REPORT OF THE
JOINT COMMISSION ON HEALTH CARE

ADHD Prevalence and Risks of ADHD Medications in Virginia

TO THE GOVERNOR AND

THE GENERAL ASSEMBLY OF VIRGINIA

REPORT DOCUMENT NO. 486

COMMONWEALTH OF VIRGINIA
RICHMOND
2018

Code of Virginia § 30-168.

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

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November 20, 2018

The Honorable S. Chris Jones
Chair of House Appropriations
Pocahontas Building, Room: W1312
900 East Main Street
Richmond, Virginia 23219

The Honorable Thomas K. Norment, Jr. and Emmett W. Hanger, Jr.
Co-Chairs of Senate Finance
Pocahontas Building, Room: E603 and E507
900 East Main Street
Richmond, Virginia 23219

Dear Delegate Jones and Senators Norment and Hanger:

Attached please find the Joint Commission on Health Care's final report on ADHD Prevalence and Risks of ADHD Medication in Virginia, as mandated by 2018 Appropriation Act- Item 28A.

If you have any comments or questions regarding this report, please do not hesitate to contact me.

Sincerely,

Michele Chesser

Michele Chesser, Ph.D.
Executive Director,
Joint Commission on Health Care

Preface

In 2017, HB 1500 (Item 30[A]) requested that the JCHC identify methods to: raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use; compile/track statistics on Virginia school children diagnosed with ADHD; limit antipsychotic use; and identify the incidence/prevalence of prescribing anti-psychotics for off-label use. HB 1500 was passed by the General Assembly and signed by the Governor on April 28, 2017.

The study found that ADHD, which is the most commonly diagnosed neurodevelopmental childhood disorder in the United States, incurs a number of adverse impacts that may last into adulthood. While evidence indicates that ADHD medications are effective in reducing ADHD symptoms in the short-term, longer-term effectiveness is less-well established. ADHD co-occurs with other mental health conditions for which antipsychotics are commonly prescribed. The study found that a variety of methods currently exist to both raise awareness of health/addiction risks of ADHD medication use and limit antipsychotic use. However, compiling and tracking statistics on school children diagnosed with ADHD is limited by ADHD's self-reported nature and identifying the incidence/prevalence of prescribing anti-psychotics for off-label use from administrative claims data faces logistical barriers.

Six policy options were presented for consideration by members of the Joint Commission on Health Care, who voted to take no action.

Joint Commission members and staff would like to acknowledge and thank those who assisted in this study including representatives from the Department of Medical Assistance, the Department of Behavioral Health and Developmental Services, the Virginia Department of Education, and the Virginia Department of Health.

The study and this report was assigned to and completed by Andrew Mitchell, Senior Health Policy Analyst at the Joint Commission on Health Care. He may be contacted at amitchell@jchc.virginia.gov.

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Executive Summary

In 2017, HB 1500 (Item 30[A]) requested that the JCHC identify methods to: raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use; compile/track statistics on Virginia school children diagnosed with ADHD; limit antipsychotic use; and identify the incidence/prevalence of prescribing anti-psychotics for off-label use. HB 1500 was passed by the General Assembly and signed by the Governor on April 28, 2017.

ADHD is the most commonly diagnosed neurodevelopmental childhood disorders in the United States, with an estimated childhood/adolescent prevalence of around 5%. With around 60% of those diagnosed with childhood ADHD experiencing symptom persistence into adulthood, ADHD has been found to have adverse impacts on health, academic achievement, employment and criminality.

Use of ADHD stimulant medications has risen dramatically in recent decades. While ADHD medications and psychotherapy have been found to reduce symptoms in the short-term, evidence of positive longer-term effects is less consistent. ADHD can cause short-term growth reductions in children, but longer-term effects on growth is less well-established and there is little evidence that ADHD medication use is associated with other health risks. Additionally, there is evidence that sizeable percentages of college-aged individuals misuse ADHD medications, although little evidence that addiction to ADHD stimulants is of widespread concern.

ADHD is one of the most common mental health diagnoses among youth prescribed atypical antipsychotic (AAP) medications. AAPs likely reduce conduct problems, aggression and clinical severity in children with ADHD, however, they are also associated with a variety of health risks. Virginia data from insured populations indicate that 30% to 55% of those prescribed AAPs did not have a FDA-indicated diagnosis for the prescribed AAP. Additionally, foster youth populations have historically had particularly high rates of use of psychotropic medications, including AAPs.

Methods to raise awareness of ADHD medications risks include FDA safety communications and pharmaceutical labeling regulations, as well as initiatives taken at some institutions of higher learning (e.g., ADHD medication contracts). Methods used by some States to track ADHD among school children involve collaborations between health and education agencies, although the quality of those data collected is unknown. Methods used by payers to limit antipsychotic use include service authorization (i.e., prescription pre-approval), peer review (i.e., manual clinician review of prior authorization requests), and Drug Utilization Review (DUR) Programs (i.e., a process conducted by all State Medicaid agencies involving prospective screening of prescription drug claims to identify potential problems and retrospective review of claims data). There are few established methods to identify off-label prescribing of antipsychotics from payers' data because diagnosis codes are not generally required data elements on prescription claims.

Six policy options were presented for consideration by members of the Joint Commission on Health Care, who voted to take no action.

ADHD PREVALENCE AND RISKS OF ADHD MEDICATIONS IN VIRGINIA

In 2017, HB 1500 (Item 30[A]) requested that the JCHC identify methods:

1. to raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use;
2. to compile/track statistics on Virginia school children diagnosed with ADHD or other categories such as "specific learning disabilities, other health impairment, multiple disorder, and emotional disturbances;"
3. used by other states/countries to limit antipsychotic use; and
4. to identify the incidence/prevalence of prescribing anti-psychotics for off-label use.

HB 1500 (Item 30[A]) indicated that the analysis shall be reported by the JCHC to the Chairmen of the House Appropriations and Senate Finance Committees no later than November 30, 2018. HB 1500 was passed by the General Assembly and signed by the Governor on April 28, 2017.

Background

ADHD is the most commonly diagnosed neurodevelopmental childhood disorder in the United States. Symptoms include an inability to maintain focus (i.e., inattention), hyperactivity (excessive movement that is inappropriate to the setting) and acting hastily in the moment without thought (i.e., impulsivity) (American Psychiatric Association 2018). Lacking widely accepted clinical biomarkers, ADHD is diagnosed through psychological assessment. In the United States, diagnosis is made on the basis of criteria specified in the Diagnostic and Statistical Manual of Mental Disorders (DSM), including an assessment of the extent/pervasiveness of impairment across multiple settings, collection of information from multiple informants (e.g., parents, teachers, other adults involved in the child's care), and an assessment of co-existing conditions (American Psychiatric Association 2012). Globally, diagnostic methodologies differ. Some countries (e.g., UK) have historically relied on the International Classification of Disease (ICD)-based "hyperkinetic disorder", which is a more restrictive diagnosis than ADHD. By contrast, ADHD diagnosis in other countries may be based on symptomology alone and not necessarily evidence of impairment in the daily environment (Thomas et al. 2015; Visser et al. 2015).

DSM criteria for the diagnosis of ADHD have evolved as the DSM has been updated. Five editions of the DSM have been published, successively expanding ADHD diagnostic eligibility. Currently, according to the DSM-V, diagnosis should reflect evidence of multiple symptoms before age 12 with clear evidence of impairment and ruling out other underlying conditions (American Psychiatric Association 2012). Table 1, below, summarizes the current criteria for an ADHD diagnosis.

Table 1. Summary of DSM-5 diagnostic criteria for ADHD

	Current diagnostic criteria (DSM-5)	Examples
	• 6+ symptoms of inattention (≥ 6 month duration) **AND/OR**	• Has difficulty remaining focused during lengthy reading
	• 6+ symptoms (≥ 6 month duration) of hyperactivity and impulsivity	• Often fidgets with or taps hands or feet or squirms in seat
AND	• Several symptoms present: before 12 years old; in >1 setting	• Symptoms present at home, in school
AND	• Symptoms clearly interfere with/reduce quality of functioning	• Symptoms affect social, academic, and/or occupational functioning
AND	• Symptoms do not occur exclusively during course of schizophrenia / psychotic disorder and are not another mental disorder	• Symptoms do not exclusively result from: mood / anxiety / personality disorder; substance intoxication / withdrawal

Source: American Psychiatric Association (2012)

ADHD Epidemiology

National/International Prevalence

Estimates of prevalence vary by source of reported diagnosis as well as within certain populations. ADHD is diagnosed primarily by primary care physicians (53%) and psychiatrists (23%) (Visser et al. 2015). While the American Psychiatric Association estimates childhood/adolescent prevalence to be around 5% (American Psychiatric Association 2012), estimated prevalence drawn from parental reports tend to be substantially higher (e.g., 11% in 2011 (Visser et al. 2014)). In older age groups, national survey data drawn from selected colleges and universities indicate a self-reported prevalence of 6.7% (American College Health Association n.d.), and other literature indicates an adult prevalence of 2.5% (Faraone et al. 2015). Certain populations in the U.S. are more likely to be diagnosed with ADHD than others, including boys and non-Hispanic Caucasians (Thapar & Cooper 2015; Centers for Disease Control and Prevention n.d.). Additionally, ADHD is associated with a high incidence of concurrent disorders, such as conduct, mood, anxiety, and substance use disorders (Larson et al. 2011; Gau et al. 2006).

There are long-standing variations in ADHD diagnostic prevalence at the State level in the U.S.. Based on the same parental survey data, for example, childhood ADHD prevalence in California has been estimated at 6% while that of North Carolina has been estimated at 15% (Hinshaw & Scheffler 2014). While exact reasons for variations in reported prevalence of ADHD are unknown, there appear to be several drivers, including: demographic differences among States resulting in wide variations in diagnosis; several schooling-related factors; and factors that come into play at the time of the diagnosis. Schooling-related factors include:

- Accountability laws: The implementation of the federal "No Child Left Behind" law was associated with 5.5 percentage point increase in ADHD diagnosis prevalence among low-

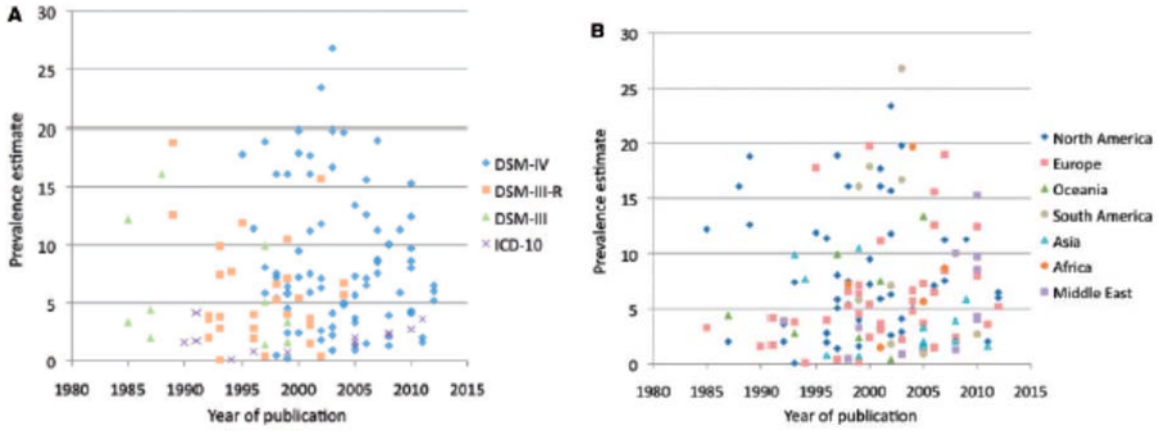
income youth populations in States without existing school accountability laws, rising from 10% to 15.5%; however, the result dissipated by 2011 and the transition to "Race to the Top" law (Hinshaw & Scheffler 2014).

- Psychotropic medication laws: There is some evidence that laws limiting school personnel recommendation of psychotropic medications and/or eliminating psychotropic medication use from school-level decisions is associated with lower diagnostic prevalence compared to no law (by 0.5% to 1% per year) (Hinshaw & Scheffler 2014).
- Relative school age: multi-country evidence indicates that children born just before school cut-off dates are 30% to 60% more likely to be diagnosed with ADHD/receive psychostimulants compared to those born after cut-off dates (Merten et al. 2017).

In terms of factors at the time of diagnosis, there is evidence that the evolving DSM criteria has resulted in an increased percentage of children meeting criteria for ADHD (e.g., 2% higher using DSM-5 vs. DSM-4 criteria) (McKeown et al. 2015). Additionally, research has found that ADHD diagnoses can be reduced by 50% when full DSM criteria are rigorously applied (Thomas et al. 2015).

Global estimates of ADHD vary as well, ranging from 3.4% to 7.2%, although generally reflect slightly lower prevalence than that found in the U.S.. (Thomas et al. 2015; Polanczyk et al. 2014). However, statistically significant geographic variations disappear if standardized diagnostic procedures are accounted for (e.g., consistent application of DSM or ICD criteria) (Polanczyk et al. 2014).

Figure 1. Global Point Estimates of ADHD Prevalence, by DSM version and Geography



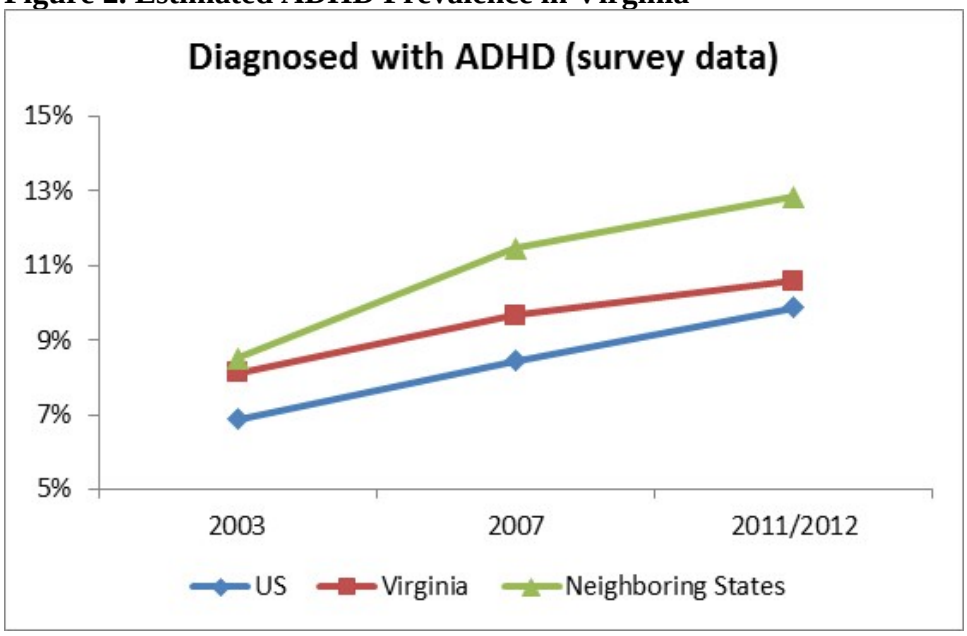
Source: Polanczyk et al. (2014)

Virginia Prevalence

Estimated childhood prevalence of ADHD in Virginia come from two main sources – surveys conducted by the Centers for Disease Control and administrative health insurance claims data – as well as data from the Virginia Department of Health (VDH). Parent-reported survey data indicates increased prevalence in Virginia over time, although the most recent estimates (2011/2012) are somewhat dated. While increased prevalence reflects national trends, prevalence in Virginia appears to remain lower than that of neighboring States (see Figure 2, below). Administrative claims data from health insurers in Virginia indicate a slightly lower diagnostic

prevalence among enrollees compared to the most recent parent-reported survey data from 2011/2012. Data from the commercial health insurance markets[i] (2014/2015) indicate a diagnostic prevalence of 6.9% to 7.8% among individuals younger than 20 years old (and 3.3% among individuals 20 years or older), while data from Medicaid (2014) indicate that 7.9% of children aged 4 to 7 (and 3.3% of adults 18 to 25) in Managed Care Organizations (MCOs) were diagnosed with ADHD (Virginia Health Information 2017; Hofford 2015). Finally, Virgina's Child Development Centers (CDCs) – overseen by VDH – offer one additional datapoint. In 2016, 1,081 children accessing CDCs were diagnosed with ADHD, representing 24% of diagnoses made. Generalizability of this datapoint to Virginia children more broadly is likely to be limited.

Figure 2. Estimated ADHD Prevalence in Virginia



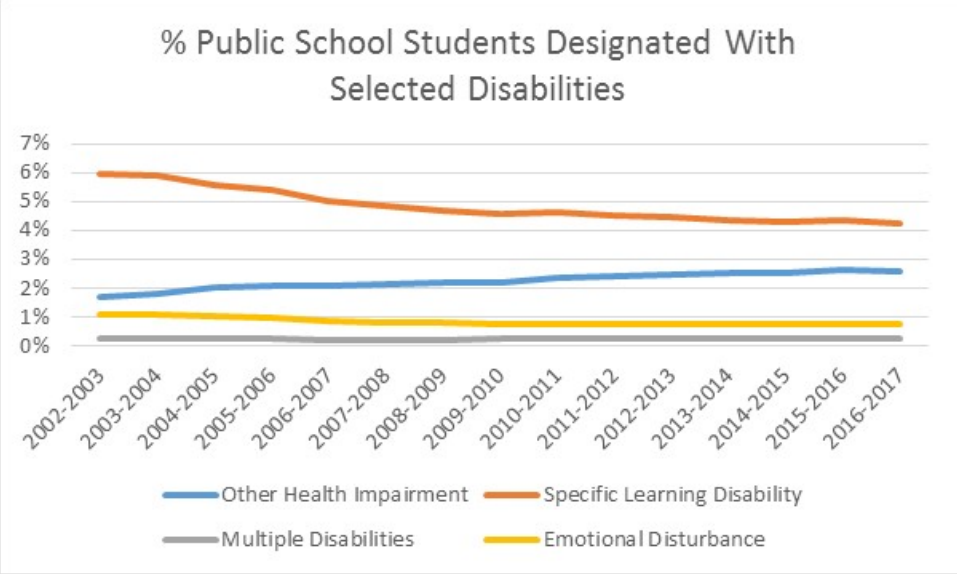
Source: Centers for Disease Control and Disease Prevention (CDC) (n.d.)

No data are currently collected in Virginia that can provide direct estimates of ADHD prevalence among schoolchildren. However, related data exist pursuant to two federal laws – the Individuals with Disabilities Education Act (IDEA) and the Rehabilitation Act – that guarantee that public school students diagnosed with disabilities are eligible for educational accommodations through Individualized Education Plans (IEPs) and "Section 504" plans, respectively. Under IDEA, ADHD is listed as an eligible disability in the "Other Health Impairment" (OHI) designation that also includes eight other conditions (diabetes, epilepsy, a heart condition, lead poisoning, leukemia, nephritis, rheumatic fever, and sickle cell anemia). While federal reporting requirements exist for maintaining statistics on schoolchildren receiving accommodations based on a disability status – including OHIs – these requirements do not include collection of data on ADHD prevalence. Data that do exist on OHIs indicate that between 2002 and 2017, the percentage of students designated with an OHI disability increased from 1.7% to 2.6% (see

[i] Data represent 100% of individuals covered by fully insured policies and an estimated 50% of individuals covered by self-insured policies.

Figure 3, below). Without ADHD-specific data, however, it is unknown the degree to which ADHD has played a role in the increase of OHI designations over time.

Figure 3. Estimated ADHD Prevalence in Virginia

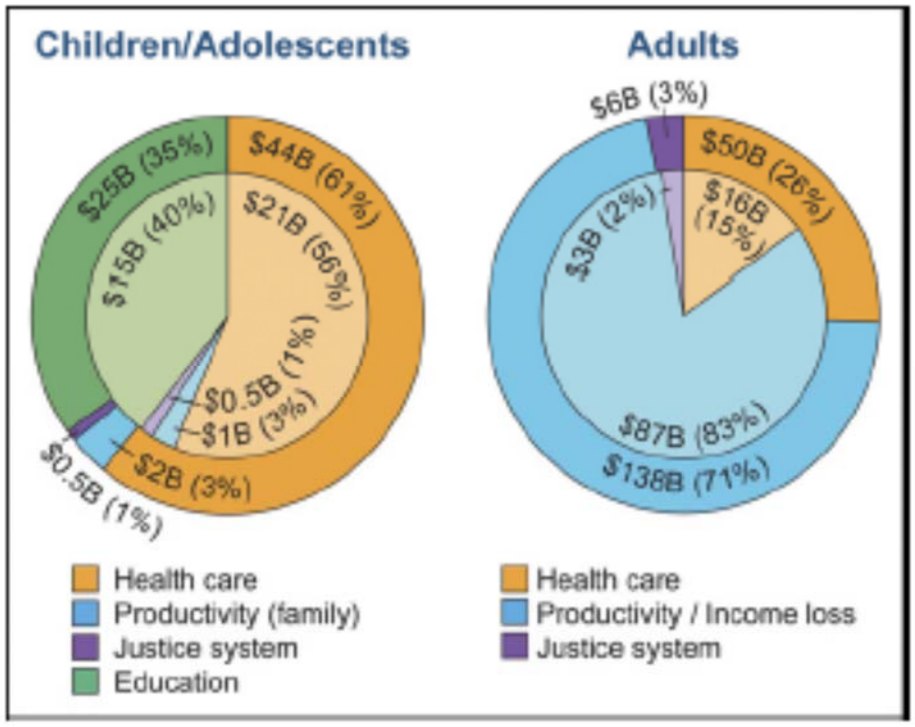


Source: Virginia Department of Education (2017)

Adverse Impacts of ADHD

While there are wide variations in estimates of ADHD symptom persistence into adulthood, evidence suggests a number of adverse impacts in terms of health, academic achievement, employment and criminality. Longitudinal studies of children diagnosed with ADHD and followed into adulthood indicate a wide range in ADHD persistence rates – from 5% to 75% (Sibley et al. 2016; Thapar & Cooper 2015; FARAONE et al. 2005). The longest-running US study on ADHD found symptom persistence of 60% and impairment persistence of 41% (Sibley et al. 2016). The wide variation in estimated symptom persistence is likely due in large part to variability in data sources (e.g., self-reported vs parental report), methods of data collection, and symptom thresholds used to define persistence (Sibley et al. 2016). Uncertainties in the degree of symptom persistence notwithstanding, research has found a number of adverse impacts in terms of health, academic achievement, employment and criminality, such as: decreased life expectancy; increased mortality risk by 50%; increased risk of vehicle accident by 36%; association with obesity (although mixed evidence); higher odds (3.7 times) of failure to complete high school; higher odds of unemployment and a 33% reduction in earnings; and increased probability (by two to three times) of arrests, convictions, and incarceration (Cortese et al. 2015; Curry et al. 2017; Dalsgaard, Østergaard, et al. 2014; Dalsgaard et al. 2013; Erskine et al. 2015)(Fletcher 2014; Mohr-Jensen & Steinhausen 2015; Nigg 2012). For the US as a whole, it is estimated that ADHD imposes costs to children and adults of $140 to $265B (see Figure 4, below) (Doshi et al. 2011; Hinshaw & Scheffler 2014). Direct health care costs predominate in childhood years, while costs to economic productivity dominate among adults.

Figure 4. Estimated Economic Impact of ADHD in the U.S.



Source: Doshi et al. (2011)

ADHD Treatment

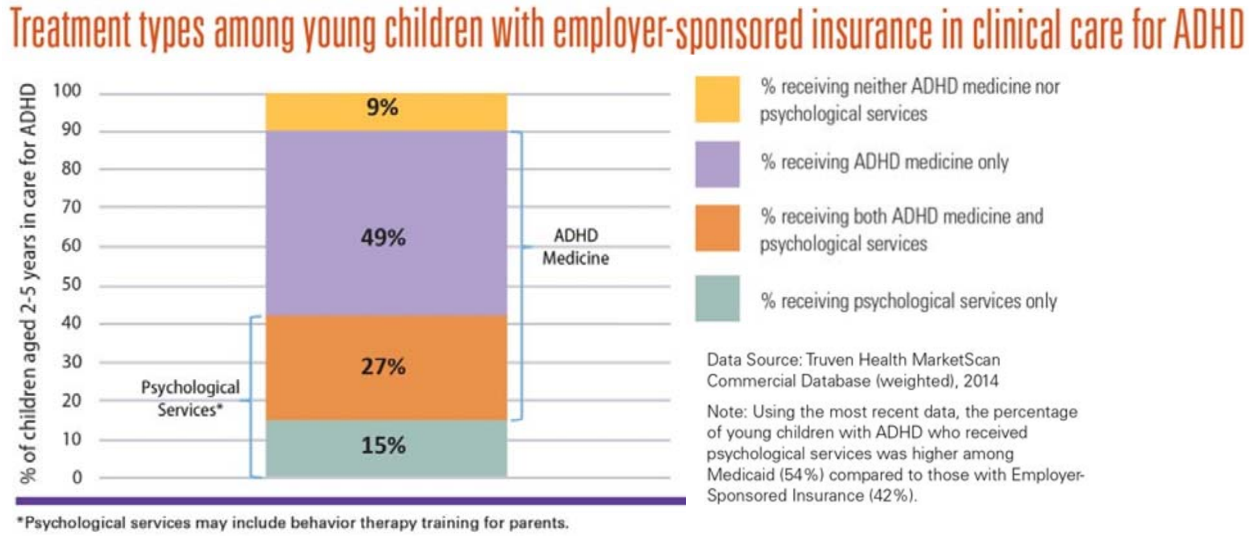
There are two main treatment options for individuals with ADHD: pharmacological treatments and psychological interventions. Stimulants constitute the majority of 1st-line medications used to treat ADHD, while non-stimulants are often used in cases in which stimulants are not effective or well-tolerated. There are currently 26 formulations of stimulant and non-stimulant medications targeting norepinephrine and dopamine that are FDA-approved for treating ADHD among varying age groups (3+ years old). There are also a variety of psychological intervention options which can involve services for both children and their parents, such as behavioral/cognitive interventions, parent training, and social skills training. In the U.S., the American Association of Pediatricians (AAP) recommends behavior therapy first for preschoolers under six years of age as the 1st-line treatment (and methylphenidate – a stimulant – if no significant improvement occurs), with medication as the 1st-line treatment from six years of age through adolescence (Subcommittee on Attention-Deficit/Hyperactivity Disorder Steering Committee on Quality Improvement and Management 2011). Globally, some countries provide differing recommendations, such as in the United Kingdom in which ADHD medication is never recommended for preschoolers (Murphy et al. 2013).

Medication Prevalence

Nationally, it is estimated that two-thirds to three-quarters of children and adolescents diagnosed with ADHD receive medications – in particular stimulants – while rates of uptake of psychological services are substantially lower (see Figure 5, below). Between 2008 and 2015, for example, 54% of Medicaid population and 45% of employer-sponsored population received

psychotherapy (Visser et al. 2014; Visser et al. 2016). Use of ADHD medications has risen dramatically in recent decades, with stimulant prescriptions tripling between 1990 and 2000 according to an analysis performed in 2009 (Hinshaw & Scheffler 2014).

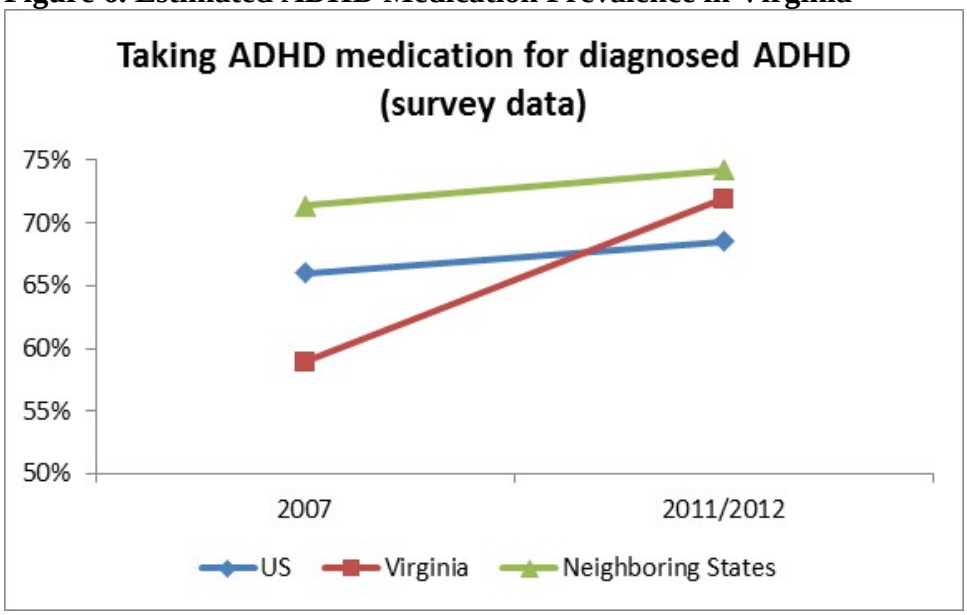
Figure 5. ADHD Treatment Prevalence Nationally



Source: Centers for Disease Control and Prevention (n.d.)

According to the most recent survey data from parental reports in Virginia, an estimated 72% of Virginia youth diagnosed with ADHD were taking ADHD medications in 2011. Both the level and increased prevalence of medication use since 2007 are consistent with data from neighboring States (see Figure 6, below).

Figure 6. Estimated ADHD Medication Prevalence in Virginia



Source: Centers for Disease Control and Disease Prevention (CDC) (n.d.)

Administrative claims data from insured populations indicate that, between 2014 and 2015 in the commercial health insurance markets, just over one-half (51% to 54%) of individuals younger than 20 years old who were diagnosed with ADHD were taking medication – a figure somewhat lower than that reported from the survey data described above. This equated to 4% of the total enrolled population in that age range. For adults 20 years or older, 61% to 64% of individuals diagnosed with ADHD were taking medication, representing around 2% of the total enrolled population in that age range. In the Medicaid population, around 7.4% of total enrolled individuals younger than 18 years old were prescribed ADHD medications in 2015 (1.2% of adults 18 years or older) (Virginia Health Information 2017; Hofford 2015). Finally, according to DBHDS 2014-2017 data, approximately 2% of the population across all facilities were prescribed ADHD medication while 15% of children at the Commonwealth Center for Children were prescribed ADHD medication (Department of Behavioral Health and Developmental Services (DBHDS), 2017). In the Community Services Boards (CSBs), between 2015 and 2017, 15% to 16% of individuals seeking any services had an ADHD diagnosis (Department of Behavioral Health and Developmental Services (DBHDS), 2017a).

Treatment Quality

Available data on treatment quality provide a mixed picture. On the one hand, recent assessments of clinical practice guidelines by Magellen of Virginia – the Commonwealth's Behavioral Health Services Administrator – suggest that there are areas in need of improvement in ADHD treatment among Medicaid-covered populations. According to Clinical Practice Guideline (CPG) reviews of 139 patient records conducted in 2015 and 2016, assessment scores for ADHD diagnostic and therapeutic practices – which relate to provider adherence to clinical practice guidelines – lagged behind those for three other behavioral health conditions reviewed (see Table 2, below).[ii] On the other hand, data from the Healthcare Effectiveness Data and Information Set (HEDIS) suggest that two indicators of quality – follow up for the MCO population during medication initiation and maintenance phases – are in line or above the national average (see Table 3, below).

[ii] Examples of clinical practice guidelines not adhered to by 50% or more of providers in records reviewed include the following. Diagnostic assessment: if provider is not a physician, reviewed findings from consultation with psychiatrist or primary care physician; Considered partial remission (fewer than full criteria met when full criteria were previously met); Considered whether few/many symptoms are in excess of those required to make diagnosis of ADHD; Coordinated care with medical provider/medical evaluation during diagnostic process ruled out medical causes of symptoms of ADHD and assessed cardiovascular functioning; If suicidal thoughts or behaviors were present, appropriate actions were taken to intervene; Therapeutic interventions: if referral for a medical/psychiatric evaluation, provider included the results of evaluation in the treatment planning; Conducted education about ADHD/treatment including psychological services/pharmacological intervention; Co-morbid medical and psychiatric conditions discussed with parents, guardians, and if applicable patient; Provider assessed if psychotherapy is indicated.

Table 2. Clinical Practice Guideline Review results

Assessment	CPG Provider Assessment Score <=3: Adherent; >3: Not Adherent	
	2015	2016
Suicide Risk	2.5	1.1
Major Depressive Disorder	3.2	2.5
Schizophrenia	4.7	1.4
ADHD	6.8	6.6

Source: Magellan of Virginia (2017); Magellan of Virginia (2016)

Table 3. ADHD Follow-Up Care

Phase	Virginia	US average
Medication initiation	44%	42%
Medication continuation / maintenance	56%	52%

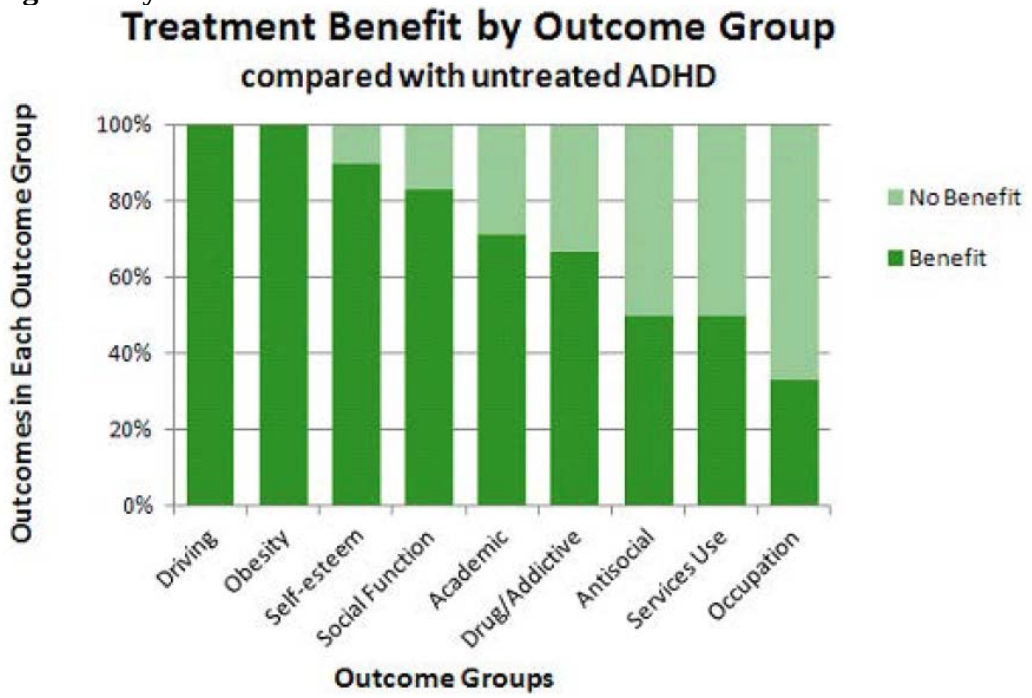
Source: Department of Medical Assistance Services (2017)

Treatment Effectiveness

There is consistent evidence that – in the short term – ADHD medications reduce core symptomology (e.g., 20% reduction in ADHD rating score (Chan et al. 2016)) and, when combined with psychotherapy, pharmacological treatment improves a variety of outcomes, such as behavioral co-morbidities, academic achievement and social functioning (Charach et al. 2011)(Hinshaw & Scheffler 2014; Punja et al. 2015). However, these findings have not gone unchallenged, with a recent meta-analysis assessing the strength of evidence as low, primarily because of several previous studies of effectiveness have received funding from pharmaceutical companies or authors reported potential conflicts of interest (Storebø et al. 2014).

Over the longer term, some reviews have found benefits of ADHD medications on multiple long-term outcomes, while others have found that initial associations between ADHD medication use and improved outcomes dissipate over time (Arnold et al. 2015; Shaw et al. 2012; Storebø et al. 2014)(Charach et al. 2011). For example, one systematic review found most studies reporting benefit of ADHD medications for multiple long-term outcomes (Shaw et al. 2012) (see Figure 7, below), and a 10-year longitudinal study of the South Carolina Medicaid population found ADHD medication to be associated with reduced Sexually Transmitted Diseases by 3.6%, Substance Use Disorders by 7.3%, and becoming injured by 2.3% (Chorniy & Kitashima 2015).

Figure 7. Systematic Review of ADHD Treatment Benefits



Source: Shaw et al. (2012)

However, three years after enrollment in a landmark 14-month Randomized Control Trial on ADHD (the Multimodal Treatment of Attention Deficit Hyperactivity Disorder study), no significant differences were detected on ADHD symptoms, other behavioral symptoms, or on functioning (e.g., grades earned in school) between children treated with ADHD medications and those not treated (Molina et al. 2009). Additionally, a natural experiment study from Canada found little evidence of positive effects on schooling attainment over the long term from ADHD medications (Currie et al. 2014). It is unknown the degree to which diminished long-term effectiveness reflects long-term efficacy of the medication itself, variations in provider prescribing practices over time, and/or varying patient practices such as medication adherence.

ADHD Medication Safety

As highlighted by the Food and Drug Administration (FDA) through multiple communications and "black box" warnings on manufacturers' labels, use of ADHD medications incur potential risks to patients.[iii] Studies generally find increased risk of non-serious adverse events (AEs) from stimulant use (e.g., decreased appetite, GI pain, headache) (Storebø et al. 2014). However, follow up periods in these studies are typically short-term, and one review of pediatric populations found that a large number of individuals drop out of studies on AEs, which may result in underestimation of AEs associated with ADHD medications (Aagaard & Hansen 2011). Additionally, concerns have been raised that authors of studies assessing safety of ADHD medications have interests that may bias their results (Storebø et al. 2014).

[iii] See Section on Methods to Raise Awareness of ADHD Medications Risks for more information on FDA safety communications and black box label warnings.

Figure 8. Common Side-Effects of Selected ADHD medications

	Methylphenidate (MPH)	Atomoxetine (ATX)
Loss of appetite	+	+
Growth restriction	++	+
Other gastrointestinal symptoms: abdominal pain, nausea, vomiting, diarrhoea (MPH), constipation (ATX), dyspepsia, dry mouth	+	+
Increase in blood pressure and heart rate	+	+
Cough, nasopharyngitis	+	--
Sleep disturbances	++	+
Tics	+	--
Irritability, mood changes	+	+
Drowsiness	+	++
Dizziness	+	+
Headache	++	+

+=common side-effect. ++=if the side-effect is common for both drugs, the effect is more pronounced for this drug compared with the other. --=side-effect not common.

Table: **Some of the more common side-effects associated with pharmacological treatment**

Source: Thapar & Cooper (2015)

Research on other health effects of ADHD medication use paints a similarly unclear picture. Findings include:

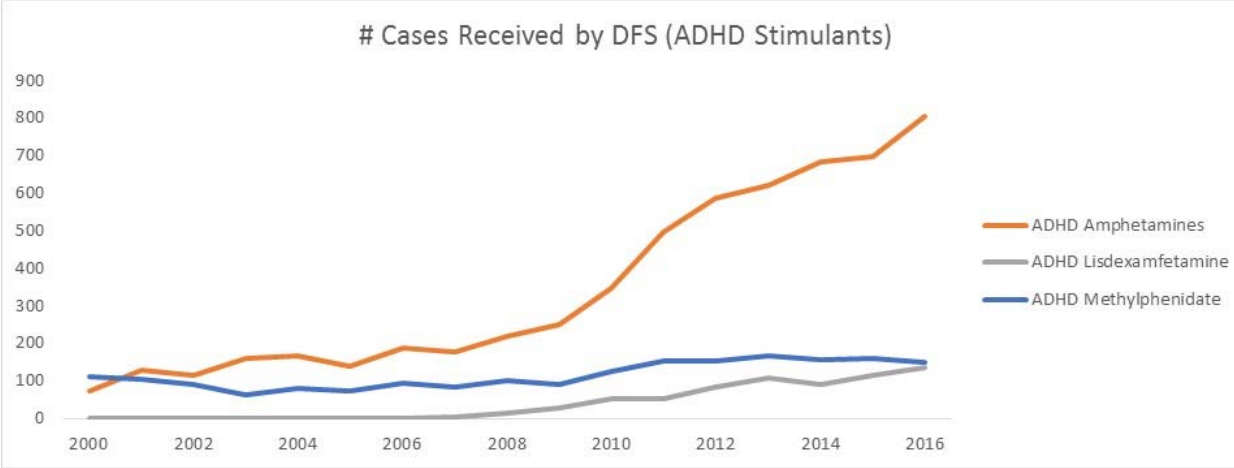
- Growth: There is a strong body of evidence that stimulant use can cause short-term weight loss and slowed growth velocity, and mixed evidence on effects in the longer-term (e.g., some studies have found growth catch-up associated with "drug holidays" or treatment cessation, others have found persistent growth retardation) (Poulton et al. 2016; Pacula et al. 2014; Powell et al. 2015; Faraone et al. 2007).
- Cardiovascular disease (CVD): There may be increased risk of CVD – ranging from small increases to over 2 times the risk – although the magnitude of association is not well-established, due in part because CVD is a relatively rare event in study populations and power to detect risk differences is generally low (Dalsgaard, Kvist, et al. 2014; Hennissen et al. 2017; Schneider & Enenbach 2013; Westover & Halm 2012).
- Substance Use Disorder (SUD): There is a large body of evidence suggesting that stimulants are either not associated with or protective against developing a SUD (Dalsgaard et al. 2013).
- Depression: There is a large body of evidence suggesting that stimulants are either not associated with or protective against developing depression (Lee et al. 2015).
- Psychotic disorders: Evidence that ADHD may be associated with reductions in psychiatric disorders (Biederman et al. 2009), and little evidence of association between stimulant use and new onset or worsening of tics (Cohen et al. 2014; Rasmussen et al. 2015).

Non-Medical Use of ADHD Stimulants

As highlighted by FDA black box warnings, some ADHD stimulant medications "have a high potential for abuse". According to survey data, 3.4% of those 12 years old or older are estimated

to have used prescription ADHD stimulants for non-medical purposes during their lifetime (Sweeney et al. 2013). Studies find non-medical use of stimulants in 5% to 9% of grade and high school-age children, and 5% to 35% of college age students (Clemow 2016; WILENS et al. 2007) – with a meta-analysis estimating a college-age point prevalence of 17% (Benson et al. 2014) – although the wide ranges may reflect uncertainties in the underlying self-reported data. While those studies rely on self-reported survey data, they are consistent with data on Emergency Department (ED) visits indicating a tripling between 2005 and 2010 – with the number of ED visits involving ADHD stimulant medications increasing significantly for adults aged 18 years or older – in the non-medical use of stimulants (Clemow & Walker 2014; Clemow 2016). As indicated in Figure 9, below, the number of law enforcement cases in Virginia involving ADHD stimulants increased from 184 in 2000 to 1,089 in 2016.

Figure 9. Law enforcement cases involving ADHD stimulants



Source: Virginia Department of Criminal Justice Services (2017)

While ADHD stimulants have abuse potential, that potential is substantially reduced compared to illicit stimulants (e.g., cocaine, methamphetamine) due to the formulation of ADHD stimulants, with long-acting formulations further limiting abuse potential (Clemow 2016)[iv]. Additionally, little evidence exists suggesting that addiction to ADHD stimulants is of widespread concern.

[iv] Misuse can be defined as use of a drug for purposes other than intended (e.g., performance enhancement), abuse can be defined as the consumption of a drug in harmful amounts, and addiction can be defined as a physical and psychological need for a drug.

Antipsychotic Medications

Atypical antipsychotics (AAPs) – which now constitute the vast majority of antipsychotics used – are FDA-approved for a variety of mental health conditions[v]. While ADHD is not one of those conditions, available evidence indicates that ADHD co-occurs in elevated levels with several of those conditions for which AAPs are FDA-approved. For instance, bipolar disorder co-occurs in 10% to 28% of inidividuals diagnosed with ADHD (van Hulzen et al. 2015), and depression, autism and Tourette's disorders are eight to ten times as likely in ADHD-diagnosed individuals than those without ADHD (Larson et al. 2011) (see Figure 10, below).

Figure 10. ADHD Co-occurance with AAP-indicated Conditions

TABLE 1 Prevalence of Comorbid Disorders for Children With ADHD Versus Those Without ($N = 61\,779$)

	No ADHD	ADHD	Adjusted Relative Risk[b]	95% CI
Learning disability (%)	5.3	46.1[a]	7.79	6.86–8.86
Conduct disorder (%)	1.8	27.4[a]	12.58	10.23–15.48
Anxiety (%)	2.1	17.8[a]	7.45	6.08–9.12
Depression (%)	1.4	13.9[a]	8.04	6.09–10.62
Speech problem (%)	2.5	11.8[a]	4.42	3.41–5.73
Autism spectrum disorder (%)	0.6	6.0[a]	8.72	5.97–12.72
Hearing problem (%)	1.2	4.2[a]	2.77	1.87–4.11
Epilepsy or seizures (%)	0.6	2.6[a]	3.93	2.19–7.06
Vision problem (%)	1.4	2.3[a]	1.47	0.98–2.20
Tourette's syndrome (%)	0.09	1.3[a]	10.70	4.72–24.23
Any MH/ND disorder (%)	11.5	66.9[a]	5.12	4.72–5.55

[a] $P < .05$ for χ^2 test.

[b] Relative risks were adjusted for child age, gender, race/ethnicity, parent education, household income, and family

Source: Larson (2011)

AAP Treatment Prevalence

Use of AAPs has grown substantially since the early 2000s, particularly in children and adolescent populations. For example, between 2002 and 2007, antipsychotic use increased by 62% in Medicaid enrolled youth (Matone et al. 2012). In light of co-occurrence between ADHD and disorders treated by AAPs, studies have found that ADHD is one of the most common mental health diagnoses among youth prescribed AAPs. Between 2001 and 2005, for example, over 60% of a State (Arkansas) Medicaid-enrolled sample of children prescribed AAPs were diagnosed with ADHD (Pathak et al. 2010). Nationally, between 2006 and 2010, 50% to 60% of children 12 years old or younger prescribed AAPs – and 35% of children 13 to 18 years old – were diagnosed with ADHD (Olfson et al. 2015). This may be due to co-occurrence of ADHD with conditions either FDA-indicated for AAPs or prescribed off-label for AAPs, or off-label use of AAPs for ADHD itself. In general, off-label use of AAPs accounts for a substantial portion of prescriptions for AAPs, with evidence of increased off-label use over time – even accounting for the majority or prescriptions (Sikirica et al. 2014). While a significant percentage of ADHD-diagnosed youth have historically been prescribed AAPs without a condition indicated for use (e.g., 18% to 20% in the mid-2000s (Birnbaum et al. 2013)), more recent data on off-label use of

[v] The FDA has approved the use of AAPs for the primary and/or adjunctive treatment of: autism; bipolar mania; major depressive disorder; schizophrenia; schizoaffective disorder; and Tourette's disorder.

AAPs among those with ADHD are limited. Finally, concurrent prescriptions for AAPs and stimulants may be common (e.g., in 2008, 59% to 69% of children 12 years old or younger prescribed antipsychotics also were prescribed stimulants (Olfson et al. 2015)).

In Virginia, data from insured populations in commercial markets indicate 5.4% to 6.1% of enrollees 19 years of age or younger and with an ADHD diagnosis were prescribed AAPs (5.0% to 6.4% of ADHD-diagnosed individuals 20 years or older with an ADHD diagnosis were prescribed AAPs). Additionally, of the approximately 29,000 individuals prescribed AAPs in commercial markets between 2014 and 2015, 31% did not have a FDA-indicated diagnosis for the prescribed AAP. Of the approximately 8,800 individuals with an ADHD diagnosis and prescribed AAPs, 46% did not have a FDA-indicated diagnosis for the prescribed AAP (Virginia Health Information 2017). Among the Medicaid population, of approximately 69,000 individuals prescribed AAPs between 2015 and 2017, 56% did not have a FDA-indicated diagnosis for the prescribed AAP (Department of Medical Assistance Services 2018). For both the commercial insurance markets and Medicaid population, it is likely that prevalence of off-label prescriptions would be higher if FDA-approved patient ages and dosage levels were also taken into consideration.

AAP Treatment Quality

According to available quality data on AAP prescribing in Virginia, children 17 years of age or younger enrolled in Medicaid Managed Care Organizations (MCOs) in 2016 had higher than national median use of multiple concurrent AAPs, around average use of metabolic monitoring for side effects, and lower than national median rates of attempting psychosocial care before turning to AAPs (see Table 4, below).

Table 4. AAP Quality Data

Indicator	VA MCO Average	National Median
Multiple concurrent antipsychotic use	2.66%	1.99%
Metabolic monitoring for side effects	29.8%	29.6%
1st-line psychosocial care (psychosocial care used before antipsychotics)	51.83%	60.43%

Source: Department of Medical Assistance Services (2017)

AAP Treatment Effectiveness and Safety

A recent Agency for Health Research Quality (AHRQ) study assessing both effectiveness and harms of AAPs (Agency for Healthcare Research and Quality 2017) found that, among patients with ADHD, use of AAPs:

- Probably reduces conduct problems and aggression in children with ADHD and/or conduct disorders;
- Appears to reduce clinical severity in patients with ADHD (although probably more for patients with a primary diagnosis for other behavioral disorder); and

- There is moderate evidence of clinical benefit only for those unresponsive to stimulant medications for ADHD or have other behavioral disorders as the primary diagnosis

In terms of AAP safety, findings from the same AHRQ study on adverse events/side effects from use of AAPs are summarized in Table 5, below:

Table 5. Safety of AAP Use

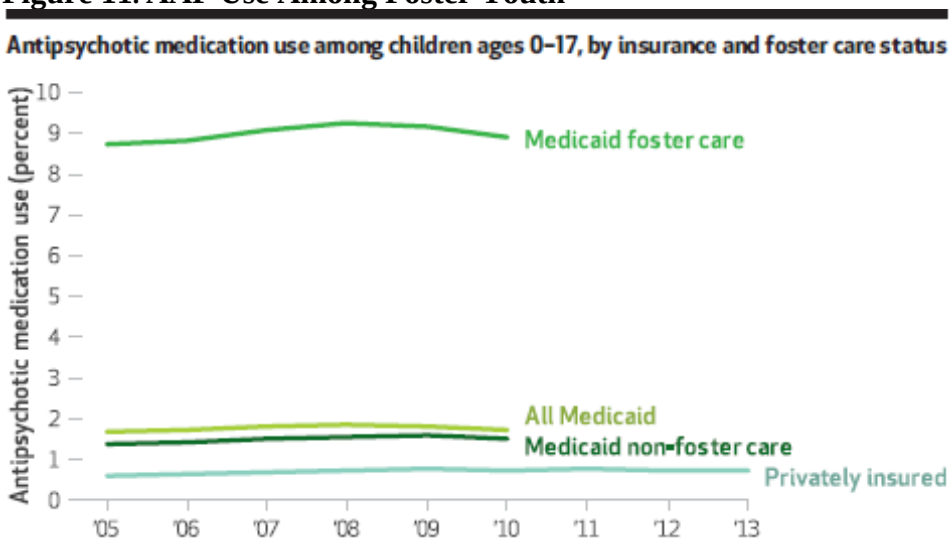
Adverse Event/Side Effect	Evidence of Risk
Any drug-induced movement disorder	Probably increases
Weight/BMI	Probably increases slightly
Total cholesterol	May increase
Triglycerides	Probably increases
Sedation/somnolescence	Probably increases

Source: Agency for Healthcare Research and Quality (2017)

Psychotropic Medications in Foster Youth Populations

Historically, a high rate of use of psychotropic medications – including AAPs – among foster youth has prompted the federal government and States to closely monitor prescribing practices in this population. In 2008, a report by the Government Accountability Office focusing on prescribing practices in five States found a concerningly high use of AAPs among foster youth compared to the general youth population. Since that time, federal legislation has required that States develop psychotropic medication monitoring programs. While AAP use among foster populations appears to have peaked in 2008 (see Figure 11, below) and States have taken a variety of steps to more closely monitor use of psychotropic medications in this population since the GAO report, their use continues to be higher than the rest of the Medicaid population. Whether the higher use is appropriate or not remains an ongoing source of discussion.

Figure 11. AAP Use Among Foster Youth



Source: Crystal et al. (2016)

In Virginia, a study from 2015-2016 on Virginia children and adolescents 17 years old or younger in foster care provide data on the use of ADHD medication and antipsychotics in this population. Compared to data from the general Medicaid population from 2016, multiple concurrent use of antipsychotics was lower compared to other Medicaid enrollees, and use of first-line psychosocial care before initiating antipsychotics was higher (see Table 6). However, the study did not provide any benchmarks by which to compare these data to other States or foster populations.

Table 6. Psychotropic Medication Use in Foster Populations

Indicator	Percentage
ADHD Medications	
ADHD medication prevalence	43%
Newly prescribed ADHD medication	9%
Antipsychotics	
Multiple concurrent antipsychotic use	1.9%
1st-line psychosocial care (psychosocial care used before antipsychotics)	86%

Source: Heath Systems Advisory Group (HSAG) (2016)

Policies on ADHD and Psychotropic Medications in Virginia

Department of Education (DOE)

Two Statutes regulate the identification or diagnosis of ADHD by personnel in Virginia's school or institutions of higher education. Virginia Code §22.1-298.1 (Regulations governing licensure (2017)), requires that a person seeking initial teaching licensure complete studies in attention deficit disorder. According to DOE staff, the Department has added ADHD content to professional studies requirements for two DOE policies: Licensure Regulations for School Personnel and Regulations Governing the Review and Approval of Education Programs in Virginia. Virginia Code §22.1-298.4 (Teacher preparation programs; learning disabilities (2016)) requires that the DOE collaborate with the State Council of Higher Education in Virginia (SCHEV) to require all teacher preparation programs offered at public institutions of higher education to convey information on the identification of students at risk for learning disabilities, including ADHD. To date, according to DOE staff, the Department has provided higher learning institutions with requirements to be included in their programs, with institutions to verify completion on a signed verification form. The DOE additionally plans to require documentation about inclusion of the competencies.

While the DOE is not mandated to directly collect data on students diagnosed with ADHD or those on ADHD medications (see previous section on ADHD Epidemiology, Virginia Prevalence), there is an additional process by which data on ADHD and/or its treatment may enter DOE records at the school level. Diagnosis of ADHD is listed on Virginia's School Entrance Health Form as a pre-populated condition for parents to report to schools upon entering their child into the public school system. However, those data are voluntarily reported by parents, the School Entrance Health Form *per se* is not a required form, and information that is required by Statutes and contained on the School Entrance Health Form – evidence of up-to-date

immunizations and a comprehensive physical examination – is only required upon entry into kindergarten or elementary school.

In terms of psychotropic medications, school personnel are permitted to administer prescription medicines – including psychotropic medications – to students. However, Virginia Code §22.1-274.3 (Policies regarding medication recommendations by school personnel (2002)) requires the DOE to develop and implement policies prohibiting school personnel from recommending the use of psychotropic medications for any student. In 2002, a DOE memo directed local school boards to review division-level policies and procedures to ensure compliance with the policy memo (Department of Education 2002). To date, almost all school divisions have documented/written policies to ensure compliance with the DOE memo. Nationally, four other States[vi] have similar policies.

Department of Medical Assistance Services

DMAS and health plans covering the Medicaid population in Managed Care Organizations (MCOs) have implemented Service Authorizations (SAs) affecting the ability of some populations to access psychotropic medications. For Medicaid enrollees in the fee-for-service (FFS) population, two SAs exist related to ADHD medications and antipsychotics. A SA for ADHD medications/stimulants is required for children outside of FDA-approved age range as well as adults 18 years or older, and lasts for one year before a new SA is required. For antipsychotics, a SA is required for children younger than 18 years old. According to the SA, medication must be prescribed by a psychiatrist or neurologist – or the prescriber must supply proof of a psychiatric consultation for the patient – and the member must be participating in a behavioral management program. This SA lasts for six months before a new SA is required.

In the MCO population whose SA requirements are regulated by health plans, SA requirements have historically been consistent with those issued by DMAS covering the FFS population. Further, under the current Medallion 4.0 contract issued by DMAS, MCO health plans are required to adopt the FFS Preferred Drug List – known as the "Common Core Formulary" – which includes accompanying DMAS-approved SA requirements. As such, MCO SA requirements are now the same as SA requirements covering the FFS population.

Department of Social Services

To address concerns surrounding the appropriate use of AAPs in the foster youth population, DSS has been working in recent years to increase capacity to monitor prescribing practices. Steps taken have included working with DMAS to implement a review process to monitor off-label use of psychotropic medications in children, raising awareness among caseworkers of the appropriate use of AAPs (e.g., e-learning on psychotropic medications; screening tools for trauma), and modification of the case worker database to better track foster youth medical and prescription history. However, data entered into the case worker database are done so manually, and the database is not synchronized with prescription history data from DMAS (Parente 2017).

[vi] Connecticut, Colorado, Oregon, and Texas

Methods to Raise Awareness of ADHD Medications Risks

A variety of methods are used in the U.S. to raise awareness of risks of ADHD medications among the general public and among college-aged individuals in particular.
For the general public, the FDA raises awareness of risks of medications, including psychotropic medications, through safety communications and regulations on labeling of pharmaceuticals. Safety communications related to ADHD medications include:

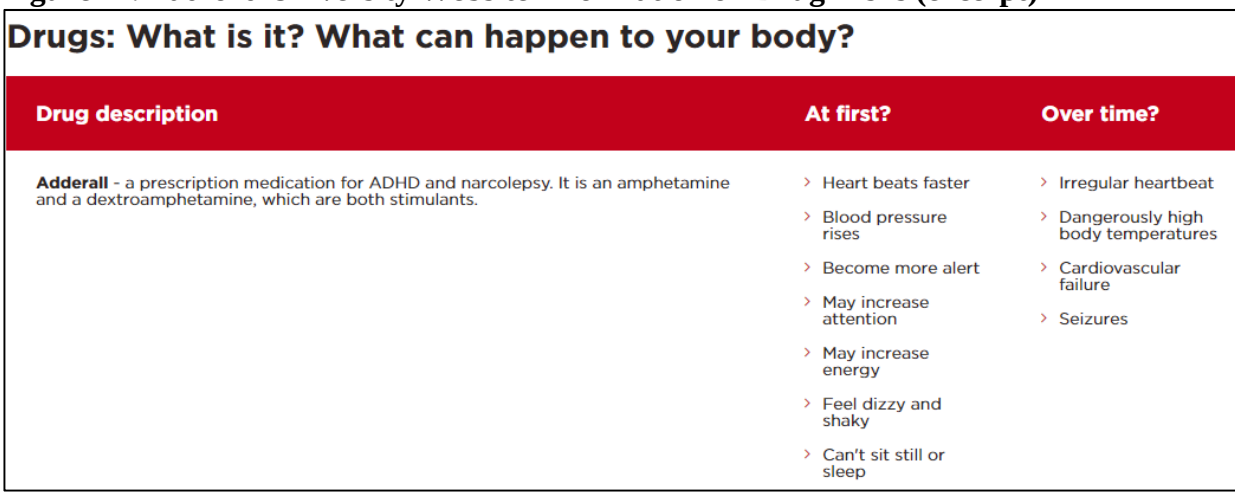
- Permanent loss of skin color may occur (2015)
- Methylphenidate may in rare instances cause prolonged/painful erections (2013)
- Studies have not shown increased risk of serious CVD AEs in adults (2011)
- Manufacturers should develop patient Medication Guides to alert patients to possible CVD/psychiatric symptoms risks (2007)

"Black box" warnings on manufacturers' labels for ADHD medications required by the FDA include:

- Amphetamines: "have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events"
- Methylphenidates: "should be given cautiously to patients with a history of drug dependence or alcoholism; chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior; frank psychotic episodes can occur, especially with parenteral abuse"
- Strattera (non-stimulant): "Increased risk of suicidal ideation in children or adolescents"

In the college and university settings, some institutions of higher learning either provide information on potential risks of psychotropic medications or require students to adhere to certain standards if prescribed these medications. For example, Radford University provides information on its website on risks of taking selected licit and illicit drugs, including Adderall (see Figure 12, below).

Figure 12. Radford University Website Information on Drug Risks (excerpt)



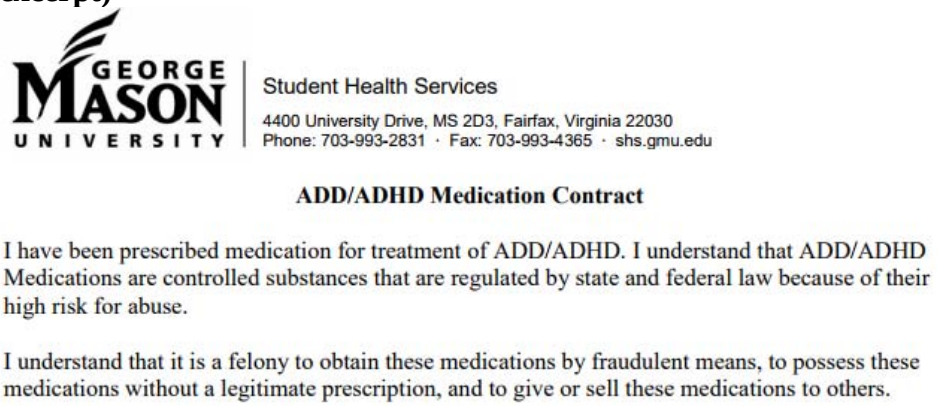
Drugs: What is it? What can happen to your body?

Drug description	At first?	Over time?
Adderall - a prescription medication for ADHD and narcolepsy. It is an amphetamine and a dextroamphetamine, which are both stimulants.	› Heart beats faster › Blood pressure rises › Become more alert › May increase attention › May increase energy › Feel dizzy and shaky › Can't sit still or sleep	› Irregular heartbeat › Dangerously high body temperatures › Cardiovascular failure › Seizures

Source: https://www.radford.edu/content/saves/home/substance-abuse/drug-use.html

Going one step further, George Mason University requires all students prescribed medication for treating ADHD to sign a "Medication Contract", outlining the patient's roles and responsibilities (e.g., patient will not seek duplicate prescriptions) (see Figure 13, below).

Figure 13. George Mason University ADHD Medication Contract (excerpt)



GEORGE MASON UNIVERSITY | Student Health Services

4400 University Drive, MS 2D3, Fairfax, Virginia 22030
Phone: 703-993-2831 · Fax: 703-993-4365 · shs.gmu.edu

ADD/ADHD Medication Contract

I have been prescribed medication for treatment of ADD/ADHD. I understand that ADD/ADHD Medications are controlled substances that are regulated by state and federal law because of their high risk for abuse.

I understand that it is a felony to obtain these medications by fraudulent means, to possess these medications without a legitimate prescription, and to give or sell these medications to others.

Source: https://shs.gmu.edu/wp-content/uploads/2013/07/ADD-ADHD-Contract-2.pdf

Methods to Track ADHD Diagnoses Among School Children

Some States actively collect statistics on ADHD diagnoses through data collection collaborations between State health and education agencies. These include:

- Tennessee: annual Health Services reports draw ADHD diagnosis data from local school division database systems (Fuhrmeister 2017)
- Connecticut: annual Health Services Program Information Surveys draw ADHD diagnosis data from local school division database systems from provider orders, children's assessments, and other methods that vary by school division (Knutson 2017)
- North Carolina: Annual School Health Services Surveys collect data on students actively receiving some level of health services from the school nurse (Nichols 2017)

While data collection methods vary between States and/or between school divisions within a State, most methods rely on information provided in IEPs, Section 504 plans and/or school entrance forms. As such, the quality (e.g., reliability, validity) of data across school divisions is unknown.

Virginia's DOE estimates that establishing an ADHD diagnosis data collection system for Virginia public school children would incur a one-time investment cost of $2.9M and annual recurrent costs of $81,200 and would be operational in two years and be able to produce reports in three years. However, DOE officials expressed concerns that data quality uncertainties found in other States would be similar for Virginia should such a data collection system be established (Eisenberg 2017).

Methods Used to Limit Antipsychotic Use

Nationally, States commonly employ a variety of methods to limit and/or ensure the appropriate use of psychotropic medications. These include:

- Prior authorization: Medication pre-approval form that requires prescribers to provide information that allows the payer to check appropriateness of requested medication. Information commonly relates to: dosage limits; polypharmacy and/or therapeutic duplication; metabolic monitoring; and informed consent from parents/guardians (for antipsychotics).
- Peer review: a process for manual clinician review and/or consultation of prior authorization requests. For example, Maryland's Medicaid agency requires review by a child psychiatrist of antipsychotics prescribed off-label with respect to age (i.e., outside of the FDA-approved age bands). Among the goals of Maryland's program is enhanced use of evidence-based practices, including monitoring, in treatment and management.
- Drug Utilization Review (DUR) Program: a two-phase process conducted by all State Medicaid agencies involving: a prospective DUR to screen prescription drug claims to identify potential problems (e.g., therapeutic duplication, incorrect treatment dosage/duration, clinical misuse); a retrospective DUR involving an ongoing or periodic examination of claims data. On an annual basis, States are required to report on their state's prescribing habits.

Globally, little information exists on methods to limit use of AAPs or stimulants. However, in France, it is reported that psychiatrists must initiate medications for ADHD (Zito et al. 2007).

Methods to Identify Off-label Prescribing of Antipsychotics

Identifying off-label prescribing of AAPs from administrative claims data encounters significant methodological challenges: diagnosis codes are not generally required data elements on prescription claims. While it is possible to attempt to cross-reference prescription claims – which identify a prescribing provider – with claims submitted by the prescribing provider – which contain diagnosis codes – such an indirect methodology to identify the underlying diagnosis motivating the prescription is subject to many uncertainties. For example, if a patient is prescribed an AAP but does not to fill the prescription for several months – and in the meantime continues to receive services from the prescribing provider – administrative claims data alone cannot identify the specific consultation and associated diagnosis codes that generated the prescription. Due to resulting methodological challenges, DMAS has not been able to endorse a methodology that would be able to produce public use information in tracking off-label prescribing of AAPs based on claims data (Newsome 2018).

Policy Options and Public Comment

Six policy options were provided for consideration. No public comments were received.

Study Mandate Component	Policy Option(s)
N/A	Option 1: Take No Action
Raise awareness of ADHD medication risks	Option 2: By letter from the JCHC Chair, request the governing board of each four-year public institution of higher education to: • Require ADHD stimulant medication contracts of any student prescribed ADHD stimulants by the institution, and; • Develop and implement policies that result in the provision of written information to students about the potential risks of stimulant use
Track statistics on Virginia school children diagnosed with ADHD	Option 3: Introduce a budget amendment of $2.98M for SFY 2020 for DOE to establish an ADHD diagnosis data collection system for Virginia public school children
Methods to limit antipsychotic use for ADHD	Option 4: By letter of the JCHC Chair, request that DMAS and DSS convene a stakeholder group to identify methods to ensure that DSS data on antipsychotic and other prescription medications currently being prescribed to foster populations are accurate and up-to-date Option 5: By letter of the JCHC Chair, request that DMAS require documentation of metabolic monitoring in the service authorization form for antipsychotics for children <18 years old, including documentation of: baseline and routine monitoring of weight or body mass index (BMI); waist circumference; blood pressure; fasting glucose; fasting lipid panel; and Extrapyramidal Symptoms (EPS) using Abnormal Involuntary Movement Scale (AIMS)
Methods to track off-label prescribing of antipsychotics	Option 6: By letter of the JCHC Chair, request that DMAS cost out an appropriate methodology to track off-label prescribing of AAPs among FFS beneficiaries – and determine required contract modifications with contracted health plans to track off-label prescribing of AAPs among MCO beneficiaries – with the Department reporting back to the Commission with a proposed implementation plan by October, 2019

Subsequent Actions by the Joint Commission on Health Care

JCHC members voted to take no action.

JCHC Staff for this Report

Andrew Mitchell, Senior Health Policy Analyst

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ADHD Prevalence and Risks of ADHD Medications in Virginia Interim Report

Joint Commission on Health Care
September 19, 2017 Meeting

Andrew Mitchell

Senior Health Policy Analyst

Outline

- Study mandate
- Background to ADHD and psychotropic treatment
- ADHD epidemiology
- ADHD treatment
- ADHD diagnosis and treatment policies in Virginia

Study Mandate

HB1500, Item 30(A), requested that JCHC identify methods:

1. To raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use
2. To compile/track statistics on Virginia school children diagnosed with ADHD or other categories such as “specific learning disabilities, other health impairment, multiple disorder, and emotional disturbances”
3. Used by other states/countries to limit antipsychotic use
4. To identify the incidence/prevalence of prescribing anti-psychotics for off-label use

The analysis shall be reported by the JCHC to the Chairmen of the House Appropriations and Senate Finance Committees no later than November 30, 2018

Background – Terms and Definitions

- Psychotropic, psychiatric, antipsychotic medications
  - Psychotropic/psychiatric medications: psychoactive medications that change brain function and result in alterations in perception, mood, consciousness or behavior
  - Antipsychotic medications: subset of psychotropic medications
- Typical and atypical antipsychotic medications
  - FDA-approved medications for various mental disorders (e.g., schizophrenia)
- Off label: use of a medicine outside scope of marketing authorization from the Food and Drug Administration (FDA) with respect to:
  - Disorder being treated;
  - Patient demographics (e.g., age); and/or
  - Prescribed dosage/route of administration
  - Note: “From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient.”
- Misuse/non-medical use, abuse, dependence, addiction:
  - Misuse/non-medical use: use of drug for purpose other than intended (e.g., performance enhancement)
  - Abuse: consumption of drug in harmful amounts
  - Dependence: physical need for drug
  - Addiction: physical/psychological need for drug

Background – ADHD Diagnosis

- Diagnosis by psychological assessment (no clinical biomarkers)
  - In the United States, diagnoses are guided by American Academy of Pediatrics (AAP) recommendations:
    - Diagnostic evaluation using DSM criteria
    - Assessment of extent/pervasiveness of impairment across multiple settings
    - Collection of information from multiple informants (e.g., parents, teachers, other adults involved in the child's care)
    - Assessment of co-existing conditions
  - Globally, diagnostic methodologies differ:
    - Some countries (e.g., UK) have historically relied on more restrictive ICD-based hyperkinetic disorder
    - Some countries rely on symptomology alone (vs. requiring evidence of impairment in the daily environment)

Background – DSM Criteria

- DSM criteria have evolved: five editions of the DSM have been published, expanding ADHD diagnostic eligibility each time

	Current diagnostic criteria (DSM-5):	**Examples:**
	•6+ symptoms of inattention (≥6 month duration) AND/OR	•Has difficulty remaining focused during lengthy reading
	•6+ symptoms (>=6 month duration) of Hyperactivity and impulsivity	•Often fidgets with or taps hands or feet or squirms in seat
AND	•Several symptoms present: before 12 years old; in >1 setting	•At home, in school
AND	•Symptoms clearly interfere with/reduce quality of functioning	•Social, academic, occupational
AND	•Symptoms do not occur exclusively during course of schizophrenia/psychotic disorder and are not another mental disorder	•Mood/anxiety/personality disorder; substance intoxication/withdrawal

ADHD Epidemiology: Nationally

- ADHD is most diagnosed neurodevelopmental disorder among children and adolescents in U.S.
  - 53% of diagnoses by primary care physicians; 23% by psychiatrists
- Estimated children/adolescent prevalence:
  - 2011 (parent reports): 11%
  - 2013 DSM-5 estimate: 5%
  - Note: Estimated global prevalence among children / adolescents is 3.4% - 7.2% (2014) and 2.5% for adults (2015)
- 2016 prevalence in colleges/Universities: 6.7% (national student survey)
- Populations more likely to be diagnosed in U.S.: boys, non-Hispanic Caucasians, southern/Midwest States
- High incidence of concurrent disorders (e.g., conduct, mood, anxiety, substance use disorders)

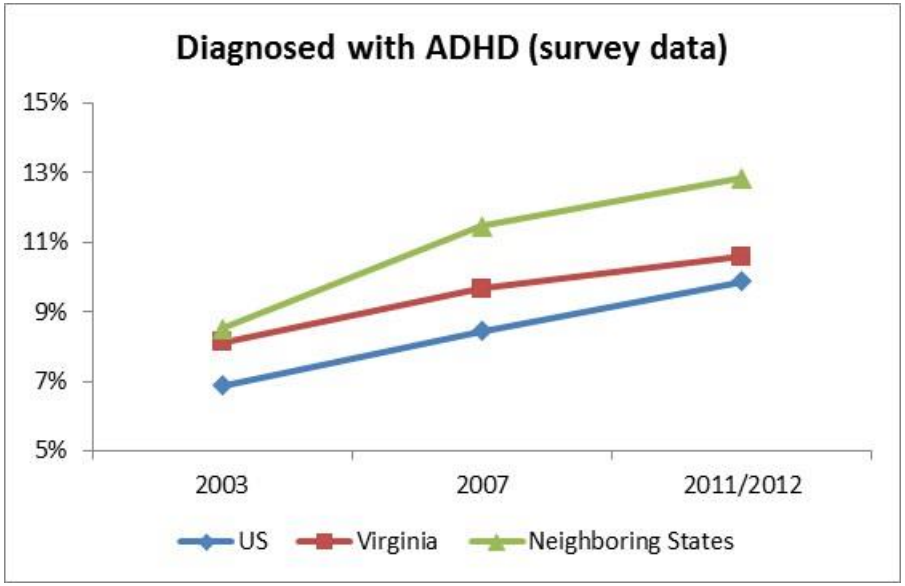
Possible Drivers of ADHD Diagnostic Variation in the US*

- State-level demographic differences (e.g., ADHD prevalence in CA and NC is 6% and 15.5%, respectively)
- Schooling factors
  - Evidence that No Child Left Behind law was associated with increase in ADHD diagnosis among certain populations
  - Laws limiting school involvement in recommendation and/or administration of psychotropic medications may be associated with lower diagnostic prevalence
  - Children born just before school cut-off dates are more likely to be diagnosed with ADHD/receive stimulants compared to those born after cut-off dates
- Diagnostic factors
  - Evolving DSM criteria
  - Application of DSM criteria used (e.g., diagnoses can be reduced by 50% when full criteria are rigorously applied)

* See Appendix for additional detail on the content of this slide

ADHD Epidemiology: Prevalence in Virginia*

- ADHD prevalence in general population (2003-2012):



Source: National Survey on Child Health (NSCH)

- ADHD prevalence in insured populations:
  - Commercial health insurance markets (2014/2015): 6.9%-7.8% of individuals <20 (3.3% of individuals 20+)**
  - Medicaid (2014): 7.9% of children 4-17 (3.3% of adults 18-25) in Managed Care Organizations (MCO)

* See Appendix for additional detail on the content of this slide

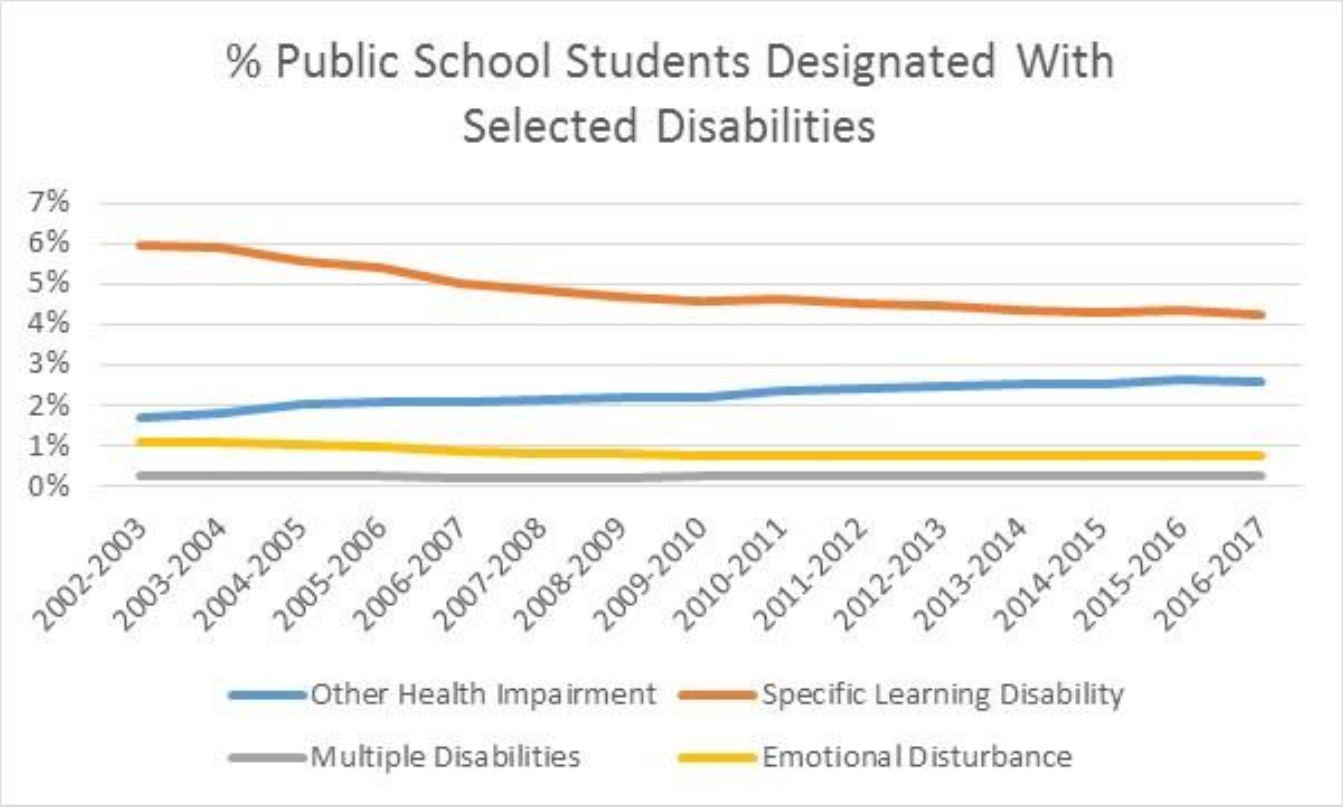
**Data represent: 100% of individuals with fully insured policies; an estimated 50% of individuals with self-insured policies

ADHD Epidemiology: Prevalence in Virginian School Children

- Two federal laws – the Individuals with Disabilities Education Act (IDEA) and Rehabilitation Act – guarantee that public school students diagnosed with disabilities are eligible for educational accommodations through Individualized Education Plans (IEPs) and "Section 504" plans, respectively
- Under IDEA, ADHD is listed as an eligible disability in the "Other Health Impairment" (OHI) designation that also includes:
  - Diabetes
  - Epilepsy
  - A heart condition
  - Lead poisoning
  - Leukemia
  - Nephritis
  - Rheumatic fever
  - Sickle cell anemia
- While federal reporting requirements exist for disabilities including OHIs, no direct measure of ADHD is collected by the Virginia Department of Education (DOE)

ADHD Epidemiology: Prevalence in Virginian School Children (2)

- Between 2002 and 2017, the percentage of students designated with an OHI disability increased from 1.7% to 2.6%
  - Without ADHD-specific data, it is unknown the degree to which ADHD has played a role in the increase of OHI designations over time.



Source: Virginia Department of Education

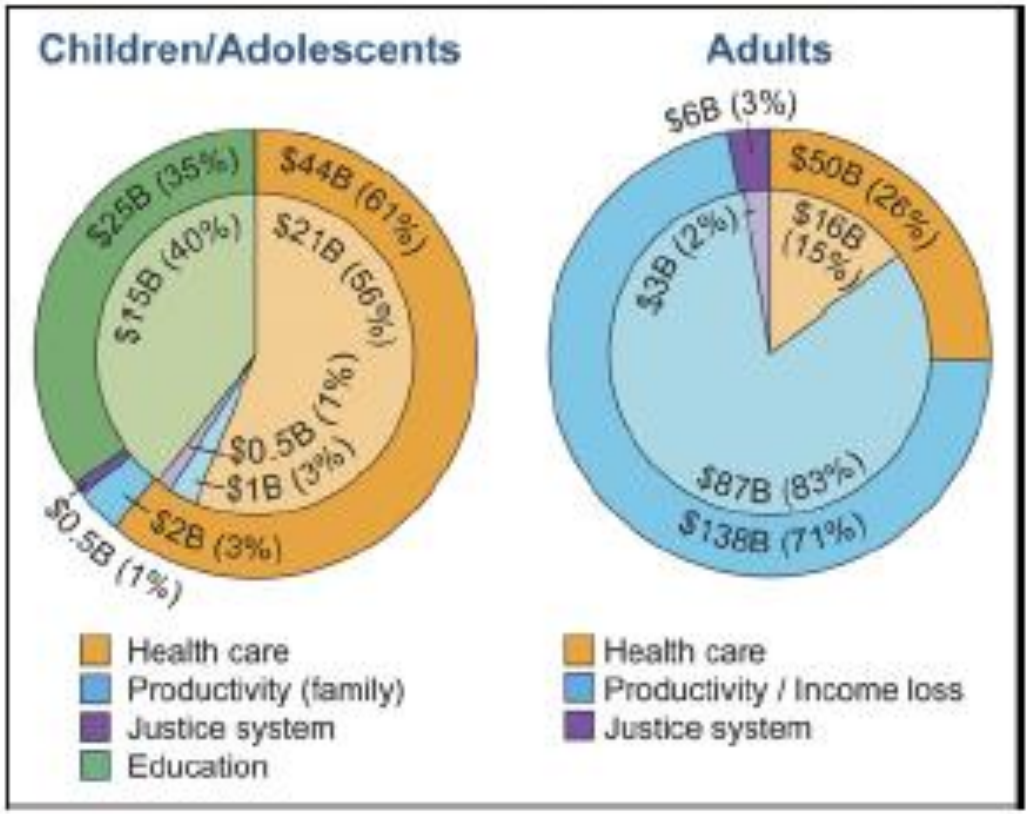
Adverse Impacts of ADHD – Individuals*

- An estimated 15%-65% of ADHD-diagnosed children experience symptoms into adulthood
  - Wide variation likely reflects heterogeneity in definition of symptom persistence
- Impacts on health/social outcomes include:
  - Decreased life expectancy; increased mortality risk
  - Increased risk of vehicle accident
  - Mixed evidence of association with obesity
  - Higher odds of failure to complete high school
  - Higher odds of unemployment; reduction in earnings
  - Increased probability of arrests, convictions, and incarcerations

* See Appendix for additional detail on the content of this slide

Adverse Impacts of ADHD – Societal

- Estimated annual national costs are $140B - $265B



Source: Doshi et al (2011)

ADHD Treatment

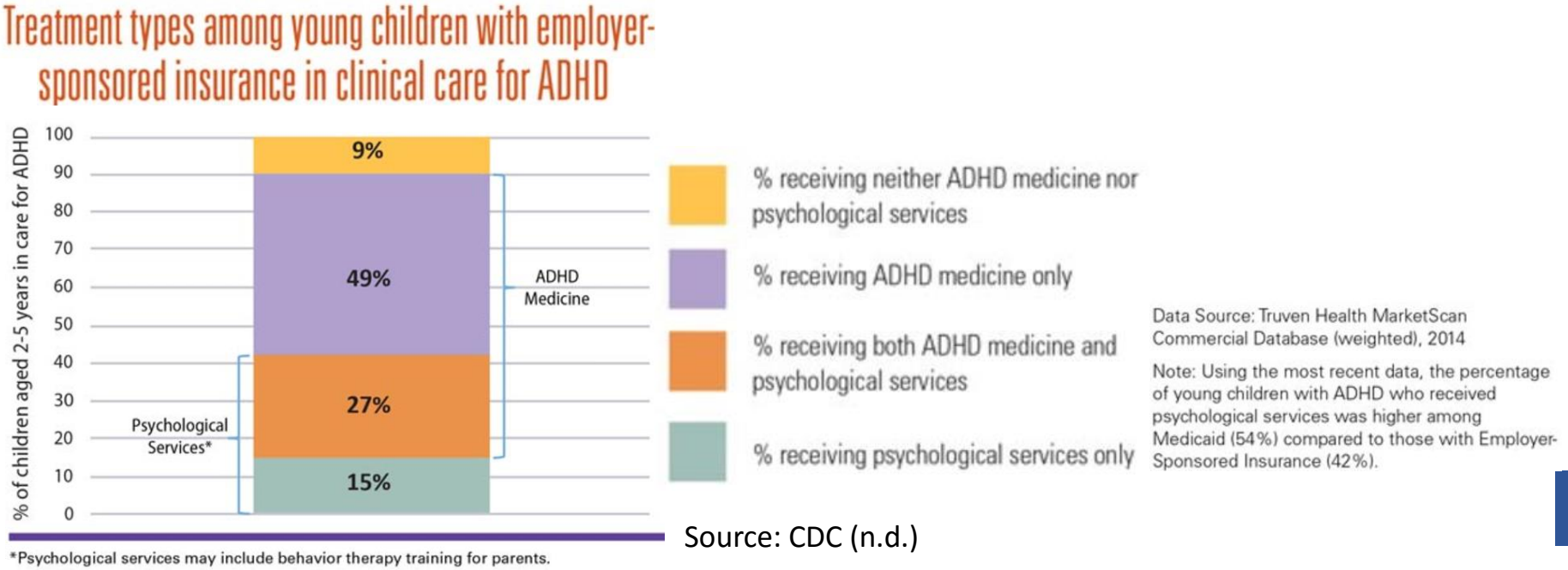
- Pharmacological treatments
  - 26 formulations of stimulant and non-stimulant medications targeting norepinephrine and dopamine are FDA-approved for treating ADHD among varying age groups (3+ years old)
  - AAP recommendations:

• Preschoolers (< 6 years of age)	• Behavior therapy; methylphenidate (stimulant) if no significant improvement
• Elementary age (>=6 – <12)	• ADHD medications (preferably stimulants) and/or behavior therapy
• Adolescents (12 - <19)	• ADHD medications; behavior therapy optional (but combination preferable)

  - Differing recommendations in other countries (e.g., UK: medications never recommended for preschoolers)
- Psychological interventions (e.g., behavioral/cognitive interventions, parent training, social skills training)

ADHD Treatment – National Trends

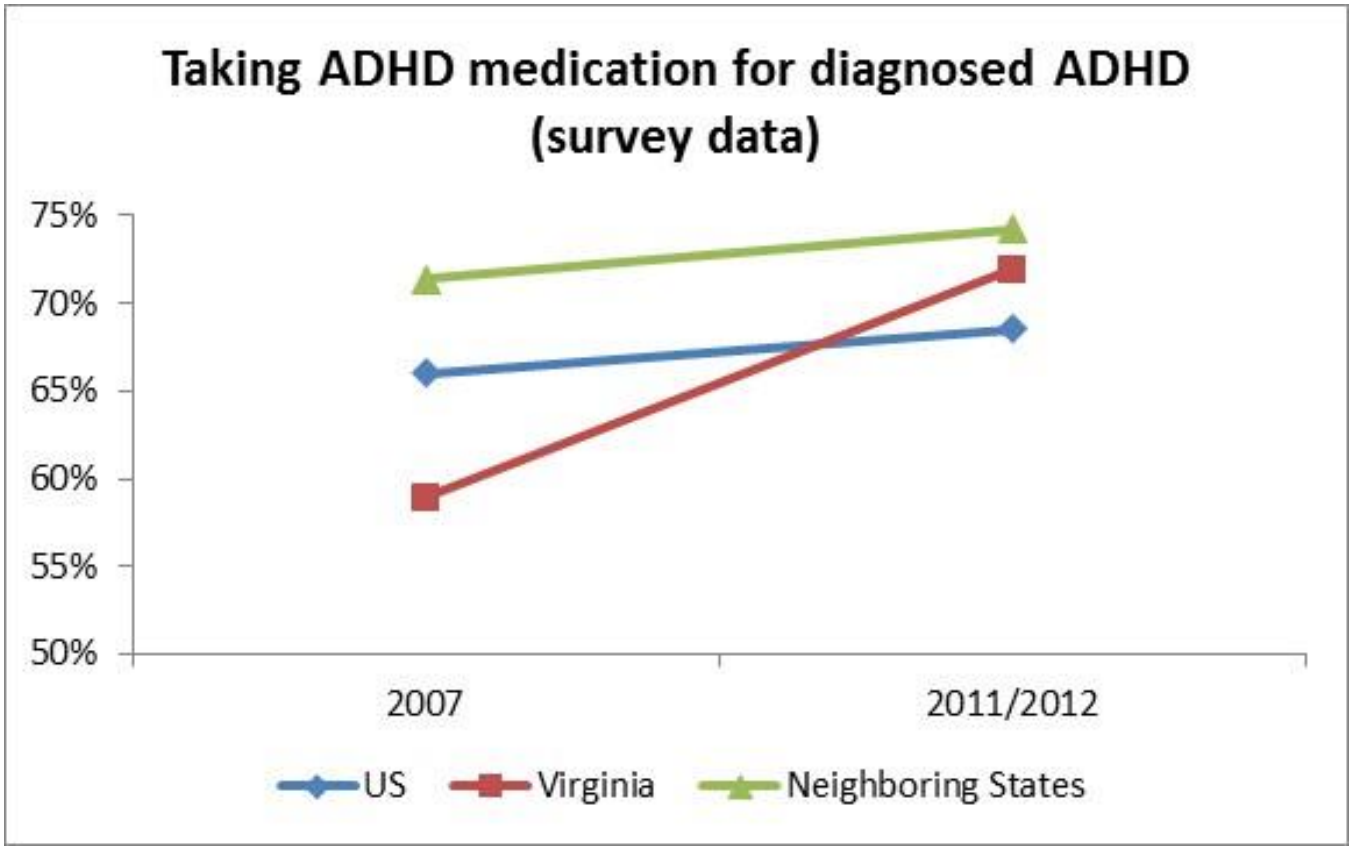
- FDA-approved ADHD medication
  - Two-thirds to 75% of children/adolescents diagnosed receive medications
  - Stimulant prescriptions tripled between 1990 and 2000
- Psychological services
  - 2008-2015: 54% of Medicaid population and 45% of employer-sponsored population received psychotherapy



Source: CDC (n.d.)

ADHD Treatment – Virginia

- ADHD treatment in general population
  - In 2011, an estimated 72% of Virginia youth diagnosed with ADHD were taking ADHD medications



Source: NSCH

ADHD Treatment – Virginia (2)*

- ADHD treatment in insured populations
  - Commercial health insurance markets (2014-2015)**
    - 51% – 54% of enrolled individuals <20 years old (61% - 64% of adults 20+) who were diagnosed with ADHD were prescribed an ADHD medication
    - Around 4% of all enrolled individuals <20 years old (2% of adults 20+) were prescribed ADHD medication
  - Medicaid (2015): around 7.4% of all enrolled individuals <18 years old (1.2% of adults 18+) were prescribed ADHD medication

* See Appendix for additional detail on the content of this slide

**Data represent: 100% of individuals with fully insured policies; an estimated 50% of individuals with self-insured policies

ADHD Treatment Quality – Medicaid*

- Magellan Clinical Practice Guideline (CPG) review of 139 patient records in 2015-2016**

Assessment	CPG Provider Assessment Score <=3: Adherent; >3: Not Adherent	
	2015	2016
Suicide Risk	2.5	1.1
Major Depressive Disorder	3.2	2.5
Schizophrenia	4.7	1.39
ADHD	6.8	6.6

Source: Magellan (2017); Magellan (2016)

- Follow-up care for children 6-12 years old prescribed ADHD medication (2016) in MCOs

Phase	Virginia	US average
Medication initiation	44%	42%
Medication continuation/maintenance	56%	52%

Source: DMAS (2017)

* See Appendix for additional detail on the content of this slide

** Records covered individuals receiving carved-out behavioral health services

ADHD Pharmacological Treatment – Effectiveness*

- In the short-term:
  - Consistent evidence that FDA-approved ADHD medications reduce symptoms (e.g., 20% reduction in ADHD rating score)
  - Consistent evidence that combined psychotherapy/ADHD medications more effectively improves outcomes beyond ADHD symptoms than ADHD medications alone (e.g., comorbidities, academic achievement, social functioning)
  - However, a recent meta-analysis concluded that the strength of evidence on ADHD medication effectiveness is low, primarily due to a high risk of bias in ADHD studies
- In the long-term:
  - Inconsistent/limited evidence of effectiveness of ADHD pharmacological treatment on outcomes
  - Evidence base may reflect limited long-term ADHD medication efficacy and/or varying provider/patient practices

* See Appendix for additional detail on the content of this slide

ADHD Pharmacological Treatment – Safety*

- Studies generally find increased risk of non-serious adverse events (AEs) from stimulant use (e.g., decreased appetite, GI pain, headache), although:
  - Follow-up periods to study AEs are typically short
  - There is evidence of a large number of individuals dropping out of studies due to serious AEs, likely underestimating the number of serious AEs
- Concerns have been raised about the number of studies conducted by the same groups of authors and/or sponsored by pharmaceutical companies manufacturing ADHD medications

* See Appendix for additional detail on the content of this slide

ADHD Pharmacological Treatment – Safety (2)*

- Strong evidence that stimulant use can cause short-term weight loss/slowed growth
- Mixed evidence on effects on longer-term growth
- Studies have found increased risk in cardiovascular disease (CVD), ranging from small increases to over 2 times the risk
- Most studies find stimulants are not associated with – or are protective against – developing a substance use disorder (SUD)
- Evidence that long-term stimulant use is protective against depression

* See Appendix for additional detail on the content of this slide

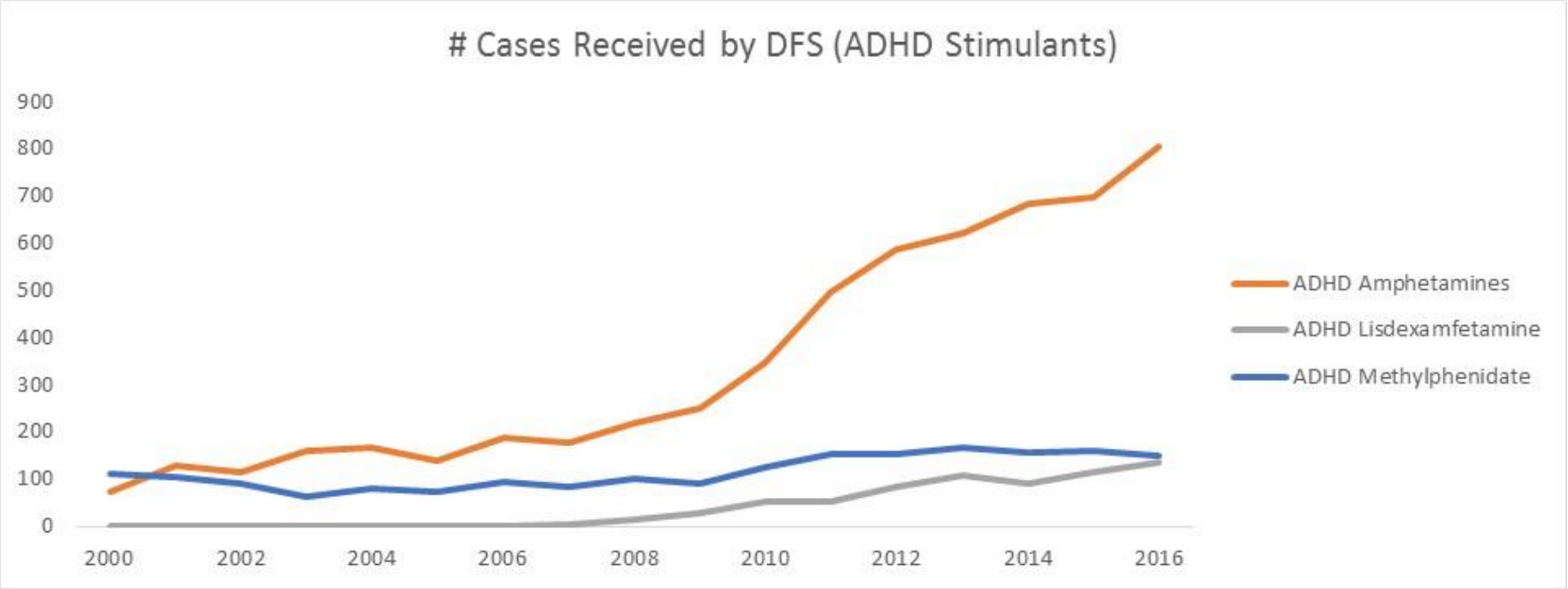
ADHD Stimulants – Non-medical Use/Misuse Nationally*

- FDA label ("black box") warnings on ADHD medications:
  - Amphetamines: have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events
- 3.4% of those 12+ years old estimated to have used prescription ADHD stimulants for non-medical purposes during their lifetime
- Misuse of stimulants among grade school and high school-age children estimated at 5% to 9%
- Misuse of stimulants among college-age population estimated at 5% to 35%
- Emergency Department (ED) visits for non-medical use of stimulants:
  - Tripled between 2005 and 2010
  - Doubled among those 18+ years old

* See Appendix for additional detail on the content of this slide

ADHD Stimulants – Non-medical Use/Misuse in Virginia

- The number of law enforcement cases in Virginia involving ADHD stimulants increased from 184 in 2000 to 1,089 in 2016



Source: Department of Forensic Sciences

ADHD Stimulants – Abuse/Addiction

- Stimulant misuse and/or abuse does not equate to addiction
- While ADHD stimulants have abuse potential:
  - Their pharmacological properties considerably reduce their abuse potential compared to non-prescription stimulants (e.g., cocaine)
  - There is evidence that long-acting formulations have successfully limited actual abuse in comparison to abuse potential
- There is little evidence of addiction to ADHD stimulants

Antipsychotic Medication Use – National Trends

- Atypical antipsychotics (AAPs) are FDA-approved for:
  - Autism
  - Bipolar mania
  - Major depressive disorder
  - Schizophrenia
  - Schizoaffective disorder
  - Tourette's disorder
- ADHD co-occurs with several of these conditions (e.g., 10% - 28% with bipolar disorder)

Antipsychotic Medication Use – National Trends (2)*

- Use of antipsychotics has grown substantially since the early 2000s
- ADHD is one of the most common mental health diagnoses among youth prescribed antipsychotics, which may reflect a combination of:
  - Co-occurrence of ADHD with FDA-indicated conditions for antipsychotics (e.g. major depressive disorder, bipolar mania, autism)
  - Off label use for a condition co-occurring with ADHD (e.g. aggression)
  - Off label use for ADHD
- In terms of off label use, studies have found:
  - Increased off-label use of Atypical Antipsychotics (AAPs) over time
  - A significant percentage (e.g., 18%-20% in the mid-2000s) of ADHD-diagnosed youth are prescribed AAPs without a condition indicated for use
  - More recent data on off label use of AAPs are limited

* See Appendix for additional detail on the content of this slide

Antipsychotic Medication Use – Virginia Trends

- AAP medication prevalence among those diagnosed with ADHD in commercial health insurance markets (2014-2015)*
  - 5.4% - 6.1% of ADHD-diagnosed individuals < 20 years (5.0% - 6.4% of ADHD-diagnosed individuals 20+ years) were prescribed atypical antipsychotics
- Off label AAP medication prevalence among all enrollees in commercial health insurance markets (2014-2015)**
  - Of the approximately 29,000 individuals prescribed AAPs, 31% did not have a FDA-indicated diagnosis for the prescribed AAP
  - Of the approximately 8,800 individuals with an ADHD diagnosis and prescribed AAPs, 46% did not have a FDA-indicated diagnosis for the prescribed AAP

* Data represent: 100% of individuals with fully insured policies; an estimated 50% of individuals with self-insured policies

** "Off label": based on non-FDA-indicated diagnosis only, not non-indicated age or dosage level

Antipsychotic Medication Use Quality – Medicaid

- Among children and adolescents 1-17 years old in the Medicaid population, data from 2016 indicate:
  - Higher than national average use of multiple concurrent antipsychotics
  - Lower than national average use of 1st-line psychosocial care
  - Around the national average use of metabolic monitoring for side effects

Indicator	VA MCO Average	National Median
Multiple concurrent antipsychotic use	2.66%	1.99%
Metabolic monitoring for side effects	29.8%	29.6%
1st-line psychosocial care (psychosocial care used before antipsychotics)	51.83%	60.43%

Source: DMAS (2017)

Atypical Antipsychotics – Effectiveness and Safety

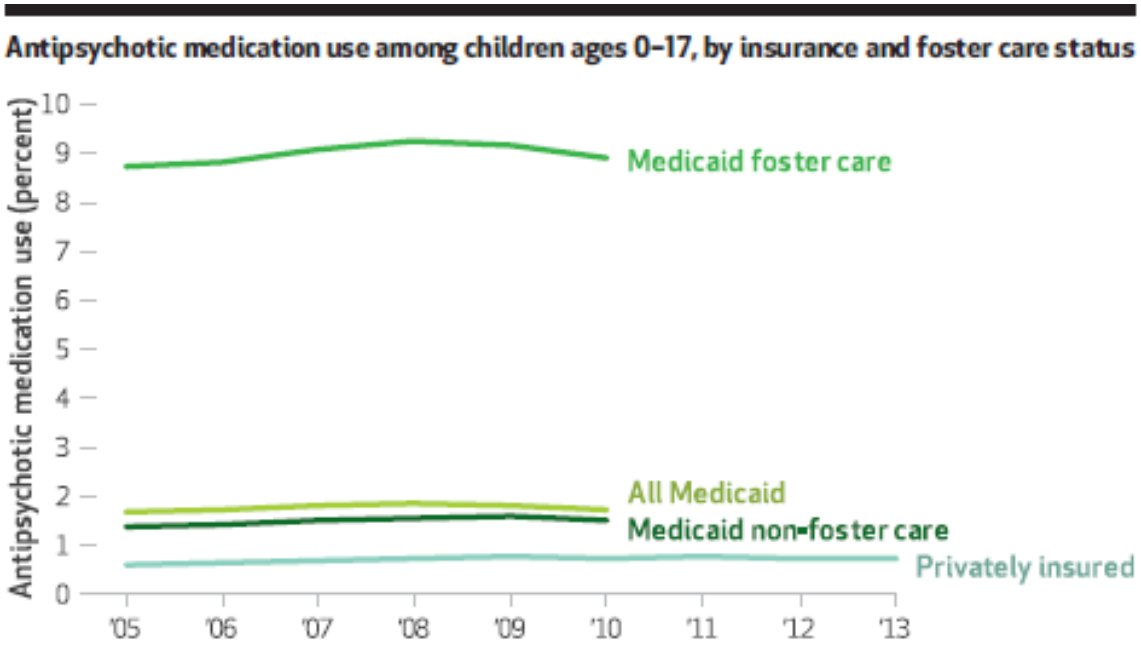
- A recent Agency for Health Research Quality (AHRQ) study (2017) assessed both effectiveness and harms of AAPs
- AAP effectiveness among patients with ADHD:
  - Probably reduces conduct problems and aggression in children with ADHD and/or conduct disorders
  - Appears to reduce clinical severity in patients with ADHD (although probably more for patients with a primary diagnosis of other behavioral disorder)
  - There is moderate evidence of clinical benefit only for those unresponsive to stimulants medications for ADHD or have other behavioral disorders as the primary diagnosis
- AAP safety among all populations:

Adverse Event/Side Effect	Evidence of Risk
Any drug-induced movement disorder	Probably increases
Weight/BMI	Probably increases slightly
Total cholesterol	May increase
Triglycerides	Probably increases
Sedation/somnolescence	Probably increases

Source: AHRQ

Psychotropic Medications – Foster Youth Populations (Nationally)

- Concerns in 2000s of use of psychotropic medications in foster care populations
- Since late 2000s, federal legislation has required States to develop psychotropic medication monitoring programs
- After peaking in 2008, rates of AAP prescriptions in foster children stabilized



Source: Crystal (2016)

Psychotropic Medications – Foster Youth populations (Virginia)

- A study from 2015-2016 on Virginia children and adolescents 1-17 years old in foster care provide data on use of ADHD medication and antipsychotics
- While no benchmarks were provided by which to compare these data to other States or foster populations, compared to data from the general Medicaid population from 2016*:
  - Multiple concurrent use of antipsychotics (1.9% compared to 2.7% of Medicaid enrollees)
  - Use of 1st-line psychosocial care before initiating antipsychotics was higher (86% compared to 52% of Medicaid enrollees)

Indicator	Percentage
ADHD Medications	
ADHD medication prevalence	43%
Newly prescribed ADHD medication	9%
Antipsychotics	
Multiple concurrent antipsychotic use	1.9%
1st-line psychosocial care (psychosocial care used before antipsychotics)	86%

Source: HSAG (2017)

* See Slide 28

Summary – ADHD

- Variations in prevalence of ADHD across countries, States and populations likely reflect a combination of inherent differences, differing diagnostic criteria (including multiple changes over time in the DSM criteria) and practices, and schooling factors.
- Untreated ADHD is associated with sizeable adverse impacts to individuals and society.
- While there is consistent evidence that 1st-line ADHD medication treatment reduces ADHD symptoms in the short-term, its longer-term effectiveness is not as well-established. Additionally, there is well-documented evidence that ADHD stimulant use can have short-term health side effects, but implications on longer-term health is more uncertain.
- Data from Virginia suggest that ADHD prevalence and medication use are largely in line with national trends. While some quality data indicate better-than-national-average practices (e.g., follow-up care), other suggest practices lag behind those for other behavioral health conditions (e.g., clinical practice guideline scores).
- Misuse of ADHD stimulants may be sizeable among some populations (e.g., college-aged individuals), although there is little evidence of addiction to stimulants.

Summary – Antipsychotics

- Conditions for which atypical antipsychotics (AAPs) are FDA-approved co-occur at elevated rates with ADHD, and ADHD is one of the most common mental health diagnoses among youth prescribed AAPs.
- Off label use of AAPs has increased over time, and there is evidence that a significant percentage of ADHD-diagnosed youth are prescribed AAPs off label.
- Recent data from the commercial health insurance markets in Virginia suggest that around 31% of individuals were prescribed antipsychotics off label.
- Concerns since the 2000s have been raised in the US about the use of AAPs among foster populations. Recent quality data from Virginia suggest that practices are favorable compared to the general Medicaid population (e.g., lower multiple concurrent antipsychotic use).

Citations

Citations

Slide 4

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Slide 6

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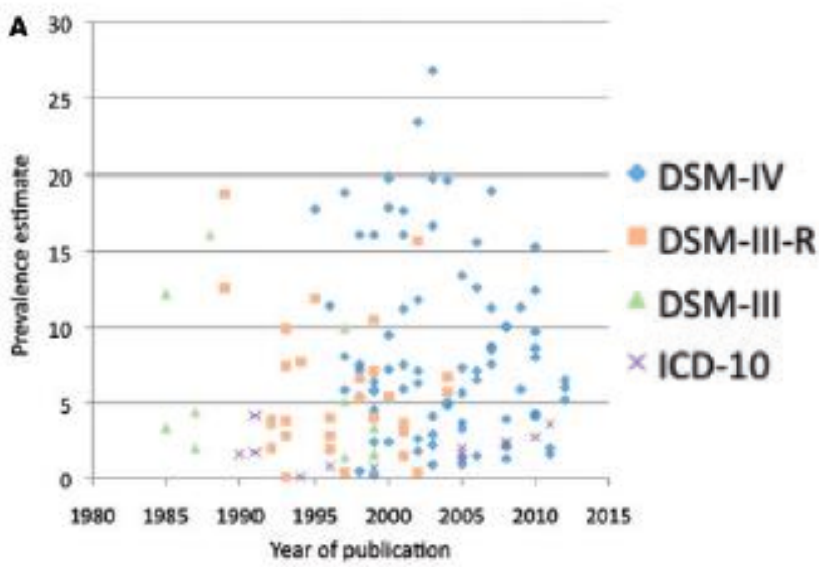
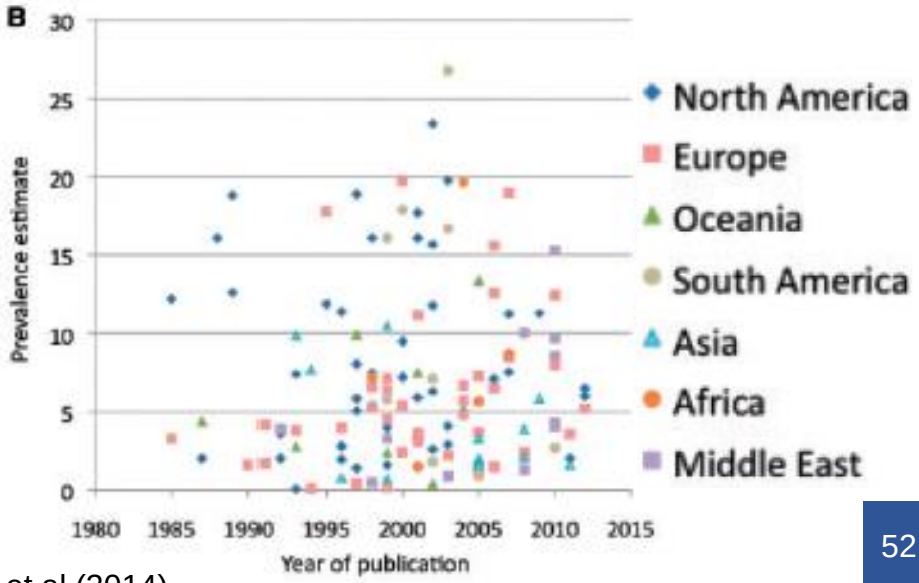
Appendix: Additional Detail

ADHD Epidemiology: Globally

- Estimated ADHD prevalence:
  - Children/adolescents: 3.4% - 7.2%; adults: 2.5%
- Time trends:
  - Evidence of increased global diagnostic prevalence driven by successive DSM versions
  - Little evidence that temporal increase/geographic variation in diagnostic prevalence if standardized diagnostic procedures followed (e.g., DSM vs ICD criteria)





Source: Polanczyk et al (2014)

ADHD Epidemiology: Prevalence in Virginia

- Sub-populations
  - Child Development Centers (CDCs) overseen by the Department of Health (VDH): In 2016, 1,081 children accessing CDCs were diagnosed with ADHD, representing 24% of diagnoses made

Adverse Impacts of ADHD – Individuals

- An estimated 5% - 75% of ADHD-diagnosed youth experience symptoms into adulthood
  - Wide variation likely reflects heterogeneity in symptom assessment
  - Longest-running US study on ADHD found symptom persistence of 60% and impairment persistence of 41%.
- Estimated impacts on health/social outcomes include:
  - Health:
    - Decreased life expectancy/50% increase in mortality risk
    - 36% increase in risk of vehicle accident among adolescents/young adults
    - Mixed evidence of association with obesity
  - Academic achievement:
    - 3.7 times the odds of failure to complete high school
  - Employment:
    - Higher odds of unemployment/33% reduction in earnings
  - Criminality:
    - 2 to 3 times higher risks of arrests, convictions, and incarcerations

ADHD Treatment – Virginia

- DBHDS inpatient facilities: between 2014 and 2017, approximately:
  - 2% of individuals across all DBHDS facilities were prescribed ADHD medication
  - 15% of children at the Commonwealth Center for Children were prescribed ADHD medication
- Community Services Boards: between 2015 and 2017, 15% - 16% of individuals seeking any services had an ADHD diagnosis

ADHD Treatment Quality – Medicaid

- Magellan Clinical Practice Guideline (CPG) review of 139 patient records in 2015-2016*

Assessment	CPG Provider Assessment Score <=3: Adherent; >3: Not Adherent	
	2015	2016
Suicide Risk	2.5	1.1
Major Depressive Disorder	3.2	2.5
Schizophrenia	4.7	1.39
ADHD	6.8	6.6

- Practices scoring <50% adherence (2015):

Diagnostic assessment	Therapeutic interventions
• If provider is not a physician, reviewed findings from consultation with psychiatrist or primary care physician	• If referral for a medical/psychiatric evaluation, provider included the results of evaluation in the treatment planning
• Considered partial remission (fewer than full criteria met when full criteria were previously met	• Conducted education about ADHD/treatment including psychological services/pharmacological intervention
• Considered whether few/many symptoms are in excess of those required to make diagnosis of ADHD	• Co-morbid medical and psychiatric conditions discussed with parents, guardians, and if applicable patient
• Coordinated care with medical provider/medical evaluation during diagnostic process ruled out medical causes of symptoms of ADHD and assessed cardiovascular functioning	• Provider assessed if psychotherapy is indicated
• If suicidal thoughts or behaviors were present, appropriate actions were taken to intervene	

* Records covered individuals receiving carved-out behavioral health services

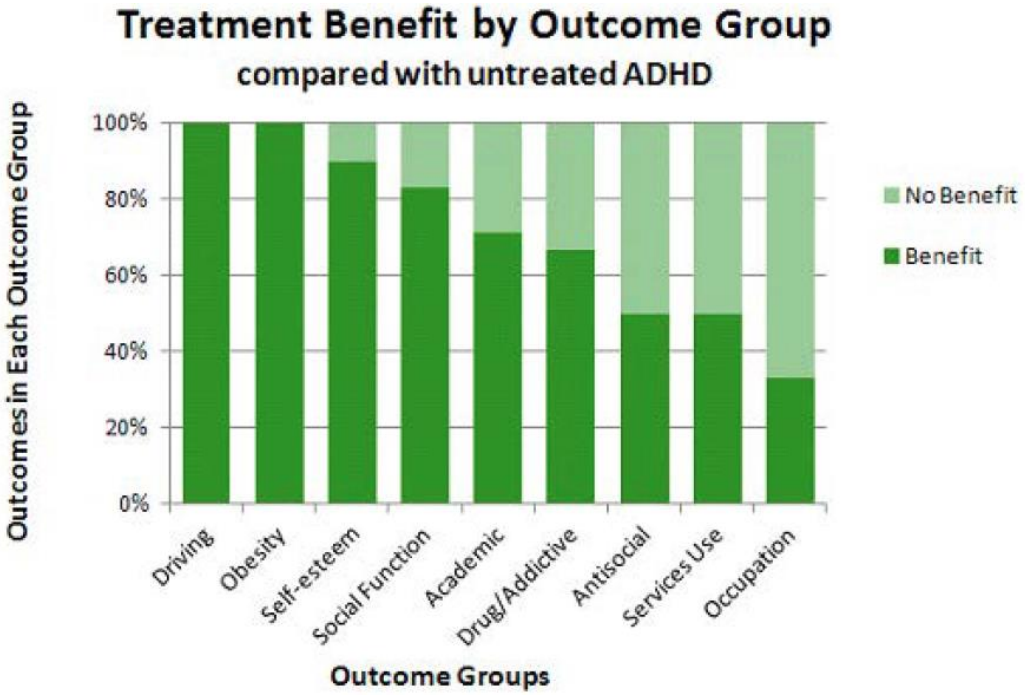
ADHD Pharmacological Treatment – Long-term Effectiveness

- There is inconsistent/limited evidence of effectiveness of ADHD pharmacological treatment on outcomes. Strength of evidence may reflect limited long-term ADHD medication efficacy and/or varying provider/patient practices (e.g., treatment adherence) under uncontrolled/long-term conditions.

- For example:
  - Systematic review found most studies reporting benefit of ADHD medications for multiple long-term outcomes
  - Study of South Carolina Medicaid population over 10 years found ADHD medication associated with reduced: STDs by 3.6%; SUDs by 7.3%; injuries becoming injured by 2.3%

BUT

  - Three years after enrollment in landmark 14-month Randomized Control Trial on ADHD, no significant differences detected between children treated with ADHD medications and those without, on: ADHD/other behavioral symptoms; or functioning (e.g., grades earned in school)
  - Natural experiment study from Canada: little evidence of positive effects on schooling attainment



ADHD Pharmacological Treatment – Safety

- FDA safety communications on ADHD medications:
  - Permanent loss of skin color may occur (2015)
  - Methylphenidate may in rare instances cause prolonged/painful erections (2013)
  - Studies have not shown increased risk of serious CVD AEs in adults (2011)
  - Manufacturers should develop patient Medication Guides to alert patients to possible CVD/psychiatric symptoms risks (2007)
- FDA label ("black box") warnings on ADHD medications:
  - Amphetamines: have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events
  - Methylphenidates: should be given cautiously to patients with a history of drug dependence or alcoholism; chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior; frank psychotic episodes can occur, especially with parenteral abuse
  - Strattera (non-stimulant): Increased risk of suicidal ideation in children or adolescents
- Meta analyses/systematic reviews generally find increased risk of non-serious adverse events (AEs) from stimulant use, although follow-up periods to study AEs are typically short-term
- Review study of AEs in pediatric populations (2011):
  - Very few reported serious AEs. However, a large number of children found to drop out of studies due to serious AEs, likely underestimating the number of serious AEs.
  - A large number of studies conducted by the same groups of authors and sponsored by the pharmaceutical companies manufacturing the respective medications effectiveness/safety

	Methylphenidate (MPH)	Atomoxetine (ATX)
Loss of appetite	+	+
Growth restriction	++	+
Other gastrointestinal symptoms: abdominal pain, nausea, vomiting, diarrhoea (MPH), constipation (ATX), dyspepsia, dry mouth	+	+
Increase in blood pressure and heart rate	+	+
Cough, nasopharyngitis	+	--
Sleep disturbances	++	+
Tics	+	--
Irritability, mood changes	+	+
Drowsiness	+	++
Dizziness	+	+
Headache	++	+

+=common side-effect. ++=if the side-effect is common for both drugs, the effect is more pronounced for this drug compared with the other. --=side-effect not common.

Table: **Some of the more common side-effects associated with pharmacological treatment**

* Thapar et al (2016)

ADHD Pharmacological Treatment – Side Effects

- Growth
  - Strong evidence that stimulant use can cause short-term weight loss/slowed growth
  - Mixed evidence on effects on longer-term growth (some studies have found growth catch-up associated with “drug holidays” or treatment cessation, others have found persistent growth retardation)
- Cardiovascular Disease (CVD)
  - Studies have found increased risk in CVD, ranging from small increases to over 2 times the risk
  - Power of most studies to detect risk differences is generally low because CVD is a relatively rare event in study populations
- Substance Use Disorder (SUD)
  - Most studies find stimulants are not associated with – or are protective against – developing a SUD (over short- and long-term follow up)
- Depression
  - Evidence that long-term stimulant use is protective against depression
- Psychotic disorders
  - Little evidence of association between stimulant use and new onset or worsening of tics

ADHD Stimulants – Non-medical Use/Misuse Nationally

- 3.4% of those 12+ years old estimated to have used prescription ADHD stimulants for non-medical purposes
  - School-age population:
    - Misuse of stimulants estimated at 5% to 9%
    - 7.5% of high school seniors reported past-year nonmedical use of Adderall (2015)
  - College-age population:
    - Misuse of stimulants estimated at 5% to 35%
    - Recent data indicate 17% of students estimated to have used prescription stimulants
- Among those using stimulants for non-medical use:
  - >95% use an illicit drug/non-medical use of another prescription drug
  - 10% - 13% have substance dependence
- Emergency Department (ED) visits for non-medical use of stimulants tripled between 2005 and 2010 (from 5,212 to 15,585)
  - Medical use ED visits doubled among those 18+ years old

Antipsychotic Medication Use – National Trends

- Atypical antipsychotics (AAPs) are FDA-approved for:
  - Autism
  - Bipolar mania
  - Major depressive disorder
  - Schizophrenia
  - Schizoaffective disorder
  - Tourette's disorder
- ADHD co-occurs with several of these conditions
  - Patients with psychotic disorders in general are twice as likely to have childhood ADHD diagnosis (2003 study)
  - Bipolar disorder: co-occurrence of ADHD: 10% - 28%
  - Other disorders indicated for AAPs:

TABLE 1 Prevalence of Comorbid Disorders for Children With ADHD Versus Those Without ($N = 61\,779$)

	No ADHD	ADHD	Adjusted Relative Risk[b]	95% CI
Learning disability (%)	5.3	46.1[a]	7.79	6.86–8.86
Conduct disorder (%)	1.8	27.4[a]	12.58	10.23–15.48
Anxiety (%)	2.1	17.8[a]	7.45	6.08–9.12
Depression (%)	1.4	13.9[a]	8.04	6.09–10.62
Speech problem (%)	2.5	11.8[a]	4.42	3.41–5.73
Autism spectrum disorder (%)	0.6	6.0[a]	8.72	5.97–12.72
Hearing problem (%)	1.2	4.2[a]	2.77	1.87–4.11
Epilepsy or seizures (%)	0.6	2.6[a]	3.93	2.19–7.06
Vision problem (%)	1.4	2.3[a]	1.47	0.98–2.20
Tourette's syndrome (%)	0.09	1.3[a]	10.70	4.72–24.23
Any MH/ND disorder (%)	11.5	66.9[a]	5.12	4.72–5.55

[a] $P < .05$ for χ^2 test.

[b] Relative risks were adjusted for child age, gender, race/ethnicity, parent education, household income, and family structure.

Source: Larson (2011)

Antipsychotic Medication Use – National Trends

- Use of AAPs has grown substantially since the early 2000s (e.g., between 2002 and 2007, antipsychotic use increased by 62% in Medicaid enrolled children)
- Increased off-label use of Atypical Antipsychotics (AAPs) over time
  - ADHD is one of the most common mental health diagnoses among youth prescribed AAPs
    - 2001-2005: over 60% of Medicaid enrolled children prescribed AAPs diagnosed with ADHD
    - 2006-2010: 50% - 60% of children <12 years old prescribed AAPs diagnosed with ADHD (35% of children 13-18 years old)
  - A significant percentage of ADHD-diagnosed youth prescribed AAPs without an AAP-indicated condition (e.g., 18%-20% in the mid-2000s)
  - Concurrent used of ADHD medications and antipsychotics (e.g., in 2008, 59% to 69% of children <12 years old prescribed antipsychotics also prescribed stimulants)

ADHD Prevalence and Risks of ADHD Medications in Virginia Final Report

Joint Commission on Health Care
June 15, 2018 Meeting

Andrew Mitchell
Senior Health Policy Analyst

Study Mandate

HB1500, Item 30(A), requested that JCHC identify methods:

1. To raise awareness of health/addiction risks of Attention Deficit Hyperactivity Disorder (ADHD) medication use
2. To compile/track statistics on Virginia school children diagnosed with ADHD or other categories such as “specific learning disabilities, other health impairment, multiple disorder, and emotional disturbances”
3. Used by other states/countries to limit antipsychotic use
4. To identify the incidence/prevalence of prescribing anti-psychotics for off-label use

The analysis shall be reported by the JCHC to the Chairmen of the House Appropriations and Senate Finance Committees no later than November 30, 2018

Interim Report Summary – ADHD

- Variations in prevalence of ADHD across countries, States and populations likely reflect a combination of inherent differences, differing diagnostic criteria – including multiple changes over time in the DSM criteria – and schooling factors.
- Untreated ADHD is associated with sizeable adverse impacts to individuals and society.
- While there is consistent evidence that 1st-line ADHD medication treatment reduces ADHD symptoms in the short-term, its longer-term effectiveness is not as well-established. Additionally, there is well-documented evidence that ADHD stimulant use can have adverse short-term health side effects, but implications on longer-term health is more uncertain.
- Data from Virginia suggest that ADHD prevalence and medication use are largely in line with national trends.
- Misuse of ADHD stimulants may be sizeable among some populations (e.g., college-aged individuals), although there is little evidence of addiction to stimulants.

Interim Report Summary – Antipsychotics

- Conditions for which atypical antipsychotics (AAPs) are FDA-approved co-occur at elevated rates with ADHD, and ADHD is one of the most common mental health diagnoses among youth prescribed AAPs.
- Off label use of AAPs has increased over time, and there is evidence that a significant percentage of ADHD-diagnosed youth (e.g., 20%) are prescribed AAPs off label.
- Concerns since the 2000s have been raised in the US about the use of AAPs among foster populations. Recent quality data from Virginia suggest that practices are favorable compared to the general Medicaid population (e.g., lower multiple concurrent antipsychotic use).

ADHD and AAP Data in insured populations – Virginia

- ADHD
  - Diagnosed prevalence (commercial health insurance/Medicaid populations): 7% - 8% of individuals <20 (3% of individuals 20+)
  - ADHD medication treatment (commercial health insurance/Medicaid populations): 4% - 7% of enrolled individuals <20 years old were prescribed ADHD medication (1% - 2% of adults 20+)
- Off label use of AAPs*
  - Commercial health insurance markets: Of the approximately 29,000 individuals prescribed AAPs (2014-2015), 31% did not have a FDA-indicated diagnosis for the prescribed AAP
  - Medicaid population: Of approximately 69,000 individuals prescribed AAPs (2015-2017), 56% did not have a FDA-indicated diagnosis for the prescribed AAP

* Data relate to all individuals prescribed AAPs, not just individuals diagnosed with ADHD

Virginia ADHD Diagnosis Policies – DOE

- Virginia Code §22.1-298.1 requires completion of study in ADHD to obtain an initial teacher licensure
  - DOE has added ADHD content to professional studies requirements for both school personnel and education programs
- Virginia Code §22.1-298.4 mandates that DOE, in collaboration with SCHEV, require all teacher preparation programs offered at public institutions of higher education to convey information on the identification of students at risk for learning disabilities, including ADHD
  - DOE plans to require documentation about inclusion of the competencies

Virginia ADHD & Psychotropic Medication Policies – DOE

- School personnel are permitted to administer prescription medicines – including psychotropic medications – to students
- Virginia Code §22.1-274.3 requires DOE to develop and implement policies prohibiting school personnel from recommending the use of psychotropic medications for students
  - Almost all Virginia school divisions have documented/written policies
  - Nationally, 4 other States have similar policies (CT, CO, OR, TX)

Virginia ADHD & Psychotropic Medication Policies – DMAS

- Service Authorizations (SAs) for psychotropic medications are required for fee-for-service (FFS) population
  - ADHD medications/stimulants: children outside of FDA-approved age range; adults 18+
  - Antipsychotics: children <18 years old
    - Medication must be prescribed by a psychiatrist/neurologist or prescriber must supply proof of a psychiatric consultation
    - Member must be participating in a behavioral management program
    - SA Duration: 6 months
- SA requirements for Managed Care Organization (MCO) population are consistent with FFS requirements
- Under Medallion 4.0, MCO health plans are required to adopt the FFS Preferred Drug List, including accompanying SA requirements (“Common Core Formulary”)

Virginia ADHD & Psychotropic Medication Policies – DSS

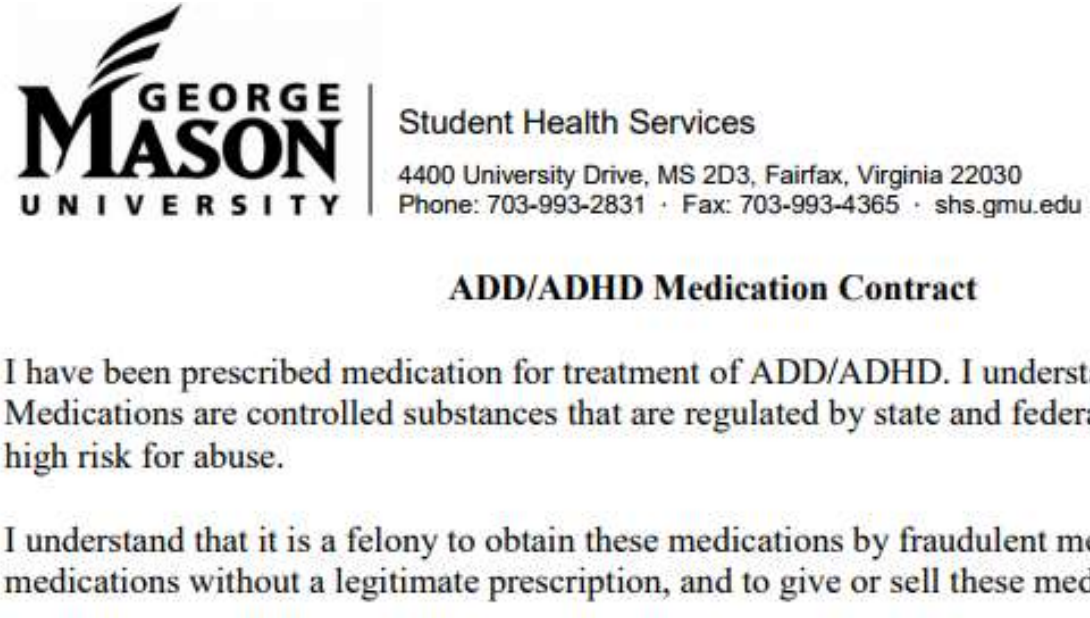
- In recent years, DSS has increased monitoring of psychotropic prescribing practices for foster youth by:
  - Working with DMAS to increase level of medical oversight and implement review process to monitor off label use of psychotropic/AAPs for children
  - Raising awareness of issue among caseworkers (e.g., e-learning on psychotropic medications; screening tools for trauma) and modification of case worker database in 2016 to track foster youth medical/prescription history
    - However, data are currently entered manually by caseworkers and not synchronized with DMAS data

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential

- General public
  - FDA safety communications on ADHD medications (e.g., “Permanent loss of skin color may occur” (2015))
  - FDA label (“black box”) warnings on ADHD medications:
    - E.g., Amphetamines: have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential (2)

- Providers
  - Insurer guidelines to prescribers (e.g., provision of information on FDA black box warnings)
- College/University setting
  - ADHD Medication Contract. For example:



GEORGE MASON UNIVERSITY | Student Health Services

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ADD/ADHD Medication Contract

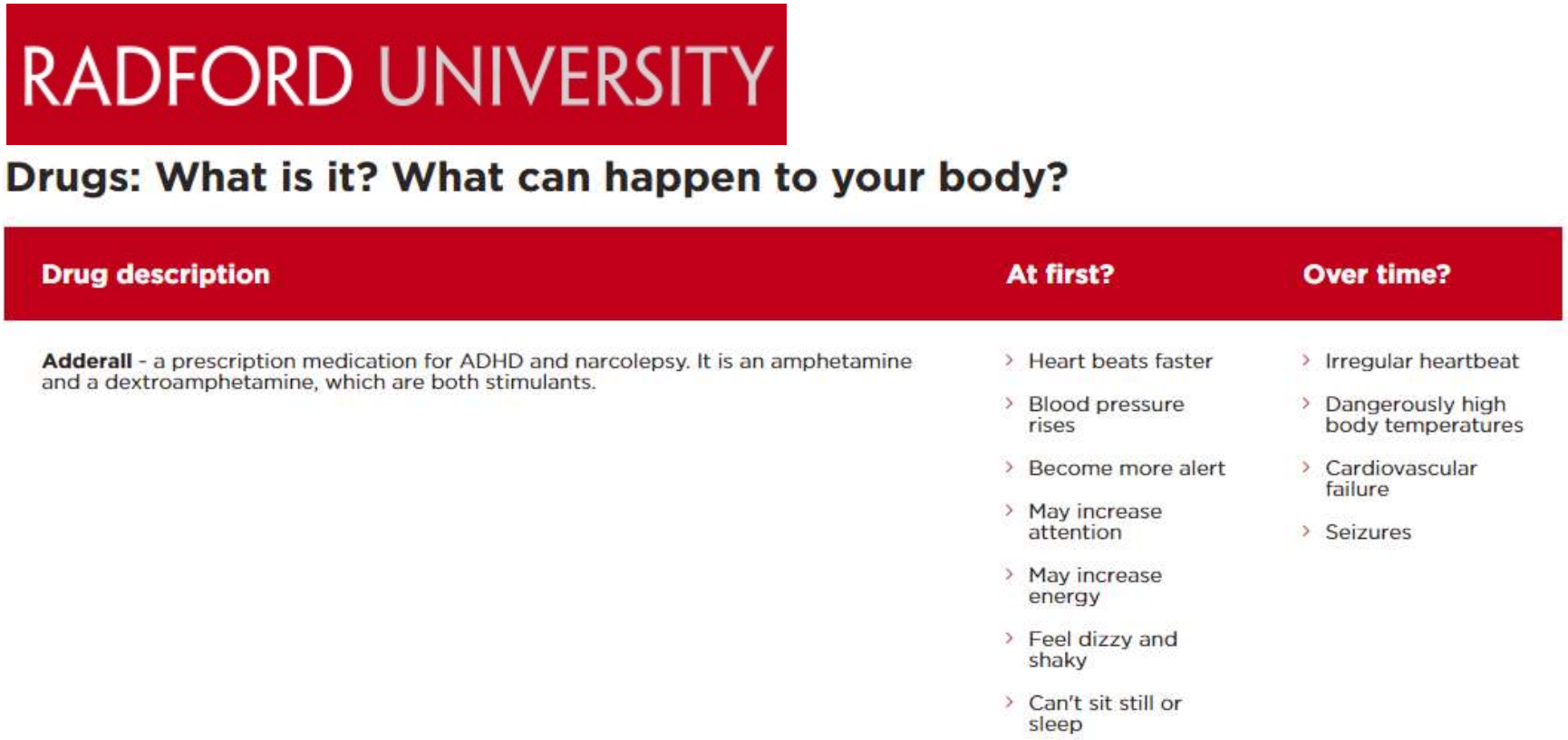
I have been prescribed medication for treatment of ADD/ADHD. I understand that ADD/ADHD Medications are controlled substances that are regulated by state and federal law because of their high risk for abuse.

I understand that it is a felony to obtain these medications by fraudulent means, to possess these medications without a legitimate prescription, and to give or sell these medications to others.

Source: https://shs.gmu.edu/wp-content/uploads/2013/07/ADD-ADHD-Contract-2.pdf

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential (3)

- College/University setting
  - Information on drug risks. For example:



RADFORD UNIVERSITY

Drugs: What is it? What can happen to your body?

Drug description	At first?	Over time?
Adderall - a prescription medication for ADHD and narcolepsy. It is an amphetamine and a dextroamphetamine, which are both stimulants.	› Heart beats faster › Blood pressure rises › Become more alert › May increase attention › May increase energy › Feel dizzy and shaky › Can't sit still or sleep	› Irregular heartbeat › Dangerously high body temperatures › Cardiovascular failure › Seizures

Source: https://www.radford.edu/content/saves/home/substance-abuse/drug-use.html

Methods to Track ADHD Diagnosis Statistics in Schools

- Some States collect statistics on ADHD diagnoses through data collection collaborations between State health and education agencies. However:
  - Data collection methods vary between States/school divisions within States, with most relying on parent-reported information provided in IEPs, Section 504 plans and/or school entrance forms
  - Data consistency and/or quality are unknown
- Virginia's DOE estimates that establishing an ADHD diagnosis data collection system for Virginia public school children:
  - Would incur a one-time investment cost of $2.9M and annual recurrent costs of $81.2K
  - Would be operational in 2 years and be able to produce reports in 3 years
  - Would encounter similar data quality/consistency uncertainties as in other States

Methods to Identify Off-label Prescribing of Antipsychotics for ADHD

- Diagnosis is not required on pharmaceutical claims, making it difficult to track off-label prescribing of AAPs with certainty
- Due to methodological challenges, DMAS has not been able to endorse a methodology that would be able to produce public use information in tracking off label prescribing of AAPs based on claims data

Methods Used by Other States/Countries to Limit Antipsychotic Use

- Nationally, common methods to limit/ensure appropriate use of AAPs and/or ADHD medications

Method	Use in Virginia
• Service authorization (SA)	• Used for both ADHD and AAPs • DMAS' current antipsychotic SA does not collect information on metabolic monitoring
• Provider peer review	• Used on case-by-case basis for FFS/MCO populations
• Drug Utilization Review (DUR)	• DUR Board meets quarterly • AAP report reviewed

- Globally, little information exists on methods to limit use of AAPs or stimulants. However, in France, it is reported that a psychiatrist must be the provider to initiate medications for ADHD.

Policy Options

Study Mandate Component	Policy Option(s)
N/A	Option 1: Take No Action
Raise awareness of ADHD medication risks	Option 2: By letter from the JCHC Chair, request the governing board of each four-year public institution of higher education to: • Require ADHD stimulant medication contracts of any student prescribed ADHD stimulants by the institution, and; • Develop and implement policies that result in the provision of written information to students about the potential risks of stimulant use
Track statistics on Virginia school children diagnosed with ADHD	Option 3: Introduce a budget amendment of $2.98M for SFY 2020 for DOE to establish an ADHD diagnosis data collection system for Virginia public school children

Policy Options (2)

Study Mandate Component	Policy Option(s)
Methods to limit antipsychotic use for ADHD	Option 4: By letter of the JCHC Chair, request that DMAS and DSS convene a stakeholder group to identify methods to ensure that DSS data on antipsychotic and other prescription medications currently being prescribed to foster populations are accurate and up-to-date Option 5: By letter of the JCHC Chair, request that DMAS require documentation of metabolic monitoring in the service authorization form for antipsychotics for children <18 years old, including documentation of: baseline and routine monitoring of weight or body mass index (BMI); waist circumference; blood pressure; fasting glucose; fasting lipid panel; and Extrapyramidal Symptoms (EPS) using Abnormal Involuntary Movement Scale (AIMS)
Methods to track off label prescribing of antipsychotics	Option 6: By letter of the JCHC Chair, request that DMAS cost out an appropriate methodology to track off label prescribing of AAPs among FFS beneficiaries – and determine required contract modifications with contracted health plans to track off label prescribing of AAPs among MCO beneficiaries – with the Department reporting back to the Commission with a proposed implementation plan by October, 2019

Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on July 11, 2018.

Comments may be submitted via:

- E-mail: jchcpubliccomments@jchc.virginia.gov
- Fax: 804-786-5538
- Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 7th decision matrix meeting.

(All public comments are subject to FOIA release of records)

Appendix: Additional Detail

Methods to Track ADHD Diagnosis Statistics in Schools

- Examples of States that collect statistics on ADHD diagnoses through data collection collaborations between State health and education agencies:
  - Tennessee: annual Health Services reports draw ADHD diagnosis data from local school division database systems
  - Connecticut: annual Health Services Program Information Surveys draw ADHD diagnosis data from local school division database systems from provider orders, children's assessments, and other methods that vary by school division
  - North Carolina: Annual School Health Services Surveys collect data on students actively receiving some level of health services from the school nurse

Methods Used by Other States/Countries to Limit Antipsychotic Use

- Common methods to limit/ensure appropriate use of AAPs and/or ADHD medications include:
  - Prior/service authorization: Medication pre-approval form that requires prescribers to provide information that allows the payer to check appropriateness of requested medication.
  - Peer review: process for manual clinician review/consultation of prior authorization requests
  - Drug Utilization Review (DUR) Program: 2-phase process conducted by all State Medicaid agencies
    - Prospective DUR: electronic monitoring system screens prescription drug claims to identify potential problems (e.g., therapeutic duplication, incorrect treatment dosage/duration, clinical misuse)
    - Retrospective DUR: ongoing/periodic examination of claims data
    - On an annual basis, states are required to report on their state's prescribing habits

Virginia ADHD & Psychotropic Medication Policies – DMAS

- Fee-for-Service (FFS) population
  - ADHD medications/stimulants Service Authorization (SA):
    - Required for: children outside of FDA-approved age range; adults 18+
    - SA Duration: 1 year
  - Antipsychotics: Service Authorization (SA) required for children <18 years old
    - Medication must be prescribed by a psychiatrist/neurologist or prescriber must supply proof of a psychiatric consultation
    - Member must be participating in a behavioral management program
    - SA Duration: 6 months
- Managed Care Organization (MCO) population
  - ADHD medications
    - Most health plan requirements are consistent with FFS
  - Antipsychotics
    - Aligned with FFS requirements, except SA duration is 1 year (ages 6 – 17) after initial 6-month SA approval

Methods to Raise Awareness of ADHD Medications Risks/Addiction Potential

- General public
  - FDA safety communications on ADHD medications:
    - Permanent loss of skin color may occur (2015)
    - Methylphenidate may in rare instances cause prolonged/painful erections (2013)
    - Studies have not shown increased risk of serious cardiovascular adverse events (CVD) in adults (2011)
    - Manufacturers should develop patient Medication Guides to alert patients to possible CVD/psychiatric symptoms risks (2007)
  - FDA label ("black box") warnings on ADHD medications:
    - Amphetamines: have a high potential for abuse; administration for prolonged periods of time may lead to drug dependence and must be avoided; misuse may cause sudden death/serious cardiovascular adverse events (since 2005)
    - Methylphenidates: should be given cautiously to patients with a history of drug dependence or alcoholism; chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior; frank psychotic episodes can occur, especially with parenteral abuse (since 2001)
    - Strattera (non-stimulant): Increased risk of suicidal ideation in children or adolescents (since 2006)

Citations

Slide 5

- Virginia Health Information (commercial insurance data)
- Department of Medical Assistance Services (Medicaid data)

Slide 10

- U.S. Food & Drug Administration. Information about Medications Used to Treat Attention-Deficit/Hyperactivity Disorder (ADHD). https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm283449.htm

Slide 15

- Zito, J. et al. 2008. A three-country comparison of psychotropic medication prevalence in youth. *Child Adolesc Psychiatry Ment Health*, 2(1):26.