



Today, one in every five children and adolescents in the U.S. is diagnosed with a mental health disorder,<sup>1</sup> yet as a 2001 Report of the Surgeon General on Children's Mental Health highlighted, a significant number of these kids do not receive the treatment and care they desperately need.<sup>2</sup> In fact, fewer than 1 in 5 children actually receive treatment. And - nearly 80 percent fail to receive specialty services.<sup>3</sup> If left untreated, a mental health problem often has devastating long-term consequences including contact with the juvenile justice system, job loss, homelessness, and even suicide.

For many children, Medicaid is a critical source of health and related support services, including both outpatient and inpatient mental health services. Medicaid also funds long-term mental health care for children who need more intensive or restrictive services, including hospitalizations and residential treatments, and supports the Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program.

In recent years, Federal spending on prescription medications has consumed a greater portion of Medicaid budgets. This can in part be attributed to growing Medicaid expenditures on new and more costly psychotropic medications for children – many of which have not been proven effective or safe for use in this age group.

We believe a closer look at Medicaid expenditures for prescription medications for children will help policymakers begin to identify areas for potential intervention and improvements. Doing so is critical to ensuring that children can access appropriate, safe and consistent care through Medicaid.

In this policy brief, First Focus examines the practice of prescribing medications – specifically, atypical antipsychotics (second generation antipsychotics) - a class of psychotropic agents - for children on Medicaid. Our key findings and policy recommendations are highlighted here.

## **NATIONAL TRENDS IN PSYCHOTROPIC MEDICATION USE IN CHILDREN**

Research demonstrates a general trend of increasing prescriptions for psychotropic medications for children. In fact, the practice of prescribing this class of drugs has increased dramatically for children with behavioral and emotional problems over the last 20 years, a trend evident for younger age groups - even preschoolers.<sup>4,5,6</sup>

Many have expressed concerns about the safety, efficacy and long-term consequences of psychotropic medication use in children, especially younger age groups.<sup>7,8,9</sup> Specifically, researchers have questioned the effects of these medications on the developing brain, and the safety and effectiveness of medications tested in adults for attenuating behavioral and emotional symptoms in children.

## **PSYCHOTROPIC MEDICATION USE IN MEDICAID AND SCHIP VS PRIVATELY INSURED**

Research has shown that children enrolled in Medicaid generally experience greater chronic health conditions and impairment,<sup>10</sup> and have a higher prevalence of psychotropic medication use than those privately insured.<sup>11,12,13</sup> In fact, in one study, the rate of psychotropic drug use was nearly double among Medicaid-insured children as compared to privately insured children, and, a greater proportion of Medicaid enrolled children were given prescriptions for multiple psychotropic medications, even though fewer received outpatient mental health services.<sup>14</sup> Similarly, in a recent report, Safer and colleagues (2004) found that psychotropic medication usage rates are significantly higher for SCHIP participants than privately insured children.<sup>15</sup>

In fact, prescription rates for atypical antipsychotics for children have increased more than fivefold over the past decade and a half. As Jeffrey Thompson, the Chief Medical Officer of Washington State's Medical program noted in a recent interview, "The number one drug class in expenditures is atypical antipsychotics in almost every state. And the fastest growing utilization is for both on and off-label use in children."

Within the Medicaid program, certain populations are even more likely to utilize psychotropic medications. Specifically, children in foster care are much more likely to use psychotropic medications than children who qualify for Medicaid through other aid categories.<sup>16</sup>

For instance, a recent study found that in Connecticut, while children in state custody represented only 4.8 percent of the Medicaid population, they accounted for 17.8 percent of the psychotropic prescriptions filled – a 4.5 fold higher usage rate.<sup>17</sup> Similarly, a study of children in the Los Angeles County foster care system found that these youth had a threefold higher rate of psychotropic drug use than the broader youth population, a pattern similar to a study of a mid-Atlantic state Medicaid program. In addition, youth in foster care are often prescribed two or three medications – the effects of which are not well-known in combination.<sup>18</sup>

## **SAFETY OF PSYCHOTROPIC MEDICATION USE IN CHILDREN**

Today, atypical antipsychotics are being prescribed at a much higher rate today than ever, yet, they have limited FDA approval in older children and little is known of their impact on younger children. Although the practice of prescribing psychotropic medications for children continues to grow, serious concerns about the safety and efficacy of use for this population have been raised.

In fact, between 50% to 75% of psychotropic drugs are not approved for use in children or adolescents.<sup>20</sup> For certain newer classes of drugs, medications have not been licensed for use in children. As a result, providers are often prescribing drugs “off-label” (practice of prescribing meds for use other than the intended indication).

To date, we have no safety data and little understanding of the long-term neurological effects of the use of atypical antipsychotics in younger children. In addition, available research suggests that use in younger children may contribute to weight gain and diabetes, may yield extrapyramidal side effects, and contribute to aggressive behaviors.<sup>21</sup>

## **MEDICAID EXPENDITURES FOR PRESCRIPTION DRUGS**

In recent years, expenditures for prescription drugs have grown considerably, and now consume an increasingly larger portion of Medicaid budgets. Banthin and Miller (2006) highlight a number of critical points with respect to Medicaid practices, specifically: (1) there is a rapid take-up of new drugs (e.g., a significant shift away from prescribing first generation drugs to atypical antipsychotics – known as second generation; and (2) a number of Medicaid children were prescribed antidepressants, despite recent warnings issued by the FDA regarding antidepressant use by this population. We should note that similar issues are raised by the growing use of atypical antipsychotics drugs by children.

Furthermore, their findings highlight the following: between 1996-1997 and 2001-2002, children and nondisabled adults, who are often the parents of Medicaid and SCHIP enrolled children, experienced large percent increases in total expenditures for prescription drugs. For children, total expenditures jumped 162% from \$1.2 billion to \$3.1 billion in 2001/2002. As the authors note, the data also show a large percentage increases in expenditures per user to \$265 per child in 2001/2002.<sup>19</sup>

## **A LOOK AT STATE PRACTICES: ATYPICAL ANTIPSYCHOTICS AND MEDICAID**

A number of states have raised significant concerns about the rapid increase in antipsychotic medication prescriptions for children in government health programs.

As reported in a May 2, 2006 USA Today story, “For Foster Kids, Oversight of Prescriptions in Scarce,” “in California, Med-Cal prescription claims for atypicals for kids in foster care increased 77% between 2001 and 2005, to 70,879.” In addition, “in Illinois, the number of children covered under the state's public health care program — not just foster children — who had an atypical prescription went up 39% between fiscal years 2003 and 2005, to 17,746.”

And, in Florida, the state's "health care agency ordered an independent investigation into why the number of Medicaid children taking anti-psychotics nearly doubled in the past five years. The numbers jumped from 9,500 to 17,900."

Moreover, in Fiscal Year 2007 alone, Arkansas spent \$23.5 million on atypical antipsychotics for Medicaid recipients under age 18. That year, 12,418 Medicaid-covered children aged 0-18 were prescribed antipsychotic medications.<sup>22</sup>

Also, a study of the Texas Medicaid program found that the number of children and adolescents receiving treatment with antipsychotic medications increased significantly from 1996-2000. Also, the prevalence rate of children and adolescents receiving atypical antipsychotics increased 494% during that time. Total expenditures for antipsychotics increased from \$2,278,134 in 1996 to \$13,730,220 in 2000 (an increase of 473%).<sup>23</sup>

And - according to a recent New York Post story, "Medicaid Kids in Psych-Rx Surge," New York State's Medicaid program paid \$82.8 million in 2006 for psychiatric drugs for children, many of which are not approved for use in children. That year, Risperdal - manufactured by Johnson & Johnson - was given to 17,393 children on Medicaid in New York, making it the most heavily prescribed psychiatric drug in the program. New York's Medicaid program spending on the drugs in 2006 increased \$8 million from the previous year and \$15 million from 2004.<sup>24</sup>

## **STATE ACTION: LAWSUITS, INVESTIGATIONS AND INQUIRIES**

Arkansas has filed a lawsuit against three major drug companies - Janssen Pharmaceutica of Johnson & Johnson Inc., Eli Lilly & Co. and more recently, AstraZeneca, claiming each illegally marketed antipsychotic drugs to be paid for by the states Medicaid and employee health-insurance programs. The case against AstraZeneca claims that the company encouraged doctors to prescribe Seroquel - an atypical antipsychotic - to children and the elderly for non-FDA approved uses, thereby endangering patients and costing the states millions of dollars. The Arkansas Medicaid program has spent \$200 million on Seroquel and

two other atypical antipsychotics (Zyprexa and Risperdal) since they came on the market.<sup>25</sup>

Other states, including Pennsylvania, Connecticut and South Carolina have followed suit, suing drug manufacturers and seeking to recoup Medicaid payments and compensation for ill effects suffered by patients. For instance, Connecticut is suing drug maker Eli Lilly & Co over the antipsychotic drug Zyprexa, claiming that it ran an illegal marketing campaign to promote the drug for unapproved off-label use, including treating children.<sup>26</sup>

In several states, legislators have responded by seeking probes into the practice of antipsychotic drug use in children, and questioning spending on this class of drugs. For instance, in Florida, the number of Medicaid-enrolled children prescribed antipsychotics doubled between 2000 and 2006. In response, Florida's Agency for Health Care Administration recently reviewed new guidelines on paying for antipsychotic drugs for children, and proposed rule changes to permit Medicaid reimbursement under one or two circumstances: if an antipsychotic has an FDA-approved use or is listed in an official compendium, or, if prior authorization is granted. A legislator has since questioned the practice of permitting Medicaid to pay for antipsychotic prescriptions for off-label use.<sup>27</sup>

In New Jersey, between 2000 and 2007, the Medicaid program spent over \$37 million on antipsychotic medications for children under the age of 18.<sup>28</sup> In response, two state legislations have demanded action, one seeking an investigation by the state's Attorney General and another pressing the state's Department of Health and Human Services.<sup>29</sup>

In addition, in New Hampshire, 17 state legislators have joined to ask the state's Attorney General to pursue a criminal investigation into several drug manufacturers after learning that the state's Medicaid program has spent a significant amount on purchasing medications for children.<sup>30</sup>

And, a consortium of state Medicaid directors is currently evaluating the use of atypical antipsychotics in children on Medicaid, and is expected to report its findings at the National Association of State Medicaid Medical Directors in November.<sup>31</sup>

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## FIRST FOCUS POLICY RECOMMENDATIONS:

- *It is critical that a child receives a comprehensive medical evaluation and a medical diagnosis before beginning treatment for a mental or behavioral disorder.*
- *Gleason and colleagues (2007) recently reviewed available literature and developed recommendations regarding the psychopharmacologic treatment of preschool children. The researchers emphasized the importance of psychosocial interventions before medications are utilized.<sup>32</sup> We strongly support this practice, and believe that non-pharmacological interventions (e.g. psychotherapy) should be considered as an alternative to psychotropic medication, or if appropriate, in combination with pharmaceutical treatment.*
- *Children on psychotropic medications should receive routine follow-up care and their prescription dosages should be regularly monitored and adjusted as appropriate. Any potential side-effects of medications should be carefully monitored.*
- *We strongly support efforts to better understand the effects of atypical antipsychotic medications usage for children.*
- *The GAO should review the practice of prescribing psychotropic medications, specifically atypical antipsychotics, for children on Medicaid to determine if these prescriptions are safe, appropriate and cost effective, and to examine the practice of prescribing these medications to young children, specifically children ages 0 to 4. The study should also examine the practice of providers prescribing medications “off-label,” the frequency of prescribing concomitant use of psychotropic medications for this population, and marketing practices by pharmaceutical companies for psychotropic medications – specifically those targeting children.*
- *We must also invest in long-term drug safety investigations, provide ongoing clinical monitoring of psychotropic medication use in children, and develop the most appropriate and effective treatments possible for children. A number of prominent researchers have recommended expanding studies of the benefits and risks of pharmaceutical treatments beyond clinical trials and into sustained studies in community-based youth populations – especially high-risk populations on Medicaid (e.g., children in foster care), given the rather complicated and poorly evidenced, high-cost medication regimens these children typically receive.*

## FOR MORE INFORMATION:

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## NOTES

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