed knowledge of the patient history.

Furthermore, the potential for confusion is great if a patient experiences an adverse effect from a therapeutic substitute and the prescribing physician thinks the patient has been taking the NSAID that was originally ordered. It is, therefore, essential that

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physicians be informed of such substitution. There is more there on NSAIDs.

It gives, I think, four reasons under the next bullet, it says, therapeutic substitution of NSAID for ambulatory patients may result in compromised clinical outcomes because: Patient response is unpredictable and selection of the optimal agent must be tailored for each patient. Secondly, substantial differences exist in adverse reaction profiles. Third, drug interaction studies are lacking. And, fourth, selection of an agent must be individualized to insure compliance with the dosing regimen.

The final prescribing decision, at least in the NSAID category, must be based on seven factors: Therapeutic efficacy; safety;--kind of what Mr. Szalwinski was talking about--adverse reaction profile; concurrent therapy; simplicity of dosage regimen; patient acceptance and compliance; and, the overall cost of treatment.

I don't know that those seven were listed in order of importance. In other words, Number 7 may not be the lowest one.

Okay. A little bit on cost data. You had indicated that you would like to see some information

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on cost. You will see a couple of items here on some cost studies, if you will. But, then, when they go into the next category of where substitution or interchange has worked, according to the literature, you will also see more cost information. So it's kind of scattered throughout these two headings here.

Someone had indicated at the first meeting that there needed to be some discussion of the ancillary cost associated with substitution. This first bullet addresses that. It says cost, and it's, again, dealing with NSAID. It says, cost savings achieved through therapeutic substitution of NSAID may be lost by additional overall treatment costs because of adverse reactions or suboptimal therapy. The occurrence of adverse or suboptimal effects in ambulatory patients is more likely if NSAIDs are substituted without full knowledge of the patient's medical history and clinical status.

Communication between the pharmacy and the prescribing physician regarding a patient's specific needs is essential for rational substitution among NSAID. I think we're starting to see some themes here.

The next one was more of the more interesting pieces of research to me.

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In a three-month study of arthritic patients in the New Jersey Medicaid Program, the total cost of therapy with aspirin was compared with that of Piroxicam. Gastrointestinal problems were twice as frequent in the aspirin group. Twenty-seven percent of patients receiving aspirin also needed drugs to treat the GI effects, as compared with 18 percent of the Piroxicam patients. Three of the patients receiving aspirins were hospitalized for peptic ulcers. None of the Piroxicam patients were hospitalized for peptic ulcers. The price of aspirin per patient, $35.80, was much less than the price of Piroxicam, which was $67.38. However, when the GI-related hospital and physician costs were factored in, the overall cost of aspirin therapy per patient turned out to be $100.43, which was greater than that for Piroxicam, which was $76.65. So, that addresses, at least in this one instance, some of the ancillary costs associated with these particular medications.

Okay. Where substitution or interchange has worked, that's the next heading, I think, to summarize this up front before I get into it more detailed. From the literature, it indicates that it can "work" in acute care settings for specific drugs under very specific conditions. And, I think I'll get into those

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in a little bit. Just bear that in mind as I go through here.

A therapeutic interchange program based on institution-specific microbial patterns and educational efforts by the Pharmacy Department produced a change in physician prescribing -- ampicillin-sulbactam was substituted for cefoxitin. Is that correct?

MS. SISLER: Yes.

MR. WORTHINGTON: The infectious disease pharmacist provided education through one or more of three methods, and I think this is a critical component to making it work in an institutional setting: That's education, communication. The first thing--continuing education programs were made available. Provision of concise guidelines for ways to suggest antibiotic interchange to a prescribing physician or follow-up to further enhance the knowledge base of the pharmacist when lack of knowledge by the pharmacist was determined to be the apparent cause for any reluctance or inability to ma a successful interchange.

The next bullet talks about a two-tiered approach to therapeutic interchange in a hospital setting. It argues that it can be successful in

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reducing costs. Again, I should point out that the literature that I reviewed, at least in successful cases, in cases where substitution allegedly worked, primarily focused on the cost of the medication. There was very little literature on the quality of patient care.

This two-tiered approach, it says, in such a system, some drugs are considered interchangeable and are automatically interchanged by pharmacy for the prescribed product. For other drugs, for which therapeutic equivalence is not as close or the dosing regimens differ, the concept of "class representative" is used, i.e., only one drug, determined by price, is on the formulary, and the physician is contacted to change the order if a nonformulary alternative is prescribed. When the "class representative" concept is used, the pharmacy can switch the formulary status of "equivalent" products without bringing the entire issue before the P and T Committee.

Here is another one. In a nonteaching community hospital, they were substituting -- Well, let me read it. It was shown that Famotidine was as safe and effective as IV Cimetidine or-- Help me, David--

MR. SHEPHERD: Ranitidine.

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MR. WORTHINGTON: --Ranitidine. It sounds like I'm stuttering.

And that it was feasible to add Famotidine to TPN solutions. Blah, blah, blah. It was projected that the interchange of IV Famotidine or Cimetidine or Ranitidine would result in a total savings of over $37,000 during the first year, due to reductions in cost of drugs, supplies and nursing labor. More examples, again, of specific drugs and specific cost savings are through that part. I don't know that I want to go over each one of them.

However, on Page 6, in the third bullet, I think it points out, again, the programmatic aspects of therapeutic substitution which are critical to it working, when it is done in a hospital setting. It says in a hospital setting a therapeutic interchange program was initiated for drug products such as vitamins and antacids. Products for which interchanges are essentially noncontroversial. A newsletter describing the Program was distributed and in-service education sessions were held. A reminder was placed on order forms that an interchange for nonformulary drugs would be made, unless the nonformulary agent was deemed "medically necessary" by the doctor. In such cases, the physician was

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contacted to discuss the therapeutic alternative. As acceptance of the Program and cost efficiencies were demonstrated, more controversial agents were phased in. Some agents, for example, third generation cephalosporins were difficult to obtain approval for addition to the program. That piece of literature I remember very well David and I said why. Although we can probably speculate. Again, more examples of where the drugs have been substituted, where cost savings have been realized and those programs that were employed to substitute or follow.

Let's get in a little bit, then, to the next heading which is "Legal Issues." Let's see, one source says, of course, we all know this, the FDA approves indications for drugs. Back on the NSAID, again, different NSAIDs are approved for different uses. Consequently, therapeutic substitution of one NSAID for another may result in a situation in which the patient received a drug that is not approved for his or her condition. The legal implications of such substitutions are unresolved.

The next bullet, I think, will illustrate for all of us some of the scenarios we have been discussing this morning about the relationship of a patient to a pharmacist. Let's look at this one

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closely. In the chain of assumptions regarding a hypothetical prescription, several events can occur. Okay. Event one, let's look at that. Drug X1 is substituted by a pharmacist without the patient's knowledge from a formulary list of equivalent drugs. The patient thought he was to get drug X not drug X1, and his informed consent did not extend beyond X, a brand name of a specified manufacturer. Or, two, drug X1 is substituted by a pharmacist who informs the patient that X1 is "the same as X," because, A, he does not have X in stock or, B, X1 is a cheaper anyway. The patient, thus informed, accepts the pharmacist's recommendation and consents to the substitution. In this scenario a serious reaction attributed to X1 results.

Okay. The third scenario. Drug X1 is substituted only after the patient says to the pharmacist, don't you have anything cheaper but just as good? Well, the pharmacist dispenses X1 without informing the prescribing practitioner. A complication allegedly results from the use of X1 in this case.

Okay. These three hypothetical substitution problems illustrate how legal liability could shift among potential defendants. Liability may not be limited to the physician and the pharmacist,

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interestingly, but also it could possibly include the formulary committee and/or the hospital, if the hospital is solely controlling the pharmacy.

The next section of the literature review is what I call "Commentaries and Positions." The literature, at least what I have looked at, is rife with both hard data, soft data--I think you all may have referred to it as anecdotes before, and what I call commentaries and positions.

Let's look at the first one. The American College of Rheumatology opposes legislation or regulation that would permit prescription therapeutic substitution by a pharmacist as an action which is not consistent with quality patient care and which will pose unnecessary risks to patients' well-being.

The next one applies to generic substitution. Let me go over that one. The practice of therapeutic substitution represents an important therapeutic modification with potential clinical significance far beyond that of generic substitution.

Some political remarks. I guess this was during health care reform. I wasn't clear of the date of that particular piece of research.

The next to the last bullet on Page 8, is very strongly worded. The term "therapeutic

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substitution" should be expunged from the pharmacists' professional vocabulary. The term "substitution" evokes deep, negative feelings, especially among physicians. It means to them that a pharmacist intends to change their orders, without their consent and without their knowledge.

The next bullet. Active participation of pharmacists with physicians in the drug therapy decision-making process results in fewer drug-drug interactions and adverse drug reactions, better control of disease conditions, shorter lengths of stay, lower costs, and so forth, than when that does not occur. The key here is not to give all the credit to pharmacy. It's not pharmacists alone who are responsible for these positive outcomes. It's the pharmacist-physician team that is responsible. It transcends the individual pharmacist himself or herself.

One author kind of waxed polemic on us. He said a therapeutic interchange has been practiced successfully in hospitals for so long as part of formulary systems, why now is it becoming such a hot topic? Well, the answer is that as the health care system continues to change, and as more care is being provided in nonhospital environments, pharmacists,

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physicians, administrators, and payers are looking to apply the positive lessons of the formulary system to the ambulatory sector. Efforts to duplicate hospital outcomes in the ambulatory sector will be misguided because they will substitute the decisions of facility managers for those of pharmacist-physician teams. There was some discussion of that, also, this morning.

Then, one more bullet. To summarize, I found and I am not an advocate one way or the other. I'm staffing the group. But, I found no position that categorically supports the policy decision, if you will, to therapeutically substitute or to therapeutically interchange. However, I found and reported to you specific instances where specific drugs were determined to be substitutable--if that's a word--and cost savings could result. But, I think, based upon my analysis and synthesis of all this, critical to doing that, is the approach to how you do it. You know, involving pharmacists, involving the P and T Committee, having a strong formulary, communication, training, all of that. That's, basically, the literature in a nutshell, as I see it.

Any comments or questions?

DR. DALTON: I'd like to comment. That was a good summary, and I think that coming into this, I

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think we've recognized that we, as physicians, are able to compromise and be flexible, as appropriate, when it doesn't compromise patient care.

I think criticism of some of the drug switching that was done was that the primary incentive was economic, and I think we've focused on individuals who were paid a specific bounty for switching drugs and that was the reason for switching. And I think that this next to the last bullet does summarize things well, that, the extrapolation of the inpatient type of patient management to outpatient management and drug switching is fraught with a lot of potential disaster, because of the controls not being in place.

I think there are instances of harm being done that we, as physicians, are aware of. Someone asked for cases. I know that, in one particular class of drugs, the ACE inhibitors, angiotensin-converting enzyme inhibitors, there's a specific side effect that is present in all of those specific medications, to some extent, but it ranges from one percent, maybe, for one to up to eight or ten percent for others. And that is a reaction where there is airway swelling and compromise of breathing. Patients I am called in to see on occasion and sometimes patients have been on the medication for a while, it's hard to say why they

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have the reaction at a particular time after they were started on it. And I think some of it is because they were probably switched to another medication in the class or other interactions may be involved. But I think that we need to limit the reasons why we allow substitutions, to the extent that's acceptable, and I think that we need to carve out that part where the primary reason to switch is for financial gain.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Senator Newman.

SENATOR NEWMAN: This was hard work for you guys, and I know, going out there and gleaning this information is not easy. However, it appears from a cursory view that it could have been called, because of what you have to work with, the entire thing could have been commentaried positions. And the reason is because you're going out there and getting commentaried positions of both sides. And, if I were to think anecdotally about which example I would use as a bad example, it would be with aspirin. We all understand that aspirin can have negative effects, and it's the perfect anecdotal reason. And that's what I'm hoping that, while the document is maybe what's out there, maybe what we're saying is there is not much out there.

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MR. WORTHINGTON: Exactly.

SENATOR NEWMAN: Now, the other problem is proving the negative on cost is almost as impossible. Proving that it didn't save money in some cases is almost impossible. So, I know this is the best that's probably out there, but I'm worried about putting too much stock in something like this, because it is somewhat anecdotal and commentaried positions of others.

MR WORTHINGTON: Well, there is a good deal -- I concur with most of what you said, Senator Newman. But I think in the specific drug illustrations that are provided in the literature, there are some hard data indicating that some drugs may be substituted for other drugs, at least in an acute care hospital setting. It may be different. I think we'll get into some of this, in any event. Dr. Carroll will probably be addressing access to data, too. But, yeah, when you start thinking about who funded the research and for what purpose, and so forth and so on, you have to look at all research with a, not necessarily a jaundiced eye, but with a cautious eye, anyway. And I think that the committee is wise to take that approach.

MR. AYOTTE: Mr. Chairman?

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CHAIRMAN TEEFEY: Yes.

MR. AYOTTE: I have to go back to my original point, Mike.

MR. WORTHINGTON: Okay, Mike.

What problem do you have with that definition, if we try to buy off--

MR. AYOTTE: Well, my problem is very simply this. And, again, representing the community setting, it's illegal to make a switch, therapeutically, on a chemically-dissimilar drug, without a physician's consent. Now, this definition of therapeutic substitution may exist in a closed environment or in a closed hospital setting where that can occur. Inferring into a definition that it can happen in the retail setting, I think, is wrong. And I think in the testimony that we got in the first meeting, if you review it, someone had asked for a Board of Pharmacy regulation to look at what really is there in writing and in regulations now that would do this. And I think you're saying that, yes, a therapeutic interchange can occur with a physician; that's perfect. But, also, I think a therapeutic substitution in a nonclosed environment, okay, a nonhospital, which a lot of these examples are hospital environments, I think we need to clarify that so that we're all clear,

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because you don't have pharmacists out there substituting without physicians' consent.

MR. WORTHINGTON: So there is no therapeutic substitution then in an ambulatory care setting in Virginia?

MR. AYOTTE: The only thing you can substitute for ambulatory setting is if it's voluntary formulary and it shows on the Virginia formulary, which is, realistically, a list of drugs that are chemically similar to each other.

MR. WORTHINGTON: And generic substitutions.

MR. AYOTTE: Right. But, the generic drugs are listed in the Virginia voluntary formulary.

DR. KNAPP: And from the DHP perspective, I can speak to that. I didn't bring my code book with me. I apologize. But, I think the interpretation of the scope of the practice of pharmacy would make that a true statement that, without, in an ambulatory setting, it would not be legal. Your definition of therapeutic substitution would not be legal. It would be outside of the scope of practice of a pharmacist in the Commonwealth of Virginia, and they would be hauled up in front of the DHP.

MR. WORTHINGTON: Has that ever happened, by the way? Has it ever occurred, that someone has been

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punished?
DR. KNAPP: Not in the last five years, that I can think of.
MR. WORTHINGTON: Okay.
DR. KNAPP: But I can't tell you definitively. And that was going to be my question, actually, assuming there is a pharmacist Code of Ethics, are any of these assumptions about these hypothetical situations, would this be considered unethical?
Cindy, even from a pharmacy perspective, I would think that most of them would be considered either illegal or unethical, from a pharmacist's perspective.
MS. WARRINER: I know that -- I agree with Mike Ayotte's statement as far as what was occurring in an ambulatory setting. The only exception I would take is to believe there is some nonresident mail-order pharmacies that are out-of-state that may not necessarily comply with all of those statutes that those practicing within the State would have to comply with, and whether or not they adhere to the Virginia voluntary formulary. I think that remains to be seen. So, at least, with the ones that have their buildings in Virginia, I think Mike's statement is

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accurate. So,--
MR. AYOTTE: Cindy, I'm sorry to interrupt you. But you would then look towards amending current Board regulations, because I believe Wyatt sent a letter to the Board of Pharmacy last year indicating the laws that exist and how they would be able to be applicable for this situation. So, I mean, the Board, I believe is also looking at telepharmacists and having them registered within the State, I believe.
CHAIRMAN TEEFEY: Yes, sir?
MR. WALKER: Mr. Chairman, it's been alluded to earlier today that the Board of Pharmacy does have purview over the drug switching people. I'm Chairman of the Board of Pharmacy, currently, and we've been advised by Counsel that we currently do not have the statutory or the regulatory authority to regulate these now.
I believe, when the Durrette Group had their Bill proposed, there was some alternative regulation changes that would have given us that authority. But, I think it was opted to proceed with the Durrette Bill at that time. So, currently, the advice that our Counsel gives us is that we do not have the ability to, and I see that as a problem--a big problem. But you do have the ability, if they do it without

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contacting the prescriber, it does fall within the practice of pharmacy. ?
MR. WALKER: They are not, if they're not licensed by the Board, then we have no authority, and currently they are not.
MS. PIGG: Who is the "they"?
MR. WALKER: Whoever is, it would be alluding to a pharmacy out-of-state or someone, you know, whatever.
DR. KNAPP: But if it's a licensed pharmacy from within the State, you've got jurisdiction.
MR. WALKER: Yes. We have jurisdiction over that, yes. But if the switch, like I say, it was mentioned today that we had authority over all the parties that are involved, and we do not. Only the pharmacists who are licensed by the State do. So,--
MR. SZALWINSKI: Well, a remedy to that might be that all prescriptions dispensed for residents of Virginia must be dispensed by pharmacists licensed in Virginia.
DR. KNAPP: We have visited this issue on the Board of Medicine lots of times and, actually, there is wording to that effect running around out at the DHP; that if you're going to practice, operate, prescribe, or otherwise on a patient or on a resident

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of the Commonwealth of Virginia, that you need to be licensed by the Board of Medicine in the Commonwealth. And, obviously, that is a hugely controversial perspective that I'm a sure a lot of people don't agree with.
But, you know, I think to tell a pharmacy is probably even a bigger problem or a mail order pharmacy might even be a bigger problem than telemedicine is for the moment, but not for the long run. You know, I would question whether or not that is a topic that we really want to tackle, but we may have to.
DR. BLANCHARD: It is my opinion, based on some of the comments last meeting, that it was at least fairly clear to me that there was a distinct difference between therapeutic substitution, as you define it here, and therapeutic interchange. And that, in fact, what we were looking for in this committee, unless people are talking about legalizing therapeutic substitution in Virginia, was a discussion of the pros cons and risk benefits of therapeutic interchange.
I think it would be very helpful if, as we receive data from other people, and as we discuss it among ourselves, that we are very clear on how we use

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those two terms. There is a huge difference between whether a physician is consulted or whether the physician is not consulted. I would make one point,, to clarify that, though, is that if a formulary is sufficiently restrictive, that therapeutic interchange with a consultation back to the physician, it de facto becomes therapeutic substitution, because there is no other drug. And, in deference to the patient's wallet, the physician, generally, is going to have to defer and acquiesce to that substitution, if you will, that interchange. But, I think we do need to keep in mind that we're talking about therapeutic interchange, and I would have liked to have seen this report or would like to see in the future, more information on pros and cons of therapeutic interchange, if they exist.

MR. WORTHINGTON: It's not there. It's not there.

DR. BLANCHARD: I'm particularly interested that you chose not to review the paper that's been bandied about right and left by Susan Horn with respect to the cost to the total system and systems that had what I understand were therapeutic interchange and restrictive formularies and the effect that had on total cost. And, members of this

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committee, I think, are interested in how they should evaluate that particular study since it's--

MR. WORTHINGTON: Well, I guess it's, with all due respect, Dr. Blanchard, it's like everything else that I get involved in, anyway. I know that I'm involved with the Liaison Committee, the Pharmacy Liaison Committee, and language is thrown around, with all due respect to the Legislature, language is thrown around that's not always accurate. We had some, referring to DUR that Dr. Pugh gave a presentation about. There's some language on, DUR shall do this and DUR– When, in fact, it was prior authorization is what they were talking about. So, I'm not so sure that restricting ourselves to therapeutic interchange, if that's what you're saying is necessarily our sole charge. I think that, perhaps, the language "therapeutic interchange" encompasses substitution, and so forth and so on. I think we would be remiss if we didn't at least address all of them.

DR. BLANCHARD: But Dr. Horn's study was--

MR. WORTHINGTON: Right.

DR. BLANCHARD: –not reviewed by you for a particular reason or--

DR. PUGH: I didn't get it. It was just not given to me. It was certainly not purposeful. I was

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not at the first meeting. I was under the impression that you-all may have discussed some of that at the first meeting. But, maybe that's erroneous--

DR. BLANCHARD: No. I think many of us have not seen or read the entire--

MR. WORTHINGTON: I'll get that for the Committee.

DR. BLANCHARD: –study. I certainly appreciate the input from pharmacists and academicians on how much faith to put into conclusions of that particular study.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: Just one other comment. I think that the comment that was just made is awfully important, because the effects and risks associated with substitution, if it is beyond our purview of our discussion, then we're bringing in information that really won't have an effect on our indecision if our indecision is going to be something about interchange. So, if the committee, I don't know Mr. Chairman, if it is, but if we are, mostly on this particular subject, going do be dealing with interchange, then we need to be dealing mostly with risks as other things associated with interchange and understand that there

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is something else out there called substitution, but that's not what we are going to be discussing.

MR. WORTHINGTON: Well, I concur, then. I think this afternoon, in this afternoon's session, when Mike and I get together and work you through that, that we may be able to come up with some consensus on, not just definitions, but the purview of the Committee, if you will.

To illustrate and, Michael, maybe you can help me out a second. I won't take but one more minute. But, I'm a subscriber or beneficiary, whatever, with HealthKeepers, Blue Cross. I take, in the fall, I get all sorts of sinus infections. I'm an outdoor kind of guy, you know, work in the yard and all that. And, I found--I've tried, everything. I have switched, I guess, and Hismanal is the drug that I found that does me the best to treat this sinus infection stuff. I got a letter from HealthKeepers back in February saying that this is no longer paid for by HealthKeepers. We suggest you use Claritin. And, if you have a problem with that, see your doctor.

Now, is that a substitute? What is that? Is that therapeutic substitution? What is the basis of that decision? I'm not addressing it just to you, Mike, but illustrative of what I have been through. I

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don't know anything about Claritin. I know that Hismanal works for me.
DR. BLANCHARD: Your doctor also received a letter, as I did, saying that Mr. So and So is taking Hismanal and Hismanal will no longer be covered starting January 1. You need to make another decision. We suggest, and they list whatever their suggestion is. I would suggest that that is a request for you to make a request--
MR. WORTHINGTON: To my physician.
DR. BLANCHARD: -for an interchange.
MR. WORTHINGTON: Got it.
DR. BLANCHARD: Because, obviously, the pharmacist cannot fill Claritin in place of your Hismanal without the physician's consent.
MR. WORTHINGTON: Okay.
CHAIRMAN TEEFEY: Does that clarify it?
MR. WORTHINGTON: Of course.
MR. SZALWINSKI: Dr. Blanchard,--
DR. BLANCHARD: Yes, sir.
MR. SZALWINSKI: -- can I ask you question? Prevalence in the United States documented here, did you find anything about prevalence in Virginia?
MR. WORTHINGTON: Did you find anything, Julie?

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MS. SISLER: No.
MR. WORTHINGTON: No.
MR. SZALWINSKI: So, we don't know what the prevalence is in Virginia?
MR. WORTHINGTON: At least, not based on our search.
DR. PYLES: Not at the present time.
MR. SZALWINSKI: So, there is no literature to substantiate any kind of a rate of this going on?
MR. WORTHINGTON: It's just not there. It's just not there.
MR. SZALWINSKI: Were there criteria that you used for pulling these studies? Were there specific key words that you may have used or was there a clinical review of the studies for how you chose to include or not include them?
DR. PYLES: Yes. I directed Julie, based on our discussions, and so she used key words, drug switching, drug interchange, anything that was related or came up in any of our previous discussions, are pretty broad-based, across all the literature. We not only looked at clinical journals, but we also looked at economic literature, because you have to look across the broad spectrum of literature to get at this issue. So, we did do a pretty broad-based search

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across several data bases using the same key words in each of the data bases.
MR. SZALWINSKI: About how many citations did you come up with?
MR. WORTHINGTON: Julie, you gave me a printout. Probably ten or twelve pages with maybe four or five cites per page. Does that sound about right? Maybe 60, I guess.
MR. SZALWINSKI: And the rationale for getting from 60 pages to 20 studies was?
MR. WORTHINGTON: I read them all. Well, I read everything that was given to me, and I pulled out what I determined to be -- I mean, I could have cited seven or eight of the same thing, that said the same thing. However, I did some synthesis, if you will, some analysis and said, well, I can't bring them all here. Let's just use these as representative. And, as I said in the beginning, this is not an exhaustive list, although there is not much more out there that's going to say anything different. But it is representative of what the literature says that's out there. I want to make that very clear.
But, what literature there is out there, I believe these remarks reflect, to the best of my ability, very accurately, the sentiments of the

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literature. Sentiments isn't the right word. The positions, if you will, of the literature.
DR. PYLES: And I can also say that one of the things that we did was, we looked, since the situation in hospitals is different from the ambulatory setting, and that's really where we are today, we have a lot of older literature from institutional settings, so we chose not to include a lot of that here, because we felt that that would pretty much have been put to rest. So, what we were trying to do is to look at this situation from the ambulatory setting, and it's just not there. It's not a lot of empirical. It's just not there.
MR. WORTHINGTON: Mike, Dr. Pyles, is correct. There were several cites, Mr. Szalwinski, that go back to the early 1970s. And I thought those were, perhaps, too dated for the group. I think I did use one from 1975, making all the positions, but I tried to stay as current as I could.
MS. PIGG: When you were reading the studies, in the ones that you elected to report, did you read them with a clinically critical eye of double-blinded, randomized, passed the wrong pole.
MR. WORTHINGTON: I looked at the methodology, sure. I didn't rate their methodologies, but I looked

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at the methodologies and, you know, these are respectable journals. You know, I can't question the Annals of Pharmacotherapy, and so I would assume that their editorial Board selected research that was done very well.

MS. PIGG: But, in our literature search, we really did not do a critical review as far as the validity of the actual study.

MR. WORTHINGTON: I don't think that's my position to do that. No, I didn't do that, and I wouldn't do that.

DR. PYLES: And, we're probably really not put in a position to talk about clinical validity, except what was reported there, in most cases.

MS. PIGG: Only to the point of, if you put a conclusion down, it's nice to have a sense of whether or not the study designed was valid, whether or not you can put any weight on the conclusion.

MR. WORTHINGTON: I can attest to the ones that are from the journals, the scientific journals. They meet their standards. If our standards are different, that's another issue. But they meet their standards, and I think we have to go on that.

Okay. Anything else?

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NOTE: (No response.)

MR. WORTHINGTON: Thank you.

CHAIRMAN TEEFEY: Dr. Carroll. Dr. Carroll is a Professor at the Pharmacy School at the Medical College of Virginia.

DR. CARROLL: Thank you, Joe. My name is Norman Carroll, and I'm a Professor of Pharmacy Administration at the School of Pharmacy at the Medical College of Virginia. Due to the sensitivity of this issue, I need to tell you that I'm here speaking as a researcher and as an individual and not as an official representative of the School.

What I would like to comment on is the lack of research information on therapeutic interchange, specifically on drug switching. As someone who has done research in this area or probably more precisely who is trying to do research in this area, I have run into three barriers to doing research. Okay. The first is, there is a pharmacy regulation which prevents pharmacists from sharing patient data with any one other than the physician or the pharmacist. Okay. From the point of view of a researcher, that prevents you from going into community pharmacies and getting drug switch information.

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The second barrier is the common practice of PBNs and managed care organizations of making pharmacists sign confidentiality statements. Again, these statements say that the pharmacists can't reveal patient information without the express written consent of the PBM or the managed care organization. So, again, there is a barrier to my going into a community pharmacy and getting drug switch information.

The last barrier is a little less obvious. And, that is I think there is a reluctance on the part of a lot of pharmacists and a lot of physicians to do anything which they think might antagonize or might criticize managed care organizations. The feeling is that if I, as a pharmacist, antagonize an insurance company, that company may then throw me out of its network or no longer allow me to participate. So if you think drug switching is something that might antagonize a managed care organization, then you're not going to get involved in research on it.

Now, these three restrictions substantially increase the difficulty and the expense of doing empirical research on drug switching. So, as a result, I think if there is going to be any large scale research efforts, they're going to have to be

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supported by the PBMs and the managed care organizations which are doing the drug switching, because they have the data. And until these organizations do the research or until they share their data with outside researchers, about all we're going to know about drug switching and about all we're going to know about the effect of drug switching on patients is what we can glean from small-scale surveys and anecdotal evidence.

Any questions?

NOTE: (No response.)

MR. SZALWINSKI: Just for the record, there is legislation in Virginia which prevents managed care organizations from excluding pharmacies from their network, I believe. Am I correct?

SENATOR NEWMAN: Yes. Unless it's an ERISA Plan.

MR. SZALWINSKI: Right, unless it's self funded.

DR. KNAPP: Unless it's an ERISA plan, which--

MR. SZALWINSKI: Right. So commercial HMO populations have to have an open network.

SPECTATOR: That legislation is qualified by

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the fact that the pharmacists or physicians who wish to be providers in that network must be willing to comply with all terms and conditions that other providers are complying with. So, if one of those conditions is a provision in the contract that prohibits you from disclosing information about planned participants to third party sources, you must comply with that or you can breach your contract and then the Freedom of Choice Law does not apply.

MR. SZALWINSKI: Maybe a reasoning behind that, if, and I hope that you never are in a position of having a terminal disease or one that you would not like communicated to people that don't know you, you would very much, as a consumer, want that information to be kept confidential, I would imagine.

DR. CARROLL: Absolutely.

MS. PIGG: Norman, just for your information, since I'm here as a representative of the Academy of Managed Care Pharmacy, the Foundation of Managed Care Pharmacy is actually trying to come up with a study designed to look at some of this, but it was very involved. They anticipate it to take three years. They also anticipate a cost of well over a million dollars and not desiring to seek funding from, necessarily, pharmaceutical companies. I'm not sure

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where it's going to go either.

DR. CARROLL: Yes. I agree with all of that. But, when you come down to why is there no data, it's just hard.

MR. COUNCIL: I'd just note, too, that HCFA-approved Medicaid contracts also have similar confidentiality provisions. It's not just a matter of managed care organizations and PBMs that are imposing confidentiality.

CHAIRMAN TEEFEY: I think the reason Norm is here is because, when we were searching through all of this data trying to come up with something, Norm was aware of it, and he wanted to make it clear to the Task force why we have only what we have here, basically. I think it's real important that we heard that.

Thank you, Norm.

During the break we had a few questions about materials that were handed in and some materials that weren't handed in. We had the two individuals that made presentations last time to really review the materials they sent in so we make sure that the Task Force has all the materials we need and the complete materials we need.

Kenneth, do you want to review the materials

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you sent us?

MR. McARTHUR: Yes, sir. Thank you.

CHAIRMAN TEEFEY: Kenneth sent his in. The next guy is the bad guy. He didn't send it in.

MR. McARTHUR: Let me state for the record that I'm here against my will, but here to serve at the pleasure of the Chairman. Because I do think that attorney and/or lobbyist grandstanding on these issues should be kept at an absolute minimum: preferably there should be none at all. But I will, having said that, very quickly go through and list for you, without much commentary, because I don't think that I'm nearly as qualified as the members of this Task force to assess the validity of or analyze the data that we have submitted to the Task Force.

Most of the lengthier documents that I have submitted have their own executive summaries already prepared by the authors and attached those documents, so I won't try to substitute those authors' summaries, either. And, moving on, then, to the list of documents that I have already provided to the Task Force through the facilitator, Dr. Pyles, and also in a letter to the Chairman of the Committee, Mr. Teefey, we have provided, to begin with, two letters which Wyatt Durrette and I co-authored, which were sent to the

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Virginia Board of Pharmacy last fall. And, in those letters, we tried to summarize, as best we could, the problem that we were seeing with drug switching in Virginia. In particular, with some of the new contracts that we saw emerging beginning last summer-- By "contracts," what I mean are Provider Agreements that were being issued by certain managed care organizations to pharmacists.

In those letters, we attempted not only to bring what we saw clearly as a problem to the Virginia Board of Pharmacy, but to review for them the existing Virginia law that we thought would give them the jurisdiction or authority to actually take action against some of these companies for engaging in the practices that we were seeing, which we believe were harmful.

The Virginia Board of Pharmacy, I believe, did look closely at this issue. I believe that they publicly stated concern with the problem of drug switching in Virginia. I believe they held a hearing in which at least one PBM was present and attempted to describe its policies in a particular contract that it had issued to Virginia pharmacists. I don't know that the Virginia Board of Pharmacy has taken any action, any affirmative steps since then. It's my

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understanding that their legal counsel, who, of course, is the Attorney General's Office, has advised them that while they may have general statutory authority to take action to regulate some of these practices, it's the Attorney General's Office's opinion that they do not have specific authority and don't feel comfortable in advising the Virginia Board of Pharmacy to take action absent that specific authority.

Just as a word of explanation, that is what led to the Virginia Anti-Drug Switching Patient Protection Act last year. That was an attempt to get that express authority. It would have provided that, that statute would have provided that authority not only to the Virginia Board of Pharmacy, but to the Virginia Board of Medicine, to the Attorney General's Office, who would have also created a private cause of action.

Beyond those two letters, we provided, at Dr. Pyles' request, a copy of the final version of the Virginia Anti-Drug Switching Patient Protection Act which was considered, in its last forum, by the House Committee on Health, Welfare and Institutions, and that was Senate Bill Number 1114, as amended. We also provided a copy of a statement which was prepared and

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presented by the New York Public Advocate, Mark Green, who, incidentally, had conducted, just prior to last year's legislative session, a six-month long investigation in the State of New York on the practice of drug switching. His Staff had gone out into pharmacies and into doctors' offices, and had looked at documents provided by managed care organizations. Having conducted this six-month long study, prepared an approximately 100-page report in which the New York Public Advocates Office denounced the practice of drug switching, and pointed out examples of, specific examples of patients who had suffered harm from the practice, pointed out concerns voiced by various health care provider and consumer groups, and also made recommendations for legislation, which were similar to what eventually became the language that was advanced in the Virginia Anti-Drug Switching Patient Protection Act here in Virginia.

Mr. Green, and by the way, we also included a copy of that six-month-long study, as well as an executive summary of the study. Mr. Green's statement was included. These were his comments that he presented to the House Committee on Health, Welfare and Institutions during last year's General Assembly session.

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In addition to that, we also produced a document which was prepared by two PhDs who, I believe, were contracted by the National Pharmaceutical Council and these two individuals surveyed the existing published literature on the subject of restrictive drug formularies and the various practices associated with enforcing those, including drug switching, therapeutic interchange, therapeutic substitution, generic substitution and a host of others. I won't try to summarize that report, but I will just read very briefly for the Task Force Committee what the authors stated at the very beginning of that report, which was that,-- That report, by the way, was entitled, "Component Management Fails To Save Health Care System Costs -- The Case of Restrictive Formularies," and it was published in August of 1996. The statement at the beginning of that report was, This report is a comprehensive overview of the published literature going back several decades on the impact of restrictive formularies. This body of literature indicates that such formularies often have a negative impact on overall cost and quality of care; that they often fail to achieve their fundamental goals and may paradoxically exert adverse effects on budgets,

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patients, doctors and pharmacists. Taken together, these studies show that although drug costs in the restrictive category were often decreased, the predominant effects of restriction were to shift costs by increasing utilization of either nonrestricted drugs or other health care services. None of the studies clearly showed an association between drug restriction and reduced costs in other health service categories.

In addition to that survey of the literature which we've produced, which, by the way, included the study which was conducted by Dr. Susan Horn that I believe Dr. Blanchard referred to earlier, we produced an individual copy of the Susan Horn study, as well as an executive summary of that study. In addition to that, we produced a copy of a document which was some 50 or 60 pages in length. It was a document that was prepared by the California State Senate Committee on Insurance. That Committee is chaired by Senator Herschel Rosenthal. That Committee has had hearings and the Staffers from that Committee, I have talked with them, have conducted an investigation, which I believe is ongoing, into the practice of drug switching and the use of restrictive drug formularies. That document contains a number of

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statements by various health care provider associations, consumer groups, and others concerned with the potential harm and actual harm caused by drug switching practices. That has been provided to the study committee, as well.

Finally, we have produced to the Task Force some, what I would call, just lobbying materials. These were simply statements which were prepared last General Assembly session in an effort to try to summarize some of the arguments on the side of those who supported the Virginia Anti-Drug Switching Patient Protection Act. I asked Dr. Pyles whether he was interested in those, and he said he was interested in any information that we had on the subject, and so I gave him those. There were also some documents which were used to attempt to dispel some of the myths and some of the confusion that I think surrounded the Bill and what it did, what it did, in fact, do or would have, in fact, done had it been enacted into law.

Finally, I also asked Dr. Pyles if he would be interested in various articles related to this subject which have appeared both in Virginia State, local Richmond and even other state's publications and in national publications, both trade press articles specific to the pharmaceutical industry, articles that

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are a little broader in the sense that they would be classified, I think, as health care articles, in general, and not necessarily related, specifically, to the pharmaceutical industry, and then articles that appeared in the more popular press such as the Wall Street Journal, the New York Times, transcripts of programs that appeared in the CBS evening news, CNN and the like. In these articles, there are quotes from various interested parties in the issue of drug switching. And, more interesting to me, I think, there are some accounts of consumers who have been affected by the practice of drug switching. What we have not produced and which we intend to produce very quickly, and I apologize that we haven't yet gotten this to the Task Force, is all of the legislation that we could find that we think is, either has been considered, in some cases enacted, or is currently being considered in other states. I would say that we have, in the California Senate Committee on Insurance, a report on this subject. There are, I believe, there's at least one Bill there. I believe that there is a Bill being considered in New York, which is similar to the Virginia Bill from last year, and I also understand, because I've called and checked on this, and spoken with some folks last week, that a

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coalition of health care providers and consumer groups in Maryland and D.C. are also currently considering, and at least, at this point, favorably considering Bills which have wording which are identical to the Virginia Anti-Drug Switching Patient Protection Act, which was introduced in Virginia last year.

I belief that is everything that we have produced to the Task Force to date. We do have some other documents which we're accumulating, including the legislation, which we would like to continue to offer to the Task Force. And, as we discover other items, we would also like to be able to supplement that, from time to time, if we could. I believe that that is it.

CHAIRMAN TEEFEY: Do you have any, Mike?

MR. AYOTTE: I guess I want to piggyback on Senator Newman's comment earlier about where we stick on information concerning therapeutic interchange and not formulating utilization and not switching. I mean, I really want to stay focused on that one terminology.

The other thing is, can we, when I spoke the last time and that's on Page 29 of the transcript, we were talking about cost factors and how there were some statements made about increase in costs, and you

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stated that, in fact, I see ample evidence that will decrease costs in the overall health care plan. So, in my view, passing the Bill would decrease costs, not increase costs. Is there any evidence that you can show or any studies that you have that you would be able to provide us?

MR. MCARTHUR: I may not have understood your question. Did you say, are there studies to show that there would be an increase in overall health care costs as a result of therapeutic interchange?

MR. AYOTTE: You stated on Page 29 that you had evidence that it would decrease costs by passing that Bill.

MR. MCARTHUR: Oh, yes. Well, I think what that is, is the corollary to the fact that there are studies that show that the practice increases costs. Logic would dictate that, if you end the practice, then, that those costs would decrease.

MR. AYOTTE: There's no hard studies or facts that show that?

MR. MCARTHUR: Not to my personal knowledge, no.

CHAIRMAN TEEFEY: Yes.

DR. KNAPP: I think you brought up a point that needs to be clarified. What pharmacy practices do

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the Board, do the Board counsel say you don't have jurisdiction over? If a pharmacist taking a $12 kickback for-- Let me step back.

The pharmacist gets the prescription from the patient. If the pharmacist does not call the practitioner who wrote the prescription and fills the prescription with a different drug, that's legal or illegal?

MS. WARRINER: That is illegal and you have jurisdiction over that pharmacist and that pharmacist's license.

MR. WALKER: Where we don't have the jurisdiction is a third party being involved and saying, we want you to make this switch.

DR. KNAPP: Right. Right. But you do have --

MR. WALKER: For the pharmacist that practices in Virginia, of course, we do.

DR. KNAPP: Would it be considered unethical conduct under the current Code regulating the practice of pharmacy in the Commonwealth of Virginia, would it be considered unethical conduct to accept a $12 kickback to change a prescription? Would you bring somebody up before the Board of Pharmacy saying, we consider this unethical conduct, if you've done this?

MR. WALKER: I'm not sure.

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DR. KNAPP: And you have never brought anybody up?

MR. WALKER: To my knowledge, it has not been done.

DR. KNAPP: So, where the counsel for the Board of Pharmacy is telling you, you don't have jurisdiction over the PCMs and the third party pharmacies and all the rest, that would be--

MR. WALKER: That's correct.

DR. KNAPP: That's one of the same problems we have in medicine.

MR. WALKER: That's right. Yes.

DR. KNAPP: I just think that's really important, because I hear the whole issue of the $12 going to the pharmacists for changing the prescription is one of the questions and one of the problems they've been asked to address. Is that not ethical conduct and that's something that can already be addressed in the Code under the auspices of the Board of Pharmacy?

MR. WALKER: I'm not sure that it is. We are not allowed to take kickbacks from physicians or physicians from us, as you know. But, as far are as, you know, from other individuals, I'm not sure how they -- I'd have to check on that.

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DR. BLANCHARD: Can we read the statute that applies to that? I think it's just important. I think we have it right here.

What is prohibited in Virginia, and I have the Number 110-20 through 90. Pharmacists shall not solicit or foster a prescription practice with a prescriber of drugs or any other person providing rebates, kickbacks, fee splitting, or special charges in exchange for the prescription order, plus fully disclose in writing to the patient and the third-party payer. What's not clear, I guess, to me is whether that's only a relationship between you and the physician.

MR. WALKER: That's right.

DR. BLANCHARD: Or the interaction occurred between you and the physician in order to get the permission to get the switch, but the kickback comes from a third-party payer. And, if it is unclear to you, in your position, it certainly deserves some attention by this Committee to make sure that we are going to suggest that we don't need legislation, that the Board of the Medicine can take, the Board of Pharmacy can take care of this; that we need to make sure that the statute is clearly written and fully understandable of this.

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So I'm concerned that you're confused.

MR. MCARTHUR: Mr. Chairman, would it be possible for a representative of the Attorney General's Office to prepare and appear at the next meeting before the Task Force to address this issue?

CHAIRMAN TEEFEY: I think what the Attorney General is going to want to do is respond to the Board of Medicine, rather than come here.

I'm almost sure that's what they are going to--

DR. KNAPP: They give you written legal opinion on your jurisdiction.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: If I could, the Attorney General sits over there to help us, though. I think that we can ask him to come in here and give us some opinions.

CHAIRMAN TEEFEY: Oh, I'll ask him. I'll ask the Attorney General.

SENATOR NEWMAN: He's got a lot to do, but he doesn't have--

MR. MCARTHUR: You might want to let Senator Newman ask him.

CHAIRMAN TEEFEY: I think it will go a lot

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farther. But, usually, when we have the Attorney General come to a meeting like this, they always tell us they would rather respond to the question that comes from whichever Board. I think that's the response we're going to get, unless Senator Newman asks him.

MR. COUNCIL: Mr. McArthur?

MR. MCARTHUR: Yes, sir.

MR. COUNCIL: Has the AG's Office even expressed to you that it disagrees with the conclusions in the September 10 letter to the Board?

MR. MCARTHUR: No, sir. They have not expressed disagreement with that to me. They have expressed concern that the individual members of the Board of Pharmacy and that the Board of Pharmacy, in general, would be sued by managed care organizations if they were to attempt to regulate the practice of drug switching in Virginia.

MR. COUNCIL: Well, how does that -- I'm not sure how that language jives with your conclusion.

MR. MCARTHUR: I don't know. You have to ask the Attorney General's Office, sir. That's why I was suggesting that we --

Let me see if I understand what you just said. I mean, as I understand what the Chairman of

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the Board of Pharmacy just said that if you're Virginia licensed and you drug switch, they can regulate you. And, if it is a drug switch, it's unlawful, as that term has been used here, meaning without the consent of the physician.

MR. MCARTHUR: Right.

MR. COUNCIL: Okay. So, I mean, your response was broad, then. You were talking about out-of-state pharmacists who are not licensed in Virginia?

MR. MCARTHUR: No, sir. My understanding, from discussions with the representatives of the Attorney General's Office is that it is not crystal clear enough for the Attorney General's Office to advise the Virginia Board of Pharmacy that they can or should take action with comfort, even as against licensed resident Virginia pharmacists.

A SPECTATOR: That's very interesting. The issue is the therapeutic interchange where the financial incentive is to the individual community pharmacist. In that context, in our letter, we throughout the Board did have the authority to reach that and we set that out and cited the Code Section, and so forth. In the meeting with the AG, as we understand it, the one advising the Board, told the Board that he was not as confident as we were, and

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that they may not have the authority to reach that practice and that they risked being sued if they sought to reach that practice.

MR. AYOTTE: Under current regulation?

A SPECTATOR: Yes.

MR. AYOTTE: Right. So regulation could easily be changed to accommodate that problem.

MR. MCARTHUR: Well, except that the Attorney General's Office went on to say that they also are not clear that there is express authority to promulgate regulations that regulate the practice, and they feel they--

MR. AYOTTE: Well, I would be willing to discuss that with the Attorney General. I mean, there are few Boards in the Commonwealth that don't have widespread authority to regulate the practice that they're directed to regulate.

MR. MCARTHUR: Steve, understand that we--

SENATOR NEWMAN: We don't disagree with you.

MR. MCARTHUR: We don't disagree with that. We think they do have the authority. But, when our legal opinion was put before them, the Attorney General's representative disagreed with us. So,--

MR. AYOTTE: I understand.

CHAIRMAN TEEFEY: Are you in complete

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agreement with that?

SENATOR NEWMAN: Almost.

MR. WALKER: I'm in agreement with, as they stated, that's the AG's response. I'm not -- Well,--

CHAIRMAN TEEFEY: I mean, not in agreement with what, but I mean in agreement that the AG's response --

MR. WALKER: Yes, sir.

CHAIRMAN TEEFEY: Okay. So we've got a problem with the regulations?

DR. KNAPP: Yes.

MR. JENKINS: Mr. Chairman?

CHAIRMAN TEEFEY: Yes.

MR. JENKINS: I attended a Board of Pharmacy meeting where one of the PBMs was asked to explain its practices. And one of the issues that was covered in that meeting has been glossed over here, and it's the regulation that's cited in Mr. Durrette's letter of September 10, to which Mr. Council alluded, and which Dr. Blanchard read. That regulation is keyed to disclosure. And, if you're doing this behind somebody's back without disclosure, you violate this regulation, and I didn't hear anyone from the Attorney General's Office say that if this practice is engaged in without disclosure, the Board could not take

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appropriate action.

The questions, some of the questions that were asked at that Board meeting, as I recall, had to do with the adequacy of disclosure, and whether the spirit that is embodied in the disclosure requirement in this regulation was being honored. And, so, I think that it may be necessary for the Attorney General to state what its position is on the current regulations, rather than all of us speculating as to whether the Board does or doesn't have power. Because, if the Board has power to regulate appropriately, then, to Ayotte's question, why are we here? I haven't figured that one out yet.

CHAIRMAN TEEFEY: Okay. We will get a -- I will get with you-all and we'll see if we can't-- We'll get a clarification.

MS. WARRINER: I was going to say, Joe, to clarify that, too, I think there was also some confusion about the dollars that we talked about, the $12 that you keep hearing, and whether or not that was, in fact, payment for service provided to the patient or whether or not, in fact, that was payment for completing a drug switch. And I see those as two separate entities, too, and I think there was some confusion as to whether or not those were two separate

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entities.

CHAIRMAN TEEFEY: Okay. Mr. Rosenthal?

Steve kind of misunderstood what we talked about last time, and he's brought his information in today and we'll have it to all by tomorrow.

MR. ROSENTHAL: Yes. I apologize. There was some conversation subsequent to the last meeting in which I thought there was a different plan of action and so I apologize for not getting this material to you earlier. However, I'm confident that the quality of material will more than offset my transgression.

I also apologize, having walked in and seeing that you have notebooks in front of you, I apologize for putting these in notebooks. I probably should have just stapled them altogether with holes. But, be that as it may.

Let me, while he's passing those out, I would like to pick up on a comment that Senator Newman made, and I believe some others at the end of the desk over here made about the literature review and combing through carefully how much weight should be put on some of these things.

I notice, for example, I couldn't help, since I'm a lawyer, I couldn't help noticing that under the "Legal Issues" part that one of the cites is to an

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article that dates back to 1975, some 22 years old now, and it applies to generic drug substitution. So, and I say that, not at all to be critical, because I'm not being critical. I say that in the sense that, as Senator Newman said, we need to look at all of this material carefully, look at the date of it, see if there's been any new material since then, and, if there are studies, who funded the studies, for example, and what the quality of those studies is.

I did not include in my notebook any lobbying materials. Believe me, we have plenty if you want them, and they all relate to Senate Bill 1114. My understanding is, I would hope that this Task Force, as I suggested last time, starting from a clean slate, and that that piece of legislation, which did not pass the General Assembly, is not going to be used as a springboard to whatever this Task Force does. That is why I have not included any lobbying materials in there, and I don't intend to, unless you ask me to.

Very briefly, since you have not had a chance to review this material prior to the meeting, I will just quickly go through and tell you what's here.

I have divided it into, if you look at the Table of Contents, into five different sections. The first section is, are documents, basic definitions and

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explanations of drug formularies, the ways that they should be properly used, and therapeutic interchange. Probably the most important section is the next section which is Therapeutic Interchange/Clinical Research.

Note importantly that none of this research is older than a year. All of this is since, I believe, the summer of,-- Well, since September of 1996. So, this is all current literature. What most of these are, are actual tests that were done on therapeutic substitutions and what the results were. And I ask you to look at those carefully, because, number one, you will see how seriously these tests are taken and the depth with which the researchers go, to which the researchers go. And they are done by pharmacists, PhDs. Two of them are from universities, schools of pharmacy and schools of medicine. The last one is from Creighton University, both the School of Pharmacy and the School of Medicine. I'm referring now to Tabs 5 through 8.

What these show are two things. One is, the first question they always ask, and the overall question of value, is, what is the value the patient, which I think we all agree is the most important question. And these studies find, at least as to these

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drugs, that there were the same or better outcomes from switching, number one, and, number two, significant cost savings, which is the second value issue. In one study, the savings, without any overall adverse outcomes, savings of over a quarter of a million dollars over a two-year period. These numbers take into account, by the way, something that Mr. McArthur mentioned to you at the last meeting, which I think is important, and that is the components of health care costs.

Mr. McArthur stated to you that while you may reduce costs in one component area, you may increase in cost in another component area or component areas. For example, if a person doesn't do well on a medication, having been put on that after taking the first medication, the person may end up in the emergency room, which is ultimately going to cost more than if they had stayed on the first medication. And, therefore, the total health care costs rise because of that switch.

What you will find here is that these studies do look at the component parts of health care costs, and they quantify those and they show, again, after finding value to the patient, they find significant cost savings. So I ask you to look at those with the

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same critical eye that I mentioned earlier and the same critical eye that Senator Newman suggested. Look at who's doing the study, how it was funded, and the parameters within which the study was done.

The third section is responses to the Horn study. At the risk of being redundant and picking up on Dr. Blanchard's comment, how seriously you should take that study, I think, is well reflected in Tabs 9 through 13. I will not tell you what, I will not go through in detail what those responses to that study say. But, what you will find is it has been roundly criticized as poorly modeled, extremely superficial, with absolutely no correlation between the results that were purported and the basis for those. In other words, there is no causal connection between an alleged switch and the results that they report. That's what those responses are going to say.

Now, two of those articles are by a PhD, Frederick Curtis. We will present to you, at the appropriate time, at the appropriate meeting, Mr. Curtis, who is from Texas. We will bring him up here so that you will have the benefit of discussing this issue directly with him.

The fourth section and earlier Mr. Green's, Mark Green, the New York City Public Advocate, his

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comments were referenced and what they found. You will find at Tab 14 an exhaustive analysis and criticism of the study done by Mark Green, almost a line by line analysis and the defects in that study. Everything from the monolene to the results. While I discussed the inadequacies last time of the Money Magazine article, there is another article in the fifth section of Tab 16 about how unfair that article was.

I would hope that my example to you last time showed how poorly done and how unfair and also the comments by Dr. Hadley, who had spoken with the physician involved in that case, how poorly and unfair that article was done.

With that, we will continue to rummage the record, see what we can find to try to be helpful, and I hope this material is helpful to you, and I will get with the Chairman and find an appropriate time to have Dr. Curtis address you.

CHAIRMAN TEEFEY: Are there any questions?

NOTE: (No response.)

CHAIRMAN TEEFEY: There was some discussion at the break that we didn't have the complete Horn

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study. Is this true?

DR. BLANCHARD: That's correct. At least, the packet of material that I received did not include much of the information that Ken McArthur suggested was sent in. Obviously, that included that study.

CHAIRMAN TEEFEY: Ken, did you get a copy of the complete study?

MR. MCARTHUR: Yes, sir.

I think Dr. Pyles said he was going to rectify whatever wasn't sent out.

DR. PYLES: It's a voluminous amount of material, so we'll do the best we can.

Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

MR. AYOTTE: One of the things, and I know you will probably get to it, just to get the information, if this is all that's out there now from both sides of the issue, that's great. But, if there is sometime where we could get it and have time to review it, and I know we have limited meetings left to make a decision, it just seems to continue to gather information and getting this stuff the day of the meeting, I find it very difficult to absorb it. So, if we can get that in advance, it would be very helpful.

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CHAIRMAN TEEFEY: It's 12:30 right now, and I have some physicians up here that told me if you think this switching is bad, if I don't have them out of here by 12:30, about the switching I'm going to get.

So, we have a couple other things on the Agenda, and we might have to bypass those. But, I have one important question. I need to know what the Task Force needs, and what they want to do in our next meeting. I think that's very important that we come to this point right now. If we could just go through and if you have some suggestions, what you need in the next Task Force. One other thing, I would like to bring speakers in from the different associations: Pharmaceutical Association, the Medical Society, et cetera, to give some testimony and probably take up Mr. Rosenthal on his offer to bring that person in.

DR. PYLES: Mr. Chair, if I could just interject one second before they tell us what their needs are. Could I just bring us up-to-date in terms of what I foresee in terms of getting to the final report, and then we can hear what their needs are. Is that all right? It will just take about a second.

CHAIRMAN TEEFEY: That's great.

DR. PYLES: As you-all are aware, one of the things that we need to do in the report that we have

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to prepare is to make a statement about therapeutic substitution or therapeutic interchange, and I think we have pretty much, and, again, as you speak, you can address this. I believe that we pretty much have decided that we're not, in that report, and consistent with the resolution, that we're not talking about drug switching here, but we're looking at the impact of therapeutic substitution and interchange. But, because of the fact that these terms are often used interchangeably, I think that one of the things that we need to do pretty quickly, if we're going to move along here, is we do need a statement, a consensus statement at this point, from the Task Force in terms of what it is we are talking about. Something that we can all live with, that summarizes the issue, and I think that's absolutely essential, Mr. Chair, before we can move on to addressing the issue of impact. Because, if one group or a couple of people are talking about one thing, apples, and another group is talking about oranges, we can't really talk about impact.

So, I think that's one of the real key things that we need to do. And, in the interest of time, what I was going to suggest that we might do is, before the next meeting, we need to circulate a

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statement; that's the starting point. We need to circulate something that all of you would be comfortable having your names attached to as this is whatever it is. This is therapeutic substitution therapeutic interchange. And, Mr. Chair, if it was all right with you, I was going to suggest that, if we could get a couple of people, maybe a subcommittee, two or three, to work with me to develop that statement and circulate it, and then, from there, we could begin talking about how we can look at impact and also what other speakers we need to bring in to help us.

CHAIRMAN TEEFEY: All right. That would be fine. But, I think I have been hearing it from a couple of people that we are talking about therapeutic interchange.

DR. PYLES: Okay.

CHAIRMAN TEEFEY: That we are not talking about switching.

DR. PYLES: Right. Exactly.

CHAIRMAN TEEFEY: We are talking about therapeutic interchange.

DR. PYLES: Okay.

CHAIRMAN TEEFEY: And I think that's the starting point.

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DR. PYLES: That's the starting point.

CHAIRMAN TEEFEY: What we'll do is maybe get four people, five people, on the Committee here and we'll give you-all a call and set up a conference call with some of them.

DR. PYLES: With a statement that--

CHAIRMAN TEEFEY: With a statement--

DR. PYLES: Right.

CHAIRMAN TEEFEY: --within the next week, so we can send it out before the next meeting and everybody will have it.

Go ahead, Dr. Blanchard.

DR. BLANCHARD: Mr. Chairman, I'm not sure exactly where to start on suggestions on how we move forward in the future. You made a comment at the first meeting, that I didn't hear anybody object to, that you have a lot of busy people on this committee that have voluntarily given up their time to come in and try to make the right sort of decisions; that we already, that we agreed that we needed to do a lot of homework, and we were willing to do the reading necessary to take care of these problems. And, without sounding disrespectful to people who make presentations of written documents and knowing that both sides of the issues have had at least three

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months to think about this process, I'm a little concerned by the fact that we didn't have all the data available from both sides way in advance of this meeting.

I would personally prefer to have read these documents at home, had a chance to think about them and come in and ask pointed questions of those people so that we can clarify the issues. Just as a starting point, I might suggest, then, that we request and expect that any interested parties that have information related to our Task Force agenda provide that information to Mr. Pyles no later than, say, next Wednesday afternoon and that information submitted after that be accepted with prejudice, unless we honestly feel it is newly-discovered information.

Secondly, I had sent Mr. Pyles a letter requesting information about 12 or 15 different practices within the concept of therapeutic interchange, and would hope, and I will be glad to resubmit that letter if you didn't get it. I don't have documentation that you got it, but those items are the areas that I felt were of potential concern within that topic. And I would hope that if people on this subcommittee, this Committee, have requested that sort of information, that we would get responses to

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that prior to the meeting.

Then, when we come to the meeting, then we can talk among ourselves in a way to try to assess where we should come down on these issues. I'm not sure we all need to hear from a lot more speakers and, in particular, Mr. Rosenthal's suggestion that we might hear from somebody rebutting Dr. Horn's study, I would think you would have to have Dr. Horn here, as well. So, this could go on and on forever listening to lawyer-type presentations.

I think we're very smart people on this Committee. I think we ought to be able to do the business of this Committee in fairly short order if we can decide what it is we want to do and decide that this is the data that we're going to deal with. And, from that point on, it's up to our brains to make those decisions.

CHAIRMAN TEEFEY: All right. That's a good idea. And, if anybody wants to submit any materials, we have to have them by next Wednesday so we can get them to the Committee. Then, I think the next thing that you expressed, we'll take those, that list that you sent us, and we'll start working, the letter that you sent, we'll work with that letter.

Yes, ma'am.

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DR. KNAPP: I think we do need to hear from the AG's office one way or the other.

CHAIRMAN TEEFEY: All right. I will get with the Board and we'll hook up with you and get Casway and find out what the situation is.

CHAIRMAN TEEFEY: Yes, sir.

MR. AYOTTE: I think if you're going to have speakers come at any point, and I agree with Dr. Blanchard, I'm not sure at this point we haven't heard pretty much all the argument. If they were going to submit something, that they could go through the Committee first and either give them their comments -- I just, when you look at the sheet, it just concerns me, because the first meeting we talked so much about facts, and that, to me, hasn't happened.

CHAIRMAN TEEFEY: Okay. Good. Do you have anything? Senator Newman?

SENATOR NEWMAN: I'm glad what was mentioned earlier was mentioned. I had written down "multiple problems/multiple cures." As we talk along, I'm identifying, for instance, things like the problem of out-of-state vendors not going through the Board of Pharmacy and these other things which are passing by, which I see as solvable problems. Unless there is some problem in the U.S. Constitution and the Commerce

Page 1

Clause or something, I think we should be able to solve some of these problems. And, I'm wondering if what has been done on the other end of the table might be done by some of us, but maybe, more importantly, by the opponents/proponents here where they can present the multitude of problems. The large issue of drug switching has many aspects to it that can be broken down. And, if we can break them down, then we may pick A, B and C, but we may not pick the rest.

We may be able to cure those and the rest we may not be able to cure, and I'm wondering if we cannot get from them the number of problems that exist and then what their cures are and maybe hear from the other side on what their cures are and maybe collectively we can come up with some cures, as well, and maybe even put some of them to bed quickly.

For instance, maybe we can ask that legislation be drafted that requires everyone to go through the Board of Pharmacy if they're going to practice in Virginia, if we agree on that and, if that's wrong, then we can build on that information, and Staff has done such a great job. But if that's a possibility of organization, that would help the guy who is not a doctor on this Committee.

CHAIRMAN TEEFEY: well, I think we have heard

what your needs and what your requests are, and we'll design the next meeting for those things, because I know we only have two more meetings left.

This is a hard subject to get your hands on. I think we have defined part of it today by saying we're dealing with strictly interchange and not with switching, because we do get those two in together and they're two different animals.

So I want to thank you all for coming, and we will probably get with Dr. Blanchard, because we don't have that letter, and make sure to get that.

Thank you all so much for coming.

* * * * * * * * * * *

HEARING CONCLUDED.

NOTE: The hearing was concluded at 12:44 p.m.

CERTIFICATE OF COURT REPORTER

I, PATRICIA PRICE WHITE, hereby certify that I was the Court Reporter in the hearing as captioned on Page 1 hereof, when heard on the 16th day of July, 1997.

I further certify that the foregoing transcript is a true and accurate record of the testimony and other incidents of the HEARING herein.

Given under my hand this 21st day of July, 1997.

PATRICIA PRICE WHITE, RPR, CP

CRANE-SNEAD & ASSOCIATES, INC.

4914 Fitzhugh Avenue, Suite 203
Richmond, Virginia 23230
Tel. No. (804) 355-4335

July 21, 1997

Mr. Michael Worthington
Dr. Michael A. Pyles
Department of Medical Assistance Services
600 East Broad Street
Richmond, Virginia 23219

BY HAND DELIVERED
July 22, 1997

IN RE: HJR 630- July 16, 1997 Hearing

Dear Mr. Worthing and Dr. Pyles:

Please find enclosed an original and one copy of the transcript of the above hearing when heard on the 16th day of July, 1997.

Also, please find enclosed the miniscript version I told you I would include at no charge. I thought this might help you with your copying time and cost of paper.

Thank you for your business.

Very truly yours,

(Mrs.) Patricia Price White, RPR, CP

Enclosures

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VIRGINIA:

DEPARTMENT OF MEDICAL ASSISTANCE

IN RE: HJR 630 SPECIAL TASK FORCE

Meeting of the Special Task Force held on August 20, 1997, General Assembly Building, House Room D, at 8:30 a.m.

CRANE-SNEAD & ASSOCIATES, INC.
4914 Fitzhugh Avenue
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(804) 355-4335

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MR. TEEFEY: I'd like to thank everyone for coming out on this nice rainy morning. And I want to thank Howard and Scotti for being here. They're with the Pharmacy Board. We talked to them numerous times on the phone during the month.

We went into the minutes and took the questions that were asked at the last meeting and we reviewed those questions. Scotti and Howard will help us answer some of these questions.

Mike, do you want to go over the materials and update?

DR. PILES: Yes, sir.

Good morning. You did receive quite a bit of material since our last meeting. I wanted to make sure you all got a copy of the letter that one of our Task Force members wrote, Larry Blanchard; also, the transcript from the last meeting. I noticed there was a missing page, which I have placed at each of your desks there. One single page representing 33 through 36 of that transcript. That missing page is there.

We have also been working to

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get some information. Earlier on someone had raised questions about some numbers in terms of how many Virginians may be covered by prescription-benefit programs. We're still working on getting that information. It's not in one location. I made several phone calls and may be on to something. It's kind of difficult to estimate. But we have been working on that.

I have spoken to someone with the Bureau of Insurance at the State Corporation Commission. I think I'm getting to a point where I can come up, at least, with numbers in terms of how many Virginians are covered by prescription-benefit plans, so we might have an idea of, looking at impact, how they might be affected by that.

Also, since our last meeting, you will hear some of this information today later, but I have included a copy of materials that we received from Scotti Russell from the Virginia Board of Pharmacy. She is the Executive Director. What you have are copies of material that she faxed to us. Those just came in so I provided them for you this morning on your desks. I think that's everything.

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MR. TEEFEY: We polled the Committee-- There were some requests by both sides to bring in speakers. And we polled the Committee. I think Dr. Blanchard last time worded it extremely well that we heard enough from outsiders that we wanted to get the Committee and get this thing on the road.

We are not going to have any speakers from outside come in, but we do have a public comment period. Mary wants to speak during the public comment period.

I would like you to hold the comments to two or three minutes.

MS. ROULEAU: Good morning, everyone. My name is Mary Rouleau. I represent Arlington, Virginia. I'm also representing the Consumer Federation of America. We're a federation of about 240 nationwide organizations providing membership of about 15 million people.

CFA has been active on this drug switching issue. A week ago we held a press conference in Washington, D.C., along with public advocate for the state of New York, Mark Green. I believe you're all familiar with him.

The big reason we held this

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press conference is because we think virtually none of the public and very, very few lawmakers are aware of either the industry's structure of the pharmaceutical benefit manager industry and/or the implications of drug switching.

We have been involved for a couple of years in front of the Federal Trade Commission, Food and Drug Administration, and now we're taking our case to the Congress.

We obviously have some very important anti-trust considerations associated with the vertical integration of this industry. But the major thrust of our press conference--our major concern--is the impact of drug switching on the quality of care for patients. We believe in some patients it presents very serious risks.

I gave to Mr. Teefey's assistant here a packet of my material to give to you all.

Suffice it say that the cornerstone of our press conference last week was a report from Mark Green's office. He had done a survey of pharmacists and physicians in the state of New York, and it's in the material.

I just want to highlight a few

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of the findings. Of the physicians surveyed, he found that 83 percent of physicians are contacted by health care and pharmacists to change--to perform a drug switch, and 76 percent of physicians believe that a plan's use of therapeutic interchange significantly diminishes or diminishes the quality of care. 57 percent of the physicians responding reported that patients had problems after the prescription was switched.

Mark Green's office also surveyed pharmacists in the New York City area. 74 percent believed that substitutions diminished the quality of medical care. 79 percent are somewhat uncomfortable making drug substitutions.

This I find troubling: Almost half of the pharmacists responding believe that by not cooperating sufficiently with the plan substitution request, they will be penalized either by being audited or dropped from the network.

Many pharmacists also testified at about four field hearings that they had in New York State on this issue, and several had to do it anonymously because they were afraid of retaliation. You'll find it in the material.

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Specific reports have been filed with the FDA regarding adverse impacts of drug switching, and other reports have been filed with the American Psychiatric Association.

The report that you'll find in the materials builds on a December report release by Mr. Green, which describes at length the various tactics used on pharmacists and doctors in an attempt to get them to switch drugs.

I will say generally, since this report--since we had our press conference--it got pretty good pick up nationally. I have had calls. Personally, I've had calls from the Pharmacy Board, a pharmacist and a patient all expressing their concern about these practices, and, basically, we are glad you're up front trying to do something. We're very concerned.

I've given you a few facts and there's more in the materials. But I already know what the response is going to be from folks who think that the drug switching is not a problem.

They'll say, "Well, this is nice, but this is all antidotal; isn't it?"

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Well, I have a couple of responses to that. First of all, how would you feel if the antidote was your mother or your daughter? I think we need to personalize these issues because these are happening to real people. Secondly, I find extremely troubling, is that this whole exercise is really premised upon the antidote that drug switching contains health care costs in a way that does not diminish quality. This is what the PBM industry says and it's about time they proved it. Make a mistake and the burden of proof is on the Industry, not on the patients or health care providers.

The Industry is going to have to stop using the tired claim that this is proprietary data and can't give up certain information that people could use to quantify these claims.

The government and private studies that I've reviewed, and I'm sure you all have them in your materials, suggest that the Industry has a long way to go before making its case. You know, for example, from the recent Inspector General's report that essentially no one is minding the stores. HMO is not

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overlooking the practices of PBMs. That's why I think it's compelling for the state of Virginia to act.

Now, CFA and our other partners are pursuing this issue at the federal level. Congress, as you probably know, is examining a whole range of issues regarding managed care. But we don't expect a quick resolution at the federal level. Among other things, there are splits in the jurisdiction over what these agencies can do. We believe that states can and should act in regard to formulary and drug switching practices.

The patient needs the right to see the formulary list for their plan before they enroll. They need a quick-- And this applies also to the providers. They need a quick appeal process for doctor and patient when a non-formulary drug is prescribed. There needs to be oversight by the state, including issues such as whether the PMT Committee is really independent and what practices HMO and others engage in to secure formulary compliance.

We believe that practices that allow financial considerations by HMOs or doctors

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or pharmacists to overwrite some medical decisions should be prohibited, and there should be severe and certain penalty for noncompliance.

You will find in the material there is a California bill pending right now that addresses many of these issues.

Those are my remarks, Mr. Chairman. I would be happy to take any questions.

MR. TEEFEY: Are there any questions?

MS. PIGG: Can you give me an example of where a financial consideration should not be a part of the equation?

MS. ROULEAU: Yeah. I think when you have flyers that are sent out to pharmacists that say, "Step right up. Get $12 for hitting a home run," it sends the pharmacist to go beyond normal drug counselling, which I understand is not being performed that much anyhow because pharmacists are being overworked. It's improper financial consideration.

In other words, it's clear that the amount of money on the table is on the table solely to get them to switch--encourage the

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doctors to switch.

MS. PIGG: So that's not--pharmacists should not receive payment for doing that service.

MS. ROULEAU: For drug switching, no. I think they should be compensated for proper drug counselling. But it's very clear from the evidence, especially in Mark Green's uncover, this is not about patient counselling. This is clearly about incentive to get pharmacists to switch.

Don't take my word for it. Look at the survey results from our survey. It is a limited survey. It is the New York City area. But it is some statistical evidence in response to the fact that it's all antidotal.

I think there's a burden on the Industry to step forward and prove its case.

MS. PIGG: So, from the consumer's point of view, do you think having a pharmacy benefit is valuable or should we go back to the old system where people pay for their drugs and physicians get a lot of their prescribing information from the drug manufacturer?

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MS. ROULEAU: I think those are two different things you're saying. I think its important to have prescription drug benefits and health care plans. I don't have to tell you what that is for people who don't have that. It's important for the pharmacy benefits in a health plan. The benefits translate into a health system that allows pharmacy benefit managers to set the rules of the game.

MS. PIGG: Is your concern solely with the PBM and not with the HMO that run their own type of business?

MS. ROULEAU: No. It's with both. The thing that I find incredibly troubling-- It's in the Inspector General report. I'm assuming you're all familiar with it. It's in the material I gave you. It basically says HMOs are-- The use of PBMs is growing by HMOs. I think it's 75 percent. I could be off on that.

So here is a bunch of HMOs that are contracting with these PBMs that provide virtually no oversight over their practices. To me that's unacceptable. The HMO has a responsibility to its enrollees to provide

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oversight. It's not just the PBM.

Our particular concern, CFA's, on the PBM issue is that an industry that started looking one way in 1990 looks very different in 1997 because of drug integration. We think you cannot separate the two out. So we have some very compelling arguments to make about industry structure. But that doesn't necessarily address the subject of quality of care.

MR. AYOTTE: One of the issues of the PMT Committee is, did you recommend independence for PBM?

MS. ROULEAU: Absolutely.

MR. AYOTTE: Wasn't that part of the PCS and Federal Trade Commission consent agreement?

MS. ROULEAU: It sure was. But the question is are they effective. That is the $64,000 question. It's clearly built in the consent agreement. But the issue is, are they really independent.

I don't know if you all saw the Money magazine article a few months ago. That was just impressed upon me. A statement of one doctor, who happened to be from Virginia by

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the way, about how she thought it was a rubber stamp.

Yes, absolutely. Putting the word independent in a statute, frankly means nothing unless someone provides that oversight. What the Roosevelt Bill--California bill and it's in your materials, requires--would require these PMT committees to make their notes public.

This is since the Department of Insurance oversees this stuff in California. The Department of Insurance would be able to look and see that these are independent bodies making independent decisions. It's an oversight question, I think, is where the problem is, not the language.

MR. TEEFEY: Thank you.

MS. ROULEAU: Thank you for your time.

MR. TEEFEY: Are there any other speakers?

We had a lot of very good questions asked of our member of the Task Force with the Pharmacy Board last time. We went back to the minutes and pulled these questions out and Howard Casway and Scotti Russell were kind enough

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to come today to answer those questions. We had talked to Scotti and Howard a number of times on the phone. I think a lot of answers will be given by them today.

Michael, review the questions and Howard and Scotti can help us with this.

MR. WORTHINGTON: Task Force members, as Mr. Teefey indicated I got on the telephone with Mr. Casway and Scotti Russell, Executive Director of the Board of Pharmacy, earlier this week. Dr. Piles and I did.

We had previously gone over the transcript and looked through for the questions you had asked regarding legality issues surrounding that. I pulled four or five of them out of there. And I would like to summarize Mr. Casway's and Ms. Russell's responses. If we need further clarification, they are here.

The first question I found is: What has been done in other states to address therapeutic interchange or substitution?

North Carolina recently passed a regulation requiring full disclosure if a pharmacist contacts a physician to try to switch drugs.

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The regulation reads: A permit holder or a register requesting a change for the prescription drug originally prescribed to a different prescription drug, shall disclose to the prescriber at the time of the request any business relationship between the permit holder or the register and the manufacturer of the requested prescription drug.

This action was a result of a settlement agreement in 1995. In October of that year the Attorney General of 17 states, including North Carolina, entered into a settlement agreement with Merck & Company and prescription drug benefit management subsidiary, Medco Containment Services.

The agreement recognizes Medco's practice of contacting prescribers that request changes of prescriptions from non-Merck drugs to Merck drugs. Payments were made by Merck Medco to each state in the amount of $115,000.

The Medco practice was not prohibited. But Medco employees requesting a prescription change were required to disclose the relationship between Medco and Merck.

The next question: Does state law prohibit the practice of therapeutic interchange/substitution? Does the practice define the law? Does state law say anything about switching drugs based on rebates?

The answer is: The law does not address the subject. Last year the Board of Pharmacy proposed the following language to the Division of Legislative Services as an alternative to Mr. Durrett's proposal--that was at Section 54.1.33.15, Code of Virginia.

That proposal reads: Any pharmacist shall be considered guilty of unprofessional conduct who solicits the patient, prescriber or another pharmacist to permit substitution of a drug which is not the generic equivalent for the drug originally prescribed.

Where the purpose for the proposed substitution is to assist the practitioner or the employer of the practitioner in receiving a rebate, kick back, fee, special charge or other monetary incentive directly or indirectly from the manufacturer of the drug to be substituted.

For purposes of enforcing this

section it shall be assumed that the solicitation for the substitution of a drug which is not the generic equivalent to the drug originally prescribed, shall be for the purpose of receiving a rebate, kick back, fee, special charge or other monetary incentive.

This section shall not apply where the drug substitution either reduces the actual cost, co-payment or co-insurance percentage payment required of the patient for the prescription or where the drug originally prescribed is not covered by the patient's health insurance plan.

Next is: Is it illegal in Virginia for a pharmacist to switch a patient's drug to a chemically dissimilar drug without physician's consent?

That's a roundabout way of asking the first question. The answer is: Yes. This practice is prohibited. The pharmacist has to dispense what the prescriber prescribed.

Does the Virginia Board of Pharmacy have the statutory or regulatory authority to regulate the practice of therapeutic interchange/substitution? Are there any special

provisions for managed care organizations?

The response: The Board of Pharmacy can regulate pharmacists and the practice of pharmacy. PBMs are beyond the Board's authority.

Does Virginia law state that all prescription drugs dispensed for residents in Virginia must be dispensed by pharmacists licensed in Virginia?

The answer is: The Board of Pharmacy regulates non-resident pharmacies. But all they have to do to conduct business in Virginia is to register with the Board of Pharmacy.

The non-resident pharmacy--this is a definition--is any pharmacy located outside the Commonwealth of Virginia, which ships, mails or delivers in any manner Schedule II through Schedule VI drugs or devices pursuant to a prescription into the Commonwealth. The Board, again, has no jurisdiction over out-of-state PBMs.

Mr. Casway and Ms. Russell are available if you have any questions.

MR. TEEFEY: Howard, can I get

you and Scotti-- I've got two questions. The first one: Can you go over the responsibilities under the law of what the pharmacist's jurisdiction is and what the physician's jurisdiction is.

MR. CASWAY: Speaking about the Board of Pharmacy's or the individual pharmacists?

MR. TEEFEY: The individuals under the Board of Pharmacy.

MR. CASWAY: The statue in Chapter 33 of 54.1 sets out the definition of the practice of pharmacy. Basically, among other things, is to dispense prescriptions. Counselling has been added to it. Let me look at--

The practice of pharmacy means personal health service concerned with the art and science of selecting, procuring, recommending, administrating, preparing, compounding, packaging and dispensing of drugs, medicines or devices used in the diagnosis, treatment or prevention of diseases whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed.

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MR. TEEFEY: So that's the pharmacist.

MR. CASWAY: That's what the pharmacists' responsibility is.

MR. TEEFEY: When the pharmacist gets a script, what can that pharmacist do with that script?

MS. RUSSELL: The pharmacist can only dispense that prescription-- There's nothing that obligates him to dispense that prescription. But if he elects to do so, he can only dispense within the parameters of what the prescriber prescribed.

MR. TEEFEY: So, if he changes that script al all, he has to get back with that physician.

MS. RUSSELL: That's correct. The prescriber can, on the prescription, indicate his or her willingness to allow generic substitution by checking the formulary box or not checking the box at all. It would allow the pharmacist to substitute a formulary product. But if they are going to actually change the drug, they have to contact the prescriber.

MR. TEEFEY: But it would have

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to be on the prescription to check off or something like that before--

MS. RUSSELL: What the statute says--if you're talking about generic substitution now--is if voluntary formulary box is checked or no box is checked at all, then the pharmacist is bound to dispense the formulary product.

MR. CASWAY: The product that is on the Virginia Voluntarily Formulary.

There is also another box, dispense as written. That means the physician wants that drug to be the one that will be dispensed. Now, if there's a problem, that's when the pharmacist may have-- For instance, the insurance plan may not cover it. Many, many prescription plans do not cover name brands where there is a generic available.

MR. TEEFEY: You have total control over all pharmacists and pharmacies in the state of Virginia; right?

MR. CASWAY: If they're licensed and practicing, yes. If a pharmacist, by education a pharmacist, and practicing pharmacy but they're not licensed, then the Board

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has no jurisdiction. The court has jurisdiction through criminal prosecution or the Board could go in and seek injunctive relief to prevent the practice of pharmacy.

MR. TEEFEY: Go over the state situation that Mike went over. Scotti, you went over it on the phone with me.

MS. RUSSELL: Excuse me?

MR. TEEFEY: The out-of-state mail order.

MS. RUSSELL: A mail order pharmacy that actually dispenses drugs to patients who have residence in Virginia would have to register with the Board of Pharmacy as a non-resident pharmacy.

In order to get that registration the only thing that the statute requires that they do is provide evidence that they are licensed in their resident state. They have to have an 800 number for the patient to contact them and they have be able to separate out the Virginia data of drugs dispensed upon request. They have to abide by all the laws and regulations of the resident state.

They are not bound to abide by

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Virginia laws and regulations. So in a state that possibly allowed for therapeutic interchange without contacting the physician, if that was their resident state, then they could do that legally the way the law is written right now.

In Virginia mail order pharmacies located in Virginia mailing out to other states, they typically somehow contact the physician either by fax or telephone and request permission for a therapeutic interchange.

MR. TEEFEY: I have one more question. I'll hold that and see if anybody else has questions.

MS. PIGG: What happened to the draft--working draft definition that addressed therapy, the switching by the pharmacist?

MS. RUSSELL: Are you talking about the draft you were given this morning?

MS. PIGG: Yeah, 5413300.

MS. RUSSELL: Back in, I guess, November when we first saw Mr. Durrett's bill we provided--the staff of the Board of Pharmacy and Howard--we provided the Division of Legislative Services with a draft as a possible

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alternative to that bill. We do that frequently if we look at something that's going to affect the Department of the Pharmacy.

We offered that. We did not put that forward as a legislative proposal. This came up in November of last year. We saw it in June. So it was a little late for us to actually submit something as proposed legislation.

We just offered this to the staff of Legislative Services in terms of technical assistance if they wanted to use it. They elected not to. It was offered as a possible alternative, but it was not used.

MS. PIGG: Do you know why they elected not to use it?

MS. RUSSELL: I assume the patron Butch Davie preferred to put in Mr. Durrett's bill instead.

MS. PIGG: Help me understand the technical piece of this. The Board of Pharmacy felt that it affected therapeutic interchange or that issue that affected the practice of pharmacy, so you submitted legislation--language to deal with that.

MS. RUSSELL: Let me correct

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that. The Board of Pharmacy-- This was after the last Board of Pharmacy meeting for the year that we did this. The Board never met actually and approved this draft legislation. This was just some technical assistance the staff offered as a possible alternative. This was never-- At the time of last year, this was never adopted by the Board of Pharmacy as something they wanted to put forward.

MS. PIGG: Where I'm going is if the staff of the Board of Pharmacy felt it was within their purview of the practice of pharmacy to submit language even addressing this issue, is that best where we put this, back to the Board of Pharmacy as opposed to legilsative efforts?

MS. RUSSELL: The problem is I don't think the Board of Pharmacy has the statutory authority right now to deal with this issue in regulation.

Maybe Howard can address some of the problems we might have with restraint of trade if we try to do something in regulation versus having some statutory authority specifically designed to deal with this problem.

MR. CASWAY: What we attempted

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to do-- The problem was brought up to the Board in the concept of-- The PCS program was brought to the Board and there was a fair amount of discussion and communication. And actually representatives from PCS came to the Board meeting prior to this November drafting of this. The Board was aware of what the problem was and we discussed some of the various things this committee is looking at.

The problem that was clear, and as I stated before, the Board of Pharmacy regulates licensed activities within the state. There are a lot of things that may constitute the practice of pharmacy arguably. But certainly, if it's within the state, there are either criminal or civil sanctions to deal with it.

However, if this is taking place outside the state--if a pharmacist or staff person from Arizona calls up a pharmacist in Virginia or calls up a doctor in Virginia regarding a prescription, the long arm of Virginia law does not extend that far.

What we attempted to do was to create a mechanism as one of the alternatives that the Board of Pharmacy, by expanding the

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scope of the practice of pharmacy, to include this kind of practice and then to expand as the result who had to register.

Because pharmacists right now, as Ms. Russell indicated before, non-resident pharmacies have to register with the Board. What we tried to do is expand that to include PBMs--what essentially would be a PBM. That includes the practice of pharmacy. We expanded.

I think the three things that we did was expand the practice of pharmacy; also, the definition of the term dispense to make the act of communication with the prescriber for the purpose of obtaining the authorization to dispense a different drug than the one originally prescribed to be in the practice of pharmacy.

Secondly, we made it unprofessional--attempted to make it unprofessional the act of solicitation to permit this switch if there was a financial incentive. Last, the switch would benefit the patient.

And thirdly, we changed the statute to make it non-resident pharmacies; to require any pharmacist located outside Virginia engaging in the practice of pharmacy with respect

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to any Virginia citizen, to do so only in association with a non-resident pharmacy.

What we attempted to do is take the problem and bring it in clearly, statutorily within the control and regulation of the Virginia Board of Pharmacy.

MS. RUSSELL: Also, we expanded the non-resident pharmacy to make them have to comply with the laws and regulations of Virginia, not just their resident state.

MS. PIGG: It sounds like that process was started but never completed.

MR. CASWAY: It was sort of, we through our hat into the ring and--

MS. RUSSELL: --it didn't get picked up.

MS. PIGG: Okay.

DR. HADLEY: Can I just get some clarification? If we have a pharmacist who is registered with the Board in the state of Virginia, who makes a therapeutic substitution for a chemically dissimilar drug without consulting a physician, regardless of what the motivation is, whether financial gain or any other reason, you currently have jurisdiction

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over that and that would be illegal.

MS. RUSSELL: Absolutely.

DR. HADLEY: Secondly then, how about clarifying again-- I understand the PBMs are an issue. But for a pharmacist or a mail order pharmacy outside the state of Virginia if they are registered with you, do you have that same level of control?

If they make a therapeutic substitution without consulting the physician, do you have any ability, regardless of the reason, to discipline them?

MS. RUSSELL: No. It's a non-resident pharmacy outside of Virginia.

DR. HADLEY: But they're registered with you.

MS. RUSSELL: The only thing we could potentially do is, in theory, I suppose, revoke or suspend their registration as a non- resident pharmacy. But do we have grounds to do that if the law says all they have to do is comply with the rules and laws of the resident state and if, in fact, their state permits that?

MR. CASWAY: Also, the question would be getting jurisdiction over them.

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Certainly, we could revoke their registration if there was a legal and factual basis to take action. They could perhaps continue to operate. It might be difficult for us to get jurisdiction.

DR. HADLEY: Then for a pharmacist--again, let's confine this to a pharmacist in the state of Virginia, who is registered--would you, if a pharmacist calls a physician on a therapeutic substitution for the purpose of assisting a patient to comply with formulary requirements of their plan, whatever it is, so there is an economic benefit to the member, is that legal for the pharmacist, whether or not they're going to get a rebate from a company for doing such a service or payment?

In other words, they do consult with the physician and it is for the purpose of aiding the patient to receive drugs under their formulary.

MS. RUSSELL: For whatever reason right now it would be not be illegal for a pharmacist to contact a physician and request a switch.

MR. CASWAY: That would be in compliance with the law. That would require the

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pharmacist to do so.

DR. HADLEY: Do we have a sense-- You mentioned earlier, Michael, that you're trying to get a sense of prescribing habits. Do we have a sense of what percentage of prescriptions are prescribed outside the state? Is it one percent, 10 percent?

DR. PILES: No. It's real difficult to do that.

MS. RUSSELL: There's probably a very small percentage prescribed outside of the state. Maybe how many are filled outside the state.

DR. HADLEY: That's what I mean.

MS. RUSSELL: I don't have that.

DR. PILES: I'm still working, but it's hard to get that data.

DR. KNAPP: Would legislation-- Would this be restraint of trade? The same issue we get into with medicine and one of the issues hammering legislation.

We're going to get into trouble with restraint of trade if we mandate

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licensure of a practitioner who is outside the Commonwealth of Virginia but essentially practicing medicine on a patient in the Commonwealth.

If we expand the definition of the scope of practice, the pharmacy, which is clearly one of the things that needs to happen, and basically try and make pharmacists outside of the state somehow culpable, is that a restraint of trade issue?

MR. CASWAY: I suspect that as long as those being kept out or restrained, are going to consider it so. I think-- I don't hold myself out as being an expert in restraint of trade. I don't think it would be. I think the states have a right to regulate, under the police powers, the matter dealing with health, safety and welfare of the public.

DR. KNAPP: Are there any other states that have done this--passed either statutory change--changed the scope of the practice of pharmacy or somehow held pharmacists outside the state culpable?

MS. RUSSELL: I only know of the North Carolina regulation that talks about

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disclosure.

DR. KNAPP: Do you think that does any good?

MS. RUSSELL: I doubt it. That's fairly new. We don't have information on how that's worked so far.

Idaho does apparently have enough in their definition of the practice of pharmacy that they had their Attorney General, I think, write a letter to a couple of PBMs and tell them what they were doing is practicing pharmacy in Idaho and that was prohibited unless they were licensed in Idaho. That's about the only other state that I know has done anything.

DR. KNAPP: Do you think that's a good idea?

MS. RUSSELL: I think it's one way to try to get a handle on it. Whether it works or not--

MR. CASWAY: That doesn't resolve the ultimate question of whether or not therapeutic switching is good or bad. But it does resolve the question of who has the jurisdiction.

It would clearly put the Board

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with a clear state mandate to regulate those practices as opposed to attempting, based on a somewhat ambiguous or unclear or maybe even a grant of authority, to regulate the practice.

A state law passed that directs the Board to do is eminently more defensible and would more clearly define what the issues are.

DR. KNAPP: It seems to me that therapeutic interchange is a symptom, not the problem. And at least a piece of the real problem, aside from money and greed, is jurisdiction. That's a reasonable--at least one response to this.

MR. CASWAY: Here it is in terms of who can do something about it. Certainly pharmacy, if it had jurisdiction over them, if a required pharmacist-- If you expand the scope to practice pharmacy to include out-of-state pharmacists in that scope, then the Board has jurisdiction to at least take some action.

DR. HADLEY: Has the Board of Pharmacy ever investigated or disciplined in any way any pharmacist in the state of

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Virginia--let's confine it to that--for therapeutic substitution without consulting the physician for the purpose of monetary gain? Has there ever been a case of that brought before you?

MS. RUSSELL: No.

MR. CASWAY: We've had pharmacists who write prescriptions without doctor's authority, and they have been disciplined. What their purpose was, whether for their own use or for conversion--

MS. RUSSELL: But not for monetary gain.

DR. HADLEY: Thank you.

MR. TEEFEY: Any other questions?

MS. PIGG: When the Board of Pharmacy, who governs the practice of pharmacy in the state of Virginia, throws that hat in the ring with the suggested language, who elected not to pick up that hat?

MR. CASWAY: I think maybe he-- The Board never voted, never adopted it. Scotti and myself had, in the process of doing it for the Board, we were going to present it to the

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Board. The opportunity came to assist the legislative group that was looking at the issue. And we just suggested to them, here's another alternative to look at it.

There were some concerns that the proposal that the committee was reviewing was fairly expansive and perhaps broader than it had to be.

MS. PIGG: In reading some of the information I see here, the Board got a letter coming out of the Task Force on the demise of independent pharmacy and somehow or another--

Can you help me understand how the demise of an independent pharmacy got tied into a regulation or statute, I don't know, regarding therapeutic interchange?

I couldn't quite understand where that letter was coming from from the demise of independent pharmacy suddenly talking about therapeutic interchange.

MS. RUSSELL: You've lost me. I'm not sure I know what you're talking about.

MS. PIGG: There's a letter in this binder, and I don't know which tab--

MS. RUSSELL: The letter from

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the committee?

MS. PIGG: I guess it was. Can somebody help me who might have it.

MS. RUSSELL: I didn't bring my book with me. I don't remember a letter from the committee.

Now, Mr. Durrett's, about the PCS issue--

DR. PILES: I think it's a related bill that dealt with the demise.

MS. PIGG: It was a letter from Mr. Durrett or maybe from Mr. McArthur that started out talking about the demise of independent pharmacists and then flipped over and was talking about therapeutic interchange.

I didn't make the conversion from what does that topic got to do with this one.

MR. TEEFEY: Let me help out a little bit. Whenever a bill comes out, the Department, or whoever it affects, will write their opinion of that bill and try to give better language or credence to the bill. Some of the time it's accepted, and some of the time it's not accepted.

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But every bill that comes out of the General Assembly, we look at those bills that affect Medicaid, and we write a response back on those bills. I think that's basically what they did.

If the legislator wants to accept what you give back, then they can use it. If not, they don't use it. I think that's--

MS. RUSSELL: Thank you. That's exactly what happened.

DR. BLANCHARD: If a pharmaceutical company approaches a pharmacist and says if you will offer patients the opportunity to switch from drug A to our drug, we will give you a significant kick back rebate, and we'll also give coupons to the patients for the next six months so they do not have to pay the co-pay, and a pharmacist goes along with that and calls physicians and encourages that switch, using whatever views appropriate, is that unethical behavior? My understanding from the current statute, that's the way things are written.

MS. RUSSELL: The Board of Pharmacy does have a regulation that deals with

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kick back.

However, this is an old regulation and it was written back years ago when what the Board was trying to prohibit was-- This was way before the current practice of pharmacy. What the Board was trying to prohibit was pharmacists giving a kick back to a prescriber, a physician, in order to foster prescription practice, a prescription directed to that particular pharmacy. That's the way that kick back regulation is written.

It's a little bit difficult to look at the language in that kick back and twist it around to say it's not acceptable for a pharmacist to accept a kick back. Conceivably, you could. But still, there is still the allowance that it is okay to do the first thing as long as there is written disclosure to the patient and the prescriber.

DR. BLANCHARD: Does the Board of Pharmacy consider that scenario still to be appropriate in the public opinion?

MS. RUSSELL: I can't speak for the Board of Pharmacy. We're looking at that regulation as a part of our current regulation

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review, but we're actually having a fairly difficult time with it since you're doing your study now.

DR. BLANCHARD: The issue that Ms. Pigg was talking about is still under consideration by the Board of Pharmacy.

MS. RUSSELL: As far as the Board is--

MR. CASWAY: I think the Board is trying to find ways to get some control given the current statutory basis. What the Board has in-- The Board, in the few times it has come up, has indicated in one instance that it required clear disclosure.

In the PCS matter, they had been calling it a performance drug program, which the Board felt it may be misleading in and of itself. Its performance could have a couple of different meanings.

Secondly, it wasn't clear if there was a script that the pharmacist was offered and a script that the Board felt asked for more clarification from PCS as to how that was full disclosure to them--disclose the whole process to the patient before the patient would

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authorize--go to the physician to change the drug.

MR. TEEFEY: Howard, we keep talking about kick backs and incentives. I asked, when we talked on the phone, when we pay AWP minus nine to the pharmacist for the drugs that they fill for us--

Let's say company A sells that drug to a pharmacist for the AWP minus nine. That's the average wholesale price minus nine percent. Let's say pharmacy B sells that drug to the pharmacist for AWP minus 20. It would be an incentive for that pharmacist to use the drug that is AWP minus 20 from pharmacy B.

Wouldn't that be an incentive? Aren't we talking about-- Does it affect all discounts? Does it affect all rebates? Does it affect everything?

I mean, we're talking about just kick backs now. We're talking about a bigger picture than what the bill was talking about.

MS. RUSSELL: I think that's why we need to be careful in any statute we write or regulation, because there may be cases where

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it would be appropriate for a pharmacist to call the physician to switch. Suppose a patient didn't have insurance and the prescriber wrote for a high-cost drug and there was a lower-cost drug alternative. It might be appropriate for the patient to call the prescriber.

I think we need to be careful with this so we don't prohibit activity that we think is okay and not unethical.

I think in the language we originally submitted we said the section should not apply to drug substitution reducing the actual cost, co-payment or co-insurance percentage payment required for the prescription, or where the drug originally prescribed is not covered by the patient's health insurance plan.

I'm not sure if that completely covers it, but it's a start. I don't think it's unethical in every case. You have to look at the individual circumstances.

What the Board was trying to do is get some kind of control or handle over these things so that we could look at it on a case-by-case basis.

DR. BLANCHARD: Without asking

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you to speak for the Board of Medicine, do you perceive-- I'm trying to understand this.

There's a difference between Advil versus Aleve, pharmaceutical companies. On the recommendation of a patient who comes in who has a headache, which one do I use? Which one is on sale? Do we transfer that same approach of sale items to our prescription medication, where the physician actually made a decision that drug A is what he or she wants, if the same pharmaceutical company came to the physician's office and offered me the same rebate along with coupons to hand to patients. Would that be perceived differently ethically?

My contention is it would be. I'm having difficulty trying to assimilate all of this. If that's unethical, why isn't it the same degree of unethical if the pharmaceutical company pays my pharmacist to lobby on their behalf to the physician? Why is it not similarly unethical for a PBM to direct the creation of formulary where the PBM is owned by that pharmaceutical and that's above reproach because it's a PBT committee?

I'm fully sympathetic to the

concept of trying to keep a competitive market place. I understand the implications of keeping open formularies out there.

But it's a perceptual problem and ethical problem for the physician and pharmacist to engage in that sort of very intimate relationship with the pharmaceutical companies, who obviously have incentive to get their drug sold to the patient as opposed to their competitors' drug. Some of it doesn't smell right.

And I agree with you. It's difficult to write legislation.

HON. NEWMAN: The other side of it, of course, is what this side does like, that side doesn't like. The difference between a physician and a contract is that Blue Cross-Blue Shield, or whoever it is, is in business to keep those health care costs low.

They are not in the business the same as the doctor is. They are there to say we want to make sure that a drug that will do the same job that we are covering. We are covering X, that's the contract you contracted with us to get. You have not contracted for every drug out

there. And if you did, your insurance premium would be Y instead.

The question is whether we want to get into the widest base of formulary to be the bottom of the contract basis. I agree with part of what he says. But I also think that the industry needs to be able to draw up those contracts to keep health costs at a reasonable level, too.

MS. RUSSELL: I don't have any answer for either, just a comment. I think that if companies that contract with someone to manage their health care benefits knew up front what they were contracting for. I think that's important. Again, it goes back to the issue of full disclosure.

Maybe if the physician knew ahead of time that the patient could walk in with a copy of the formulary with them, maybe the physician would prescribe that in the first place.

I think a lot of the problem is you don't always know what drugs are on the formulary. I'm not sure if people contracting with these PBMs actually know that.

HON. NEWMAN: That's a major problem with, as I knew it, the incentive of the Hawkins bill. That if you do have a good person out there who wants to call that pharmacist and make a good recommendation, this is not covered by an insurance company; you're prescribing a $400 item for this person; they need help; they need another option, that would have been possibly illegal.

DR. KNAPP: I think you speak to the other problem relative to this. Again, the therapeutic substitution/interchange is a symptom, not a problem.

You addressed it beautifully. I think the underlying assumption that the formulary saves money is not proven. We have a lot of good studies. There are some good points in many of these.

I do think that part of what this committee should recommend is that HMOs not be allowed to say anymore that this is proprietary information. This needs to be proven once and for all.

Unless somebody says to them, they need to cut loose with this information so a

good study can be done. We simply cannot answer some of the questions we have been charged to answer.

MR. TEEFEY: Any other questions?

MR. AYOTTE: Can we request that proprietary information be made public?

I guess what I want to focus on is the issue that if we have a multitude of approaches to this issue. One may be the Board of Pharmacy language that they recommend they propose. The other may be something through the Bureau of Insurance that talks about the disclosure up front with the patient and the insurance company and the PBM.

I just want to make sure that the counsel understands that. Recommend what we can legally request of them.

DR. KNAPP: I think the Task Force-- I don't mean to make this leap. But it's certainly within the realm of recommendation of this Task Force to recommend a statutory ability to do this or regulatory ability to do this. You have to be careful when you're attacking something from a multi-pronged

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perspective.

But if you look at the questions they asked us or charged us with, we can't answer the question of how many Virginians this affects. We're how far into this and we don't even know that basic number. How can we possibly presume that we're going to able to answer the majority of questions they charge us to answer? We very simply don't have the data. That seems to be one of the problems.

DR. HADLEY: I would make the comment to that that I think it would be very difficult for this Task Force to really answer the scientific question of are formularies cost effective or not.

I mean, look at the sophistication, the length of time and the studies that went into the Horren (phonetic) study, which is a very provocative study.

I think it's not realistic for us to say that we're going to have that information. That's going to have to be something that's going to have to be debated in scientific literature.

What I would say is if the

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findings of the Horren study are validated, I think you can pretty well assume that HMOs and others that run formularies are going to take that into consideration. Since they are in the business of lowering costs, they are not going to do something that's against their basic charter.

And just to try to follow troublemaker cost, which is what the Susan Marr article is about, is very difficult and not an easy thing to do. I don't think it's realistic to say this committee will have that scientific question answered. That's going to have to be further litigated scientifically.

It seems to me that the basic problem is one of jurisdiction. It sounds like the Board of Pharmacy has adequate resources at its hands to regulate the kinds of unethical behavior that I think we all have a sense for, where a pharmacist wants to make a switch where it's not in the best interest of the patient, not consulting the physician, or doing it simply for a kick back, which in and of itself has a negative connotation.

That's completely different than organizations trying to structure health

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care programs that will be as cost effective as they can. You already admitted that that is acceptable.

I think that, to me, seems to be the problem here. You don't have the jurisdiction or the out-of-state or the PBM. And you can't get a handle on that same unethical behavior as you can for the in-state pharmacy.

MR. TOWLER: Just a comment in regard to the HMO industry responding to cost elevating across the board which has been an overall expense scenario. They seem to be moving into a capitated fee agreement. In a capitated system, I don't think they would take that into consideration. If there were more doctor visits being referred for drug switching, that would not be an issue to them.

DR. HADLEY: I would tell you that it is because in any capitated program, when you negotiate for rates on that and a renewal of a contract, because those things don't go forever, I can tell you every physician that I dealt with when it comes time for renewal is looking at what is the visit rate, surgery rate, whatever it might be. They do take that into

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account. It does get figured in.

The only thing that capitation does is fix the cost for a period of time; one year, two years, whatever it is. But what are the inputs to the system are very clearly taken into account in setting that cap rate. They are not set in a vacuum.

MR. SZALWINSKI: Mr. Chairman, if I could just try to perhaps identify some of the major issues. I think you can put them into a level of ethical issues and then jurisdiction issues.

I've heard a lot about incentives. Who has them and who doesn't have them. If we look at the market place today, I think we need to recognize that there are lots of providers of care with varying levels of incentives now.

There are lots of people, lots of providers; pharmacists, physicians administrators, lots of people accepting what one would call in loose relationships, gratuities or whatever.

I'm speaking of the pharmacist or the physician who goes on a golf outing with a

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drug company or the alleged CE that is something more akin to a recreational affair; the dinners, the plays. There are all kinds of incentives out there today and we don't regulate those.

We look at professional judgment of the providers to stay out of the red zone, if you will, to make sure that what they feel they are doing passes the test. Those are fairly loose relationships between vendors and providers. They're not contractual.

We hear about the pharmacist who has the best interest of the patient at heart who doesn't have insurance and wants to be sure that that patient gets the lowest cost therapy that would provide the same outcome and make the switch because their incentive is to keep that patient healthy and do the right thing for them and to continually get that patient's business.

Then you translate that to a formalized contract between an insurance company and an insured beneficiary. You get to the point where who's controlling that best interest of the patient. Herein lies, I believe part of the nexus is, who has that jurisdiction.

If we can understand that we

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need to be sure in that formalized setting, we're comfortable with the jurisdiction, I think we'll go a long way to fixing the drug switching piece.

It all kind of interweaves in there. It's a matter of understanding who we trust to help us deliver the best care at the lowest cost.

I don't know if that of-- I kind of rambled.

MR. TEEFEY: I think you summarized it real well. The ultimate responsibility comes back to the physician. I think that's what-- The physician is the one that prescribes the drug in the first place.

DR. BLANCHARD: The physician may still come back afterwards and suggest that there is-- Perhaps the difference we ought to consider in this process between the patient that is already well managed on a medication, and his employer going to a new HMO, he then becomes subject to a new formulary.

Even with informed consent and incentives it's quite--from a physician's perspective quite appropriately uninterested in changing that medication. We're not talking

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formulary change where there's a safety issue.

Likewise, a patient who's in an HMO, is on the same medication, on the formulary, well managed, and January 1st they changed their formulary because you have a new contract or cheaper version. Every time you change drugs, you have some risk of new side effects.

The solution to that, to me, is to grandfather--for the HMO industry to develop systems to grandfather protection for those patients. Recognizing that in the grand scheme of things this is not the largest part of the financial pie.

Does that need to be legislated? Not if the industry changes it before the public demand. There are issues here that-- If you will, the market place could change if they were willing to change. Many of these problems could be softened if the HMO industry would take a compassionate view, as they claim to, to put the patient first. That would help us out a lot here.

There's a big difference between somebody trying to educate people, fill

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me, as they do, with information why I should use drug A instead of drug B while I'm considering writing the prescription. But a whole different set of ethics are involved when I am faced with a request to change somebody when they are doing quite well. I see those as two separate problems that require two separate solutions. I would request that the Task Force continue to keep those two issues separated.

I'm not sure all of that discussion we had earlier about out-of-state pharmacists and therapeutic substitutions without consulting a physician is particularly germane with what we are considering. Therapeutic substitution without consultation with a physician almost never occurs.

The question we're talking about is therapeutic interchange when we do call. The question is why are they calling and how strongly should we listen to those requests to change somebody already on medication and already has a prescription written.

DR. HADLEY: Dr. Blanchard, I think that question has been answered. I sent a letter to our Chairman July 23rd, in which I

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enclosed--that should be available in your packet--a survey that we took of the HMOs in the state of Virginia. Of the 10 health plans that have a closed formulary, in which this would apply-- The difference between a closed and open formulary; a open formulary means they are recommended drugs but you don't have to prescribe off of it. The HMO will fill the drug. The closed formulary is the one they have the problem with. If it's not on the formulary, it's not a benefit.

In our survey that we looked at of all the HMOs in Virginia that's not a closed formulary, 100 percent have a process for formulary exceptions. So that a physician can call and explain the situation where the patient is on the drug, even though it's no longer on your formulary, they're stable on it and obtain an exception.

Also, we looked at the grandfather issue that you raised. Grandfather issue is where a patient is currently on a chronic medication, and either they just joined the health plan or the PMT committee removed a drug from the formulary.

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Of the HMOs, 70 percent have a grandfather rule so that patients can be kept on that if there's a formulary change for the type of patient I talked about that's stable and on chronic medication.

This is one of the safety provisions that the PMT committee will insist on. We don't think you need to legislate that.

We think the vast majority of the HMOs in the state are already following these kinds of rules in the interest of quality care. We don't see that as a problem in these legislations.

DR. BLANCHARD: The purpose of my comment earlier was to suggest that it may not require legislation. And it would be unlikely that I would come pressuring for legislative changes if that figure were 93 percent. I think it would be associated with the 30 percent. You might have a grandfather clause that works.

And whatever percentage of HMOs--100 percent that have the mechanism in place for review is sometimes irrelevant when that review requires a letter and a several week determination and the patient is calling me from

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the pharmacy.

Again, I think there's room in the HMO industry for setting up criteria for good behavior, which would be a several hour turn around for simple drug request and the pressure to get more than 70 percent of the industry having a grandfather clause.

Just as with whether it's drive through or out patient. A lot of the hassles of the industry in which I practice-- I practice with 30 percent of my business in HMOs. A lot of the public relations problems come about because of failure of the industry to recognize those public relations potential fiascoes and solve them before they reach this level of debate.

I don't have any reason to be here other than to give my--don't want to call it antidotal, but my experience with having to make those phone calls. I explained to you today with one of my phone calls to your company resulted in a two-minute phone call and a quick approval.

Whereas, my phone call yesterday to another HMO, I was told I had to write a letter. The letter takes awhile to get

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there and awhile to get back. The reasons for denial are not ever stated. The reasons for inclusion of one drug in the formulary as opposed to another drug are not stated--the rationale. It's hard to phrase a letter that will fit the screen that somebody will read off on the computer.

I concur with you. I saw the data in the information piece that a lot of HMOs handle this properly. The purpose of the government is try to insure that those who don't follow the same good practice standards that you're suggesting everybody should emulate.

Let me clarify that. The question that we asked was does your house plan have a protocol to grant exceptions where the patient is maintained on a non-formulary drug at the time the patient becomes a member of the plan. That's a grandfather rule.

30 percent said, no, they don't have a protocol, but 100 percent of those have a regular exception clause. So 100 percent of HMOs in the state have a process, whether they call it the grandfather protocol, they all have an exception process. And you're right, some are

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easier than others. Some give you an 800 number to do it and take care of it right on the phone. Others require a letter or something, more documentation from the physician. I think that is a difficult thing to legislate.

We could make recommendations to the HMO Association as to what might be good practices. But, again, I would say, currently 100 percent of patients--the physicians have access to getting exceptions in this state.

DR. KNAPP: Dr. Hadley, I didn't mean to suggest that we were going to be able to come up with a scientific resolution about whether or not formularies are cost effective.

Everybody has a vested interest in knowing whether or not that is true. After you read the title of the article, you read who responded to it. I think that there's nobody who can read the scientific literature with a critical eye that they wouldn't be jaded if an article regarding the cost efficiency of formularies came out of HMO. I don't think it necessarily needs to be legislation.

My point was, and after

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listening to you, the HMO would be in favor of this. In the interest of finding the answer for the public to somehow strongly recommend that this be investigated.

Part of the public perception and part of the problem is who is overseeing the process. To have somebody accountable who can either perform a study or whatever to help answer that question and really look at the data.

You're right. It's something very difficult to do but would be very useful. We had a young man from VCU last time that said this is what he wants to do but can't do it. I can't do it because I can't get the data. Would that not be a worthwhile thing to undertake for all interested parties? Again, I would challenge us also to remember that we are here for the Commonwealth.

DR. HADLEY: Wasn't the Horne study jointly founded by the Rand corporation and the six HMOs that participated in that? I think the Industry is interested in that issue. They need to know this; whether or not restriction of formularies will effect total medical cost. Whether it's happening in the Commonwealth of

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Virginia, I don't know.

MR. TEEFEY: Are there any other questions of Scotti and Howard?

Thank you for coming down.

The two Mikes worked real hard with members of the committee to come up with a statement of a therapeutic interchange statement.

Do you want to go over that?

DR. PILES: I trust that you all did receive the E-mail of that statement. I would add that in the development of that statement we did have two conference calls with the subcommittee and two of the members were out of town or on vacation at the time, Drs. Dalton and Blanchard.

At this time, basically, what we need to do so that we can decide what our next course of action will be is to come to a consensus that we are all talking about the same thing and singing from the same sheet of music.

I have placed before you a copy of the current proposed definition of therapeutic interchange that this Task Force will use for its work and that will lead us to our next task.

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I guess for the sake of getting started I will read it here and you all have copies.

Therapeutic Interchange is the dispensing of a drug, by any person authorized by law to prescribe drugs, that is an alternative for the drug initially prescribed and that is of the same pharmacological class and/or therapeutic class as the drug initially prescribed. The alternative drug is expected to have the same clinical results and safety profile, when administered to patients in therapeutically equivalent doses, as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug, or their lawful designee, and the consent of the patient.

That's only two sentences believe it or not.

DR. HADLEY: The first problem is you can't dispense and prescribe. Therapeutic interchange is the dispensing of a drug prescribed by any person authorized by law.

The physicians prescribe. The pharmacists dispense. The way it's written is

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the dispensing by any person authorized by law--

DR. PILES: To dispense a drug, you mean. So, that second line "to prescribe" should be to dispense.

MS. PIGG: No.

DR. HADLEY: Which was prescribed by any person.

MS. PIGG: One the first line, is the dispensing of a drug, prescribed by any person authorized by law to prescribe drugs.

DR. PILES: Just prescribe in there. So, it would be therapeutic interchange is the dispensing of a drug prescribed by any person authorized by law to prescribe drugs. Does that fix it?

HON. NEWMAN: I have a concern about another part of it. That is, this as written will go to generic drugs, which is required by law to switch. And so I think the Doctor may have in our discussion maybe a bit of language speaking about chemically dissimilar alternatives to help fix that problem. That would go on line two of the non-bolded area, chemically dissimilar alternative.

DR. PILES: That is a

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chemically dissimilar alternative.

HON. NEWMAN: That would cover generic drugs being switched.

DR. PILES: That is a chemically dissimilar alternative for the drug initially prescribed and that is of the same pharmacological class and/or therapeutic class as the drug initially prescribed.

DR. BLANCHARD: I have two editorial suggestions. I'm not completely comfortable with suggesting that the alternative drug is expected to have the same clinical results. It's hard for something to have the same safety profile. I wondered--

DR. PILES: Similar, perhaps. It would read the alternative drug is expected to have--

DR. BLANCHARD: You don't want to change the drug. You don't want to suggest the interchange unless you'll have pretty close to the same clinical results. I think what you're trying to get at is similar.

DR. PILES: And similar safety profile.

DR. BLANCHARD: Right.

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DR. PILES: Clinical results and similar safety profile.

DR. BLANCHARD: Additionally, I would like the Task Force's opinion on my feeling about adding before the word "consent" on the last line, lawful designee and the informed consent of the patient. I think what we may end up discussing is how informed the patient should be.

DR. PILES: Actually, that was a part of the discussion when we were doing this. Basically, we did raise that question. What does consent of the patient really mean in this context?

DR. BLANCHARD: I have to refer to the lawyers. Does it make a difference between when you say informed consent or consent? What I have to get from my patients is something called informed consent. I've always been told it's different than consent.

DR. PILES: One of the things we did talk about and one of the scenarios that we considered when we were putting this together is that since the patient is standing at the counter and some other conversation may be going

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on between the pharmacist and physician or pharmacist and insurer, the patient may, of course, be asking questions.

But ultimately, the only thing that I think we were getting at is that the patient would be aware of the fact that the pharmacist needs to call someone, had done so, and this is what they authorized them to do. That was, I think, what was suggested to me as informed consent.

DR. BLANCHARD: I think I would be more comfortable if the word informed was in there.

HON. NEWMAN: He might be right, but it is a reasonably large policy decision if we go this way now. Let me tell you why. The definition is what we're working on now. If we want to go into the decisions of the finality, he has great ideas. What we're looking for is just a common ground on the definition.

After prescribed, three lines up, in which follows "and is dispensed with the approval" goes beyond the definition. And it goes into what we may want or not want the process to be one day.

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I think if what we're doing is just giving a definition to what therapeutic interchange is, it should stop at "prescribed" and include a period. Unless you want to put the next little bit in that says you do it by law, which means you have to have approval before you do it.

I would urge that we consider at least not putting that part in, and especially the amendment yet until we get to a discussion of whether or not we want that policy or another policy.

I don't know what the committee thinks about that. But I think the definition itself should end after "prescribed".

DR. PILES: One of the things we did talk about was the fact that we needed a definition for common ground and that any of the nuances beyond that ground go beyond the scope of what we're doing.

You suggested that it should read, and is dispensed with the approval of the person who prescribed the initial drug, period.

MR. TEEFEY: No. He's saying after prescribed on the third line--

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DR. PILES: I'm sorry.

MR. TEEFEY: Put a period and just eliminate the rest of it.

DR. PILES: I'm sorry. I was on the wrong line.

MR. AYOTTE: I think the issue became that we're trying to determine between therapeutic interchange and therapeutic substitution. At the substitution level, in a hospital, closed environment, where there was no approval necessary. On the interchange you're in an out-patient environment where that prescriber has to be informed. You have to have that discussion with the doctor. I think that's why that piece was added into this definition.

MS. PIGG: I understand where you're coming from in the basic definition, but I think inherent in therapeutic interchange are the other pieces that it has to be the same similar drug that does the same similar thing. Otherwise, it's just an interchange. It's not a therapeutic interchange.

HON. NEWMAN: I'm not taking that part out. "Prescribed" on the third to last line is where we're talking about. All we would

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be taking out is the consent of the patient or not consent of the patient, which is a discussion currently not in law. And if we made the recommendation, it would be a change.

DR. PILES: That second sentence would read: The alternative drug is expected to have the same clinical results and similar safety profile when administered to patients in therapeutically equivalent doses as the drug initially prescribed.

DR. BLANCHARD: If what we're trying to do is keep things in the current confines of law, I don't think the period actually ought to go after "is dispensed with the approval of the person who prescribed the initial drug." Because the current law requires that the doctor be consulted. It does not require the patient be consulted.

HON. NEWMAN: I would concur with that.

DR. BLANCHARD: Where is the difference between current law and where the policy might try to enhance things if we put the period after initial drug or their lawful designee.

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HON. NEWMAN: That's fine.

DR. BLANCHARD: Leave out "and the consent of the patient."

DR. PILES: That sentence would then read: The alternative drug is expected to have the same clinical results and similar safety profile when administered to patients in therapeutically equivalent doses, as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug, or their lawful--

HON. NEWMAN: No. Period.

DR. PILES: He suggested lawful designee, period.

HON. NEWMAN: That states current law.

MR. TEEFEY: We eliminate "and informed consent of the patient."

DR. PILES: Yes.

MR. TEEFEY: Is there any disagreement with that?

MS. POWELL: Mr. Chairman, to address Ms. Pigg's concern, do we need to indicate that we're talking about in the retail or non-institutional setting?

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MS. PIGG: I'm okay with it the way it is. I was on the wrong "prescribed".

DR. PILES: Ms. Powell, what the subcommittee had talked about was a definition that we thought could be used in any setting. The only difference was-- We did talk about the hospital or other institutional setting. And they have in place a procedure. It still goes through law. It's just they have another piece of it where the physician is able through a mechanism established in a hospital to give a blanket approval to that kind of thing occurring.

MR. TEEFEY: Go through the whole thing again.

DR. PILES: Therapeutic interchange is the dispensing of a drug prescribed by any person authorized by law to prescribe drugs that is a chemically dissimilar alternative for the drug initially prescribed and that is of the same pharmacological class and/or therapeutic class as the drug initially prescribed. The alternative drug is expected to have the same clinical results and similar safety profile when administered to patients in

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therapeutically equivalent doses as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug or their lawful designee.

MR. TEEFEY: Any disagreement?

HON. NEWMAN: I don't want to take this and draw it out, but if we're going to make this statement, and because there will be three other times that this committee meets, we may want to hear from proponents and opponents of this thing for a minute or two. Just to make sure that we're not doing something that somebody could correct very quickly.

I wondered if the Chair might consider amending it or so, if there is any concern from the public about what we are doing.

MR. TEEFEY: No problem at all.

MS. RUSSELL: I just had a technical problem with the way you changed--when you put "prescribed by any person authorized by law to prescribe drugs."

I think what you mean to say is the dispensing of a drug by any person authorized by law to dispense drugs. Because you

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don't want to put that that person dispensing has prescribed, because it hasn't. They're dispensing something else for the drug originally prescribed.

DR. PILES: I follow you.

MS. RUSSELL: It would read: Therapeutic interchange is the dispensing of a drug by any person authorized by law to dispense drugs, that is a chemically dissimilar alternative for the drug initially prescribed.

DR. PILES: Which would suggest then that the rest of the process would be that that dispensing occurs only as a result of those other things happening. That is, doing what they needed to do.

Again, Ms. Russell's suggestion is that it would read, therapeutic interchange is the dispensing of a drug by any person authorized by law to dispense drugs.

Was the rest of it okay?

MS. RUSSELL: Yes. I don't have a problem with it.

MR. TEEFEY: Let's take a five minute recess. I'm going to give you all an opportunity so that you can get your thoughts

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together.

(A brief recess is taken, after which hearing continued as follows:)

MR. TEEFEY: Senator Newman suggested that we give the audience an opportunity to speak on the therapeutic interchange definition. And I think Mr. Rosenthal--

DR. ROSENTHAL: Two people have mentioned this to me. The suggestion is that in the third line, strike all that part that says that it is of the same pharmacological class and/or therapeutic class as the drug initially prescribed.

There are two reasons for it. One is, it seems to me that that phrase doesn't matter as long as what you accomplish is covered in the next paragraph. That is that it has the same effect.

Secondly, there are several drugs out there that are switchable, if you will, but not of the same pharmacological or therapeutic class.

MS. PIGG: A couple of examples; the use of H2 prior to a proton

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inhibitor. I think one of the other pharmacists said that perhaps the use of an ace inhibitor in place of a channel blocker may be a situation that may be limited by this. What you're trying to achieve is that the outcome is the same.

DR. BLANCHARD: The second example, similar therapeutic class, it does the same general thing for a general disease.

DR. HADLEY: There is no scientifically accepted definition of how big you make a therapeutic class. You could say a therapeutic class is all GI drugs. In which case, H2 blockers and proton inhibitors are in the same therapeutic class. So I think you would have a very difficult time defining something.

From a legal point, is it or isn't it in the same pharmacological class? It probably is irrelevant as long as it has the same functional results and similar safety profile.

DR. BLANCHARD: I think particularly in light of the fact that the suggested substitutions that I've had recommended to me are not in the same pharmacological class. That's reflective of the way this practice is being practiced in Virginia, to leave those words

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out. I'm sure what people are desiring is greater flexibility in controlling the asthma or whatever. I don't have any objection.

MR. TEEFEY: What do you want to strike out?

DR. ROSENTHAL: On the third line beginning with "and". Strike "and" through the end of the sentence.

DR. PILES: That sentence then would read: Therapeutic interchange is the dispensing of a drug--and actually we left with two possibilities at that point, but I will read the one that we had before the break--dispensing of a drug by any person authorized by law to dispense drugs, that is a chemically dissimilar alternative for the drug initially prescribed. That's the latest suggested change. A period after "prescribed" in line three.

MR. TEEFEY: And then the next sentence?

DR. PILES: The next sentence would read; the alternative drug is expected to have the same clinical results and similar safety profile when administered to patients in therapeutically equivalent doses as the drug

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initially prescribed, and dispensed with the approval of the person who prescribed the initial drug or their lawful designee, period.

MR. TEEFEY: Any problems?

Okay. Can we accept that if there is no one that has any problems with it?

MR. SZALWINSKI: I might just ask that--to be sure that I'm clear about this--we don't intend for this to apply to the hospital basis of care. It's solely for the out-patient arena; is that correct?

DR. PILES: The subcommittee, when we talked about it, thought it would apply across the board. But that's up to--

MS. PIGG: The differentiation was that therapeutic substitution applied to hospitals where you may have implied consent, not direct consent. Where this was really-- The definition was formed on the basis of out-patient.

DR. HADLEY: But the definition would apply wherever these activities would occur. And it would up to regulation to say whether it's appropriate or inappropriate in the hospital, out-patient. This is just a

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definition. It doesn't state whether it's positive or negative in any given environment.

MR. SZALWINSKI: In the hospital you have the approval of the medical staff that applies to the approval of the therapeutic committee to conduct a substitution without contacting the prescriber every time.

DR. PILES: Correct.

DR. HADLEY: That's the origin of the phrase lawful designee.

MR. SZALWINSKI: Okay.

DR. BLANCHARD: Or the differentiation from this and therapeutic substitution. We should be clear about therapeutic interchange. This is the definition of therapeutic interchange.

DR. PILES: Right.

MR. MCARTHUR: I would respectfully caution the Task Force members to be careful with the second sentence. The alternative drug is expected to have the same clinical results and similar safety profile. It's unclear to me from this definition who would have the expectation and who would make the determination.

I think one of the core issues that's being debated in this Task Force issue is which drugs are in fact substitutionable for others with an adequate amount of safety for the patient.

I want to caution the Task Force members to be careful not to assume away or accept that there is a consensus among the Task Force members as to either which drugs are safety substitutionable and to who would make a determination.

Looking at the materials that have been submitted, I saw precious few studies on the subject. That is my only comment.

DR. PILES: Perhaps one more reading to make sure everybody has the periods and commas.

MR. TEEFEY: I think we're okay.

We're down to the discussion where do we want to go from here.

Jim Counsel, who is on the Task Force, couldn't be here. He sent a letter that Mike Worthington is going to read.

MR. WORTHINGTON: This is a

letter from James Counsel, vice-president and corporate counsel of First Health and a member of this Task Force, dated August 18th.

In re: Special Task Force.

Dear Mr. Chairman, I regret to advise you that I will not be able to attend the August 20, 1997, meeting of the above. The executive committee of our new parent company is flying in to meet with us on Wednesday.

Since our last Task Force meeting I have been on the phone with other members to discuss refinement of our definition of therapeutic interchange. My impression is that there is general agreement on the definition at this time. Not withstanding that, modifications may be made to this definition at the upcoming meeting. It appears to me that a consensus exists that any definition must include pervago that such an interchange--there's a word missing--that such an interchange can be made with the consent of the person prescribing the initial drug.

Given the above and Mr. Walker's statement at the last meeting to the effect that the Virginia Board of Pharmacy has

jurisdiction over interchanges made by pharmacists who are licensed by the state, it appears to me that sufficient patient protection is in place under existing regulations.

In addition, other regulations govern the regulation of prescription drugs by pharmacists and impose disclosure requirements.

Based on the above and the various documents I have reviewed and arguments I have heard at Task Force meetings, I am of the mind that no legislation would be appropriate.

I note that those in favor of legislation have also argued that in fact the practice of which they complain result in higher health care costs. It appears to me that there is much conflict among the authorities on this issue.

More importantly, it is my view the cost issue is one that should be addressed by employers and others providing the pharmacy benefit, not by a legislative body.

Again, I regret that I cannot be in attendance. Very truly yours, James G. Counsel.

MR. TEEFEY: Where do we go

from here?

DR. PILES: Mr. Chairman, if I might, what I've done is just gone back to the resolution and what it calls for and where we are today. We do have now on the table a definition that we're comfortable with.

The rest of our task includes now describing in our report to the General Assembly the practice. In fact, what it says here in the resolution was that we would determine the impact of the practice on therapeutic interchange, as we have just described it, on health care, affected professions, the overall cost of health care products and services and patients.

DR. KNAPP: With all due respect, we can't do that. I mean, we can't even get the numbers of people in Virginia that this affects. I guess that's the really frustrating part. We can't get to that. If there is something wrong with the answer, how do we propose to find out?

MR. TEEFEY: One of the problems that we have is that the Pharmacy Board doesn't know, because we have talked to them.

You have HMO. You have private insurers. You have-- Really, the Bureau of Insurance is trying to put some figures together. But I don't know how effective those figures will be.

DR. PILES: I spoke to Rebecca Shelton, and she said they did not have figures. She gave me the names of a few people that I have contacted. One of them was a person at Trigon Blue Cross. But the only problem we would run-- There are two sources that I contacted that I'm waiting to get some information.

One is called the Employee Research Benefit Institute, or something like that, in Washington, D.C. They may, in fact, have figures but I'm not--employee/employer. That would only cover employer-based plans.

Then from Trigon we probably could find out from all of their plans that they cover. But that's about as close as we can come to real numbers without knowing every single citizen's insurance status and who covered them.

MR. TEEFEY: Senator, do you have a recommendation?

HON. NEWMAN: I don't know where everybody out there is. We have received,

I understand, a list of things that they would like to be considered. I've seen some from the other side where they would like to make arguments where these are good ideas.

My concern is that there is a current, concurrent study going on with the Harvey Morgan study out there right now to study the base of these things, these PBMs, to understand how that component works and the affects of that component.

Quite honestly, we have been stumbling around with who am I, why am I here, since we got here. My wondering aloud is whether or not we should not have the opportunity and the permission from the Assembly to wait until after the Morgan study is complete on that intricate portion of PBM and then have some discussions after that some time next year.

I wonder, Mr. Chairman, if you have any thoughts from Mr. Rosenthal and some about what they think about that.

I don't want to postpone the inevitable. I don't think we have enough information this time and I think the Harvey group is studying a very important component and

of what we are studying.

MR. TEEFEY: Steve, do you have any thoughts on that?

DR. ROSENTHAL: I have no problem with it. I know that PBM has been mentioned a lot. I know that study is directed to PBM. I assume that study will also address the out-of-state piece.

MR. TEEFEY: I think most of the PBMs are from out of state anyway.

MR. SZALWINSKI: Could somebody educate me about what the Harvey Morgan study is?

DR. ROSENTHAL: Yes.

HON. NEWMAN: If all we do is say we don't know-- The General Assembly with a bill like what we had last year, and say we're going to solve it, we're going to kill it, or whatever we're going to do this time, but they didn't know. I think that with more information and extending this Task Force for another year, after we can get information from the Morgan study, at least we come out with cohesive thoughts about whether we should or not. I think if you brought the two minds together it might be

available.

MR. TEEFEY: Would you read that statement?

DR. ROSENTHAL: This is House Joint Resolution 574. I believe this is the latest version of it. Whereas, the health insurance industry, figures in managed care programs become pervasive, the effects on patient care in small businesses delivering all services are far reaching; and whereas, a recent development in managed care approaches is the implementation of contracting for pharmacy benefits management. Whereas, pharmacy services are essential for the well-being of many elderly and disabled persons for the maintenance of their health.

And whereas,(inaudible) pharmacy services can prevent hospital admissions and the need for emergency care, extended services, place a greater demand on society resources; and whereas, the present management techniques practiced by some pharmacists may interfere in the statutory required condition patient-physician relationship; and whereas, personal consultation and direct knowledge of the

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patient's conditions and medications are an important part of handling many chronic conditions. Whereas, so-called desk audits are allegedly being conducted many months after the dispensing of the prescriptions.

Therefore, we have resolved, by the House of Delegates concurring, that the Department of Medical Assistance Services be requested to examine the practices of the pharmacy benefits management firms.

In conducting its study, the Department shall coordinate its efforts with any similar studies that are taking place in the interim by the Department or by other state entities. In addition, the Department shall solicit input from such experts as may be appointed to a special task force established pursuant to House Joint Resolution 630 in relation to the practice of therapeutic interchange.

Technical assistance shall be provided by the Bureau of Insurance of the State Corporation Commission. All agencies for the Commonwealth shall provide the (inaudible) for the study upon request.

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The Department of Medical Assistance Services shall complete its work in time to submit its finding and recommendation to the Governor and the General Assembly as provided in the procedures of the automated system for the processing of legislative documents.

MR. TEEFEY: It does go beyond PBMs. It goes to HMO.

We contracted with Norm Carroll. He's the professor from MCV that came up and chatted with us two meetings ago--the last meeting. We contracted with him to start this study to get the information together. We are pretty much on a way as far as the study is concerned.

I totally agree with the Senator that the information we get from that study would be extremely beneficial in what we are trying to do here.

Is Ken still here?

MR. MCARTHUR: Yes, I am here. And I do have a comment.

I appreciate Senator Newman's suggestion. However, I am gravely disappointed in the notion that this Task Force is not

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suitable or at a point where they can make a recommendation about some of these practices.

I think this issue was discussed and debated in front of a committee two years ago. It was discussed in the General Assembly session last year.

This Task Force was specifically created as a vehicle through which there would be time to have reason--debate on both sides and come out with a recommendation for the General Assembly for next session.

I think that the PBM study that's been referenced here is broader in one sense and narrower in another. I think it's broader in that it addresses a whole range of practices that PBMs are engaged in, which include drug switching, but also include other practices. I think it's broader in that sense.

It's narrower in the sense that it focuses primarily on PBMs and does not on a whole range of other entities, which are also engaged in the practice.

I would strongly recommend that the Task Force address this issue and make recommendations to the General Assembly before

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this upcoming session.

DR. KNAPP: I didn't mean to imply that we couldn't do anything. I would ask people if there are some recommendations--

If I was hearing people correctly, I'm hearing a fairly strong feeling to expand the powers of the Board of Pharmacy is appropriate. I'm hearing that people aren't hearing from the citizens of the Commonwealth that accountability is an issue. I'm hearing that the HMOs are open to letting people know that they have good PMT committees.

I think some recommendations about education or expanding the jurisdiction of the Board of Pharmacy, encouraging us to wait for some study, our reason would be recommendation--

I guess at this point, what do we feel comfortable recommending? I don't believe that there's nothing at this point.

MR. TEEFEY: I would like to clarify one point. It is not uncommon to have a task force extended to another year. I want to make sure I lay that out. We have one right now that was due two years ago that you just couldn't do in a year, and we had to extend it for another

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year. It's not uncommon to extend the authority of the Task Force for another year if you feel you do not have a good solution to what the General Assembly is looking for.

DR. HADLEY: I agree with that, generally, and also the letter from Mr. Counsel. I think there are a lot of controversies and unanswered questions. I think there are a lot of things in the market place that is going to affect the kind of changes that we're looking at, and it may be premature to interfere in that process.

I think that the most propounding thing that I heard is that the Board of Pharmacy does have the authority to deal with those factors that we think are unethical. It seems to me the problem again is trying to get a handle on some of the out-of-the state issues and PBMs.

If there was any recommendation, it would be around that, to get some more authority to the Board of Pharmacy to deal with that. I think that is the proper way to deal with it. Because most of the issues that we're talking about it's a question of

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professional judgment. Did the pharmacist or the physician, did they properly deal with this issue, or did they use whatever incentive there was in an improper way?

We know that those professional Boards are really the best place to have those kinds of very fine judgment and disciplinary action. That would be my lien, to somehow assist the Board of Pharmacy in what they need to do with that.

MS. RUSSELL: I just wanted to clarify. I'm not sure we do have all the tools we need right now to deal with what we might consider unethical conduct even by practitioners in the state.

Our kick back regulation, as I mentioned before, is not very well worded to cover what's going on today. I think we still need to make changes.

I think the problem is our unprofessional conduct definition in the statute is very narrowly drawn. It's difficult to pull other things in. I think we need some statutory relief to be able to deal with the unethical practices and to we consider unethical practices

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in the state.

MR. TEEFEY: Are you looking into these even beyond this Task Force?

MS. RUSSELL: We are looking into clarification of the regulation but we're kind of stuck right now with the some statutory problems.

Something similar to what we submitted last year would assist even-- If you notice there is a part in there that talks about unprofessional conduct. There was some language in that draft to assist us even with practitioners in the state, an authority we don't currently have.

DR. BLANCHARD: Mr. Chairman, I would like to see the Task Force accomplish whatever it accomplishes. The perception is process as legitimate.

Although it is not unheard of to have task forces to go onto the next year, we in effect here are voting on extending to next year without ever having a chance to discuss, much less vote on any policy options. We spent the better part of the last few months just coming up with a definition of what we have to

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study. There are copious quantities of data we have been exposed to.

I would think it would lend some legitimacy to the Task Force's final recommendations, if any, if we had another meeting in which to discuss possible policy options and recommendations.

I don't think anybody is prepared today to make specific resolutions. I would think it's not unreasonable to say that September is plenty of time to have to suggest recommendations. The Task Force ought to have the opportunity, I think, to vote ye or nay on those recommendations at the next meeting.

Having done that, you can at least say in public that we've considered some recommendations and have decided yes or we decided.

No. I think the Senator suggested we may not have the ability to make any legislative recommendations. I would feel much more comfortable having had the opportunity to review both sides of their ideas on policy options.

MR. AYOTTE: May I suggest

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that if we had an opportunity to submit the proposals that we wanted to have and let staff take those proposals, and give us some idea of what the impact would be of those proposals.

If it is through the Board of Pharmacy, what move has to happen through the Board of Pharmacy to make it happen. If it is through the Bureau of Insurance, what things need to happen. If it is done, then what impacts are there so we're not coming in September, if that's what the pleasure of the Committee is, to discuss and debate what we're going to do.

In other words, be prepared in advance for what side of the road to go to, what options we'll have in front of us so we can make a good, intelligent decision and think and sleep on them and make sure they're right. Rather than saying, that's a great idea. Let's do that.

I also don't want to make a decision that may not be--you know, tell Scotti this is the way we want the Board of Pharmacy heading this way. It may not be something they can do on their own. They may need additional support from either us or another body.

MR. TEEFEY: Whatever

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recommendations that we get in, we have to have them in early because we have to work with the Bureau of Insurance and with the Board of Pharmacy to make sure we have those intelligent answers.

HON. NEWMAN: If we want to have more meetings, that's fine by me. If we do and if we're looking for information though, the two pieces of information I found would be helpful, and even with this much information we haven't gotten or been able to get it, and that is what is health care costs, up or down, of the closed or open formularies. Is there a definitive answer on that?

Two, is there a cost effect--a health cost effect of therapeutic interchange. We have discussed back and forth that currently we don't have that information. If we come back and if we have that information, those two things would be helpful. So it can help make a decision.

If not, I think the Committee might want to consider waiting for the Morgan study and then asking that we go out in the next year and find all this information--as much of

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this information as we possibly can.

Because we are currently in the same position as the General Assembly. They had a lot of this information. We're still searching for what they're searching for. To make a recommendation to them right now is just our judgment versus their judgment based on the information.

I think the Doctor may have a reasonable idea. Maybe get together in September and some of this information can surface and we can get some resolution. I hope that we won't make a recommendation without some of this information, which is base information we should have before we make a recommendation.

MR. TEEFEY: I think we have a couple of PBMs here and I would like to ask them a question.

Can you answer the question related to PBMs that the Senator just asked?

The only way we're going to get the answer is to ask the PBMs to give us the answer to that question.

DR. ROSENTHAL: Are we talking PBM and/or HMO?

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Senator, could you state your question again?

HON. NEWMAN: Well, I can, but let me put this one caveat to it. The question is: If you get this information, is the Committee going to believe what comes from the HMO?

The second question: What is the cost impact, in other words by having therapeutic interchange, are you saving health care dollars that are decreasing premium or is it costing more as has been discussed by some of the other groups? The second part is: Is there a health care cost effect and if so what is it on therapeutic interchange? If you're changing the drug, what is the effect of it? Has it been a nominal effect, and therefore, there is very little effect?

How many people might drop off health care if you raise the premium again? But if that information was made available to us maybe it wouldn't take as long as a year. If it's not, then maybe another year might be needed.

DR. ROSENTHAL: I'll vouch to

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you, I'll do my best to see if I can. I'm familiar with one PBM that I represent. I can certainly ask those questions. I don't know if it even exits.

MR. TEEFEY: How about the HMO?

DR. HADLEY: I think it's very difficult information to get. It gets back to the kind of information process that you have to do to see what affects total health care costs.

One of the articles we looked at and read; it's difficult to isolate one component of your health care costs. And if you change that, what effect would it have on the others?

I think that the problem that the HMO industry has in dealing with this is that in many cases it is difficult to link pharmacy information to specific diagnosis. I know in my own company--and I think this is fairly typical--the database for pharmacy claims is kept in one file.

As you know, or maybe you don't know, when you fill a prescription and then send that in to have it paid, you are not

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required to put a diagnosis with that particular claim. So if a drug is filled, you haven't got a way to link that back to a diagnosis.

We did a study in our own HMO locally trying to look at the prescribing of stimulant medication, which is used for children with ADHD. We had a devil of a time trying to link it up to children that actually that diagnosis. It turned out we had twice as many people receiving the drug as we had those with the diagnosis.

There's a real problem here in the industry in devising ways to link this up and what it's going to take to solve this. Again, this is a problem that I think the HMO is very interested in because we want to control total medical costs. And if we were to adjust the drug cost of formulary, it increases our ER visits or hospitalizations. We're not going to do that.

The problem is we're still struggling to figure out that problem. And it is a very difficult information process to find a solution. I don't think it's a proprietary issue. I think it's an issue that the HMOs really don't have the information. There's a lot

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of controversy on that study. It's still a very provocative study. And if that is borne out, I guarantee you that HMOs don't want to do things to increase medical cost.

I don't think we have the data to share with you that would be convincing, any more than what you have seen.

These are active problems. But it's going to take a different level, a next generation of databases to be able to answer these questions.

What you're talking about is called epidemiology of cost or disease management strategies. I was talking with Dr. Blanchard about this before we started. How our company has been able to do some disease management strategies. Primarily, have gotten involved with the drugs that are given for asthma and have lowered our hospital cost and ER visits and so forth for asthma by about 17 percent.

But I don't know really what the costs or the prescription drugs are because again we can't link the prescribing patterns back to the specific diagnosis. I think it's going to be awhile before that information is out there.

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I guess the only information I would like to see in the near future is what are the Board of Pharmacy's recommendations of what they would like to see from a regulatory point of view. I think that would be very useful information.

You made reference to a previous bill, which I haven't seen. I think that's the base of information I would like to see.

MR. MCARTHUR: I cannot resist making a point right here and now at this moment in time. At the very first meeting--at the very beginning of the first meeting I stated to the Task Force members that I would like to see evidence that the practices engaged by HMOs, PBMs and others in Virginia that effect Virginia's patients, that evidence be produced to show that these practices were sufficiently safe and that there was some public policy reason for engaging in them. That there is some evidence that there is cost containment, there is some cost savings.

I have sat out here patiently for three months waiting for someone to ask the questions to those who are engaged in the

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practice to produce this evidence. I'm thrilled that finally today it's happened. However, what I'm hearing is that the evidence doesn't exist or that for some other reason it can't be produced.

I would submit to the Task Force that what this means is that these companies engaged in drug switching practices in Virginia are engaged in a practice which is based on untested assumptions. They are engaging in a practice for which they have absolutely no studies whatsoever to support that they are safe and absolutely no evidence to show that there's an overall health care cost reduction.

In light of that, I would ask the Committee to consider immediately legislation, which would outlaw this practice until such time that such evidence is produced to protect the health and safety and welfare of Virginians.

HON. NEWMAN: You and I agree on some things, but that statement I particularly disagree with. I can't imagine us going around to Virginia businesses and saying prove to us what you're doing is good or we're going to make it illegal. We don't do that. I can't imagine

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it being true here.

If there is a public safety problem, which I think you enumerated some concerns, that need to be discussed at this Committee and the Harvey committee and others. We need to discuss them on the effects of them, but not the presumption that if you don't show us where this is good, then we'll make it illegal. I've just never seen that in legislation.

MR. MCARTHUR: Your point is very well taken. I apologize. I did not have a prepared speech on this point. I didn't know this point was going to come up.

I did leave out one critical component to this whole problem. That is that health care provider groups, both in Virginia and around the country, have submitted documents to this Task Force telling the Task Force members that they have personally observed problems with this practice. Consumer groups have now appeared and told the Task Force that they had concerns about it. Studies have been produced and shown that there are problems.

I don't think that I'm suggesting legislation to address something that

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no one has spoken to or some problem that no one has proven exists. I think it's clear the problem exits. The extent to which the problem exists has not yet been determined.

I would submit that part of the problem with that is that those engaged in the practice aren't telling us what they're doing.

DR. ROSENTHAL: I'm very concerned about Mr. McArthur's comments. When Dr. Hadley, not three minutes ago--well, not ten minutes ago told you precisely what the problem is with the data. You ask me whether my client, which is a client, is intentionally withholding data. The answer is no.

I told you all I will try to get the data Senator Newman suggested. That's important data. The fact is, the data doesn't exist, at least not at this point.

I agree with Dr. Hadley that we're talking about another level of databases some time in the future when this information's had time to be gathered.

I can't say strongly enough how I agree with Senator Newman that we don't do

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business by telling businesses what Mr. McArthur would have us tell them.

SPEAKER: Mr. Chairman, I wonder if it's presumptuous to wonder if this answer is ever going to be obtained. One of the components of obtaining this answer, facilitating it, is going to have diagnoses on prescriptions. I know that is a fairly revolutionary and dramatic thing to suggest.

But if diagnoses were on prescriptions either by ICN-9 codes or some mechanism that was coded in, then the answer could be obtained in a relatively short period of time, in a year or two I would think, over a large patient population.

I wonder if we can make a fundamental recommendation that might allow the information to be gathered quickly to get to the answer. I know that's not done now. It would cause a big change.

DR. BLANCHARD: I think that's a good example of the type of recommendation we may end up making that will not necessarily be germane to that one little charge that we have.

I think we spent a lot of

people's intelligent time in the last few months evaluating the situation. Again, I think this lends some legitimacy, if you give us a chance to express what we think, to what might be a solution to the problem.

Then when one side or the other goes to the legislature in January, they can appoint the Task Committee as having provided some basis on the answer to make decisions in the next General Assembly.

MR. TEEFEY: I think we took the Senator's recommendation-- We haven't voted on it. I think some of you feel that we already accepted Senator Newman's recommendation to extend it another year. I don't think we've done that.

HON. NEWMAN: It's just one suggestion given the impasse where we are or may be. If there is a desire for a meeting or two meetings or a number, I know that Mr. Durrett's group has come out and Ken's come out with some policy options, if you want to look at those, that's fine.

I don't know if the underlying data to make a decision on some of these is there

yet. I'm hoping that with the Harvey commission and with what we're doing, that maybe together by the end of next year, if we can't come to a consensus, we'll be able to give the General Assembly more than we can give them right now by extending it another year. I'm not opposed to other meetings if there is more information to come.

DR. BLANCHARD: I wonder if it's acceptable to the Task Force members to have parties interested in any sort of policy options, have them submitted to Dr. Piles by two to three weeks from now. That will give us two weeks to circulate and come back here.

MR. SZALWINSKI: I'm not interested in having 10 more meetings. I'm particularly not interested in having more meetings if we don't have a basis to make any progress.

MR. TEEFEY: The big thing we have to do is the report and get it to the Committee and General Assembly. That would be no problem at all as long as we get your policy early enough for us to work with the appropriate people to get the responses back.

DR. BLANCHARD: My feeling is that what we're trying to do is urge people to work quickly and not slowly.

HON. NEWMAN: If we do get that information in, which I would hope Ken and Steve and all those who give information to the staff, so it's not just coming from us, but that that information be allowed to be given to everybody else at least a week ahead of time so we can get an argument on why policy consideration thirteen is a good idea. Then there at least can be a cogent debate as to why it is not heard.

MR. TEEFEY: How many weeks do we have before the next?

DR. PILES: September 17th.

MR. TEEFEY: Four and a half weeks. If we could have everything in within a week and a half, it would give us two and a half-- But he wants it before.

DR. BLANCHARD: A week to disseminate it.

DR. PILES: What I could do to expedite things is as soon as we get some of this--I think he would like a summary after we

get everything. But at the same time as things come in, I can get it out as fast as I get it.

MR. TEEFEY: The sooner you get it in, the faster we can get it out. We'll try to have it to you longer than a week prior to the next meeting.

DR. PILES: Right. At the very latest a week before. With a deadline of getting everything in, will give us an opportunity to put it together in some cogent fashion that will facilitate your next discussion.

MR. AYOTTE: I think-- To the Senator's point earlier, I would hope that in our report, we not give final recommendations until after the Morgan test is done. We all have been exposed to how things can be chopped and taken out of context. I would hate for our preliminary evaluations to be used as our final evaluations. I think that we may find information from that subcommittee that would be very helpful in making our final.

MR. TEEFEY: Mike, do you feel we could make recommendations as to who supports the Board of Pharmacy?

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MR. AYOTTE: Yes. As long as-- What the Senator said earlier, that Ken McArthur has given where there are some policy proposals. I don't have them in front of me to look at.

I would hate to have whatever we give as a preliminary be assumed as a final, because I think that what comes out of the Harvey study may give a final recommendation which encompasses all of that at one time. But I think we may have preliminary issues that we need to start on now. But I would hate anybody to take that as our final word.

MR. TEEFEY: Are we all in agreement that you'll get your policy statements in? We'll work on those policy statements--

DR. PILES: And I'll get things in the interim.

MR. TEEFEY: --just as soon as we get some answers. We'll try to have everything to you longer than a week before the next meeting.

In the policy statement, don't give us a thesis, please. Come out with a policy statement--specific policy statements because

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I've four or five of these notebooks now. Some of these people are brave. They only brought one of them. Somebody even gave us a hand truck to use over the holidays so we could deliver these things. We want to make sure they're good, concise policy statements.

DR. PILES: The next meeting will be in House Room C instead of D, but I will remind you.

DR. HADLEY: Will we get from Ms. Russell from the Board of Pharmacy, will we get your policy recommendations in that time interval?

MS. RUSSELL: I would be glad to supply you with some staff recommendations. The problem is I will not have a Board meeting prior to that date. My regulation meets on the 15th of September and could review staff policy options.

I can certainly tell you whether it would have been approved by the regulation committee, but I have to get them to you prior to the regulation committee seeing them. So there may be changes or modifications from the committee.

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DR. HADLEY: Okay.

MR. TEEFEY: Is there anything else? I think we all know what our mission is prior to the next meeting.

(CONCLUDED AT 11:25 A.M.)

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STATE OF VIRGINIA
COUNTY OF CHESTERFIELD, TO WIT:

I, Therese A. Rothchild, certify I reported and transcribed the foregoing, which is complete and accurate, to the best of my ability.

I am not related to nor employed by any counsel, party or witness, and have no interest in this matter.

Given under my hand this 2nd day of September, 1995.

Therese A. Rothchild

VIRGINIA:

HOUSE JOINT RESOLUTION 630
SPECIAL TASK FORCE
Studying Practice of Therapeutic Interchange
of Chemically Dissimilar Drugs

Fourth Meeting

September 17, 1997

When heard at:
8:30 a.m.
General Assembly Building
House Room C
Richmond, Virginia 23219

CRANE-SNEAD & ASSOCIATES, INC.
4914 Fitzhugh Avenue, Suite 203
Richmond, Virginia 23230
Tel. No. (804) 355-4335

APPEARANCES:

Mr. Joseph M. Teefey, Chairman;
Mr. Michael J. Ayotte;
The Honorable I. Vincent Behm, Jr.; (Absent)
Dr. Lawrence E. Blanchard, III;
Dr. Randall E. Dalton;
Mr. James G. Council;
Dr. Douglas R. Hadley;
Dr. Karen E. Knapp; (Absent)
Mr. Charles E. James, Sr.; (Absent)
Dr. Thomas L. Moffatt;
Ms. Cynthia J. Pigg;
Mr. Mark A. Szalwinski;
Mr. William Alan Towler;
The Honorable Senator Stephen D. Newman;
Ms. Marjorie E. Powell;
Mr. W. Tommy Walker.

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September 17, 1997

NOTE: The following hearing was called to be heard at 8:40 a.m., viz:

CHAIRMAN TEEFEY: All right. We'll want to go ahead and get started, if we can. I know some people are not here, and they'll probably be coming in a little bit later. I want to welcome everybody and thank you-all for coming.

I have two short announcements that I'd like to go over. There was a piece that was FAXed out by the Virginia Hospital and Health Care Association. Did everybody get this? It was FAXed out, I think, Monday. If you didn't get it, I've got ten copies here that I --

A SPECTATOR: We have some extras, too.

CHAIRMAN TEEFEY: I think some people didn't get it. Can you give those out, if you would?

DR. PYLES: May I have one, if you would? Okay.

CHAIRMAN TEEFEY: Then, the other thing is, we have a Court Reporter who is going to do

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the minutes for us as they have done each time, and would you -- There are some blind spots in the room, so, when you make a comment, if you would identify yourself, it would surely help her.

All right. We want to get right on into it. So, we'll start with the public comment period. What I would like to do is make sure that we hold the public comments to no more than three minutes, because we want the Task Force to be long-winded and not the public comments to be long-winded. So whoever wants to speak, speak.

Cindy?

MS. WARRINER: My name is Cindy Warriner, and I am here representing today the Virginia Pharmacists' Association.

My first is just a question and a concern, and I apologize for missing the last meeting. I was enjoying the sunny beach. The definition of therapeutic interchange. The original discussion of what has been handed out included the fact that there was some type of patient knowledge. And I noticed in what was printed and sent out had dropped the patient knowledge or consent, and that that was a concern or a question, as far as, that I wanted to raise. I read the transcript, and I didn't

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see, unless I overlooked it, any discussions about that. And then on to the comments.

The recommendations of this Task Force need to be patient focused, industry embraced and practical for the health care providers to implement. It's amazing to me the number of groups which are still confused about this issue and the positive impact oversight would have with regard to patients' quality of care.

There are three points I wish to make. The intent of oversight would be to eliminate the bad programs and support the good programs. A good compromise as opposed to outlawing the practice altogether. This process would not create one state formulary, but rather allow approved programs to function and still ensure the safety for the patient.

Number 2, the oversight of the individual therapeutic interchange programs. Once again, I want to emphasize "programs." It would not cripple formularies nor would it outlaw them. The members of the Task Force or the groups that they represent have all acknowledged that not all formularies nor all methods of enforcing those formularies are consistent throughout the health care marketplace. There are other methods of enforcing

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formularies, such as influencing physicians' original prescribing, detailing the pharmacists for generic substitution, distributing the information to the payer and the patients to crease their knowledge of what is covered, et cetera. None of those mechanisms are influenced by therapeutic interchange.

My third and final point, drug therapy decisions contingent upon monetary incentives do not best serve the patient. Oversight would enable and ensure better marketing of the drug products based on the positive clinical aspects of the drug, as well as the impact on the patient populations. Thus, once again, improving and identifying patient quality of care as a number one priority.

Thank you.

CHAIRMAN TEEFEY: Thank you, Cindy.

Yes, Steve?

MR. ROSENTHAL: Mr. Chairman, I just--I'm Steve Rosenthal--I just have an administrative matter. On the list of entities supporting the policy options sent out by Matt Jenkins' office, there is one deletion and one addition. Prudential Insurance Company should be deleted. I just haven't received final approval of

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that yet. And, added to that list, should be the Academy of Managed Care Pharmacy.

CHAIRMAN TEEFEY: Okay. Great. Thank you.

Is there anyone else that would like to speak?

NOTE: (No response.)

CHAIRMAN TEEFEY: Scotti Russell has worked extremely hard trying to help us understand what we are doing in my Department, and Scotti would like to present some policy options that the Virginia Board of Pharmacy has come up with.

MS. RUSSELL: I apologize. These would have been in your packet earlier, but the committee didn't meet until yesterday, and I didn't have a chance to review what staff had drafted.

Does everybody have a copy of the draft?

NOTE: (No response.)

MS. RUSSELL: The first suggested policy option would be to somehow define Pharmacy

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Benefit Manager to include any current PBMs, HMOs or any other third-party payers or managers of pharmacy benefits, and do a statute to require registration with the Board of Pharmacy in order to operate in Virginia.

The Board of Pharmacy really does not have the ability, at this point in time, to effectively carry out its statutory obligation to regulate the practice of pharmacy in Virginia, because so many decisions that affect the practice of pharmacy are being made by entities other than those which we license or register. This would give the Board the ability to have some oversight over these entities that are currently operating in Virginia and impact the practice of pharmacy so greatly.

The Board, at this time, doesn't want to specifically make recommendations as to what they do and don't consider appropriate practice, but allow you, the Committee, or the public pharmacists to have plenty of time to develop regulations as to what may or may not be considered appropriate in the drug-switching issue. We've had other problems related to, I think I mentioned last time, the sale of confidential patient-specific information. We're now having problems with imposition of certain

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requirements on pharmacies in Virginia that are contrary to other State laws and regulations, such as time lines for the length of time that a prescription would be good for that's contrary to current State laws and regulation that are affecting the practice of pharmacy. Different types of activity that some oversight by the Board would be, would give the Board the ability to truly regulate the practice of pharmacy.

The second policy option that the Board would like to see considered would be to require, and I think I heard last week that just about all PBMs and HMOs do have some type of an appeals process, but require all PBMs to have a written appeals process whereby a patient or a practitioner may appeal a PBM's denial of payment for a prescribed drug in favor of a preferred or formulary drug and require that the denial of the prescribed drug not take effect until after the completion of the appeals process.

The third option that the Board would like you to consider, and realizing that this would be a lengthy process, would be to consider possibly setting up an independent board or committee to develop standards and guidelines, maybe something

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similar to the Virginia Voluntary Formulary that sets standards for exchange of generic drugs for brand name drugs, to set up a Board which would set standards for therapeutic interchange as to which drugs could be maybe safely, in some cases, substituted for other drugs; define what therapeutic classes really are. And, after that is done, consider changing the prescription blank format to have a third check box wherein physicians, prescribers could, up front, allow therapeutic interchange with complete knowledge of what that meant, and in cases where they felt it maybe didn't impact public safety.

This might eventually cut down on a lot of the phone calls that pharmacists have to make, allow the physician some choice up front, and, cut down on some of the workloads for both PBMs, pharmacists and prescribers.

I don't think we could be quite ready to put a proposal together in time for this particular General Assembly session. I mean, this would take a lot of work. But I think it's something, if we're going to keep using formularies, if PBMs are going to keep using preferred drug lists as a mechanism for reducing cost, then this might be something we would want to consider looking at.

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Questions?

MS. PIGG: This is Cindy Pigg.

Scotti, can you just help me understand, are there practices that you're hearing reports of that said, and it's kind of jumping off of your point, too, here, I think, that there is a distinction between what the contract between the patient, the member, and their insurer is versus the patient care.

And, point number two, and then maybe even in point number three, but that's not the point, it seems like the Board is getting--the assumption is that just because the prescription is not paid for, that means that the patient cannot have it. And that's a contractual relationship. I don't know that there are PBMs, and maybe there are, that are saying, you can't dispense this drug. I don't think they're saying you can't dispense it. They're saying it's not a covered part of the contract.

MS. RUSSELL: Well, I think that's a problem that all the health professions are having to deal with. Yeah, you're right, the PBMs are saying, we're not going to pay for it, not that you can't have it or you can't comply with the State law, but we're just not going to pay for it. If you

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dispense it for two years then, you know,--
But, as a matter of, you know, fact, in a lot of cases, that does create a denial for that patient, because they can't afford to pay for it.
MS. PIGG: But, if they didn't have a drug rider at all, would you feel it was the Board's responsibility to say to the pharmacist, you've got to give that drug to the patient, even if they can't pay for it? I'm just wondering; I guess my question is, is the Board interested in entering into the relationship that's a contract between the employer and the member and the payer?
MS. RUSSELL: No. I mean, I think some of the business aspects of this are best left to the Bureau of Insurance, but only, I mean, I think that certain policies by PBMs do affect the practice of pharmacy, such as a company saying, we are not going to pay for a prescription that's over a year old or over six months old, when, in fact, State law regulations may allow it to be refilled for a longer period of time. It creates additional workload for pharmacists, which ultimately can create additional mistakes. It creates extra workload on the prescriber when the doctor--when pharmacists have to

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call and get a second prescription. And it also creates the situation where you've got two open prescriptions for the same drug for the same patient, and I think that's a problem.
Whether we would -- What we would want to do to resolve that, I don't have that answer at this point in time, but, yeah, I do think when policies, business decisions, affect, get into affecting the actual practice of pharmacy, that maybe the Board should have some oversight. But only to the extent that it does affect the practice of pharmacy and not necessarily the business decisions or the contract. I doubt many patients really know what's in the fine print of their contract.
MS. PIGG: I can't speak to that. The information is there. They may or may not elect to read it.
MS. RUSSELL: Or may or may not get it even.
DR. HADLEY: Ms. Russell?
MS. RUSSELL: Yes.
DR. HADLEY: Dr. Hadley. Your recommendation about how the denials should be handled with respect to the appeal process, I think, is problematic, and that would be a little bit

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different than how appeals are handled for other things of which there are already statutes involving, that have been, you know, set up for HMOs.
Typically, in a situation like that, if there is and then, first of all, you don't even--an HMO doesn't always know, if a denial is issued, whether or not it is even going to be appealed. Typically, there is a period of time that you allow up to 60 days. So, if a denial is issued, maybe only, you know, a fraction of those are even going to be appealed.
So I think that that is very problematic to say that if an HMO or a PBM issues a denial that that doesn't take effect until somebody, you know, appeals it, and they go through that whole process. And you're allowed, you know, by the State statutes, a certain period of time to respond to those.
So, I think what would be better, if there would be something like that, would be rules that would be consistent with the other kind of appeals. And, typically, what that would mean is, if the appeal was won by the patient, that the payment for that would then be retroactively applied. But not that the denial wouldn't take effect until there

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had been an appeal and it had been heard.
I think just technically that would be very difficult to do what you're talking about.
MS. RUSSELL: The difference I see with pharmacy benefits and other types of denials is that you've got to have immediate permission to make that switch before the drug is dispensed. So, if it's denied, I mean, if you call the prescriber and the prescriber says, no, I do not want this drug switched, then you've got, I mean, you've got immediate notification that they're appealing. I mean, --
DR. HADLEY: Well, there are expedited appeal procedures. I mean, you know, that's allowed by current statute for the HMOs.
But, to give you another example of this, I mean, there are more than just the therapeutic interchange kinds of appeals that take place. Some of them have to do with the generic drugs.
MS. RUSSELL: And that's not what we're talking about.
DR. HADLEY: Patients are appealing, you know. They want the brand name or

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they appeal, you know. And it's very clear in their contract that there are certain drugs that are excluded by a contract, you know, such as the cosmetic ones we talked about--Minoxidil for hair loss. I mean, believe it or not, even though that's written clear in black and white in the contract, people appeal that sort of thing.

MS. RUSSELL: And that's not what we're talking about.

DR. HADLEY: So, I think that's the problem.

MS. RUSSELL: Yes, and maybe I didn't make that clear. I'm not talking about generic versus brand, and we're not talking about drugs that would be normally denied, blanketly denied because they're for cosmetic purposes or whatever reason. I'm talking about the issue that you're here to talk about, which is the drug-switch issue, the switching of chemically dissimilar drugs for the same therapeutic purpose where you would pay for one drug in a therapeutic class, but not necessarily another.

MS. PIGG: But it does get to the same issue as covered versus noncovered, because, again, getting back to the contract, it says drugs not on the formulary are not covered benefits, unless

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the exception process is gone through. So it really is the same issue of covered/noncovered. That's what formulary equals, covered; nonformulary equals noncovered.

MS. RUSSELL: But, again, you have got a drug for a prescription and you're going to probably-- If something was not covered for cosmetic purposes, for example, you would tell the patient right then it was not covered. If you want it, you have to pay for it.

In the other situation, you wouldn't tell the patient that. You would say, let me call the prescriber and see if we can get them to switch to this other drug that is covered. The patient may or may not have been on the other drug for a period of time. And you're either going to get a yes or a no within a certain period of time whether they want to switch or not. And I guess the committee or Board felt that if the PBM had to pay for the denied drug until they could get through the appeals process, that it might have the effect of making the appeals process go a little bit faster.

MS. PIGG: But, again, that recommendation would go directly in conflict with the contract. And, again, I just think the Board needs

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to consider that and-- Well, I heard you say that's not where you're going with this at all. You're trying to focus in on the practice of pharmacy, things that may affect the practice of pharmacy. But, I think you're -- It needs to be real -- The Task Force needs to be very cautious in the fact that it's very explicitly stated or else you do have a problem with the Bureau of Insurance that nonformulary drugs are not covered benefits.

DR. HADLEY: Again, I think you have the problem, too: suppose you require the PBM to pay for a drug until it is appealed. Again, the majority of these are never even appealed. So does that mean they're supposed to pay for that drug ad infinitum? You would set up a situation where it would be in the patient's and the doctor's interest never to appeal it, because you'd have to pay for that until "an appeal was worked through."

MS. RUSSELL: Not necessarily.

DR. HADLEY: So, I think, the other thing, just one other point. I think the other thing that we might need to make a distinction on, I think, which is not apparent in this, there are differences--I think Dr. Blanchard has brought this out in some of his discussions--where sometimes a

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patient will present a new prescription, has never been on a particular drug entity. They have just been diagnosed for whatever condition, presents with a drug in a particular therapeutic category. They're informed, this particular drug is not on our formulary, but we have another drug in our formulary in the same drug, you know, class. We'd like to substitute that. There's really-- The patient has never been put on that drug, has never been titrated and that probably is a different situation than the patient who, let's say, joins a particular health plan and has maybe been on Drug A for ten years, well titrated, doing well, and this is the transition-type of situation that we talked about. That may be a specific situation where, you know, some things, such as you're talking about, a patient who is on a chronic medication, was well titrated, well controlled, no side effects, that may require some special handling.

But I think to make a blanket statement like that, that, you know, you have to pay for it until the appeals process is worked through, would be very difficult and problematic. Again, there are expedited appeal situations so that if the doctor and the patient decided to take advantage of that

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for, say, a transition drug, I mean, then you could, for example, have a rule where you dispense, you know, 72 hours worth of medication. And an expedited appeal is supposed to be resolved within two business days.

So, you know, perhaps something like that, but not to leave it completely open that you could get the medication forever by just not appealing, it doesn't seem to me to make sense.

MS. RUSSELL: And I don't think that's what we had anticipated, and this is not, by any means, worked out in detail.

DR. HADLEY: Yes.

MS. RUSSELL: It's just a concept whereby the patient would not be immediately denied. If you call the physician to make a switch, and he says, no, to me, that ought to institute the appeal process. I mean, if he says, no, I don't want to switch, because, you know, I want this patient on this particular drug for whatever reason, you're going to deny payment of the drug to that patient until they can get it worked out.

DR. MOFFATT: I've got a handful of problems, and I am not sure where they all come from.

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It started out-- I certainly share your concern. I can't make the company pay for a drug just because I've liked it forever and stall appeal until my patient doesn't need the drug anymore. So, obviously, that needs a little polishing. I don't find that a cogent argument against your point in saying that they have got to provide the drug at first. I think that's a technical problem that is certainly surmountable.

I'm very uncomfortable with the Defense, if that's the right word, that "it's in the contract." The patient should have read the contract. All right. That's talking about a legal gotcha. That's not talking about the practice of medicine. Maybe I'm a little pollyanna about this, but I see a significant difference.

I don't know what the drugs are that are included in my insurance. I would wager most patients don't. To know that my patient understands the difference between being given Biaxin and being given Erythromycin, so that when he signs the contract, he really has informed consent on what he's buying is ludicrous. That's not going to happen. Our challenge here is to protect the citizens of the Commonwealth, not to rape the

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insurance companies or the HMOs or anybody else. But, you can't use that kind of gotcha mentality when you're talking about taking care of patients' lives.

The last thing, and I promise to shut up after that, is your proposal number three. Were you not happy with the definitions that are being made of therapeutic interchange the last time through? Because I think that addresses the problem. The problem with having an extra box on a prescription pad is that if two or three physicians have such prescription pads, and we all check the boxes, then we end up with patients taking Macrolides biotics, antiulcer medications and antifungal medications, and getting cardiac arrests because we don't really know what drug our patient is taking.

If you specify drugs that you know are safe, regardless of the fact that your patient is also seeing an allergist and everybody else, then you feel much more comfortable about that. I don't think we can use this kind of a blanket approach to therapeutic interchange. Although it's probably well-intended, I think it's a little misguided.

Thanks.

MS. RUSSELL: I didn't mean it to

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be an easy, quick solution, and I think, again, there would need to be a lot of details worked out. I think that if a change was made, the physician, prescribing physician, should be immediately notified in writing that that change was made and what it was switched to. I think there should be a limitation on the number of switches you could do per prescription, like maybe one, as a maximum. And I think there should be a book like the formulary. You know which drugs could possibly be substituted for a brand name drug that was prescribed and you okay that by checking a voluntary formulary box.

If you know-- When I say define therapeutic interchange, yeah, I'm comfortable with the definition that was done last time. But I think that needs to be expanded upon. I mean, we don't really know what a therapeutic class is. We don't know, if you said that right now, you wouldn't know what that really meant, what the pharmacist was going to do. If the pharmacist had a book and could only do exchanges within certain parameters, that this drug was approximately equivalent to this dose of this drug, given at these particular times, and you knew what the choices were, you might have a little bit more of a comfort level, maybe. And, in some

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patients, say you've never had a patient on a particular class of drugs before, it was a new drug, and you didn't really care which one he was put on as part of the formulary, if you knew it was--that an independent body had looked at this and said, okay, this one, this one, this one are okay within certain parameters. And this may not even be able to be done. It was just a suggestion. I mean, I have heard concerns that the formulary committees for the various HMOs and the PBMs, you know, are not truly independent, and maybe if we had some State independent body that was coming up with standard guidelines for this type of thing, that might be a better way to do it.

MR. SZALWINSKI: If I may, Mr. Chairman, it's Mark Szalwinski.

I would hesitate to make that blanket statement. There are many very good P and T and formulary committees out there with significant local control. And I think that there is really a risk of taking that local control away by putting some supra authority over designing that. And you could really -- You run the risk of really hurting those processes that are functioning well and have established good credibility with physicians in the

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community and members.

So I would just, I would caution that. There are those committees that are doing very well and are independently functioning. But, I'd like to also go back to Cindy's point and remind everyone that there is data out there from IMS that last year prescription drug volume grew 10.1 percent in real dollars and in real prescription numbers due to and attributable to the coverage of prescriptions by managed care. Patients are getting more drugs because managed care is covering them. And there's a cost and a benefit to that, and managed care is doing the best they can by trying to administer the cost and provide that additional benefit.

I would just be very cautious because it is our job to protect the consumer, and the consumer has benefited by additional drug coverage. So, we need to be very careful how we now try and regulate that practice, and I don't think that there is any real, the intent behind these I could support, but we need to be very sensitive, particularly to the appeals process and for regulating the P and T process that we aren't onerous or obstructionists in allowing the managed care to continue to provide that additional benefit.

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MS. RUSSELL: And I don't disagree with you. That's why the Committee would recommend not doing anything on option number three this year, but take a year with a Committee to even take a look at what could be done. It may not be possible.

DR. DALTON: Dr. Randall Dalton.

Your point number three concerns me, like a lot of the discussions we have that make it look like physicians are going to get to the point where we are not writing for prescriptions, but writing a diagnosis and saying, well, prescribe something for our patient for this, because it's going to -- It's out of our hands as it is.

Right now prescriptions aren't determined in a vacuum. The physician has a lot of history on the patient, background, his thought process as to the likely pathogens that are involved, if it's an antibiotic that's being prescribed, the side effects, additional costs that would be involved if you need to get laboratory work if you're going with a limited spectrum-type of antibiotic as opposed to going with something that covers more pathogens and being able to treat more empirically on patients. A lot of things go into that, and I think that we're taking the physician out of the process more and more

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as we sort of broaden the options that the patient can get from the pharmacy, and I think that most physicians are willing to be flexible with changes, generically, changes within a class of medications.

But, we need to be involved in that with a phone call and checking a box, probably, is being a little too insensitive to the input of the physician, even though you said you sent a letter out saying this is what the patient got. And I think we need to remember that the patient is getting something that the patient needs in order to get better and that the more times he gets that specific medication, the more times, of course, a treatment is going to be successful.

CHAIRMAN TEEFEY: But haven't we gotten to a point now, and I hear the discussion, haven't we got to the point now that we are calling for a switch because the drug is not on the formulary, and if they don't get the switch, they don't get anything?

MS. PIGG: They don't get anything. Again, they don't get anything as a covered benefit. Nowhere does the PBM say you cannot have that. Again, I didn't mean to convey it's kind of a gotcha attitude. That's why we set up appeals

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processes, because it would be very shortsighted for us to say, just like my homeowner's when my roof got ripped off. They said, sorry, it's not in the contract and that's all, end of discussion. It wasn't really an appeals process.

But because HMOs or managed-care entities really are charged with looking at the total health care cost, that's why we set up appeals processes, because I agree, if we use the gotcha mentality when that wasn't the best choice for the patient. That would be shortsighted.

CHAIRMAN TEEFEY: Well, and I agree. But, do we set up an appeals process to make a person go through an appeal knowing they're not going to get anything out of the appeal? And I think that appeals process, if we do that, it's wrong having an appeals process.

I think what Scotti is trying to say is, really it might not be a Pharmacy Board issue. It might be a Bureau of Insurance Board issue, because, you know, we're all thinking about the patient and good practice as far as the patient is concerned. But I think we've gotten to a point where, in our interchange, are we calling the physician to tell the physician that the prescription

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you wrote we can't fill because it's not on the formulary, and if you don't switch it to this new, to the drug that I have prescribed, then the patient, the person has got to pay for that drug?

MS. PIGG: I think it's real important to use the right terminology, though, to say--

CHAIRMAN TEEFEY: Yes, and that's what I want to lay out and make sure that everybody understands that.

DR. HADLEY: If they have to, we'll pay it out of pocket--

MR. SZALWINSKI: But, that's a communications issue, and that's a, you know, that's a very important communication that needs to be done well. I mean, it's not a black and white issue. There can be expertise in accomplishing that.

MR. COUNCIL: Mr. Chairman, if I can speak to your question and also I think some comments that Dr. Moffatt had.

I think, first of all, we're making a big mistake in addressing this issue because, so far, everyone has referred to insurance, and insurance is not the full picture here. You know, insurance does a lot of good for a lot of people, but

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I haven't met anybody lately that stood up and sang their praises. All pharmacy benefits are not insured, and I can't give you figures on it, but I can tell you that hundreds of thousands of pharmacy benefits are straight employer, self-funded. So, I think we're making a mistake if we think about this entire benefit in terms of insurance.

Then, the second comment is, it is a specific legal mistake to talk about that all this could be regulated by the Department of Insurance, because, to the extent there are self-funded plans, there's not going to be any jurisdiction there in insurance.

So, I think we have to talk about it as a pharmacy benefit plan, not necessarily as insurance. My second comment is really to Dr. Moffatt, and I think there's a big, big mistake to look at the issue of what an employer is willing to provide as a benefit as just some legalistic argument. It's not legalistic. It's not law school debate for the fun of it. It is what employers have sat down and determined that they can afford to provide as a benefit to their employees and regardless of what more we may try and sit here and say they need to add to that plan, there are going to

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have to be parameters. And, if they're not parameters for those employers, then what we're going to see with the pharmacy benefit is the same thing we've seen in the last 15 years with our old pension defined benefit plans.

I would say 15 years ago, probably more employees in this Country were covered by defined benefit plans, which are real retirement plans. Government made it so expensive for employers, so burdensome to administer, that I bet you can hardly find a defined benefit plan anymore. And if we think about this as nothing but patient care, and it is patient care, but if we fail to acknowledge that somebody up front has determined how much they can pay to provide some pharmacy benefit to its employees, then we're going to lose sight, I think, of how the whole pharmacy benefit operates. We have just heard some suggestions right there that, in fact, many, many more prescriptions are being written as a result of pharmacy benefits being offered by employers.

So, it is not just a legalistic argument. It is a business issue of an employer having to sit down and decide how much he can afford financially to devote to providing a benefit to his

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employee. And, over and above that benefit, it becomes the employee's financial responsibility. If we sit here and continue and continue to tell the employer what he has to provide, to the point that employers decide they don't want to offer the benefit, then I really don't think people are going to feel like that we acted in the benefit of the consumers here.

DR. BLANCHARD: Mr. Chairman, Larry Blanchard.

CHAIRMAN TEEFEY: Yes, sir.

DR. BLANCHARD: Sort of two comments. One is, I hope we can recognize that Ms. Russell didn't come here to be a symbolic target of all our discussion that should take place among us. And Scotti is sitting up here having to feel the brunt of it and just propositions that may not be any more hair-brained than others that we will come up with later.

I couldn't let it rest without one comment on the contractual issue and without arguing with your concept of what's covered and what's not covered. The employer, whether he's buying coverage for himself and his family or employees and their families, no doubt is reassured

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by a language in the contract that says something along the lines of we will be covering all medical and necessary treatments. And it doesn't necessarily get communicated to the employer or the employee that this is determined at the sole discretion of the insurance company and not by the patient's physician.

There is an assumption that reasonable treatments have a reasonable chance of being covered. There is not anything in there that says, we are going to try to limit your coverage for given diseases to one out of a possible 30 choices. And, I would suggest that the employer, as I do when I buy insurance, assumes that there's going to be some choices in there that are appropriate. The arguments tend to come, as Mr. Teefey has suggested, as to when a drug prescription that is a reasonable choice for your neighbor paying the same premium with another insurance company next door is determined to be an unreasonable choice by the insurance company that you're covered by. It's difficult for physicians and patients to understand that logic. We're not talking about drugs that are eliminated because of safety reasons. We're talking about when it comes down to four, five or six drugs that are quote therapeutically equivalent, but with slightly

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different side effects, each insurance company is coming up with a formulary that says, CIGNA will cover this one; Aetna will cover this one; Prudential will cover this one. That doesn't necessarily make much sense to the public.

There are only two parts to the contract. You can say what you said, but I think the public has a perception that the contract also says they will be covered by reasonable choices. It may be a communications problem, but I don't think that's clear up front. Because, when the presentations are made to the Employee Benefits Manager, they are reassured repeatedly that, yes, we have a good formulary. We are going to cover the things that need to be covered.

DR. HADLEY: Larry, I think that that's not really what the contract is about, the prescription benefits are all about. Almost always they are a rider to the contract, because employers have the option of selecting or not selecting the pharmacy rider. So, again, this gets back to the issue of the employers are voluntarily supplying this as a benefit to their employees, but that doesn't mean they have to. But these are typically a rider to the contract. And the language that I see in all of

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them is very clear that the drugs that are covered in this are those that are on the formulary. And, if it's not on the formulary, either you have to pay it out of pocket or pay some percentage out of pocket that would be greater.

In some cases, the nonformulary drug may be covered but at a lower benefit. And, they're very clear that it isn't saying you get all drugs. It's saying, you know, these drugs are excluded and those that are on the formulary are excluded. So, I think that it's not really a bait and switch kind of thing. I think it's very clear and up front. And, you know, unfortunately, there are a lot of the physicians are writing drugs that aren't consistent with that, and I think one of the problems we have, of course, is that there are different formularies from one company to the next. In part, that's due to the competitive marketplace which allows different insurance companies and PBMs to negotiate better rates. And, to that extent that that drives down the cost of drugs, that's good.

The fastest rising part of the Health Care Bill right now is the pharmaceutical bill. I mean, there is no question that's being subject to the highest inflationary rate. So it's a

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big problem.
MR. AYOTTE: Mr. Chairman, can I--
CHAIRMAN TEEFEY: Yes, sir.
MR. AYOTTE: I feel like I'm in between the -- I'm the pharmacy group, so I guess I want to talk to a couple of points that I just want to clarify in my head.
First of all, the State has the authority, although Virginia pharmacists use therapeutic interchanges? We have established that? The doctor in Virginia has the final say on therapeutic interchanges in Virginia? The Board of Pharmacy has, at the current time, no oversight over prescriptions filled for the citizens in other states?
MS. RUSSELL: Correct.
MR. AYOTTE: Okay. So, I guess what I would like to do is kind of refocus, if we can. You know, it just seems like Senator Newman, at the last meeting, brought up an outstanding point, and it seems more outstanding today than it did the last time, is that Delegate Morgan's subcommittee on PBMs can deal with many of the issues that I hear today that we may not be able to. You know, whether it's the degree of the ability for someone to appeal;

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the ability for someone to cover an open formulary issue; some issue that has to do with one formulary book.
I guess I just want to make sure that we're still focusing on alternatives to this. And I know Scotti worked hard on the ones that you have, and there are some good points in there. But, I want to make sure that we don't get off and never get to the point of coming up with some recommendations.
DR. BLANCHARD: Can we excuse Ms. Russell?
CHAIRMAN TEEFEY: Well, yes.
MS. PIGG: I just have one more question. As I tried to kind of look into the Board's thoughts, and I know I can't speak for the whole Board, but some of the practices being implemented by PBMs are affecting the practice of pharmacy and specific things that pharmacists have to comply with. In the scenario where you mentioned that the phone calls,--the pharmacists having to call the physicians back, potentially is interrupting the work flow and leading to adverse outcomes. But, I want to understand. Is the standard going to be applied across all types of customers in that if the PBM, as

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the payer, says, we're not paying for this, that, potentially, is interrupting the work flow? But, if a patient comes in, a cash-paying customer, and says, that's too, as the payer, and says, that's too expensive, can you call the doctor and get something less expensive, do you think that the same standard applies there? It's the payer saying that's too expensive, please call the doctor in that practice, because the payers are now such a big volume and are affecting the practice of pharmacy and their work flows?
I mean, I'd hate for the tried and true thing of the patient coming in and saying, I can't pay for that, and the pharmacist saying, let's see what else we can find, I have to call the physician to discuss that, being usurped by-- It's all the same thing. The payer says, it's too expensive. Call the physician. And I would hate to see that cash paying customer --
MS. RUSSELL: I don't think I have said anything that would make you think that the Board is considering prohibiting the ability of the pharmacist to call the physician in either one of these cases. Like, in option number three, it was maybe a way we could look at, explore for the future

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in cutting down on some of these calls. I think what I talked about was that a problem that we're seeing with some PBMs blanketly saying, we're not going to honor any prescriptions over "X" number of months or one year old, when, in fact, the physician expects that it's going to be honored for two years. The law says it can be honored for two years, and there's really no, you know, that I'm aware of, good reason why the PBMs are doing that.
Looking at that, I haven't even said that that's -- I think all the Board would like -- And we get people, pharmacists calling us, why can't you do something about this practice? Because we don't have jurisdiction over the people making the decisions. We don't have any jurisdiction.
My thought right now, just at this, you know, at this juncture, is to give the Board some ability to register these people who are impacting the practice of pharmacy in Virginia and even, at first, on a case-by-case basis. I mean if there is some fraudulent practice going on, that somebody could do something about it. You know, if it impacted the practice of pharmacy, it ought to be the Board of Pharmacy that has the ability to do something about it.

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MR. TOWLER: Mr. Chairman?
CHAIRMAN TEEFEY: Yes, sir.
MR. TOWLER: Briefly, in regard to some of the things I have seen at the street level, very early on, it has been going on for years, is in regard to, say, generic substitution. Some parts, not only PBMs, we're being told to dispense or the benefits would be increased to the patient. But, in a therapeutic interchange sense, I see a bait and switch going on in some regards where an Imitrex prescription is covered and the patient walks in for their refill and it is not covered, and it's a very sudden event. To have some sort of an override capability that would be short-term, I think would be reasonable, in regard to having time for the patient to address these issues. What we're seeing now is kind of a run-into-the-wall effect, and it's having a lot of adverse impact on the work place condition.
CHAIRMAN TEEFEY: Well, I hope we never even think about taking the right away from the individual.
MS. RUSSELL: Oh, absolutely not.
CHAIRMAN TEEFEY: I just hope we never, ever think about taking that right, because that individual is the one that everybody is

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concerned about, the medical community, the pharmaceutical community, and I just hope we never think about taking that freedom of choice away from the individual.
MS. PIGG: But that doesn't inflate the payment or nonpayment.
MR. SZALWINSKI: Well, I'm curious as to what rights, specifically, you're speaking of.
CHAIRMAN TEEFEY: Denying that person the right to have the pharmacist call the doctor. That is all I'm saying. I just think that they're the, that's the center of the nucleus right there, and I just hope we never take that right away from the individual to do it by checking any box or anything.
MS. RUSSELL: No.
CHAIRMAN TEEFEY: I'm not a pharmacist or a doctor, either.
MS. RUSSELL: No. And I guess--
CHAIRMAN TEEFEY: And you weren't suggesting that?
MS. RUSSELL: No, not at all. And I guess our policy option number one is what we would really like to see and what the Board feels it needs in order to start having some control over the

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practice of pharmacy again.
Number two is sort of a wish list.
And number three is something that we would like the Committee to look into as a future option. I know it can't be done right now.
CHAIRMAN TEEFEY: I think the three suggestions you brought are excellent, and I think it does open up a whole other arena of thought.
And, again, Scotti, you know, you and the Board do a wonderful job, and we really want to thank you for coming down here.
MS. RUSSELL: Thank you.
MR. SZALWINSKI: Can I just add one more thing? If we do proceed ahead with number one, we may want to consider that someone from managed care be added to the Board of Pharmacy. A pharmacist in the practice of managed-care pharmacy be on the Board of pharmacy, because you would want that input on a regular basis if you were regulating managed care and PBM.
MS. RUSSELL: Frankly, we don't have any required composition of the Board of Pharmacy now. It's, you know, whoever the Governor wants to appoint. You know, I don't have any problem

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with that. I mean, it would be nice to have pharmacists from all walks represented on the Board.
CHAIRMAN TEEFEY: Thank you, Scotti.
I know some of the members of the Task Force have sent some things in over the past couple of weeks. Does anybody on the Task Force want to go over any of the information that they sent in?
DR. DALTON: I sent in a letter that a patient brought in to me that they got from Rite Aid that pretty much gives us an idea of the direction a lot of these switches are taking.
It was a letter telling a patient that--they had a recent prescription filled for a topical steroidal nasal spray, and Rite Aid suggested that the one that the prescription was written for is not the best, and that they could provide the patient with a better one that's going to be cheaper for the patient and the patient would get some other benefits. And, it, obviously, had a disclaimer at the bottom that you need to talk to your physician since he's the one who ultimately has to make the decision. And, it also included information that the mailing had been paid for by the manufacturer of the product that they were pushing.

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I think that this is something else that undermines patient/physician relationships. It shows that the physician can be bypassed and taken out of the loop. At least, when we get a call from the pharmacist about switching, we know what's going on. This is something that if the patient hadn't brought in this mailing to me, I'd have no idea that it was going on. And I think it's something that we, as we deliberate about these issues, need to know that if we don't put down some guidelines or parameters, that these things are going to get even more blatant.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: The doctor knows much more about these things than I do. But, I was somewhat thrilled by the letter, and let me tell you why. I trust patients with all the information they can possibly get. And, if they can be given information that there is a cheaper alternative drug out there, and then they have to go back to their doctor to determine whether or not that's the appropriate item to choose or not, I think this letter causes no problems, except maybe to the medical profession who is a bit concerned that it

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does undermine some of their authority, although I don't really think it does that.

So, I think there's two sides to the way to look at this letter. I think this is full information, and I think it's wholly appropriate. I hope that there will be even more information like this out there.

DR. DALTON: Okay. Who determines if this is cheaper? What is a cheaper comparative?

It's information that implies that this is a public service to the patient; that this is cheaper, this is better; that your doctor doesn't know what's going on; he doesn't know what one brand costs. We make our prescription decision based on the knowledge that this is out there, this is out there, I've got them all lined up, and, yes, we are being taken out of the loop. And, if you don't think that's a problem, then it's no problem except the doctor thinks that his relationship with his patient management is being undermined. So? So what?

That is the type of problem that we're going to see as long as you don't see a problem with this type of thing.

MR. AYOTTE: Mr. Chairman, I have

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a question for the Doctor.

Your feelings on the advertisements that are in Parade on Sunday, I mean, you know, I mean, every commercial on TV, everybody that comes in, and I can tell you from practicing pharmacy and would challenge someone to tell me that a physician knows the prices that either a plan is going to pay for or a patient is going to pay for on any level of antibiotics, unless it has been brought to him by the representative of that company, that says, here, you prescribe mine, because it is at this price point, there is no knowledge base of what it costs.

I know you're making your diagnosis based on what the patient needs, and for years we've talked about patients being informed, the consumer asking questions, and, to me, this letter, just asks a question. This--

DR. DALTON: The advertisements in Parade is not directed toward my individual patient who went in to fill an individual prescription. His name was kicked out of the computer as someone who is on a topical steroid nasal spray. So, therefore, we're going to entice that patient to be changed to our preferred brand. That is a different issue.

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This is targeting a specific patient that I made a specific therapeutic decision on. And, if there was a suggestion for change, I think that that's where it should have kicked in at the point where, Doctor--the phone call--Doctor, how about putting this patient on Lanacort because he can get it cheaper or whatever else. But this is kicking the doctor out of the loop. And, if you don't see a problem with it, then, as I said, that is a problem.

MR. AYOTTE: But, if I can go back one step. When we began this discussion many moons ago, we talked about the volume of phone calls that are received, and the workload issues at the doctors' offices. I just want to make sure that -- I mean, I don't see any malice in this. However, if you wanted the pharmacist to call, I mean, I would think that that's an alternative to this process. But, that, to me, an easy way is to just say, this is available; we're not forcing you to do this; we're not forcing the patient to switch. We're informing the patient that there is availability. If they want to, they can follow it up versus the pharmacist saying to them, you know, this is not going to be a covered benefit, but we want you to switch to this.

DR. DALTON: I don't think there

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is a pharmacist in this room or many pharmacists, I mean, physicians who really object to the phone calls, to generate the phone calls from the pharmacist. I think in a lot of cases, when we're informed, we'll change it if it's appropriate. If the patient can't afford the drug, we'll say, come on by, pick up some samples, and other things.

So, I don't think that the fact that, oh, we're trying to save you some work by communicating directly with the patient, and I think that's bogus.

MS. PIGG: Part of the driver, though, I think, and the whole reason for the legislation is that the pharmacists don't want to call.

DR. MOFFATT: I think we do have a problem. I don't mind being second-guessed so much--I'm getting kind of used to it--but, what bothers me about this letter is not what bothers Dr. Dalton. What bothers me is, why the pharmacy wants this change to happen. If Astra is paying Rite Aid to push Astra's product and that's why Rite Aid is approaching my patient, I have a problem.

If it really is just that I'm not bright enough to know that Lanacort is just as good

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as the other drug I'm using with a similar side effect profile. That's my problem, really.

But, what really bothers me is whether there is something underneath the surface that's making them push this drug on my patient. Now, what happens, as I understand it now, is an interesting double whammy on a doctor.

I have my choice. When a pharmacist calls me up and says, listen, this isn't in the patient's formulary. If you change it to drug "Y," then he gets a break. I can either be a real schmuck and make my patient pay more money. Or, I can accede to the switch, and be held liable if there is a side effect. I don't like that combination. And I really want to know what's making the pharmacist ask for this change. I believe, if I look back far enough in these proceedings, that will be one of our original worries whether what the PBMs are doing is culpable by having, basically, a kickback problem. And, I would rather you look there and look into looking whether or not this really is a cheaper alternative for a drug, that there are two of them out on the market.

DR. BLANCHARD: Mr. Chairman?

CHAIRMAN TEEFEY: Dr. Blanchard.

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DR. BLANCHARD: Is it appropriate to slightly change the subject and start talking about policy recommendations? I understand what we're talking about here. It's another one of many issues that we have talked about for the last several months on which people of good will can have significantly different opinions, you know, about which we may not reach any sort of consensus in this body, and I think the opinions expressed at both ends here have been heard.

CHAIRMAN TEEFEY: I think--

DR. BLANCHARD: We shouldn't beat that one into the ground any more.

CHAIRMAN TEEFEY: I agree with you. We asked the Task Force, and we asked the public to send in options after the last meeting, and we have got some options to work with. And Mike Worthington, do you want to go over and start with the options, and then Michael Pyles will finish up?

MR. WORTHINGTON: Mr. Chairman, Members of the Task Force, good morning.

I will briefly review --

CHAIRMAN TEEFEY: Now, before Mike gets started, we still have one option on the floor, and one option on the floor is still Senator Newman's

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option. And I want to make sure that we understand that we still have Senator Newman's option on the floor.

MR. WORTHINGTON: You should have in front of you three pages, the first of which looks like this: "Propositions To Be Considered By The Special Task Force."

SENATOR NEWMAN: Do you have more copies of this?

MR. WORTHINGTON: Do you have any we can share with them?

DR. PYLES: I don't know if we have any more.

CHAIRMAN TEEFEY: I have an extra.

MR. AYOTTE: Mike, this is what you guys have put together?

MR. WORTHINGTON: It's what was sent to us.

CHAIRMAN TEEFEY: That was sent to us.

MR. AYOTTE: Can you identify it for us, please?

MR. WORTHINGTON: For each one?

MR. AYOTTE: Yes.

MR. WORTHINGTON: Sure, as I go

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through it. Does everyone have a copy? That's it. That's correct.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: Before we get going, I do think we all need this in our hands. But, if anybody in the audience needs this, could we also have some available to interested people out there? There are copy machines all over this building that can run out as many as is necessary. Can we have that?

CHAIRMAN TEEFEY: Here is an extra one.

MR. WORTHINGTON: Would you like to take a break and allow for that? Five minutes or so?

CHAIRMAN TEEFEY: We'll be with you in a minute.

MR. WORTHINGTON: Okay.

Are we ready? Yes, ma'am?

MS. POWELL: Could we ask Senator Newman to review the option that he has on the floor for us?

CHAIRMAN TEEFEY: Yes. Senator Newman, can you remember it?

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SENATOR NEWMAN: Well, nobody likes my option. But, my option is this: There is an ongoing study out there to study the effects of the core issue that we are talking about here, and that is the Morgan Study looking at PBMs.

As I have reviewed the information that's come in, we have a lot of expertise here. I think I've gained new friends here. But, a core issue is yet to be decided by that group.

I believe that it may be of some assistance to this committee to consider the option of continuing this study, which would be a huge change no matter what we recommended and the General Assembly would have to approve almost all of the changes we have come up with, until a full amount of information can be provided by the other group that studied it. The other side of it is that we simply have gotten very little information. True empirical data that we need has been told to us by staff is simply not available and not out there.

I don't think that we can go into the General Assembly very well and say we really think that what you ought to do is this, but our basis is that we don't have much basis. I think

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that's tough to recommend to the General Assembly. So, my option is, if we can't come up with something that is strongly supported by the data, then we consider rolling this study over until next year, and we can get a better holistic approach to be given to the General Assembly.

It's not a motion yet, Mr. Chairman, because I think we need to hear all of the options that are in front of us.

MR. WORTHINGTON: Senator Newman refers to the Harvey Morgan Study. It's technically HJR 574. The School of pharmacy at the Medical College of Virginia will be doing that study for the Department, and it is due to us about this time next year. That's the technical name for it.

I will briefly, very briefly, simply review the six propositions, if you will, that you have in front of you, and then I will turn it over to Dr. Pyles who has three or four more that have been submitted. You'll notice that the six that are in front of you are pretty much dichotomized into those that require legislative action and those that require regulatory action by, I believe it's three different State agencies.

Proposition Number 1, submitted

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by Mr. Ken McArthur.

MS. WARRINER: Mike, can I just have point of clarification on these?

MR. WORTHINGTON: Yes.

MS. WARRINER: Those that were submitted by Ken McArthur were also endorsed by the Virginia Pharmacists Association.

MR. WORTHINGTON: Okay.

MS. WARRINER: I just didn't want Ken, Ken, Ken, Ken, Ken.

MR. WORTHINGTON: Thank you.

MR. COUNCIL: I'm sorry to interrupt, but what's the source of these propositions?

MR. WORTHINGTON: I will do that as I go through each one.

Okay, the first one?

MS. WARRINER: Yes.

MR. WORTHINGTON: All six, Cindy, is that correct?

MS. WARRINER: Yes.

MR. WORTHINGTON: Well, they're six submitted by Mr. McArthur and all endorsed by the Virginia Pharmacy Association. I'll get that out of the way right now.

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Proposition 1, "Outlaw Therapeutic Interchange Based Upon Monetary Incentives," e.g., Virginia Anti-Drug Switching Patient Protection Act of 1997.

A regulatory proposition that would involve the SCC Bureau of Insurance is Proposition Number 2. "Prohibit Interchange To Chemically Dissimilar Drugs For The Sole Reason" appears to be due to formulary changes by the patient's insurance plan or the patient changing from one plan to another, either voluntary or involuntary.

Number 3 would require legislative action by the Assembly, and that would require that all persons involved in any active therapeutic interchange involving citizens of the Commonwealth have a direct, personal relationship with a patient and be licensed in the Commonwealth, as required by law, to prescribe or dispense drugs.

To be unlawful to switch patients to another drug under provisions of therapeutic interchange without the patient's written approval acknowledging full disclosure the reasons for the switch.

Proposition 4, "A Legislative

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Proposition." All businesses in the Commonwealth that develop and/or implement prescription benefits plans and programs or that engage in therapeutic interchange of chemically dissimilar drugs shall be liable for any adverse health outcomes. This liability shall extend to any and all entities associated with the plan or program, including, but not limited to, P and T committees, having oversight for the company's formularies, and decisions related to the therapeutic interchange of chemically dissimilar drugs. Practitioners that are not directly involved in the daily operations of the company's business, but to transact business on the part of their patients through contractual and other means shall be held harmless.

Proposition 5, "Regulatory Action by the Health Regulatory Board." Require all persons/entities engaged in the development of formularies or the implementation of prescription plans and programs to be licensed by and registered with the appropriate regulatory authority.

In particular, health professional and practitioners that do business in the Commonwealth on a regular basis, but who are not residents of Virginia, shall be required to acquire a

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license to practice in Virginia or, in the case of a business whose home office or parent company is not located in the Commonwealth, required to be registered with the appropriate board or agency to conduct business in Virginia and required to document all instances of interchange of chemically dissimilar drugs.

The final, Number 6, "Regulatory Action by the Virginia Formulary Board." It's required that all prescription benefit plans and programs operating in the Commonwealth be preapproved or credited by the Formulary Board. Any person/entity wishing to engage in the practice of interchange must submit to the Board data necessary to prove that each proposed act of interchange will not place the patient at risk for an adverse health outcome as a result of the interchange.

Dr. Pyles will now review with you the three or four that he has.

DR. PYLES: Mr. Chairman and Members of the Task Force, we received from Matt Jenkins of Hunton & Williams some policy options to be considered by the Task Force, and I shall go through them, and we will have copies for everyone just momentarily.

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CHAIRMAN TEEFEY: Yes.

MR. JENKINS: Yes, Mr. Chairman, may I make a point of clarification? Those are not offer as policy options of Matt Jenkins. There is a list attached to the options that were offered up of the entities that are in agreement with those as options, and I would appreciate those being identified.

DR. PYLES: I will read them--

MR. JENKINS: Thank you.

DR. PYLES: --at this time. These four points that are made are endorsed by the following entities: CVS, First Health Services Corporation, Kaiser-Permanente, Merck & Company, Merck-Medco Managed Care, NYL Care, PCS Health Systems, Rite Aid Corporation, Trigon Blue Cross/Blue Shield, Virginia Association of Health Maintenance Organizations, Virginia Hospital and Health Care Association, and the Academy of Managed Care Pharmacists are the entities that have endorsed the statements that I'm about to review with the Task Force.

Their first statement refers to the definition of the practice that this Task Force developed in its earlier meetings, and they give what

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that definition is. And, since everyone in the audience does not have one, I will read it at this time, until they can get one.

The definition of the practice is defined by the Task Force. "Therapeutic interchange is the dispensing of a drug by any person authorized by law to dispense drugs that is a chemically dissimilar alternative for the drug initially prescribed. The alternative drug is expected to have the same clinical results and similar safety profile when administered to patients at therapeutically equivalent doses as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug or their lawful designee."

These entities make the statement that this term is not intended to refer to dispensing practices in licensed or State-operated hospitals with respect to hospital inpatients. But, I would like to add that in our discussions, however, that was not stated. In fact, when we developed the definition, I mean, it was stated that it could apply in all settings, but, that, in the hospital or other inpatient institutional settings, there was the more formally-approved mechanism by which the switch could

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be made. And we were dealing, with the Task Force, primarily, with this issue in the ambulatory patient care setting. But, their statement is there.

The second of these is the regulations of the practice, and they have reference to the Code of Virginia, Chapter 54.1-34.10, and also another Section 18 VAC-110-20-390. And this one requires a regulatory kind of change, a recommendation for some regulatory action, and they state here that, "To the extent that the Board of Pharmacy believes that no present law or regulation adequately protects such interests," then the Board of Pharmacy proceeding, in accordance with the Virginia Administrative Process Act, should consider promulgation of an appropriate amendment to existing regulations. So this, indeed, would be a regulatory change regarding the practice of therapeutic interchange.

Number 3, "Out-of-State Dispensing." They note here that there is already a Subsection (a) 54.1-3434.4, and they here recommend or suggest that legislative action be undertaken, which would add a Subsection (b) to that section, reading, "It is unlawful for any nonresident pharmacy to dispense a drug that is chemically dissimilar from

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the drug initially prescribed without the approval of the prescriber or his lawful designee." And that would require legislative action.

And, then, finally, the fourth point in their statements here, basically, I believe is an endorsement of an option that we believe is on the floor, and that is the continuation, Mr. Chairman, of the Task Force. The Task Force remembers that a resolution be adopted in the 1998 Session of the General Assembly to continue this Task Force to coordinate with and provide input into the Department of Medical Assistance Services, as provided in House Joint Resolution 574, which is also the Morgan Bill.

So, those are the remaining options or suggestions that we have received, Mr. Chairman, in addition to the ones we've gone over.

CHAIRMAN TEEFEY: All right. We have the options that we requested last time. Let's start off with option number one that Mike gave us, and it's open for discussion.

DR. BLANCHARD: Mr. Chairman, if what we are going to try to decide today is what sort of report to bring forth from this Committee, I wonder if it would be acceptable to have

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recommendations from anyone on the Task Force in terms of tying some of these together in ways that aren't exactly like the propositions here. We can certainly go through every one of them and beat them into the ground and then ask for our recommendations, or we can do it in reverse order. It's at your pleasure.

CHAIRMAN TEEFEY: No. I--

DR. BLANCHARD: But I feel like we can spend a lot of time on every one of these potentially flawed propositions and not necessarily get the gist, if there is anybody here working, try to get a consensus on them.

CHAIRMAN TEEFEY: I agree with you, Doctor. Would you like to open up?

DR. BLANCHARD: Yes, with your indulgence. The way I tried to express things last time is that we ought to try to get these proposals and that we ought to sit down and read them over the last few weeks, and try to figure out which of them makes some sort of sense and what ultimately that we should propose to each other that we could come to in the way of a consensus and a Task Force report.

I have to admit there have been times that it is not clear to me that there was

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anything much that we could come to with consensus, and acknowledging the copious quantities of material that we've been presented with, that it still seems be very confusing. Nevertheless, the more I have thought about it over the last few days, I think there really are some things that we can potentially reach consensus on and support recommending to the General Assembly when we give our report.

I'm going to hand out four recommendations, and I have to admit that since I didn't get Mr. Jenkins' proposals until late last night, that there are a couple of those that I may amend into this. I am actually going to make my remarks sort of in the form of a draft Task Force report, so that not only do you get an idea of what the recommendations might be, but you need to kind of have some handle on what it's going to sound like when we actually make this presentation, because my assumption is, you need to have some sort of justification for the recommendations.

CHAIRMAN TEEFEY: Can we make copies of that while you're--

DR. BLANCHARD: Yes. I actually have the recommendations here. Save one for me.

In order to come to these

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conclusions, though, I think I had to assume that we would agree on three or four points. In addition to the ones that Senator Newman and I have been discussing over here that we need to, preserving the ethics of all practices involved here, that we tend to want to involve ourselves--rely more heavily on the free market system and less on legislative solutions. I have to admit I'm very pessimistic about the ability of a Task Force such as this, either today or one year from today, being able to micromanage this practice of therapeutic substitution or therapeutic interchange.

I would hope that the basic tenets, though, are that we would have to admit that, although we have, as representatives of the Commonwealth, a lot of disparate interests to protect here, when push comes to shove, the final, absolute responsibility we have is to our patients. But, we need to acknowledge that there are other interests at work.

Second, we need to admit that when everyone switches drugs or starts a new course of medication with a different medication or a new medicine, there is some risk. It may be very small. It may be very significant. But there is some risk.

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But, on the other hand, we've heard testimony to the effect that there are potentially many positive things that can happen with the type of switches that can occur in a well-managed formulary system, and those could include increased quality, decreased side effects and, hopefully, decreased costs.

I actually have read a huge portion of the data presented to me, and I agree that we're not going to be able to agree that those studies show us the answer one way or the other, and I am adamantly of the opinion that the Harvey Morgan Study will shed some light on this, but it is not likely to tell us everything we need to know to either bless or condemn a practice in general. And I think we need to get on with the realization that there will be no magic study forthcoming, and that we're being asked to proceed with honesty and openness and a concern for the Commonwealth to come out with some sort of a report.

I think we do have a few things that we've reached a consensus on and would like to be able to say the Task Force reached consensus on. One was definition of therapeutic interchange, and the other, as I've read through both sides'

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documents, I don't find any contention necessarily with the managed care contention. I'm going to quote from several of the documents, "A well-developed and well-managed formulary may enhance quality of patient care by encouraging physicians to prescribe medications that are safe, effective, and likely to produce the best possible outcomes. Such a formulary may help patients and physicians to have access to the best and most effective drugs on the market."

I would like to hope that we could conclude that. Nevertheless, it seems to me that the public seems worried about the process. Its concern that it may affect patient outcomes; it may increase patient inconvenience; it may undermine the professional trust placed in doctors and pharmacists, and I think we have debated at length the relative values of those worries, and we may not agree on the level that we should attach importance to those. But, I think we need to make some sort of statement about the practices in general without micromanagement.

So, my recommendations are as follows, and you should have them in front of you: "Recommendation 1: Regulations should be adopted by the Board of Pharmacy to make it unethical and

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inconsistent with the accepted practice of pharmacy for a pharmacist to contact a physician to encourage a therapeutic interchange." That's the purpose for the contact. Unless the initially-prescribed drug is not on the patient's formulary or there is a patient safety issue involved, going on to say, "Supporting legislation should be introduced, if necessary. The regulations or legislation should also capture out-of-state pharmacies, to the extent possible." And, "Additionally, the regulations should apply to chain pharmacies whose policies attempt to direct their employee pharmacists to make unethical contacts with physicians."

I should apologize from the very beginning. This is written without the benefit of a lawyer or legislative services. The purpose here is to try to prohibit the types of kickbacks or significant financial inducements for a pharmacist to contact a physician.

It is, as we discussed last time in testimony, it is unethical, in many cases illegal, for a physician to accept significant monetary inducements in order to prescribe one company's drug over another, and I think the public very strongly is in favor of that and would not want it any other

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way. It seems inconsistent with me that if there is a soul left in the practice of pharmacy, that the pharmacist would want to protect this ethical relationship.

In all the discussions we've had, the only person, other than the physician, who has an "ethical relationship" with their patient as opposed to a business relationship, is the pharmacist that has been protected through a lengthy history from the Board of Pharmacy. It seems to me that the Task Force would want to find it, though, a preferable approach compared to the bill last year that tried to define what unacceptable behavior was and got into trouble, quite frankly, because it is next to impossible to go down the list and try to determine everything that might be conceivably deemed to be objectionable. It might be simpler for the Board of Pharmacy to handle this instead of us, and for the Board of Pharmacy to try to determine and define exactly what are acceptable methods of contact.

Nothing in here would prohibit anyone from contacting, for the purposes of generic substitution. It would not place limitations on the free speech of any of the pharmaceutical companies, PBMs, HMOs or patients to contact me as a physician

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for any of these reasons.

I would know where those calls are coming from, and would be expected to handle them ethically and appropriately. The patient certainly can contact me both for medical reasons and cost reasons.

"Recommendation 2, the General Assembly should request the Virginia Department of Health... to include pharmacy issues, (including therapeutic interchange issues.) in its proposed areas of quality and access assessment of managed care organizations under the directives of," I believe it's called "HB 2785 from last year. Such a standing body must possess the requisite power to certify and decertify the health care delivering systems overseen by it." As you may know, that particular Bill authorized the Department of Health, in conjunction with the Insurance Commission, to begin a process whereby a standing regulatory body would exist where appeals could be made and issues like this could be resolved in a manner that both protects patients and is consistent with allowing the industry the flexibility to continue to change as the marketplace changes and as scientific evidence changes.

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In particular, we have heard testimony on this subject. In the materials that were provided in several situations, but, in particular, in April, 1997, report from the United States Office of the Inspector General, revealed to me a surprising lack of oversight over PBMs, much more oversight over the HMOs than there are over the PBMs. They clearly say that the pharmacy benefit management companies have emerged as significant players, and I did not hear anybody refute their findings that, among other things, the HMOs' biggest concern about PBMs is their result in potential bias from their alliances with pharmaceutical manufacturers.

The Inspector General this year said that HMOs rely primarily on PBM supplied data and reports for overseeing PBMs and HCFA and State Medicaid agencies provide minimal oversight over these services. They have gone on and recommended for both Medicaid and HCFA that policies be adopted Federally and Statewide to provide oversight over the PBM portion of the health care they deliver and the HMO contracts with respect to pharmacy benefits. It seems consistent with that, that this Task Force would find that there is a need for oversight but not a need for statutory, point-by-point micromanagement

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recommendations coming out of this Task Force.
Such approach, to me, would provide a reasonable level of citizen protection again retaining the flexibility that might be lost through some sort of legislative approach. Consistent with the idea that we'd like to see the private sector take on more of those problems and solve them before we end up having to meet like this over and over again, I've made Recommendation 3, which asks, as an official request, I guess, from the Task Force, that the Virginia Association of HMOs should consider promptly adopting a strong and meaningful position statement on the inappropriateness of unduly encouraging therapeutic interchanges for patients already on clinically effective drug therapies when the patient is changed from one insurance company to another or the formulary changes. And, as Dr. Hadley was discussing before, we have heard testimony from several high quality and financially successful HMOs that allow such grandfathering and find such policies to be both medically and economically supportable.
Not all of these plans, however, have such a grandfathering clause in them, and those that do not do not all make it convenient for either the patient or the physician or realistic to expect

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grandfathering to be allowed. But, the Task Force felt that the medical and public relations issues involved here are fairly clear, and it would hope that the Association could see this as the type of issue about which it could get involved with providing a private enterprise solution as is so often recommended.
And, we would applaud the VAHMO for its acceptance of this challenge to demonstrate that it's newly-adopted national policy called "Putting Patients First," is the meaningful type of policy that the Task Force members assume that it is. And the Task Force would encourage other parties to take on more issues like this in a nonlegislative arena.
And finally Recommendation 4, which tries to tie all this together, suggests that "Legislation should be introduced to attach medical liability to those entities that provide pharmacy benefits covering a list of drugs more restrictive than the PDR. Now, PBMs operating outside of Virginia would be appropriately captured by this legislation." Now, obviously, any acting formularies that we're talking about here provide benefits for drugs, the drug list, less than PBM.

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The Task Force, though, is very sympathetic. I've heard from all ends of the table that the free market should be allowed to solve many of these problems. Many Task Force members have expressed the opinion that the free market will ultimately come out with the right solution. People won't buy their products if the solution is not of the right quality. They won't buy them if they're not of the right cost. But the Task Force should be of the opinion, also, that to be valid, all of the major forces that apply in normal checks and balances of the free market system need to apply here.
Tort liability, as hard as this is for a physician to say, tort liability in America provides one of the essential checks and balances for those persons making decisions in the marketplace. Shielded from liability, people are likely to be inappropriately cavalier in making decisions that affect their fellow citizens. And no one would suggest removing that liability from physicians.
Now the Physician's Desk Reference, the PDR, represents a listing of virtually every medicine available to physicians to treat human diseases. It's a list. It's composed entirely of those medicines carefully determined by the United

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States Food & Drug Administration to be both safe and effective in the treatment of disease. Any formulary system more restrictive than the PDR, would certainly limit the options available to patients and physicians. It's not necessarily bad, but it does, you have to admit, it limits their options.
Now, multiple documents provided to me and the Task Force indicate that no matter how restrictive the formulary is, physicians will acquiesce to the managed-care's directives and write more than 95 percent of all prescriptions on the formulary. One most conclude that the promulgation of these restrictive formularies represents a de facto practice of medicine and/or pharmacy that Ms. Russell spoke about earlier.
If it does represent the de facto practice of medicine, and you can conclude that these promulgations by the PBMs, basically, affect and determine the care of the drugs that a patient receives, and, as such, it seems logical to the Task Force that some appropriate amount of liability should be incurred in making those decisions. Without such legal exposure, the actions of the members and members of the PBM committees could be inappropriately cavalier with respect to the health

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of patients.
The Task Force, though, does feel, should feel, that such liability exposure would not burden inappropriately the managed-care firms operating in Virginia for several reasons. You can't argue with the fact that malpractice premiums would add somewhat to the cost of doing business. That this is a burden that is incurred by everybody who is involved with the delivery of health care, everybody else who is involved in the delivery of health care in the State of Virginia. The Task Force felt it unlikely that other health care providers would successfully escape liability, simply by claiming that it would add to the cost of health care.
The Task Force should acknowledge that many of the decisions made in formularies are actually based on safety issues and appropriate issues regarding cost. And the Task Force does not seek to impugn restrictive formularies. But, it's important to remember that the HMO industry endorses the statement that, and we quoted this earlier, a well-designed and well-managed formulary enhances the quality of patient care, et cetera. The Task Force assumes that HMOs with their prodigious ability to evaluate massive amounts of quality outcome data

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would be unlikely to create anything other than a well-designed and a well-managed formulary. The expected real liability exposure here resulting from a quality formulary should be slight, predictable, manageable and affordable.
Mr. Chairman, these recommendations try to do several things. Maintain the ethical relationship between pharmacists and patients. They begin to provide reasonable oversight and accountability to those systems orchestrating health care in the Commonwealth. They try to engage the managed-care industry in solving some of the perceived problems outside of any legislative arena, and they encourage the increased alliance in the free market system as opposed to piecemeal legislative solutions to health care debates.
I would suggest that the indented portions of Mr. Jenkins' Recommendations Number 1 and Number 3 would be very appropriate to attach to my four recommendations. And, Mr. Chairman, I respectfully submit these recommendations to the committee as a formal recommendation.
CHAIRMAN TEEFEY: Are there any discussion on the recommendations? That's a foolish question.

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Senator Newman?
SENATOR NEWMAN: Well, I'll go first. But, I think this amply represents one side of the debate, quite honestly. I think this represents what one side has been saying and that is that the Bill that was introduced by Senator Hawkins, basically, should, in some form, be adopted. But, we go further than that, and we go into medical liability, which I think has an interest. But, we certainly haven't even discussed that point hardly at all to come up with a recommendation that we move in that direction. In my opinion, if we were to move forward with this, we are moving forward with a much more stringent request than that which came to us from the General Assembly.
I think it's put forward in good faith. I have become a friend of my seatmate over the last few days and months, almost a year now, but I think that it would be unfortunate if we were to take the information that we have gotten thus far and have this apply, as a result.
Let me give you an example. I am deeply concerned that if you have an insurance change in Number 1 -- Is it Number 1?
MS. PIGG: Number 3.

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SENATOR NEWMAN: Number 3. --if you have the insurance change, you no longer could have the opportunity, given what is going on in Number 1, to call that doctor back and get the proper coverage that's necessary. If we are going to have an ability for a pharmacist at least to call the doctor, make sure that they're having that option to call the doctor and say, this medication is not going to be covered, instead of leaving that patient out in the dark, let us work on another, toward another goal or another drug so that we can get a proper drug, this will make that difficult.
And, the last point I will make about this is there is some dismissal on the idea of contracts. But, I think the General Assembly has often struggled with the idea of having the best practice of medicine versus the money that it will require to do that.
We have, on a very limited basis, said that the minimum drug standards that we're going to impose or the minimum amount of insurance that someone can provide has been raised very, very carefully over the years. Every time we do that, the fear always is, if we do that too much, the people who are the poorest, the companies who are the

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poorest are going to drop off the bottom.
My concern is, if we go with the approach that is presented here, I think it will represent the largest change that the General Assembly has ever requested and may very well have the worst effect on the low incomes that are, and the lower-end jobs that are right now teetering on whether or not their insurance company, their insurance is going to be continuing. So, I have, specifically, a lot of other little concerns. But, on a holistic basis, I think this is good argument for considering continuation of the study.
CHAIRMAN TEEFEY: Mike, you have some comments?
MR. AYOTTE: Yes. I have a concern with Recommendation Number 1. As a pharmacist, I think that, and with Dr. Dalton's earlier conversation, the conversations between the pharmacist and the doctor keep them in the loop. When something occurs that, A, may save a patient some money or may be beneficial to the patient is completely taken out and "made in an unethical contact," I think that the triangle of health care is there. For eight, nine years now the pharmacist has been one of the most respected professionals. I

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think you're making him, in the eyes of the world, a criminal, a money grubber. I just think that if the doctor has the ultimate control and can say yes or no, and the pharmacist uses good decision-making processes and doesn't just make that call, which I don't think is happening, I really believe that we can go with just the current Board of Pharmacy issues that protect the patient and give the doctor that control and make the pharmacist call the doctor, but loop in those people that don't have current control of the Board of Pharmacy.
I would think that the original one that takes in out-of-state prescriptions would help us more there because that seems to be the area of the most concern.
CHAIRMAN TEEFEY: Any other comments?
DR. HADLEY: Mr. Chairman. I agree with Senator Newman. I think I would have a very hard time supporting Recommendation Number 4, the issue of medical liability to PBMs. I mean, we haven't even discussed that issue, and I think it is a complex one. And, to bring that up at the Eleventh Hour seems to me to be inappropriate and it would be difficult to support that.

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With regard to Recommendation 3, again I would ask, and let me make two comments on that. Is it really appropriate for this Task Force to make recommendations to the General Assembly about a private association? Now, having said that, this issue is, in fact, being discussed. We had a committee meeting just last week with the Medical Directors and the Virginia HMO Association in which this issue and all aspects of the therapeutic substitution interchange was discussed. So, I think that that issue is being appropriately dealt with. We have presented a survey to show, in fact, that those that have closed formularies have the appropriate appeal mechanisms, and we think that this issue will be appropriately handled there.
But, beyond that, I think the other problem with making Recommendation Number 3, again, as we've talked about in more than one context, the managed formularies and, you know, formulary benefits are not just coming from the HMOs. We're probably in the minority of this, if you look at the volume of drugs that are coming across on that. Again, we talked about some of the employer-specific plans. More and more -- I have just got a survey that shows that the

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employer-specific plans are gradually increasing. Many of the PBOs, what they call in certain indemnity programs of which I have no idea how many millions of people would be covered in the Commonwealth of Virginia, many of them have managed formulary benefit programs.
So, merely to single out the Virginia HMO Association and say they're the only ones that have to deal with this issue, what the circumstances are under which you should allow, shall we say, exceptions to the formulary and allow these transition kinds of issues, just doesn't get at the heart of the problem. Because, again, this problem, this issue goes way beyond the Virginia HMO Association. So, again, I think I'd have a very difficult time supporting Recommendations 3 and 4 for those reasons.
CHAIRMAN TEEFEY: Dr. Blanchard.
DR. BLANCHARD: My assumption was, there would be more than two people taking pot shots at this. But, if I can rebut them to some extent or at least discuss them as they go along, it might help. With respect to singling out the Virginia Association HMO, I view this in a different light and that is that there has been lots of lobbying, to me,

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that this whole process of therapeutic interchange on people that are already on medications should be legislated by this Committee, and I feel very strongly that we should try to avoid that. And, I would--I don't know about the appropriateness of how you word a recommendation.

CHAIRMAN TEEFEY: Can we hold it up for one second while she changes her paper.

NOTE: (Brief pause while the Reporter adds paper to her machine.)

CHAIRMAN TEEFEY: Thank you, Dr. Blanchard.

DR. BLANCHARD: Additionally, I'm fully aware that the HMOs are not the only people dealing with this issue, and I harbor no feeling, but they're the worst offenders at all. The intent here was to try to find a private sector association that could set the standard of response to an issue that is becoming increasingly prevalent in the public's eye and see if they could come up with suggested policies that they could try to get consensus among their reputable members that might be used as an example to follow by other deliverers of health care.

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Inasmuch as the HMOs could set the standard of appropriateness for this, and inasmuch as that could be found to be acceptable whenever that policy is developed to people on the other side, you have avoided legislation, and, you, as a General Assembly, you have the ability to hold over any other health care delivery systems of, you know, at least the potential threat of legislation if you don't get your act in gear and have a decent policy. I see from my interactions with the VAHMO an expressed sincere desire to be proactive on these subjects and not to be waiting for things to blow up in the public's perception, and waiting for people to start bringing down to the legislature all sorts of examples of patients that have been injured or inconvenienced or hurt or whatever.

So I don't throw this out as a tainted gauntlet. I would hope that you would see this as an attempt to take some of these things out of the legislative arena in good faith. I, with respect to the stuff in Recommendation 1, I'm not a pharmacist. I have my opinions on what ethics ought to apply to pharmacists, and I also would like, outside of this regulatory body, this legislative body, to have the Board of Pharmacy decide how

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important ethics are and how to define that. This whole issue of exactly what is an appropriate contact and what is an appropriate reimbursement as opposed to a kickback or whatever terms, we have a very difficult time, depending on the needs to be dealt with, which the pharmacist, first, if they don't do it in a way that is appropriate and accepted by the public, then there will be a degree of loss of trust, public disgust and a demand for legislative solutions.

By sending it to the Board of Pharmacy as a recommendation, my assumption is they do not have to adopt what we send them. There is flexibility there, and it just expresses the opinion that you need to come up with some way that allows patients to communicate with doctors in the best interest of their patients and that may include costs, but in a way that the pharmacist and the patient feels comfortable with and is not tainted by inappropriate hidden financial agendas. And I don't pretend to be able to define exactly what those hidden ones are, but it seems not to be very difficult for the public to decide what it is in my case.

So, again, I'm trying to keep

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that from being legislated by us or defined by us. I know that doesn't please the people who would like it defined immediately.

MR. AYOTTE: And, if I may, Mr. Chairman?

CHAIRMAN TEEFEY: Yes.

MR. AYOTTE: I agree. I think the Board of Pharmacy has the ability to do that and can set those standards. I just want to go back to the point where, for the patients of Virginia that are serviced out of pharmacies in Virginia, they have the Board of Pharmacy that regulates the pharmacists of Virginia and the doctor has the final say over any therapeutic interchange in Virginia. You know what I mean? There is that link. I think what we're missing is what happens outside the borders of the Commonwealth.

DR. BLANCHARD: And that's why I suggested Number, whatever it is, 3 from Mr. Jenkins, which tries to capture that as best as I have seen that worded.

Now, with respect to Recommendation 4, I think we have been talking around the lines of, this is in the contract. We ought to be able to use our responsible P and T committees to set

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these policies. We acknowledge that whether it's the patient's choice or the doctor's choice, it ultimately ends up determining the care that the patient gets. But the following sentence is always, but we don't really practice the medicine, the doctor has the final say. It may be appropriate to change Recommendation 4 to have the Legislature study the appropriateness of any legislation regarding the liability of it.

I have circulated an article in Monday's Business Section of the Times-Dispatch by Jane Bryant Quinn, I think, talking about the changes across the Country with respect to managed care occurring and some degree of liability. Threatening somebody with liability is not the same as trying to put people out of business. It's simply a question of trying to keep people appropriately accountable. I have also read in the past two weeks several legal theses about the changing nature of the degree to which this and the stuff determined by the Department of Health, if they have a supervisory role, and its relationship with ERISA plans.

There is a growing body of legal case law that is beginning to apply general public safety issues to what previously have been ERISA

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protected plans. I don't know which way that is going to go, of course, in their own thing. But, to simply say that we should not proceed in any path because it is ludicrous because it won't cover Medicaid, it won't cover Medicare and it won't cover ERISA, fails to take into account that you've, at least, set the stage appropriately for what we do control and other forces will determine what other programs are covered.

CHAIRMAN TEEFEY: But, I think we still have to keep two things in mind. I think we have got two pictures here. We have got one picture that we're talking about switching drugs, therapeutic drugs, because it's not on a formulary. And, if it is on a formulary, we are talking about switching the drugs. I think we're talking about two different things. If it's not on the formulary and the pharmacist calls back and that drug is not covered, that's one thing. If it is on the formulary and the pharmacist calls back and the drug is covered and he wants it switched, that's another situation.

The problem is, I'm sure, and, in the original Bill, if there was any type of financial strings to that drug, I am sure, in every formulary, that the HMOs, the PBMs deal with pharmaceutical

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companies and on their formularies they have drugs that they get at a discount. Now, is that a kickback or is that a discount?

The other thing is, if a drug is on a formulary and the pharmacist tries to change that drug because the pharmacist is getting a kickback, that's another thing. But, the more I hear in here, and I am talking from a layman's viewpoint, now, I'm not talking as a pharmacist or a doctor, and I think I'm probably the only layman up here, but I have one lawyer up here. He's going to defend me. The only thing I'm trying to say is, is the problem as big as we think it is because are most of the switches related, are most of the requests for switches related, because the drug is not on the formulary, and, therefore, they're trying to get a drug for the patient that is on the formulary? I think that's one case.

But, I think we've got to separate those two things, because I have a feeling that a small fraction of the switch requests are requests that a person wants to switch a drug that's already on the formulary. And, I think, when we look into the final report, and I don't know, and I don't think we're going to know that until after we get the

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study back that Senator Newman was talking about. I think if we jump to conclusions and make recommendations, I'm not sure that the recommendations, when we get back to the General Assembly and discuss this next year, if we do make a recommendation, if it's going to hold any water, and I think we will have wasted the whole time that we have spent here by jumping to conclusions in making recommendations.

I just, I keep hearing that and I keep hearing the conflict, is it really switching when it's not on the formulary and the person is going to get nothing? And then when Jimmy said, it shines a whole other light on this thing, that we have businesses and we have businesses that have their own formularies. They come up with their own programs. And do we have any control over that anyway? So I think we've got a bushel of a lot of appeals here.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, Senator Newman.

SENATOR NEWMAN: I'm sorry. I'm wondering if, and this is somewhat of a proposal. I'm glad to see at least we get proposals, even

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though I may disagree with the broad nature of this, I'm wondering, Mr. Chairman, if we may hear from, maybe in a five-minute form, the proponents and opponents of this proposal that are out there. At least, we get the benefit of their input on it, and then we can discuss it. And let's vote and see what we think about this so that we can move on.

CHAIRMAN TEEFEY: All right. We have one person from each side. Do you want--

MS. PIGG: Can we take a break?

CHAIRMAN TEEFEY: Yes, can we take a break and let me choose --

MR. COUNCIL: Could I ask Dr. Blanchard one question, because I had to have heard this wrong? I think you said, Dr. Blanchard, something to the effect that the formulary de facto became the prescription because of 90-some percent acquiescence by the physician? I'm sure I didn't get that right. What was the comment?

DR. BLANCHARD: That's pretty close.

DR. PYLES: That's pretty close.

DR. BLANCHARD: The studies I have seen show that whether formulary is minimally restricted or tremendously restricted, doctors end up

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having their prescriptions okayed or originally written 95 percent of the time on formulary. So, whereas they may prefer to have some other drug, because of the pressure of either the patient saying, I don't have it covered or the pressure of HMOs evaluating what percentage of the time you write on formulary or off formulary, you end up writing, according to the directive of the PBMs formulary decision. And, in essence, that does determine the drugs the patient ends up getting, because the doctor is basically stuck in the position of picking from the drugs from that company.

MR. COUNCIL: Isn't the corollary, I mean, assuming the physician is doing his job, isn't the corollary that in ten percent of the cases it is very significant to the patient and those are the ones where the doctor would not approve the switch?

DR. MOFFATT: Five percent.

MR. COUNCIL: Five percent, okay.

DR. BLANCHARD: My only other comment, Joe, from your comments was, that the purpose of Recommendation 2 was to admit that we're not going to solve the issue and somebody ought to be able to look at it over time and determine whether

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these issues are very prevalent and as big as we're making them out to be here, and it may not be.

CHAIRMAN TEEFEY: Yes. All right. We're going to take a break.

NOTE: At this point, a recess was had from 10:35 a.m. to 10:46 a.m., whereupon the hearing proceeded, viz:

CHAIRMAN TEEFEY: All right. Let's get started again, if we can. All right. We're going to have Mr. McArthur and Mr. Jenkins respond to the Doctor's proposals. And who wants to go first? Oh, I'm sorry, Wyatt.

MR. JENKINS: I'll be happy to. Thank you, Mr. Chairman and Members of the Task Force. My name is Matt Jenkins, and I am retained by Rite Aid. But, as many of you know, I have been functioning somewhat as a coordinator for an ad hoc coalition of persons and entities that are concerned, and I want to be careful, as I make these remarks, that I don't purport to speak for persons who haven't authorized me to do so. But, in deference to the Chair's wish that we try and do this one side to another, I will ask the indulgence of those entities

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on whose behalf I have been communicating, and if they disagree with what I say, they are free to please note that.

I'm responding somewhat to Dr. Blanchard's proposal on the fly, having only seen it this morning. But, I have several concerns about the appropriateness of these as recommendations to be adopted by the Task Force, and I will tick them off in numerical order.

I'll point out that the first recommendation, if I read it right, would make it unethical and inconsistent with accepted practice of pharmacy for a pharmacist in Virginia to call a physician and inform the physician that the drug he has prescribed for the patient, cash-paying patient, is much more expensive than a therapeutically interchangeable alternative and would the physician wish to know that, because the patient might otherwise not elect to have the prescription filled. And the Chair noted earlier that the one person about whom we most wish to remain concerned is the right of the individual.

It seems to me that this recommendation, if adopted, is going to take away an important element of communication that enables the

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customer, that patient, to make an informed decision whether to acquire the drug or forego the drug therapy, especially for those cash-paying patients who aren't on a prescription benefit plan and for whom the cost of the drug may determine whether they take the drug. It seems to me that it ought not be a crime, if you will, for a pharmacist to provide that valuable information.

The second recommendation, it seems to me that if the Virginia Department of Health wants to look at pharmacy issues within the ambit of their overall charge of looking at quality and access issues, then that's fine. I'm not sure I agree with the second sentence that indicates that that standing body must possess the requisite power to certify or decertify health care delivery systems. That seems to be a rather extreme power, the right to put someone out of business, and one that we would relegate to a carefully structured and appropriately configured body. Presently, it's my understanding that insurance plans and HMOs that are regulated by the Bureau of Insurance enjoy all sorts of procedural rights before the State Corporation Commission, and I wouldn't want to openly endorse a process of certification and decertification in any sort of star chamber fashion.

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With respect to the third recommendation, I think that Dr. Hadley's comments and the comments of others have indicated that the Virginia Association of HMOs is, as a body, on top of this issue, and is, as a body, looking at best practices within the industry, and, as a body, will probably find that those who practice the best practices are probably going to be the most financially successful. And, I think, as in life, and so is true in business, imitation is a sincere form of flattery and it's also a way to fund profitable behavior and emulate it. And, from what I understood earlier, there are HMOs that are attacking this problem, and they're finding it to their benefit and the benefit of their members to deal with this.

With respect to the fourth recommendation, I am astonished by this recommendation in that what Mr. Council said earlier, I think, rings very, very true. If we wish to see entities running away from the provision of any type of benefit, put them in the line of fire on liability. If you wish to impose upon entities that prescribe--that provide prescription drug benefit plans, the liability for the way that plan works, the employer is not going to provide that plan. They just

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won't. Why provide it? Why step into that line of fire?

The PDR is a big and thick book. The existence of formularies, particularly in hospitals, particularly in well-established and long-running HMOs, indicate that P and T committees have determined that you don't need the entire PDR to treat most decease states. There are always going to be exceptions and a rational process should provide for exceptions. But, if we are to indicate that you have got to put a PDR on your prescription drug benefit plan or you're going to be in the line of fire for any alleged proximately caused adverse outcome occasioned by the failure to dispense some drug that was noncovered, those benefits are going to vanish. I can't guarantee it. I can predict it as a virtual certainty.

So, it seems to me that of the recommendations that are out here, Number 1 is antipatient and antichoice and anticonsumer.

Number 4 is antiVirginia business and is going to lead to a diminution of prescription drug benefits in the Commonwealth, if passed.

And, the second and the third are not really recommendations that do much other than, I

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think, send a message that people ought to be thinking about this in the private sector and, to my knowledge, they are.

Thank you.

CHAIRMAN TEEFEY: Thank you, Mr. Jenkins.

Mr. Durrette?

MR. DURRETTE: Thank you, Mr. Chairman and Members of the Committee. My name is Wyatt Durrette and, along with Ken McArthur, we represent a group of independent pharmacies in Virginia. I speak for them, and I think, in part, for the Virginia Pharmacists Association. But, like Mr. Jenkins, I am looking at these recommendations for almost the first time. I was able to glance at them last evening.

Ken McArthur has been covering this hearing, as all of you know, and has spoken to you on several occasions, and so I have talked with him about this and want to make just a couple of observations.

I am going to start inversely from Mr. Jenkins and talk about the fourth recommendation first, because ironically, I have been spending most of my time over the last few weeks and

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will be for the next few weeks, representing a Virginia business in a malpractice suit against a law firm, and I am the trial attorney. So, the issue of liability attached to making decisions that have consequences for people's lives is one that needs to be seriously considered, whether or not you adopt a recommendation or a recommendation that it be studied. Those who make decisions in the marketplace, effectively de facto decisions, that have consequences, need to be held accountable.

Now, they can be held accountable by Government or they can be held accountable in the private sector. But, part of being held accountable in the private sector is being financially responsible for those decisions if a Plaintiff can prove, in a Court of law, that those decisions proximally caused harm. Now, if it is correct that physicians prescribe from the formulary in 95 plus percent of the time, then the formulary becomes, de facto, the controlling authority for the prescription that's written. If the physician overrides it, nobody has to worry about it. But, to the extent that that has become the decision because the physician is busy, the pharmacist is busy, the appeals process is too protracted and too prolonged or for whatever

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reason, then, if there is harm to the consumer, to the patient, why shouldn't the one who made the decision be accountable? At least a recommendation to look seriously at that ought to be made.

Now, Recommendation 1, to go back to that, and to go to, first of all, to Matt's comment regarding the cash-paying patient, I think he's right. I think Recommendation 1, as written, would affect a phone call that ought to be made and would make that unethical. I don't think the Board of Pharmacy would literally do that. So, I would suggest that you look at Number 1 and that you either consider broadening it or make its language more general so that the Board of Pharmacy can look at the practice of pharmacy from the standpoint of its ethics and how appropriate conduct by pharmacists would influence the communication between pharmacist and physician.

Now, in that regard, let me say that while we believe these proposals, to some extent, move in the right direction, we believe they have some shortcomings, and so we don't, I don't necessarily bless them all enthusiastically. But I do believe that this Task Force needs to come forward with some kind of recommendations, if they can reach

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a consensus, on something. Remember, however, that what motivated those of us who promoted this legislation originally and accepted this Task Force as a compromise was not because the individual pharmacist in his or her store, whether it was a chain store or a community pharmacy, was creating the problem associated with therapeutic interchange or drug switching. It was the corporate entities that were driving the practice.

Whether they were PBMs, whether they were HMOs, whether they were the new arrivals to the drug-switching marketplace, chain drug stores, no matter which corporate entity it was, it was those corporate entities driven by the profit motive, which all of us who believe in the free market endorse the profit motive, but we know from a long series of legislation from antitrust laws to preventing drive-through mastectomies, we all know that Government regulates the profit motive, to some extent, when it's in the public interest to do so.

So, don't lose focus on the fact that it's not the individual pharmacist standing behind the counter that is driving this practice. It is the corporate entities who stand to profit from this practice that are driving it. And let that be

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part of your thought process.

Finally, with regard to the Recommendation Number 2, I think that given the changing nature of the marketplace, the moving target that all of this has proven to be over time, the fact that the marketplace, as we know it today, is not the same marketplace that it was last year at this time, and it won't be the same one next year at this time. So, having the appropriate regulatory body look at these practices with respect to governing them and regulating them and licensing them seems to me to be a step in the right direction.

With respect to the certification and decertification, that's no different than licenses that anybody has. If you're licensed by a regulatory body, you're expected to conform with the standards associated with your license, and, if you don't, you lose it. And if you don't have that enforcement mechanism, it's a toothless tiger. So, I think Recommendation Number 2 is solid, and ought to be passed.

Finally, Number 3, I would have -- I would make it broader. I don't think there is any -- The HMO Association probably is of less concern to many of us than the pharmacy benefit

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management firms. They have an association. So I would say for Number 3 that, perhaps, it needs to be more generic, maybe naming no association in particular, but encouraging all associations that have for its, for their membership, companies who engage in this practice to do what Recommendation Number 3 anticipates or have the General Assembly consider it.

So, Mr. Chairman, those are my comments.

CHAIRMAN TEEFEY: Thank you, sir.

MR. COUNCIL: May I just ask Mr. Durrette a couple of questions?

CHAIRMAN TEEFEY: Can I ask one question on liability? And I know we have a lot of lawyers in here. Let's say that I'm a company and I set up a drug benefit for my employees, and I leave a drug off of there. And what we're saying in here is, if I leave that drug off, then I am liable? I could be liable for leaving that drug off, because it's in the PDR?

MR. DURRETTE: Well, the question--

CHAIRMAN TEEFEY: Let me ask you--

MR. DURRETTE: Just one second,

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though.

CHAIRMAN TEEFEY: Yes.

MR. DURRETTE: The question, who do you attach that liability to? I would not, when I say I have mixed emotions about all this, I would not attach it to the employer. I think all of us know I think this is the real world. The real world is that the employer contracts with the PBM or an HMO and there may be formulary in existence at that time. I don't think anybody for that employer knows what drugs are on that formulary or off that formulary. And that formulary is only going to last for three months or six months until some manufacturer gives that, whoever creates that formulary a better deal, and then it's going to be a different formulary than the manufacturer got at the time of the contract, and he ain't going to have any idea what the employer got at the time of the contract. He doesn't have any idea what's on the formulary. So, I would not extend the liability to the employer, but to whoever makes the decision to say you can have this drug, but you can't have that one, unless you pay for it.

CHAIRMAN TEEFEY: All right. And let me put one other picture out here. Suppose, I

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have an automobile and I have air bags on both sides of my automobile. I have another automobile that has air bags on one side and not on the other. If I have an accident and the passenger in my car is killed, is the manufacturer responsible? You're saying, no, the manufacturer is not responsible. Well, I'd stop selling that car if I was the auto dealer, because what we are saying is, if I make a decision not to have a drug on a plan, and I pass it off to the person that's selling that product and handling that product for me, then that person is liable for that product. I think we've got to look at the air bags on automobiles.

You know the person bought that automobile, I don't think that the manufacturer is responsible and I don't think the dealer is responsible because that person bought that automobile that only had an air bag on one side. I think we're talking about the same thing here as we're talking about automobiles, as we're talking about drugs. And, Number 3 really worries me. And that's why I want it, because I know Matt made an inference to it.

MR. DURRETTE: Number 3?

CHAIRMAN TEEFEY: Number 4.

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MR. DURRETTE: Okay.

CHAIRMAN TEEFEY: The liability. And, you know, I just wanted to bring that out about the air bags, because I think we're talking about the same thing.

MR. DURRETTE: Well, I don't, if you want me to, I could talk for about ten minutes on the difference between your hypothetical on the air bags and the drug-switching program from the standpoint of a lawyer, but I don't know that that's profitable. They're not the same thing, and they would not have the same liability consequences.

CHAIRMAN TEEFEY: It's both. It's both health.

MS. WARRINER: Mr. Chairman, point of question. I think you were, and maybe I'm wrong and maybe Dr. Blanchard can clear it up, I don't think it was talking about full liability, Joe. I think they were talking about a shared liability. Right now they hold no liability.

CHAIRMAN TEEFEY: No, I don't think you're right, Cindy. I don't think you have shared liability. I think the one that has--somebody ends up with the full liability.

MR. DURRETTE: Well, in most

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instances it's shared. There is a concept called joint and several liability and sometimes it applies and sometimes it's doesn't. But, usually, anybody that's-- It depends on all the facts and circumstances of what you're talking about. But, most of the time there is going to be more than, it could be more than one person liable. And, in this particular context, the pharmacist may have a liability, individually, and his corporate employer may have liability. The physician may have liability and, under certain circumstances, depending on where the Courts go, the corporate employer may have liability. And the question is, should anyone else have liability in this chain?

And, all Number 4 suggests is, is that if the decision is initially driven by somebody who chooses this drug on and this drug off, and, down the chain, at the end, the patient suffers harm, why should liability stop where the decision began in the first place? Why shouldn't that decision-making process be included in the liability chain?

CHAIRMAN TEEFEY: But you still go back to my air bag. That's the same situation with my air bag. I wear two hats. I have another hat that I have 850,000 people uninsured, and we have been

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battling for years as to how to get 850,000 people insured. I don't want to create a situation where I'm going to have six million people uninsured. You know, I have people right in this room that speak to the people that are uninsured, that are speaking to this with the possibility of putting more people on the uninsured list, and hypocrisy is not real good. You can't sit, you can't have it both ways, and that's why I brought out the situation with the air bags. I mean, I just don't want us to get into a position where we force more people, where we force companies to drop insurance or pharmacy benefits. Because here are these same people that are fighting for certain things in here always talking about pharmacy benefits where there are not enough, they need more, et cetera, and that's why I brought out my air bag situation, because I think it is the same thing we're talking about.

MR. COUNCIL: A couple comments, if I may, Mr. Chairman.

CHAIRMAN TEEFEY: Yes, sir.

MR. COUNCIL: I know Mr. Durrette said that he is just seeing this language, and he would make modifications to it, also. But, that's not what Recommendation 4 says as it's written. I

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mean, it clearly pulls in the plan sponsor. It would make him liable. The sponsor is the one that's providing the pharmacy benefits, and I reiterate what I said earlier on this morning. I think any kind of legislation like this can only reduce the number of employers that are going to be willing to undertake this liability and provide a benefit. I would, secondly, say as to PBMs, for all that they're being hammered about some of their practices here, the general thought, as it was my impression, was that PBMs, in fact, have done a lot of good in delivering pharmacy benefits.

I cannot imagine that a PBM can charge somebody six cents to process a claim and undertake this kind of liability. I mean, it is going to dramatically change the industry, and it's going to have a negative long-term consumer impact.

MR. DURRETTE: Mr. Council, if what you say is true, then there must be a horrible risk to the public associated with drug switching, because there would have to be a lot of injuries and a lot of lawsuits and a lot of claims. So if you're right that creating liability for the consequences of drug switching would put PBMs out of business and drive up the cost of health care and eliminate

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pharmacy benefit programs, then there are a lot of injured people walking around out there because of this practice who now don't have the right to sue.

MR. COUNCIL: Well, now you're suggesting that intelligent companies don't look around and try and waive risk before they're sued themselves, and I don't think that's so.

MR. DURRETTE: I'm saying there isn't the risk right now because there is no liability for that practice.

MR. COUNCIL: Another comment I'd just like to make, and this has been said a lot here. I would agree that a plan sponsor may not know what particular drugs are on or not on a formulary. But, I think it's a real misperception to think that the PBMs are undertaking these practices without the plan sponsor's knowledge and consent. I'd just cite a couple of examples. The last four State employee plans that I have seen go out for request for proposals, one of the first things in the cost section they want to know is how much of the rebate am I going to get? And what they're hoping you're going to do is you're going to respond, we will give you a hundred percent of the rebates. They are fully aware of what's going on in this field. Medicaid,

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it's my understanding they get a hundred percent of the rebates.

So, I can't tell you what's on my plan's formulary in terms of one drug versus another. But, the employers that are paying for those plans have a good general idea about what's going on in relation to formularies and rebates. In addition to that, there have been recent cases interpreted in Department of Labor Regulations that basically say, the failure to disclose what rebates are received and whether they're shared back with the plan sponsor can have serious consequences. So, I can't give you statistics. But I don't think it's accurate to suggest that intelligent corporate employers who are offering plans don't have a generally good appreciation of what's going on in terms of the administration of those pharmacy benefits.

MR. DURRETTE: I didn't intend to say anything and, if I did, I misspoke, to suggest that the employer would not generally know that there was a formulary program and generally know that drugs were on and off the formulary and that there were price consequences associated with that. I think, of course, they know that. I was only commenting on whether they know the specific drugs that are on the

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formulary at any one time.

CHAIRMAN TEEFEY: Senator Newman?

SENATOR NEWMAN: That's fine. He made the point.

MR. DURRETTE: Is that it?

CHAIRMAN TEEFEY: You know, I lived through the original Bill, and I think we've changed the original Bill now. From what I'm hearing now, we are saying that you can't have formularies.

MS. PIGG: No.

MR. DURRETTE: Well, I don't think I've said that. I didn't intend to say that.

CHAIRMAN TEEFEY: Well, either what we're saying is if a drug is not on the formulary, and you don't switch the drug, and you're called in to switch the drug, and the doctor says, no, you can't switch that drug and that formulary doesn't--and that person doesn't fill that drug, then I as the employer can be sued for that. I think we've changed the whole road now. We were on 95; now we're on 64.

MR. DURRETTE: Without air bags. I guess, to some extent, we're speaking our personal opinions here. Personally, I would not make the employer incur liability for the reasons that I have

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stated. I don't think the employer is involved in the decision as to which drug is available and which drug isn't. So, to the extent that Proposal 4 extended to the employer, that would be one of the things that I might disagree about. Because I don't think the employer makes the decision. And, in order to be accountable legally, I think you have to make it, you have to consciously or carelessly do something that causes harm to someone else. I don't think the employer does that.

Now, Recommendation Number 1 contemplates a formulary, Joe.

CHAIRMAN TEEFEY: Before you go there on that, let's say we take the employer out, and we do leave the PBM in there, and they make a decision that that's not on the formulary. Aren't you still saying we're eliminating formularies?

MR. DURRETTE: No, I don't think so. Recommendation Number 1 specifically allows and approves, ethically, a contact by the pharmacist if the drug is not on the formulary to generate the change to a formulary drug. So, Recommendation Number 1 accepts formularies and accommodates them.

Recommendation Number 4 simply recognizes, I think, whether you actually recommend

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it or whether you just recommend that it be studied, it seems to me that it reflects the marketplace. The marketplace already, in almost every instance that we know of, doctors, pharmacists, automobile manufacturers, automobile operators, chain drug stores, everybody, if they do something carelessly or negligently that injures another person, all of us every day of our lives are accountable in the Courts of America if we do that.

CHAIRMAN TEEFEY: Right. And I understand that.

MR. DURRETTE: But what we have here, in the present real world, are people who are making those decisions that have those consequences who do not share that accountability with others.

MR. COUNCIL: Does it make a difference if really all they're saying is we will not pay for it? Does that have any impact on your position on that?

MR. DURRETTE: Uh-huh. That's all they are saying.

DR. HADLEY: That's right.

MR. COUNCIL: That's right. And yet they would still be liable.

DR. HADLEY: The PBMs or the HMOs

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do not make prescribing decisions; those are made by the physicians. All these kinds of decisions are to say this is the group of drugs that either are or aren't covered. It's the physicians who make the prescribing decisions.

MR. DURRETTE: But, we know--

CHAIRMAN TEEFEY: That's why I say I think we've changed the game plan I thought we came in here to talk about, and that's why I brought out a little while ago, we're talking about two different situations.

The first situation is, it's not on the formulary, that's it. The other situation is, it is on the formulary and the pharmacist calls in to try to switch to a drug that's on the formulary. I think we have a problem there.

MR. DURRETTE: And I agree with you. I thought that that delineation was a good one, and I agree with you that that situation is perhaps a more serious situation than the formulary.

CHAIRMAN TEEFEY: Yes. And then I go back to Senator Newman's recommendation that we wait until the PBM study comes out, because I don't know how many switches are one or how many switches are the other. I think we don't know how many

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switches are because it's not on the formulary and how many switches are on the formulary, and we have got, and please take this with a grain of salt, greedy pharmacists.

MR. AYOTTE: I don't take that with a grain of salt.

MR. DURRETTE: Well, remember again that Recommendation -- I think you have to look at Dr. Blanchard's Recommendations in their entirety. I would suggest, for heaven's sake, don't get hung up on Recommendation 4. I mean, things with regard to Recommendation 4 are going to come to the General Assembly whether this Committee says or does implement it or doesn't. There are other people who have an interest in the area covered by Recommendation Number 4, and you can bet your bottom dollar that the Virginia General Assembly is going to get legislation extending liability corporately to HMOs and PBMs. That's coming. Everybody knows it's coming. So, Number 4 is not the heart of this.

Number 1, Joe, contemplates the existence of a formulary and says it's okay to make the phone call. It's okay if the drug isn't on the formulary. So, Number 1 tries to accommodate the real world where formularies exist and where pharmacists

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are called upon to make those phone calls.

CHAIRMAN TEEFEY: Okay. I --

DR. BLANCHARD: Mr. Chairman?

CHAIRMAN TEEFEY: Yes.

DR. BLANCHARD: I'm a little confused, having not sat in this position before, about the process. But the spirit with which my recommendations were given were the assumption this was going to work in a situation where the Task Force members will try to decide what, if any, parts of recommendations are what they would like to accomplish, can they be rewritten in a way that works better, and in normal parliamentary procedure you may extract proposals. You can extract single items out of that. Perhaps, for purposes of discussion, we might extract Number 4 and start getting some feedback on the other proposals on what the Task Force feeling is. Otherwise, we're never going to get to vote on this up or down.

CHAIRMAN TEEFEY: All right. Well, let's do this. Let's vote on the proposal to start with.

SENATOR NEWMAN: The entire proposal?

CHAIRMAN TEEFEY: The entire

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proposal to start with.

All of those in favor of the proposal, say aye.

DR. BLANCHARD: Excuse me. We are voting on the proposal without a chance to amend the proposals in light of the comments?

CHAIRMAN TEEFEY: Well, then we're going to bring the proposal up. We're going to bring that up. You have presented a full proposal to us, and I want to deal with the full proposal first.

All in favor of the full proposal, say aye.

NOTE: (Affirmative response.)

CHAIRMAN TEEFEY: Raise your hands, please. One, two, three, four.

All opposed. One, two, three, four, five--

CHAIRMAN TEEFEY: The opposed have it.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Okay, Senator Newman.

SENATOR NEWMAN: I don't want to

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limit the debate, and we'll go down whatever processes this committee decides to do.

Wouldn't this have been a great place to start in May, because now we're talking about some things that have some relevance and some proposals back and forth. I've looked at the out-of-state dispensing idea, and maybe that's a good idea, too. But, the discussion we just had on four, we can have on one, two and three, and I may even agree with part of them and disagree with other parts, Mr. Chairman. But this is not in the last meeting, at almost noon, on this last day, the type of recommendations I think we want to give to the General Assembly.

I believe that it might be of some value to step back now and say, let us work in conjunction with the Morgan Study. Let us come up with some recommendations next year that we can have confidence in, that we have thought through.

Mr. Chairman, on that basis, I'd like to make a motion that we continue this study until next year, ask the General Assembly to do so with the current makeup of the study, and coordinate our study with the Morgan Committee.

CHAIRMAN TEEFEY: Do I have a

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second for that motion?

MR. AYOTTE: Second.

CHAIRMAN TEEFEY: Is there any discussion?

DR. DALTON: Yes, there is. I think that we need to start somewhere, and I think that the situation is a dynamic one. When the Morgan data comes out, it's going to be dated. It's going to be reflective of percentages and numbers as they are right now. I think by our doing nothing, we're going to influence those numbers because these practices are going to change in the direction where abuses are going to be increased, if there is that window of opportunity that seems to be open to those who choose to take advantage of it. I think we need to have something concrete to come out, even if it's something that is not completed. But, I think that by our just saying, let's put it on the back burner, again, is not what I have been contributing my time for.

MR. COUNCIL: Mr. Chairman?

CHAIRMAN TEEFEY: Yes, sir.

MR. COUNCIL: If I may just make a couple of comments in favor of the motion. When this Task Force started, it struck me that I thought many

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people shared my view that, perhaps, the biggest problem was out-of-state pharmacists switching drugs without consulting with the physician. Now, we're at the final hour here, and I haven't even seen that issue addressed. If anything, Recommendation 1, while it says that out-of-state pharmacists should be made accountable to this regulation, would discourage them from consulting the physician.

So, it seems to me we've gone just about 360 from where I thought we were going to address what everyone considered one of the major deficiencies at the moment. So, I'm in favor of the motion, if for no other reason, than to give us the time to address the out-of-state pharmacy situation.

MS. PIGG: I just have a question to make sure we still have a problem.

Mr. Durrette, I heard you say that representing the independent pharmacists, that they agree or endorse the whole formulary concept, which has quality of care and financial consequences. So, it was my understanding, and maybe incorrectly so, that that was really the driver behind the whole proposed legislation that the pharmacist did not endorse the formulary concept if there were financial components.

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MR. DURRETTE: If I said it the way you just quoted me back, I didn't intend to say that the pharmacists endorsed the whole formulary concept. I did intend to say that these proposals accepted the formulary in the marketplace and approved it and allowed the pharmacist to make the call if the drug wasn't on the formulary.

A formulary, the language that Dr. Blanchard read when he was making his opening remarks, about formulary having to be put together with medical considerations to find the drugs that will be most effective, that work best for the patients and influence prescribing decisions along that line, is my ideal of the way medicine should be practiced.

But, to the extent that the formulary deviates from that and substitutes the profit motive of the decision maker, or the medical considerations and the enforcement mechanisms which are the switches to serve that motive, I don't think it's the way to practice medicine or to deliver health care.

CHAIRMAN TEEFEY: Any other discussion?

DR. BLANCHARD: Yes, sir. My

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comments are in the nature of an amendment to the motion. As I understand, the motion was to postpone this until or to continue this Task Force and reconvene when we have the results of the Morgan Study.

In addition to that, then, I would recommend that we adopt Mr. Jenkins' Proposal Number 3 in my Recommendation Number 2. The out-of-state dispensing issue is one that has come before this committee and does suggest that there is a practice going on in out-of-state pharmacies that the Board of Pharmacy is unable to regulate and requires legislative rectification, and it seems reasonable to me that we do not want therapeutic substitution, which is what this practice would be, practiced by out-of-state pharmacists on patients in Virginia.

In Recommendation 2, with or without the last sentence, it's your preference, would encourage the Department of Health in its current evolving structure to begin considering pharmacy issues. And, in doing so, they may actually solve some problems that we might have before us this time next year.

UNIDENTIFIED PANEL MEMBER: I

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second the amendment.

SENATOR NEWMAN: Mr. Chairman, I have some parliamentary questions.

CHAIRMAN TEEFEY: Yes. We have to vote on the first one first before we deal with the-- because we have a second to the-- Can we withdraw the second and deal with the amended motion?

DR. BLANCHARD: Only if passage of the one that says we will postpone the action of this committee immediately doesn't end the meeting, by itself. I feel a little under the gun if we have to sneak something in here.

SENATOR NEWMAN: That's a reasonable concern. And I say that we can vote on the measure that's in front of the table, and let's continue to have some discussion. Today was a good day. We talked about some things and partly because of what you brought to the table and what the other side brought to the table, we talked about some things that made a difference today. I don't agree with all of them, and maybe we've broadened it too far, but I think we can vote on the proposal that is on the table and then continue to have a discussion, because we're going to be here, I hope, long enough to help invent some cures to this.

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I don't know if you want to vote.

DR. BLANCHARD: All right. In that atmosphere, I withdraw my motion.

CHAIRMAN TEEFEY: Okay. Do I call for the question? All in favor say aye?

NOTE: (Unanimous affirmative response.)

CHAIRMAN TEEFEY: All opposed.

NOTE: (No response.)

CHAIRMAN TEEFEY: Okay. The ayes have it. We will make a -- We will do up our paper to the General Assembly. We will use the information that we have talked about today as some guidelines. We will deal with the study that the Pharmacy School is doing with the PBMs, and I would like to work with the Bureau of Insurance, also, I mean the Pharmacy Board, also, in our deliberations of these things, if we could work pretty closely together with you-all it would really help us. And, we will carry it over to next year.

DR. BLANCHARD: Mr. Chairman,

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obviously, in my discussions with my colleague over here, misinterpreted both your ruling and his interpretation, dramatically. His assumption or his statement that we would continue to have discussions on this implied today.

CHAIRMAN TEEFEY: Oh, okay.

DR. BLANCHARD: It also implied that motions for acceptance of additional items by the Task Force were not precluded.

CHAIRMAN TEEFEY: Okay.

DR. BLANCHARD: If for no other reason than being on the public record that this committee felt that way about some of these proposals.

CHAIRMAN TEEFEY: Well, I told you-all I wasn't a lawyer.

SENATOR NEWMAN: Mr. Chairman, in fairness to the gentleman, I think that my motion did include that as not only in the sense but also in words, that we would continue, since today has been a good day, to continue to discuss some of these items within the Committee, and this may be the first meeting of next year's continuing study, would not, anyway, do harm to the motion that was voted on unanimously.

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CHAIRMAN TEEFEY: That's fine. I didn't understand that. But, --

MR. COUNCIL: Is the expectation that we will periodically continue to meet? Is that what we're saying or not?

DR. BLANCHARD: No. My expectation is that we would vote on the motion that I proposed in the midst of his motion, having been advised that it was necessary to separate the two.

SENATOR NEWMAN: I'm confused, now.

DR. BLANCHARD: I attempted to make a motion that, included in our Task Force Report, would be a recommendation that legislation be adopted by the General Assembly that accomplishes what Mr. Jenkins has so eloquently pointed out in 3 Number B on Page 2 of his letter: "It is unlawful for any nonresident pharmacy to dispense a drug that is chemically dissimilar, without the prior approval of the prescriber or his lawful designee." I think this is something that this Task Force agrees on.

SENATOR NEWMAN: Which one?

DR. BLANCHARD: 3.

CHAIRMAN TEEFEY: Number 3.

DR. HADLEY: 3-B.

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SENATOR NEWMAN: Mr. Chairman, may I?

CHAIRMAN TEEFEY: Yes, sir.

SENATOR NEWMAN: I like the proposal, too, and it's something that the Doctor and I agree on, which is movement. I am still your friend and all those good things. But, I don't know if we do want a bifurcated statement going to the General Assembly now. But, if there is a, if we don't stop here, I think we're going to go down the rest of the list, is that the-- Are we going to go that far?

DR. BLANCHARD: Two. Two things. Move on and discuss them.

SENATOR NEWMAN: Well, Mr. Chairman, the will of the Committee. I don't mind Number 3, but I don't want to go down the list of the rest of them, either, because we have agreed that we are going to look at this holistically. So, I guess the will of the Committee, if they want to take up these items.

I hope that we don't get into a situation where we say we're going to roll it over, and we're going to offer a bifurcated message to the General Assembly, also.

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MR. AYOTTE: Mr. Chairman, can I ask a question?

CHAIRMAN TEEFEY: Yes, sir.

MR. AYOTTE: Scotti, is it the intent of the Board to look at this regulation for out-of-state dispensing one way or another? Or, are you looking for us to direct that?

MS. RUSSELL: Mike, this is not a -- It's not a regulation. It's a statute. The problem with the existing statute, not just this, is that the existing statute requires nonresident pharmacies to comply with the laws and regulations of their residence state. And I think that maybe better than this particular language might be the language, at least for the nonresident pharmacy portion of the draft we submitted last year, where what we do is require nonresident pharmacies to comply with the laws and regulations of Virginia, specifically. And that would take care of this and anything else that they happen to do that was a violation of Virginia laws or regulations.

So I would go with the more general approach than just this.

MR. AYOTTE: Would that be something that you would look to find, no matter

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what? Or is this --

MS. RUSSELL: Well, we've already submitted our administrative proposals for this Bill. And we, the Board of Pharmacy, would not be looking at this change for this particular legislative session. It's a little late. But that doesn't mean you couldn't recommend that.

CHAIRMAN TEEFEY: I think we're going to have a motion.

DR. BLANCHARD: My motion is dependent, though, on the answer to that question, to some extent, and that is, if we make such a recommendation to approve or to recommend a change such as what was just recommended, would the legislature be able to act on that this year or does it still have to go through your process first? Are you precluded from supporting it because you have already sent in your other stuff?

MS. RUSSELL: No, we're not precluded from supporting it. It just would not go in as an Administration Bill.

SENATOR NEWMAN: Mr. Chairman?

CHAIRMAN TEEFEY: Yes.

SENATOR NEWMAN: Could we then consider an amendment? I think you have agreed that

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we will only consider Number 3 of Mr. Jenkins' document as saying, we want to continue this study until next year, however, let us now-- We all agree. I don't think there is any disagreement. We can disagree on Number 2 of the other document. But, there is no disagreement on Number 3 of this one. However, we asked the General Assembly to deal with these out-of-state issues as embedded in Number 3. Is that reasonable?

CHAIRMAN TEEFEY: I think the Task Force can ask that in our report, and it can come up in General Assembly and support what they are doing as the Board of Pharmacy.

DR. BLANCHARD: I'd second that motion.

CHAIRMAN TEEFEY: Any discussion?

NOTE: (No response.)

CHAIRMAN TEEFEY: Call for the question. All in favor--

DR. HADLEY: Just a clarification.

CHAIRMAN TEEFEY: Yes.

DR. HADLEY: So, we'd only be

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voting for the Amendment 3-B of Mr. Jenkins', not Recommendation 2? Is that correct?

DR. BLANCHARD: Not Recommendation 2.

My recommendation to 3-B is sort of amended by Mr. Ayotte to include what Scotti Russell suggested.

CHAIRMAN TEEFEY: Right.

DR. HADLEY: Okay. I think we can support that.

CHAIRMAN TEEFEY: All right. All in favor, say aye.

NOTE: (Unanimous affirmative response.)

CHAIRMAN TEEFEY: All opposed?

NOTE: (No response.)

CHAIRMAN TEEFEY: Do we all know where we are now?

DR. BLANCHARD: We all know where we stand.

CHAIRMAN TEEFEY: Yes, sir?

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DR. PYLES: I just wanted to, as the Facilitator, make sure that we understand. I wanted to review real quickly what we'll be thinking about as we carry this over.

One of the things that was included in HJR 630 was that the Task Force would identify the components of the cost of this practice. So we need to be thinking about, as we carry this over, how we're going to go about identifying the components of cost and be able to make recommendations on those. And the other part of it was, to determine the impact of the practice on the health care and the affected professions and the overall cost of health products and services. So I think that, as we go forward and think about it, we need to be thinking about how we're going to do that, because that was a part of the resolution, as well.

CHAIRMAN TEEFEY: I think that's a good idea, Mike, and I think we're better prepared going into next year than we were coming into this year. It's a very, very complicated and convoluted problem.

I want to thank everybody on the Task Force. This has really been very, very difficult. And, I want to thank everybody on the

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Task Force.

Scotti, I just want to thank you and your staff for helping us out on this, and I want to thank the people in the audience, because I think now that we have really a beacon that we can follow. And, Scotti, I think you helped form this beacon.

I just want to thank everybody for the time they've put into this.

MR. SZALWINSKI: Mr. Chairman, if I might.

CHAIRMAN TEEFEY: Yes, sir.

MR. SZALWINSKI: One of the things that I would also suggest is that we began to characterize data as to how managed care prescription programs benefit the public, the way that they are currently administered. Because, again, I point to the IMS data. There is significant data out there to suggest that people with managed care get more prescription drug coverage than other folks, and that's a good thing. We need to keep that in mind.

MS. PIGG: I just have a question on how the governmental process works. So, we've recommended that the Task Force be continued to continue studying this. Does that preclude or is there the potential that folks that may not agree

with that that were not on this Task Force could submit legislation to this General Assembly?

CHAIRMAN TEEFEY: That can happen at any time.

MS. PIGG: Any time? And, of course, then, I guess you can come back and say there is already a study studying this?

CHAIRMAN TEEFEY: What we're going to recommend to the General Assembly is, we discussed this, and we didn't come to a conclusion and we think another year of study is important.

DR. BLANCHARD: Mr. Chairman, will we see the draft before it hits?

DR. PYLES: Absolutely.

CHAIRMAN TEEFEY: Yes.

DR. BLANCHARD: And, the second thing, Dr. Pyles, will you be addressing some of your cost issues or referring some of those to Delegate Morgan's Committees?

DR. PYLES: Well, that is one of the other things I think we have to clarify. We need to look at exactly what that study is going to do. As I recall, it looks at various aspects of PBMs, but not so much in the context of what we've talked about. So I think that, in the interim, before the

report goes out and we get a draft to you, perhaps we need to clarify and get to you what that study is expected to produce, and then we can go from there and get your comments in terms of how we can go about that, if that's okay, Mr. Chairman.

CHAIRMAN TEEFEY: That's fine.

Thank you all for coming.

NOTE: The hearing was concluded at 11:43 a.m.

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HEARING CONCLUDED.

CERTIFICATE OF COURT REPORTER

I, PATRICIA PRICE WHITE, hereby certify that I was the Court Reporter in the foregoing Hearing, when heard on the 17th day of September, 1997.

I further certify that the foregoing transcript is a true and accurate record of the HEARING herein.

Given under my hand this 22nd day of September, 1997.

PATRICIA PRICE WHITE, RPR, CP