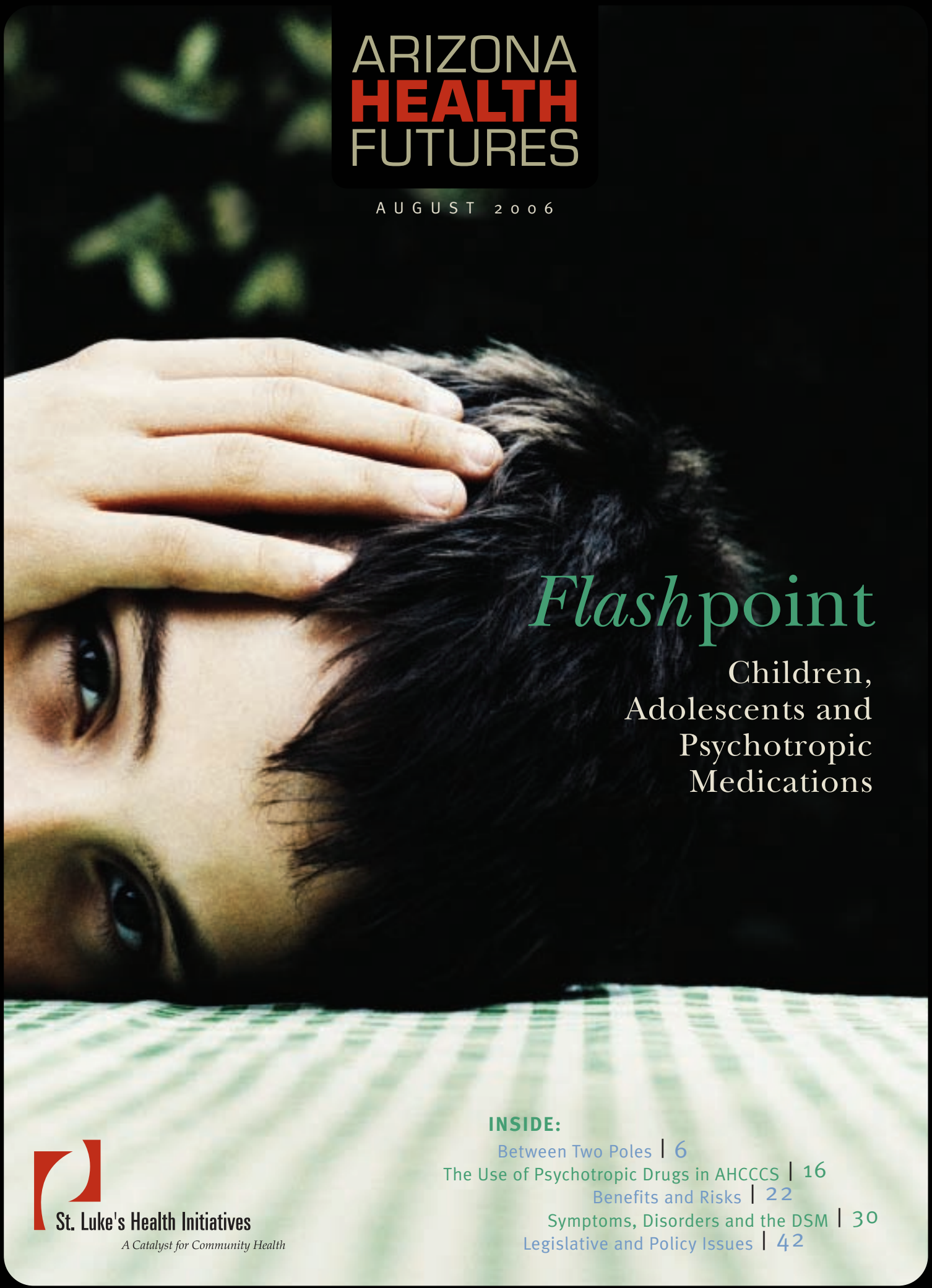


ARIZONA HEALTH FUTURES

AUGUST 2006

*Flash*point

Children, Adolescents and Psychotropic Medications

INSIDE:

St. Luke's Health Initiatives
A Catalyst for Community Health

Few issues in health care generate more heat than the growing use of psychotropic medications among children and adolescents. | Science, culture, politics and values collide in a fireball of beliefs, policies and practices that, like so much else in modern American life, flame out between two opposing poles: those who believe these medications can unlock the full potential of children to grow up and lead healthy, productive lives; and those who believe their increasing use represents the "medicalization" of normal behavior in children without considering the long-term biological and socio-cultural consequences. | Many Americans have neither the time nor patience to endure the heat. It's easier to drift to the poles, to systems of fixed belief, than to sort through the complexity embedded in the central question: More children and adolescents are taking psychotropic medications. Is this a good thing or a bad thing? | Well, it depends. Exactly what it depends on is the subject of this

Arizona Health Futures Issue Brief. | In surveying the literature on this issue, we found few attempts to provide a clear and independent overview of the central points of contention, what we know and don't know, what parents, physicians and others who face these issues on a daily basis might find useful to consider in making difficult choices; and lessons to be drawn for public policy and practice. These are topics we address here. | The use of psychotropic medications among children and adolescents is a flashpoint issue in Arizona and other states. We provide a roadmap of sorts through the minefields between two distinct poles of thought, with the caveat that any summary of a topic this complex can't cover everything. For those who wish to investigate this issue further, we provide on our website (www.slhi.org) a bibliography arranged in three time periods: 2004-2006, 2000-2003, and 1992-1999. We hope readers find it useful.

"He was bouncing off the walls and out of control. He couldn't sit still, he got kicked out of school. Ritalin literally saved his life." — Mother of a seven-year-old boy diagnosed with ADHD

"I want the doctor's hand to tremble a little before writing a prescription for some of these drugs." — Cardiologist who favors stronger label warnings on ADHD drugs

"Situation: A 12-year-old female addicted to alcohol and crack cocaine at birth. She was removed from her family at age 3 due to physical and sexual abuse. She has had six psychiatric admissions and multiple foster home placements. Her diagnoses include ADHD, PTSD, bipolar disorder, disruptive disorder, ODD and reactive attachment disorder. Medications include Seroquel, Ritalin, Lithium, Depakote." — Case in a mental health children's residential facility

"Prescription drugs are a lot easier to get than street drugs. Kids can get them on the street, from parents and friends, or on the Internet." — High school sophomore

Definitions

Part of the confusion and uncertainty underlying the use of psychotropic medications in children and adolescents starts with how the principal terms are defined and then applied in both the clinical and social context. Many people lump together quite different classes of psychotropic medications as "these drugs," and then talk about children as if they were some amorphous category of recipients who share similar characteristics and reactions to "these drugs." The debate usually cycles downhill from there.

Psychotropic Medications

Psychotropic medications can be defined as drugs that affect the psychic function, behavior and experience of a person using them.[1] Other definitions stress the effect of psychotropic drugs on mind, emotions and behavior; or use the term 'psychoactive' to refer to the "active" effects of these drugs on mental experiences and behavior.[2]

Even though we use the term 'psychotropic' to refer to these medications generally in this overview, the use of these drugs among children is more accurately assessed across the following classes of medications:[3]

- **STIMULANT MEDICATIONS** Drugs such as Ritalin (methylphenidate) and Adderall (amphetamine) that are used to treat attention deficit hyperactivity disorder (ADHD) in children and adults.
- **ANTIDEPRESSANT AND ANTIANXIETY MEDICATIONS** Drugs such as Zoloft (sertraline), Anafranil (clomipramine) and Prozac (fluoxetine) that are used to treat depression, OCD (obsessive-compulsive disorder) and related disorders in children and adults.
- **ANTIPSYCHOTIC MEDICATIONS** Drugs such as Haldol (haloperidol), Seroquel (quetiapine) and Risperdal (risperidone) that are used to treat bipolar disorder, schizophrenia, autism, Tourette's syndrome and severe conduct disorders and aggression in children and adults.
- **MOOD STABILIZING MEDICATIONS** Drugs such as Depakote (divalproex sodium) and Lithobid (lithium carbonate) that are used to treat bipolar disorder in children and adults.

Children, Adolescents and Young Adults

The confusion resulting from indiscriminately lumping together these classes of psychotropic medications in terms of diagnosis and effect is compounded by different approaches to classifying children. It is a challenge to track the increase in the use of psychotropic medications across a younger age cohort because the epidemiological studies are often based on different starting and ending points in selecting the population to study.

"These are normal children in many cases. Teachers just don't want to deal with them, so they drug them and sit them in the corner so they'll be quiet, while we destroy those beautiful little minds."
— Legislator

"The vast majority of the risks are known, understandable and controllable. If they put black boxes around everything, they will cease to have any relevance."
— Professor of Child and Adolescent Psychiatry

"Some of the newer medications out there are really life savers for some kids, but only under the right conditions. They should only be prescribed by someone who knows what they are doing, and after a comprehensive evaluation. It's not a black-and-white issue."
— Professor of Psychology

- **PRESCHOOL CHILDREN-EARLY CHILDHOOD** Some studies define preschool children as those under six years, others define it as under four years. Professionals in the child development field (developmental pediatricians, etc.) refer to this population under the 'early childhood' banner, or 0-8. The use of psychotropic drugs in this age cohort generates considerable controversy.
- **CHILDREN** Many studies define 'children' in the 6-12 years range; others use an 8-13 range; still others lump the 2-19 range as 'children.' Regional, national and international studies may start from quite different places, making comparisons difficult.
- **ADOLESCENTS** This is variously defined in the literature as 13-16, 15-18, 13-19, or 12-18. Some studies tracking the use of psychotropic medications in younger cohorts don't explicitly define the range at all, but just call them "school-age children."
- **YOUNG ADULTS** This is an emerging category, as more adolescents view themselves as "young adults." This is variously called "young people" and the "college-age crowd" (18-24, 18-22, 17-24). Much of the controversy in this age cohort centers on the increasing self-selection of psychotropic medications as "drugs of choice."

We note these ambiguities in definition of terms and the variety of ways they can be applied in the literature to illustrate where some of the confusion can begin. But this is hardly where it ends.

Method

We conducted a systematic search to identify clinical, socio-cultural and policy literature in English published from 1995-2006 (with an emphasis on the last five years) that discusses various aspects of the debate concerning the prescribing of psychotropic medications for children in the United States, Canada, the United Kingdom, Australia and New Zealand. This included journal articles, key medical/clinical databases, additional commercial databases that tap into synthesis literature (ERIC, Social Sciences Index, etc.), and a review of "grey literature" sources, such as relevant educational/advocacy organizations, think tank reports, research institute websites, book reviews and unpublished papers.

To localize and confirm various trends on use of psychotropic medications in children and adolescents, we looked at use rates among children enrolled in AHCCCS, Arizona's Medicaid program, between 2002-2005. We also interviewed a number of persons with experience and expertise in Arizona in order to flesh out what we uncovered in the literature search.

The literature search was conducted by Apex Information, a Canadian-based research firm with expertise in health issues generally. AHCCCS data were obtained from Arizona HealthQuery (AzHQ), an integrated health database at Arizona State University. SLHI conducted the interviews, as well as synthesized and interpreted the material presented here. For information on previous SLHI reports on behavioral health issues, community health and the health care system generally, please visit **www.slhi.org**.

Between Two Poles

One of the unsettling conclusions from a review of the literature on this subject is that little of it presents a balanced view of opposing positions:

The Pro Position

The use of psychotropic medications by children and adolescents, as prescribed and monitored by competent health care professionals, has major beneficial effects for those diagnosed with identifiable mental and behavioral disorders. These disorders are on the rise, and there are serious consequences for both individuals and society for not providing effective, science-based pharmacological therapy, even on a symptomatic basis. The risks for using these medications are known, understandable and controllable. We should continue to refine and improve our knowledge of these agents through research and evidenced-based practice.

The Con Position

The use of psychotropic medications by children and adolescents is reaching epidemic proportions as the result of spurious diagnoses, the medicalization of what are often normal aspects of behavior, the rapaciousness of an out-of-control drug industry, a quick-fix culture, and the need for immediate social therapy and control in the absence of family and community-based involvement in the lives of their children. The risks of using these medications with children are not known, especially over the long term, and there is growing evidence of their danger. There are ethical concerns in both prescribing such medications and engaging in further clinical research when the subjects are often unable to consent to their own treatment.

Threading a Needle

There are compelling arguments on both sides. But, as so often happens in American political and social life, the more moderate voices in the middle are drowned out by the shrill voices of certainty at either extreme.

What we often see in the literature is not a discussion, but a war.

It's an open question whether Americans can thread a fine needle through the "muddle in the middle." We have become acculturated to sound bites, extremist positions, heated exchanges, hard ideological positions and shrill advocacy. What passes for sound science in one quarter is dismissed as tainted research in the service of special interest groups in another. Authority is increasingly questioned. In the words of a teenager who tells her doctor what to prescribe for her headaches and sleep problems, and then sometimes gives her pills to friends, "I would never do just what the doctor told me because the person is a doctor. I'm sure lots of patients don't know what they're talking about. But lots of doctors don't know what they're talking about either."[4]

We start from a different place: There are people who know what they're talking about, and they are found across the spectrum of this debate. Ironically, it is in the ambiguous middle where clarity on policy and practice must finally emerge.

"If one starts from a public health perspective that there is well-documented evidence of undertreatment of child and adolescent mental disorders in all countries, and that there is an attendant high level of disability and waste of human potential because of the absence of treatment, then the evidence of increased use of psychotropic medications can be seen in very **positive** terms.

"If, on the other hand, one starts from a perspective that mental disorders don't exist and that medications are a means whereby poor parenting is being supported by inappropriate use of psychotropic medications, then there is a very **negative** spin for this information."

Darrel Regier, MD, Executive Director, American Psychiatric Institute for Research and Education

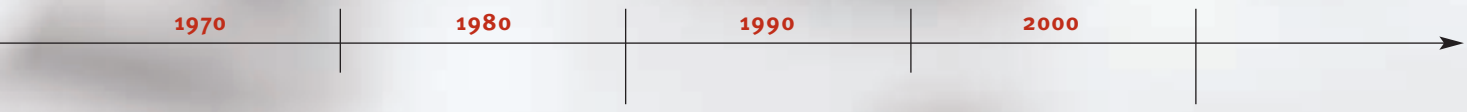
Historical Bullets[5]

Pre-1930s – A psychopharmacology for child and adolescent disorders did not exist before the 1930s.

1930s-1940s – The emphasis is on the use of Benzedrine sulfate and Dilantin sodium with hyperactive, "brain-damaged" and behavior-disordered children.

1950s — The beginning of the so-called "modern" era of psychopharmacology, with the introduction of the major tranquilizers and improvements in the stimulants. Chlorpromazine is synthesized in 1950; Methylphenidate (Ritalin) is first synthesized in 1954. The DSM-I is introduced in 1952 by the American Psychiatric Association as the first official manual of mental disorders to focus on clinical utility. Children are prescribed psychotropic medications for a variety of symptoms.

1960s – Major improvements in the study of stimulants in children with the hyperkinetic syndrome. The introduction of new classes of phenothiazine-based tranquilizers for use in childhood; the use of new antidepressant drugs (monoamine oxidase inhibitors, or MAOs; tricyclic antidepressants, or TCAs) in various categories of childhood disorders. Increased questioning of research and clinical methodology, as well as rigor of an adequate diagnostic classification. Public backlash against the use of psychotropic agents in children ensues in the late 60s.



1970s-1980s – Development, testing and application of further refinements of existing agents and new agents in children: stimulants, antidepressants (selective serotonin reuptake inhibitors, or SSRIs), antipsychotics, "minor" tranquilizers, anticonvulsants. The gradual acceptance (at least in the "established scientific order") of specific diagnostic criteria for psychiatric disorders (DSM-III, 1980); the development of a number of assessment instruments and a considerable broadening of the conditions considered responsive to medication (depressive disorders, bipolar disorder, Tourette's Syndrome, eating disorders, aggressive conduct disorders, separation anxiety disorders). Also, a growing attention to, and public concern over, the immediate and longer term adverse effects of medications, especially in children.

1990s-2000s – Mainstream prescribing practices of psychotropic meds for children and adolescents, which began to emerge in the 70s and 80s, get into full gear, stoked by aggressive marketing by pharmaceutical companies. Advances in medication lines (serotonin norepinephrine reuptake inhibitors, or SNRIs; atypical antipsychotics, etc.) continue; so do concerns about indiscriminate diagnoses, the so-called medicalization of a wide range of childhood behavior into disorders amenable to pharmacological intervention, treating symptoms with pharmacologic agents in the absence of any mental health diagnosis, and the safety and efficacy of the newer medications.

Trends *and Markers*

The increase in the use of psychotropic medications among children and adolescents is a global phenomenon.

No one disputes that there is an increased use of psychotropic medications among children and adolescents, although antidepressant prescriptions for patients 18 and younger dropped nearly 20 percent since the Food and Drug Administration (FDA) issued its 2004 warning that these medications may be associated with an increased risk of suicide in both children and adults.[6]

The rate of this increase, however, and the numbers reported can vary widely and is difficult to determine with any precision. Reasons include inconsistencies in the time span examined, different age cohorts and data sources (Medicaid records, private health plans, practice groups), variability in types of formal diagnoses and definitions of behavioral and emotional problems, variability in medication classes and specific medications included, and different research models and study design.

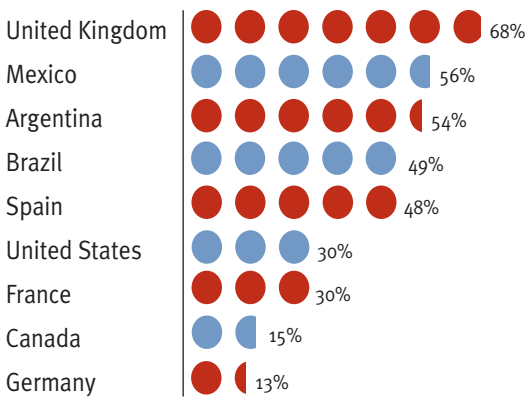
With these qualifications, we can establish some general trends and markers to set the outer boundaries for the far more vexing discussion of what the increase means.

Psychotropic Usage Among Children and Adolescents

- The increase in the use of psychotropic medications among children and adolescents is a global phenomenon. America has the highest baseline by far, but the rest of the world is catching up. See Fig. 1.
- On any given day in the U.S., an estimated six-eight million children take medications for what are classified as mental health problems. This is about 8%-10% of the 0-18 age population.[8]
- The proportion of U.S. office visits that resulted in the prescription of a psychotropic medication among adolescents increased 250% from 1994 to 2001.[9]
  - The most dramatic increase occurred after 1999 – 64.6%.
  - Largest increases were for stimulants and SSRIs.
  - One in every ten office visits by teenage boys led to a prescription for a psychotropic drug.
  - One-third of the office visits by adolescents led to an ADHD diagnosis. Between 14%-26% of visits where psychotropic medications were prescribed did not have an associated mental health diagnosis.
- The annual number of U.S. children ages 2-18 prescribed antipsychotic drugs jumped five-fold from 1995 to 2002 to an estimated 2.5 million.
  - More than half of these prescriptions were written for behavioral indications or affective disorders, for which antipsychotics have not been carefully studied in children.
  - Almost one-third of these prescriptions were written by pediatricians or family medicine physicians.[10]
  - Between 2000 and 2002, more than 90% of prescriptions were for the newer atypical antipsychotic medications, which were introduced in the 1990s.[11]

Figure 1: Psychotropic Medication Rate of Increase 2000-2002

Youth Under Age 18[7]

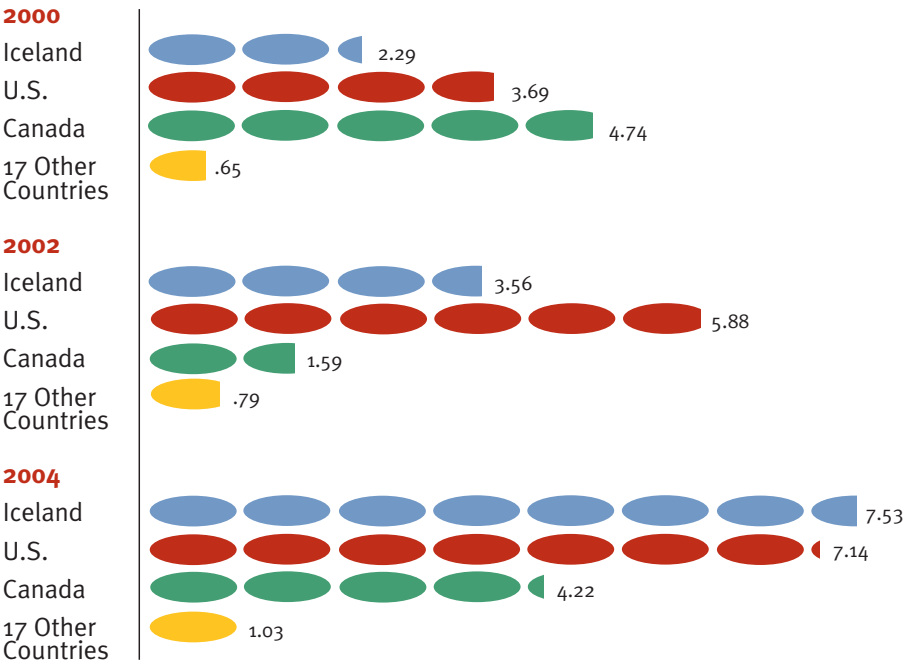


The Centers for Disease Control (CDC) estimates that approximately 3.5 million youth in the U.S. are taking stimulants as part of their treatment plan for (ADHD).[12]

- Drug treatment for ADHD, which began in the 1960s, has doubled every four to seven years in the 1971-1997 time period.[13]
- One study suggests that about 3% of American children take methylphenidate for ADHD. Other studies estimate 4%-5% of American children are taking psychotropic medications for ADHD – even as high as 12%. There can be wide variation in use rates among different communities and regions, with some reporting little use of methylphenidate and amphetamine to treat ADHD, and others reporting 10-20% of school-age children using these medications.[14]
- Outside the U.S., estimates of school-age children on stimulants for ADHD are much lower: .3% in the United Kingdom, 1.4% in Germany, 1.2% in Israel (2001).[15]
- There is some evidence that the percentage of U.S. children taking stimulants for ADHD leveled off in the 1997-2002 period, suggesting that the use of stimulants to treat ADHD is not necessarily increasing indiscriminately.[16]
- In 1999, Americans used 85% of the world's methylphenidate for medical purposes (down from 90% in 1995).[17] Methylphenidate is the most commonly prescribed psychotropic agent in preschool-age children, increasing dramatically in the 1990s.[18]
- While the U.S. leads the world in the medical use of methylphenidate, Iceland recently took the international lead on a per capita use basis. See Fig. 2.

Figure 2: Medical Consumption of Methylphenidate 2000-2004

Average daily dose per 1,000 people

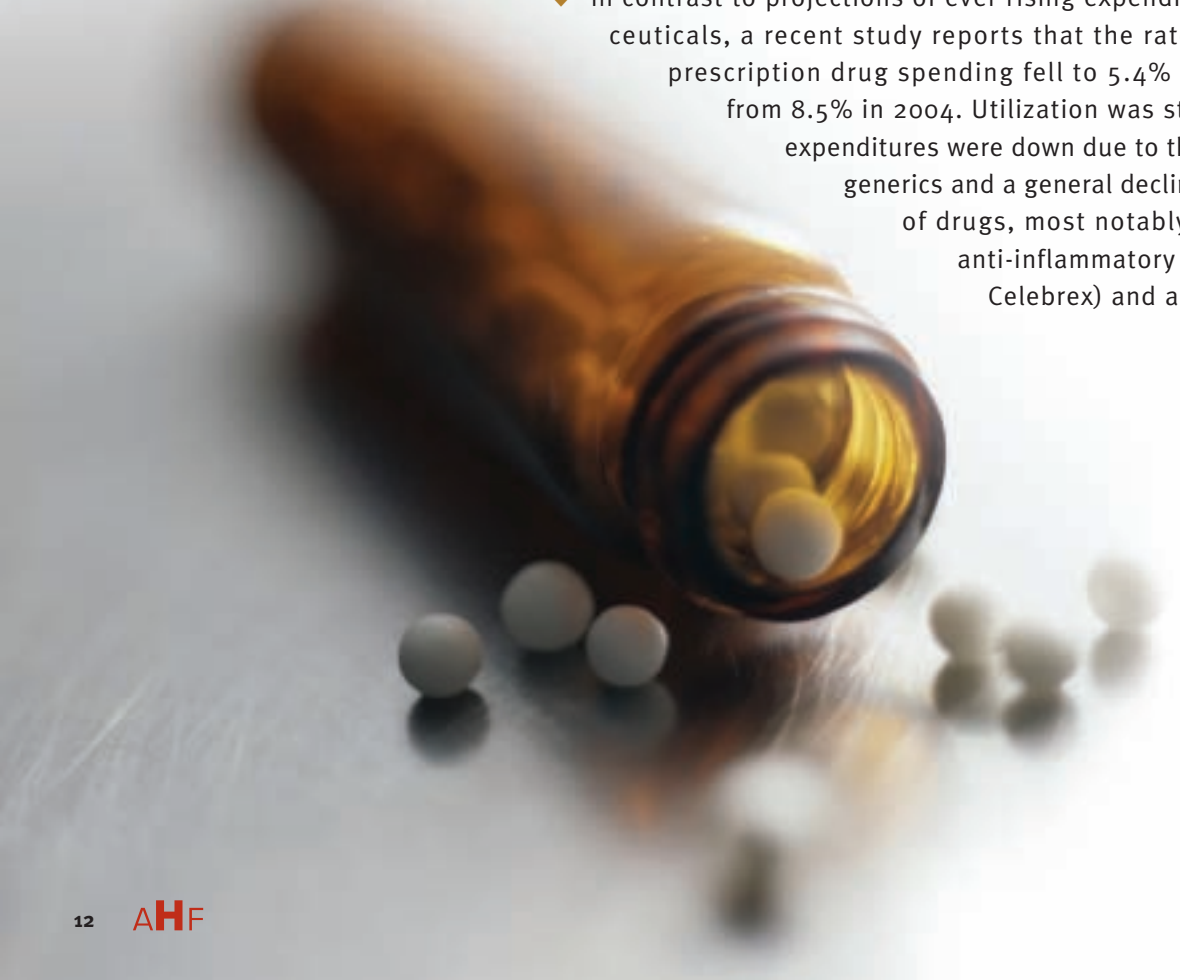


Source: Psychotropic Substances 2005, International Narcotics Control Board

The Rise of Pharmaceuticals

The increase in the use of psychotropic medications among children and adolescents occurs in the broader context of the growth of pharmaceutical use generally:

- Americans spent about $190 billion on prescription drugs in 2004 – about four times what they spent in 1993.[19] It is estimated the U.S. pharmaceutical market is $250 billion today.
- From 1993 to 2003, the number of prescription drugs purchased in the U.S. rose 70%, while the U.S. population grew 13%. Average number of prescriptions per capita increased from 7.8 to 11.8.[20]
- Prescription use and shifts to higher-priced drugs are affected by advertising: Manufacturers spent $25.3 billion for advertising in 2003 – 87% of it directed toward physicians. Direct-to-consumer advertising – typically to advertise newer, higher-priced drugs – was over eight times greater in 2003 than in 1995.[21]
- Drug use for selected categories other than behavioral and mental disorders in children and adolescents is also up sharply: the use of type 2 anti-diabetic agents among 10 to 14-year olds, for example, increased 106% from 2002 to 2005.[22]
- Prescription drugs are increasingly the "treatment of choice" among patients and providers alike. U.S. spending for prescription drugs is projected to increase by almost 11% annually from 2004 to 2013 – and that doesn't include factoring in the new Medicare drug benefit.[23]
    - In contrast to projections of ever rising expenditures for pharmaceuticals, a recent study reports that the rate of increase in prescription drug spending fell to 5.4% in 2005 – down from 8.5% in 2004. Utilization was still up (2.7%), but expenditures were down due to the increasing use of generics and a general decline of certain classes of drugs, most notably nonsteroidal anti-inflammatory drugs (e.g., Vioxx, Celebrex) and antidepressants.[24]



Prevalence of Behavioral and Mental Disorders Among Children and Adolescents

Establishing a general consensus on the degree to which behavioral and mental disorders are on the rise among children and adolescents is complicated by disagreement on what constitutes a behavioral or mental disorder in the first place, and the legitimacy of making a diagnosis where "unlike many other areas of medicine, the pathophysiologic etiology of most mental disorders is unknown."[25]

For example, there continues to be a discussion in the literature among researchers and mental health professionals on the biological and behavioral antecedents of mental illnesses such as bipolar disorder and schizophrenia among young children: what they are, when they occur, how they can be optimally assessed, and whether a legitimate diagnosis can be made at an early age as the "onset" of the disease. Progress continues to be made on this front.[26]

There is also the critical distinction between the large number of adolescents (close to 60%) who "screen positive" on the Diagnostic Interview Schedule for Children (DISC) instrument for various symptoms related to diagnosable mental disorders, but who have not been actually diagnosed by a trained mental health professional.

Further, some researchers believe that "estimates of prevalence [of psychiatric disorders] in the general U.S. adolescent population cannot be reliably made because of small samples, or samples drawn from clinics and institutions; overly specific research foci, and limited screening questions that are not necessarily closely aligned with Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria."[27]

We will return to some of these limitations. Here, we provide a few general prevalence markers as reported in the recent literature.

- At any one time, about 20% of U.S. children and adolescents have at least one diagnosable mental health disorder. An estimated 10% of children and adolescents in the U.S. suffer from mental illness severe enough to cause some level of impairment. Fewer than one in five of these children receives treatment.[28]
  - Similar percentages are reported in Canada[29] and the U.K.[30]
- Current estimates of the prevalence of psychiatric disorders among adolescents range from 13% to 21%.[31]
  - These percentages are far less as reported by *parents*: A 2003 survey found that 5% of children ages 4-17 have definite or severe difficulties with emotions, concentration, behavior or being able to get along with other people.[32]
- The prevalence of ADHD in the U.S. is estimated to be between 5%-7% of the school-aged population. Approximately 75% are boys.[33]
- The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that in 2004, 9% of adolescents 12 to 17 experienced at least one major depressive episode (MDE) in the past year. Less than half received treatment for depression at that time.[34]
  - An estimated 1.5 million adolescents 12 to 18 in the U.S. suffer from a major depressive disorder (2004).[35]
- Pediatric bipolar disorder is estimated to affect at least 1% of youth and up to 17% of psychiatrically referred samples.[36]

At any one time, about 20% of U.S. children and adolescents have at least one diagnosable mental health disorder.

Off Label

Off-label use is the prescribing of a medication in a different dose, for a longer duration of time, or for a different medical indication and/or age group than recommended in the prescribing information. Although the Food and Drug Administration (FDA) approves a drug for a specific indication, the physician has discretion to prescribe it as indicated above, or in combination with other medications in the treatment of patients.

Off-label use of psychotropic drugs in children, such as prescribing many of these medications for children under five years of age, is a common practice. Indeed, some 80% of all medications – not just psychotropics – lack adequate safety and efficacy data for children.[37] Clinicians are well aware of the risks, or should be. According to the American Psychiatric Association, "new research findings, clinical experience, and the child's and parent's personal preferences are factors considered by physicians when deciding the appropriate medications to prescribe. Prescription for 'off-label' purposes of any medication should be made only after a comprehensive evaluation has been made, other forms of therapy (or combination of) have been considered, and must be monitored closely."[38]

The literature is replete with calls for more research and caution in the off-label use of psychotropic medications for children and adolescents. Drug companies, however, have little financial incentive to fund this research, since drugs approved by the FDA for adults can be used in children. Meanwhile, many physicians find themselves under increasing pressure to write prescriptions that promise quick relief and neat solutions for complex conditions that are hard to diagnose and even harder to treat with one-size-fits-all algorithms of care.

Who Decides?

The general pattern of higher prescribing rates for psychotropic medications for children and adolescents is well established. What is less well established is exactly who is making the diagnoses and prescribing the meds.

There is little in the literature on this issue. Where it is referenced, psychiatrists have considerably higher prescription rates than generalists at baseline, as well as higher prescription rates over time.[39] This is especially true for medications such as atypical antipsychotics, where psychiatrists were reported to be involved in most cases (87% in the 1997-2002 period[40]). Primary care physician prescription rates for these medications remained fairly constant (9%-16%) in the same time period.

On the other hand, another report indicates that about one-third of the antipsychotic prescriptions for children between 1995-2002 were written by pediatricians or family medicine physicians, as referenced earlier. There is also evidence that more family physicians and pediatricians are called on to prescribe stimulants for ADHD. Reasons given include a shift to "primary care mental health" (families wish to deal with mental health issues in a primary care setting and not encounter the "stigma" of entering the mental health system) and a shortage of child and adolescent psychiatrists in the U.S.

There is more on this subject in Great Britain and Australia. In a 2003 Australian study, child psychiatrists were more likely than pediatricians to prescribe SSRIs (93% vs. 75%) and mood stabilizers (45% vs. 11%) for depression, and SSRI's (74% vs. 50%) and tricyclic antidepressants (37% vs. 12%) for obsessive compulsive disorder.[41]

Meanwhile, general practitioners in the U.S., Great Britain and Australia are more likely than psychiatrists to prescribe medications like clonidine (an anti-hypertension agent) for sleep problems in children who are also on ADHD medications. Children may be on multiple medications to treat both primary diagnoses and possible side effects of certain psychotropic medications (such as insomnia from stimulants) that are prescribed by different physicians in different systems of care (primary care and behavioral health) with little coordination and communication between them.

In this fragmented system, questions of who makes the diagnosis, who provides treatment and who follows the child's progress over time are critical.

The Use of Psychotropic Medications

Among Children and Adolescents

In Arizona's Medicaid System, 2002-2005

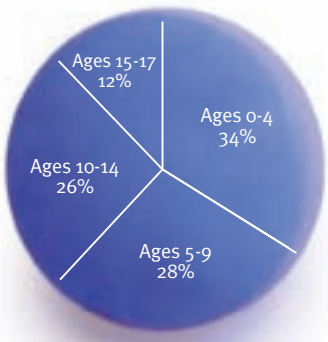
To localize reported trends on the increasing use of psychotropic medications among children and adolescents, we reviewed the records of children ages 0-17 enrolled in the Arizona Health Care Cost Containment System (AHCCCS) – Medicaid – between 2002 and 2005, based on an October 1-September 30 fiscal year.[42] Data from FY 2004 were incomplete; therefore, we focus on differences between FY 02 and FY05 here.

Summary Trends, Indicators

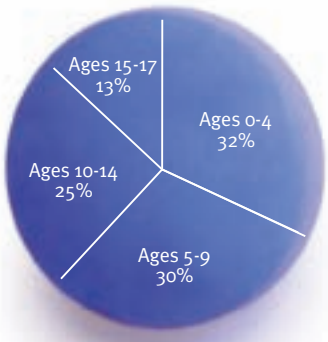
Enrollment Trends

Enrollment trends are based on the calculation of any child ages 0-17 who was enrolled in AHCCCS at any point during the fiscal year. This differs from monthly enrollment numbers reported by AHCCCS itself.

Figure 3: AHCCCS Enrollment by Age 2002 and 2005



2002
Total Enrollment 249,556



2005
Total Enrollment 688,030

Figure 4: AHCCCS Enrollment by Gender 2005

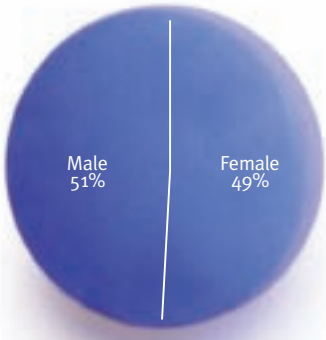


Figure 5: AHCCCS Enrollment by Race/Ethnicity 2005

Racial/Ethnic enrollment percentages do not change appreciably between 2002 and 2005.

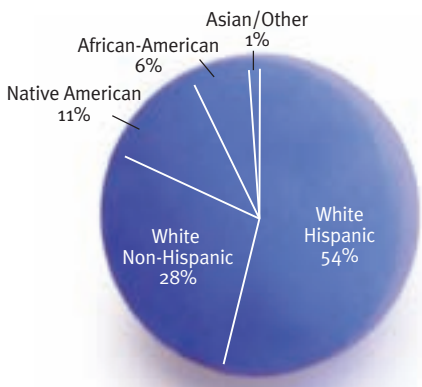
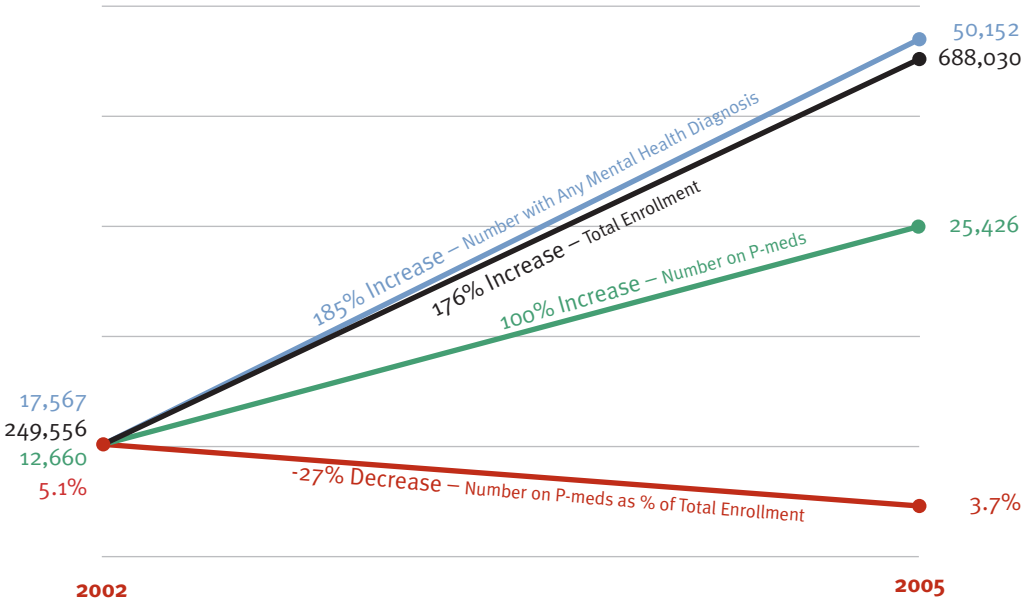


Figure 6: Growth in Total Enrollment, Number of Children with Any Mental Health Diagnosis, and Number of Children Prescribed Psychotropic Medications (P-meds) 2002 and 2005



- **FIGURE 6 TELLS THE ESSENTIAL STORY:** Total AHCCCS enrollment for ages 0-17 increased 176% from 2002 to 2005 (fueled by raising the Medicaid eligibility requirements to 100% of the federal poverty limit and general population growth). Meanwhile, the number of children with any mental health diagnosis increased 185% in the same period, slightly outpacing population growth. However, while the total number of children prescribed psychotropic medications increased 100% from 2002 to 2005, it actually *decreased* as a percent of the total enrollment, going from 5.1% of the population in 2002 to 3.7% in 2005 – a 27% relative decline.

Figure 7: Percentage of Children Receiving Any Mental Health Diagnosis 2002 and 2005*

For purposes of this study, mental health diagnoses were classified under three groups: ADHD, Depression and "Other." Excluded were learning disabilities, developmental delay, speech disorders and mental retardation.

Figure 8: Rate of Increase of Mental Health Diagnoses 2002 and 2005*

* The .3% increase in the number of children ages 0-17 in AHCCCS who received any mental health diagnosis in 2002 and 2005 is relative to the total number of children enrolled. The rate of increase in specific diagnoses, however (Fig. 8), is not portrayed relative to total population growth but represents the growth in the number of diagnoses relative to the percentage of children receiving any mental health diagnosis.

Figure 9: Percent of Children, by Age Group, on P-meds by Diagnosis 2002 and 2005

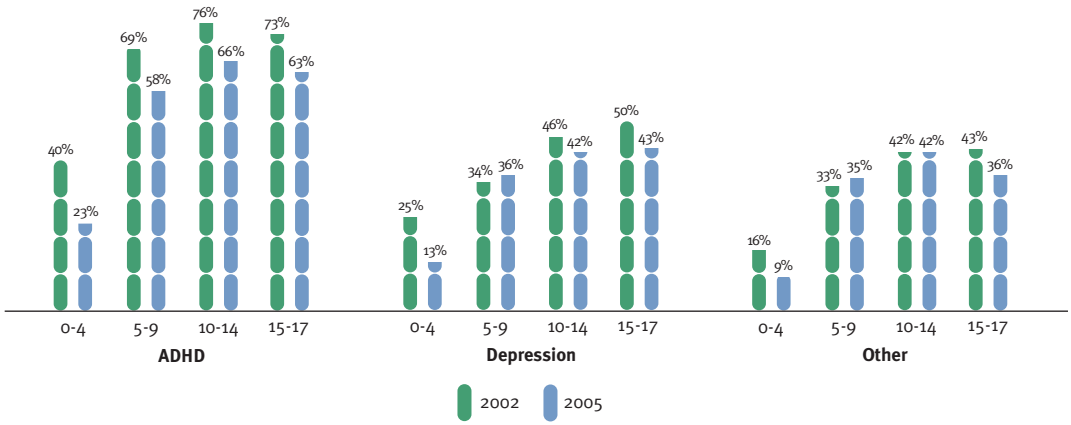


Figure 10: Percent of Children, by Age Group, on P-meds with No Mental Health Diagnosis 2002 and 2005

Children may be prescribed psychotropic medications in the absence of a mental health diagnosis, depending on the severity of symptoms, age of child, diagnostic setting (primary care, specialist), reimbursement practices, and various social and cultural factors. We do not investigate these further here.

- Over half of the AHCCCS population (54%) ages 0-17 is Hispanic (Figure 5). This is broken down in Figure 11, which underscores the difference in both the prevalence of mental health diagnoses between Whites (11.9%) and Hispanics (4.7%), and in the percentage of children prescribed P-meds (5.7% of the White population, 1.4% of Hispanics). Stated differently, Whites are over twice as likely (250%) to receive a mental health diagnosis, and almost four times (380%) as likely to be prescribed P-meds compared to Hispanics. The reasons for this have been previously noted and discussed in the literature, including work by SLHI.[43]

Figure 11: Percentage of Children Ages 0-17 with a Mental Health Diagnosis by Race/Ethnicity 2005

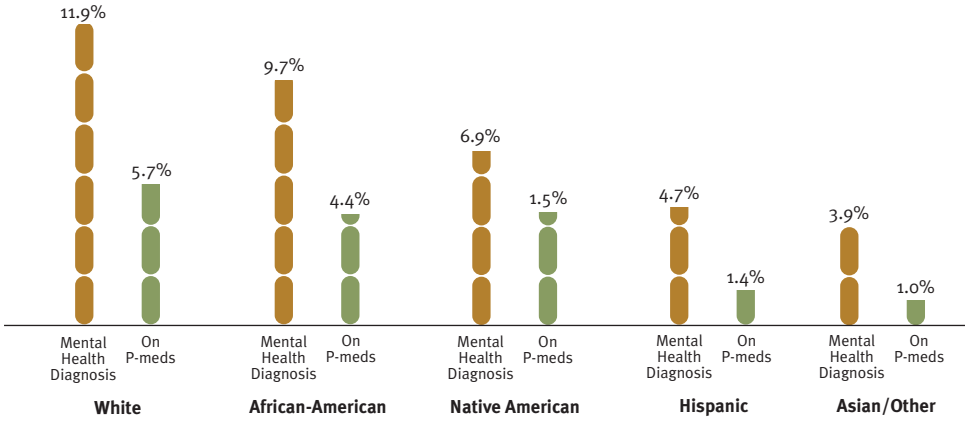
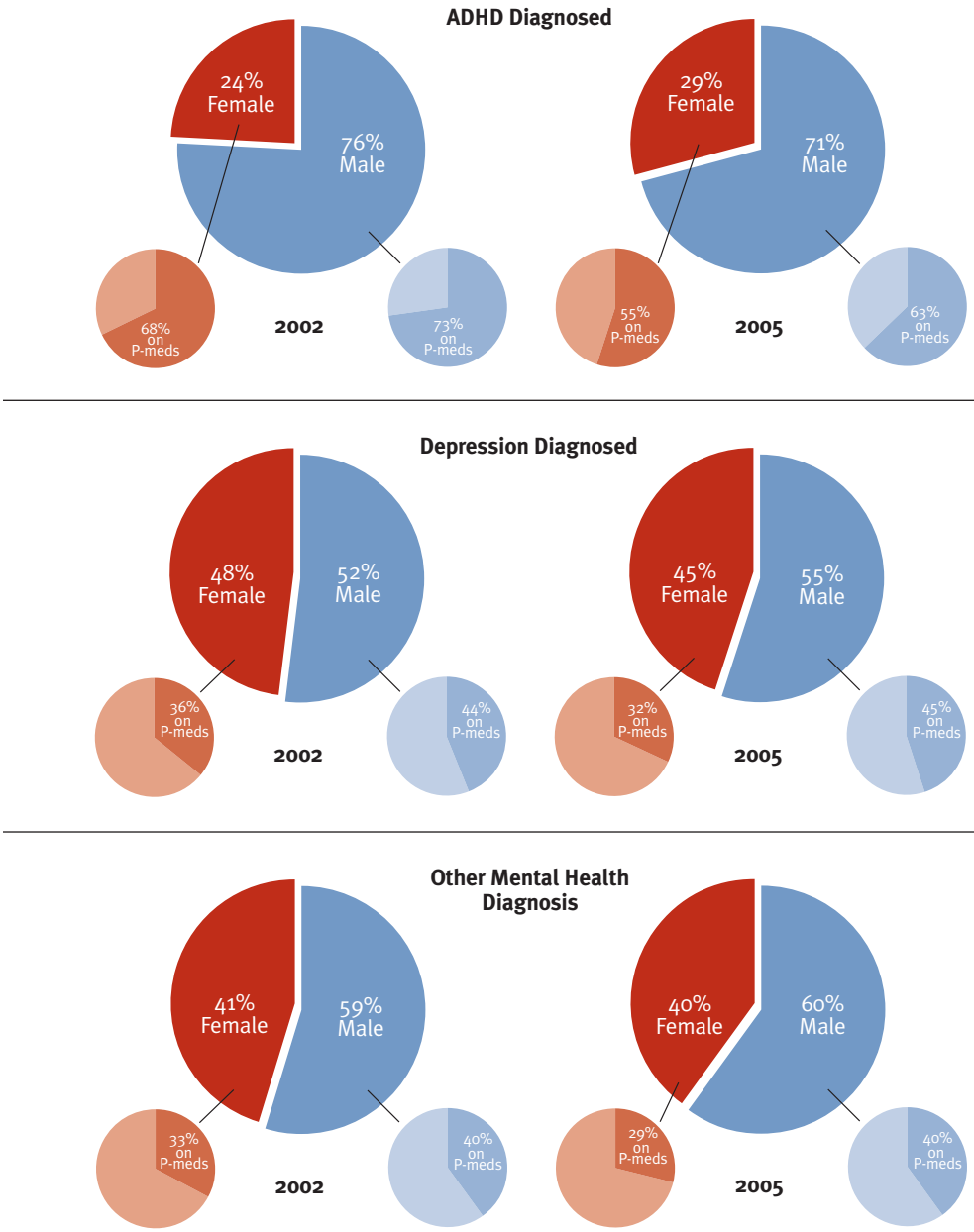


Figure 12: Mental Health Diagnosis, Percent on P-meds, by Gender 2002 and 2005



- While all mental health diagnoses increased between 2002 and 2005 (Figure 8), ADHD saw the greatest increase (13%), followed by Depression (9%) and other diagnoses (5%). Breaking down the use of P-meds by age category, however (Figure 9), we see the greatest decline ages 0-4, where medications for ADHD, Depression and other diagnoses declined 42.5%, 48% and 44% respectively. Declines are also noted for most other age groups and diagnoses, although not as steep. Interestingly, ages 0-4 are far more likely to be prescribed P-meds with no mental health diagnosis (Figure 10) than other age groups, reflecting, in our view, both the difficulty of making a valid mental health diagnosis and the hesitancy to "label" children with a "disorder" at an early age.

- The differences in both diagnoses and use of P-meds by gender (Figure 12) also confirm what we see in the literature. While males are more likely than females to be both diagnosed with a mental health condition and prescribed P-meds, the difference is most striking in ADHD, which is still a "male" diagnosis, although the percentage for females was up in 2005 compared to 2002. On the other hand, females (32%) were more likely than males (21%) to be prescribed P-meds without a mental health diagnosis (Figure 13). Differences between males and females of all ages with regard to mental health disorders are noted in the literature and traced to a complex interplay of biological, social and cultural factors that lie outside the scope of this report.

Figure 13: Percent of Children on P-meds with No Mental Health Diagnosis by Gender 2002 and 2005

Conclusions

What might we reasonably conclude from this snapshot?

- At least in the AHCCCS population, the increasing use of psychotropic medications among children is not the "runaway train" it is often portrayed to be in the popular media by the more shrill advocacy groups. Percentage-wise, use is down in 2005 compared to 2002. Our interviews confirm that more providers and parents are sensitive to the use of these medications among children, and while social and economic pressures can conspire to make drugs a strategy of "first choice," they are also investigating other alternatives.

- There are significant differences in both diagnoses and use of P-meds between Whites and other racial/ethnic groups. African-Americans are certainly closer to Whites in this regard, but Hispanics, Native Americans, Asians and other groups are far down the line. This may account in part for the lower rate of prevalence of mental health disorders (7%) in the AHCCCS population compared to figures reported in the national literature (8%-12%). Whether this is a question of under-diagnosis and treatment among these groups or reflects legitimate cultural differences in how "mental" problems are both defined and treated is worthy of further investigation and public dialogue.

- AHCCCS operates in a managed care environment and has focused in recent years on more family involvement in the treatment of children and adolescents with significant physical and mental disorders, as well as better integration of, and communication between, the primary care providers and mental health carve-outs. Issues remain, obviously, but there appears to be progress in reducing the number of children who receive P-meds with no mental health diagnosis. Primary care providers can prescribe P-meds, (AHCCCS policy permits them to prescribe for mild depression, ADHD and anxiety only), but they also refer children out to a network of specialists and other sources of support. The roadblock, as we discuss later on in this report, continues to be lack of qualified providers.

- Although we don't detail it here, the AHCCCS data indicate a significant number of children who receive multiple diagnoses and are prescribed multiple medications. For example, while the total number of children receiving any mental health diagnosis increased 185% between 2002 and 2005, the total number of diagnoses themselves increased 233%. Given the way the data are reported, however, it is difficult to track this precisely. What is clear, both from a preliminary analysis of the data and interviews with providers, is that more children are presenting with complicated conditions that often result in multiple diagnoses and prescriptions. This warrants further study.

- Inferences from the results of a study of children in the Medicaid system to children enrolled in private health insurance plans should be made with caution. Anecdotal information from Arizona providers suggests that the use of psychotropic medications is higher among those with private insurance than in AHCCCS, but we did not look at data to verify that hypothesis for this report.

Benefits *and Risks*

Conflicting evidence is found in the literature on the benefits of, and risks involved in, prescribing psychotropic medications for children and adolescents. Opinions range from specific classes of medications being beneficial and completely safe for this age group, to the use of psychotropic medications being preferable to their non-use despite certain risks, to psychotropics carrying too high a level of risk to be warranted in any situation.

The level of concern is related to a heightened awareness of the risks associated with all pharmaceuticals over the past ten years, especially in light of well-publicized cases such as Fen-phen and Vioxx. The following factors fuel the flames of the safety debate:

- The development and marketing of new drugs.
- The pressure on the FDA to both protect the public's safety and still approve medications in a timely and efficient manner.
- The use of multiple medications (polypharmacy) by individuals when there is an imperfect understanding of their chemical interactions and side effects.
- The off-label use of certain medications without the requisite research on effectiveness and safety.
- The growing – some would say unrealistic – expectation of consumers for perfect pills to solve all their ills with no risks whatsoever.

Mainline mental health associations and providers are well aware of the controversy surrounding the growing use of psychotropic medications among youth. The National Alliance on Mental Illness (NAMI) Policy Research Institute's 2004 Task Force report suggests the following:[44]

> *New studies are needed to identify the best treatments for children with mental illnesses and to better understand psychopharmacology – particularly polypharmacy in children. Children are in a state of rapid change and development…Many psychotropic medications that are prescribed for children and adolescents are not FDA approved for use in children, but are routinely used off-label…Children and adolescents who are taking psychotropic medications must be closely monitored and frequently evaluated by qualified mental health providers. The side effects common to some medications can be particularly difficult for children.*

Clinical Research: *Does the Sponsor Make a Difference?*

According to research presented at a recent conference of the American Psychiatric Association,[45] drug companies are funding more medical studies: In 2002, 57% of drug studies published in medical journals were funded by pharmaceutical companies, compared to 25% in 1992.

The findings show a favored outcome for the drugs being studied in approximately:

- Eight out of 10 studies that were paid for by the manufacturer of the drug.
- Five out of 10 studies conducted with no industry support.
- Three out of 10 studies funded by manufacturers of a competing product.

While the findings do not prove that pharmaceutical companies are conducting biased research, they lend credence to the view that pharmaceutical-sponsored research may be unduly influencing the results on efficacy and safety. One reasonable recommendation: more independent, government-funded research, and less pharmaceutical company influence.

Stimulants

Benefits

Of all the classes of psychotropic medications prescribed for children and adolescents, stimulants (methylphenidate, amphetamines) have been the most widely studied and used. In a recent press release, the American Academy of Child and Adolescent Psychiatry (AACAP) states:

> *Stimulant medications offer many benefits to a wide range of children, and have proven to be safe for over a half-century of use…There have been over 200 controlled studies over the past 50 years. These drugs produce robust responses in over two-thirds of affected youth by lowering the intensity of their ADHD symptoms.*[46]

Additionally, the American Academy of Pediatrics, upon reviewing the clinical literature, concluded:

> *The evidence strongly supports the use of stimulant medications for treating the core symptoms of children with ADHD and, to a lesser extent, for improving functioning. Behavior therapy alone has only limited effect on symptoms or functioning of children with ADHD, although combining behavior therapy with medication seems to improve functioning and may decrease the amount of (stimulant) medication needed. Comparison among stimulants (mainly methylphenidate and amphetamines) did not indicate that one class outperformed the other.*[47]

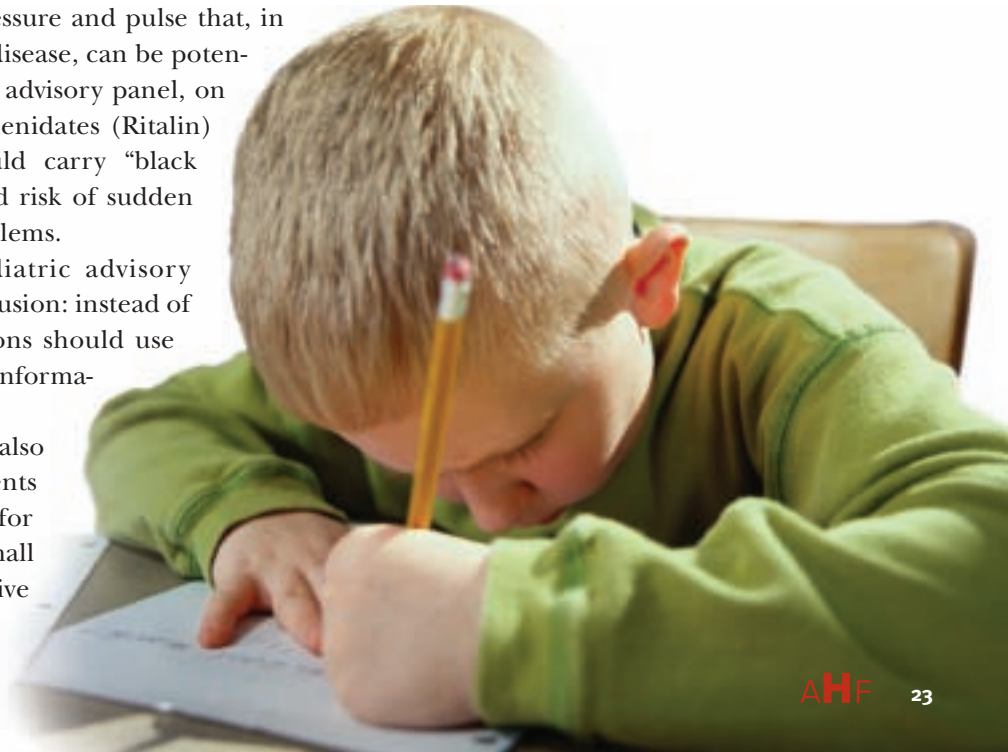
The literature supports the general consensus on the efficacy of stimulants (especially when combined with behavior therapy) in treating ADHD as prescribed by qualified health care professionals. Efficacy, however, is not the central subject of dispute. Diagnosis is – especially the assertion that ADHD is over-diagnosed in children, and increasingly in adults. Because these medications are generally perceived to be safe, they are a first line pharmacological defense against the disorder. Over time, they "crowd out" alternate methods for treating ADHD (e.g., Cognitive Behavior Therapy, or CBT) and become the de facto "gold standard" of treatment, especially in a transaction-based health care system where reimbursement and practice realities reward the short get-a-prescription visit and discourage more time-intensive patient-provider encounters.

Risks

Stimulants, like all prescription medications, can have side effects. They may cause changes in blood pressure and pulse that, in persons with hypertension and heart disease, can be potentially fatal. In February 2006, an FDA advisory panel, on an 8-7 vote, concluded that methylphenidates (Ritalin) and amphetamines (Adderall) should carry "black box" warnings regarding an increased risk of sudden death and serious cardiovascular problems.

One month later, an FDA pediatric advisory committee came to the opposite conclusion: instead of a "black box" warning, the medications should use simpler language and include more information on the labels.[48]

The pediatric advisory committee also recommended that a guide for patients should warn that using stimulants for ADHD can cause hallucinations in a small number of children – perhaps two to five out of 100.



More recently, a Centers for Disease Control and Prevention study of persons treated in emergency rooms in 2004 for adverse reactions to ADHD drugs concluded that many were the result of accidental overdoses by persons without prescriptions for the medications, and that physicians need to be more thorough in checking a child's medical history to determine if there is potential for cardiac trouble.[49] Similarly, officials in the Canadian national health care system have issued warnings on the use of ADHD drugs by both children and adults who have blood pressure and heart disease problems.

In the case of Strattera (atomoxetine), a non-stimulant drug prescribed for ADHD, there are warnings of increased risk of suicidality – an analysis of 2,200 cases in the U.S. found that .4% of children reported suicidal thoughts compared to no reports on a placebo. With the addition of a "black box" label warning, most practitioners conclude that, given the small degree of risk, children who are doing well on Strattera should continue to take the medication. On the other side, parents of children who have experienced suicidal thoughts and/or attempts while taking Strattera, along with advocates calling for greater restriction of all psychotropic medication use by children, argue that it shouldn't be prescribed at all.

The Black Box

The controversy in the medical and regulatory communities over whether certain psychotropic medications should carry "black box" warnings about increased risks associated with suicidal behavior, hallucinations, sudden death and cardiovascular problems is grounded as much in worries that the medications are being overused as by possible serious side effects.

Members of regulatory advisory committees who are concerned with high prescription rates, especially among children, believe it is unethical to "push" such medications when so little is known about their possible risks and long-term effects on physiological development. Others believe that the evidence clearly shows the risks are known, controllable with proper diagnosis and oversight and, in the larger scheme of things, less of an issue than not prescribing the medications and witnessing the consequences of potentially destructive behavior.

This debate occurs within the larger societal context of establishing public standards of risk, responsibility and accountability across a wide range of issues, products and services where scientific knowledge is imperfect and public expectations for certainty and control are increasing. Hence the tendency to put strong warning labels on products that may in fact be safe and effective for the vast majority of people, but which carry serious risks for a small minority. All things considered, it is preferable to provide as much information as possible, both on labels and in accompanying material, on the use of these products and to continue to conduct rigorous monitoring and research on their effects at all regulatory and practice levels.

It's a fine line: If everything carries a warning about serious side effects, no matter how small the number affected, the information may cease to have any practical relevance. If nothing is safe, so to speak, everything is. On the other hand, parents, medical professionals and the general public need to be fully informed and aware of research results and experience in the field. It may be messy, shrill and contentious, but searching for the signal in the noise is the only way knowledge moves forward.

Antidepressants

Benefits

Next to stimulants, antidepressants are the most commonly prescribed psychotropic medications for children and adolescents. In addition to depression, these medications are often prescribed for anxiety and related disorders (Obsessive-Compulsive Disorder, Panic Disorder, Acute Stress Disorder, etc.).

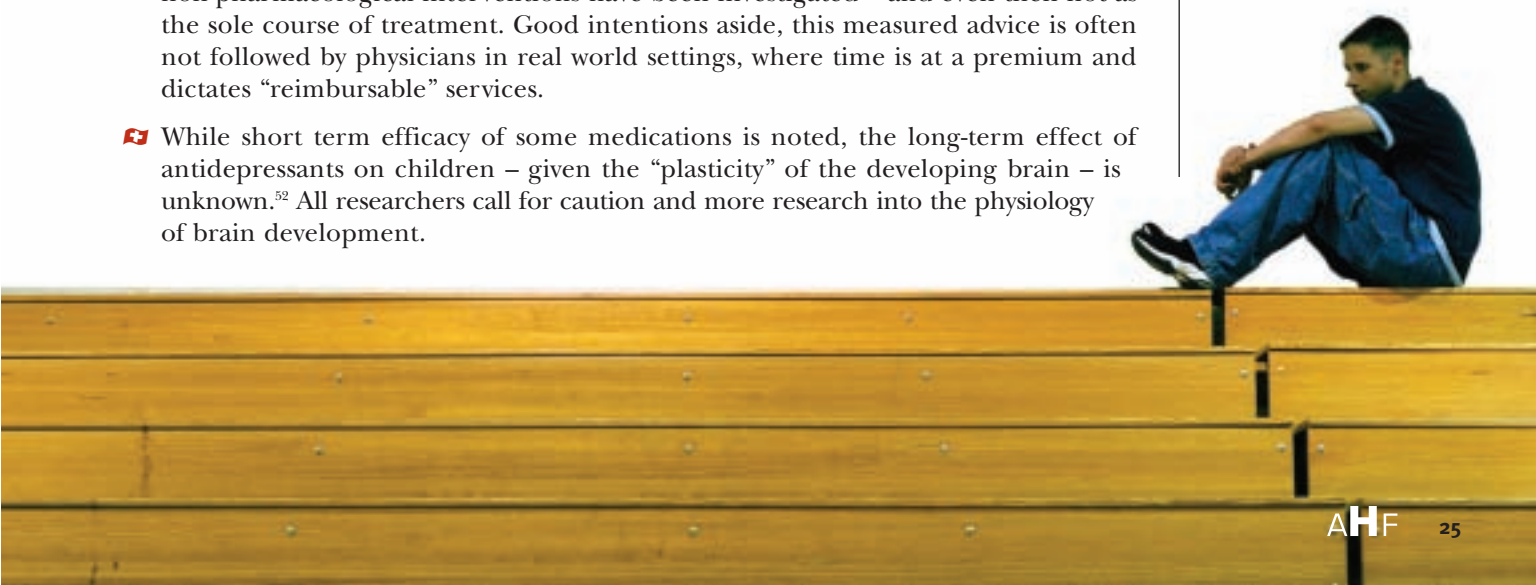
The most commonly prescribed antidepressants are selective serotonin reuptake inhibitors (SSRIs) – fluoxetine, sertraline, paroxetine, fluvoxamin, citalopram. There appears to be a general consensus in the professional literature that the SSRIs are more effective and safe than other classes of antidepressants, such as TCAs, although what determines 'efficacy' and 'safety' is a matter of some dispute.

Of the SSRIs, fluoxetine (Prozac) appears to have the best track record. One recent study confirmed a 61% response rate among adolescents to fluoxetine alone, compared to a 35% response rate to a placebo.[50] The response rate goes up when fluoxetine is combined with cognitive behavior therapy (CBT). A host of other studies have demonstrated the effectiveness of fluoxetine and other SSRIs such as sertraline (Zoloft) and paroxetine (Paxil), but the issue is always "compared to what." The research shows a consistently high response rate to placebo among children and adolescents, leading some to assert that, while the controlled studies show the "statistical" superiority of the SSRIs, they may have less "clinical" superiority to, say, combining CBT with the "expectation effect" of a placebo.

Ultimately, the cost-benefit of using SSRIs (and all medications, for that matter) must be established by weighing "the potential benefit of improved symptomatology, accompanied by adverse side effects, against the risk of leaving the disease untreated."[51]

With regard to the efficacy of antidepressants for children and adolescents, the following general points are noted:

- Efficacy is more established for adults than for children, especially the very young. The use of antidepressants for children should only be considered first-line therapy for children and adolescents who have severe symptoms that would preclude effective psychotherapy.
- Different studies produce different results. Proponents and detractors of the use of antidepressants among children trot out their confirming studies and question each other's research design, integrity of data and, most of all, motives. Studies funded by pharmaceutical companies are especially suspect; indeed, an entire cottage industry has developed around the theme of demonizing anyone with even the remotest ties to the pharmaceutical industry.
- The medical establishment consistently points out the necessity of establishing a sound diagnosis by a highly trained medical professional, and using antidepressants and other psychotropic medications with children and adolescents only after other non-pharmacological interventions have been investigated – and even then not as the sole course of treatment. Good intentions aside, this measured advice is often not followed by physicians in real world settings, where time is at a premium and dictates "reimbursable" services.
- While short term efficacy of some medications is noted, the long-term effect of antidepressants on children – given the "plasticity" of the developing brain – is unknown.[52] All researchers call for caution and more research into the physiology of brain development.



Risks

There is considerable controversy over establishing the level of risk associated with prescribing antidepressants for children and adolescents. In 2004, the FDA issued a public health advisory, and eventually a black box label, on an increased risk of suicidality in both children and adults from using antidepressants. Since that time, the number of antidepressants prescribed for children and adolescents has decreased almost 20%.

Several recent studies have presented refuting evidence: researchers in Washington state concluded that the risk of suicide was actually highest 30 days before patients begin taking antidepressant medications, rather than after taking them, and remained low with continued use.[53] In other words, antidepressants lower the risk of suicide, not increase it.

Further, the American College of Neuropsychopharmacology (ACNP) concluded that, while SSRIs and other new-generation antidepressant medications are associated "with a small increase in the rise of adverse event reports of suicidal thinking or suicide attempts in youth," these reports most likely do not reflect real changes in the incidence of actual suicide events. Citing epidemiologic studies, autopsy studies and recent cohort surveys, ACNP stated that the data "do not support the hypothesis that SSRIs induce suicidal acts and suicide, instead indicating a possible beneficial effect." They went on to cite the beneficial effects of one SSRI, fluoxetine, in treating depression with minimal risk, and called for more research to establish the efficacy of other antidepressants.[54]

Meanwhile, opponents of using psychotropic medications for children and adolescents continue to focus on the risk profile and downplay the benefit profile. In light of the black box label, there are reports of more physicians prescribing atypical antipsychotic medications in this population, for which there is even less efficacy and safety data than for the newer antidepressants.

More studies, more controversy, more polarization. It's a familiar pattern.

Antipsychotic Medications

Benefits

The use of antipsychotics among children and adolescents has increased markedly over the past decade or so, primarily with the gradual introduction of the new atypical antipsychotics (clozapine, risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole), which have fewer unfavorable side effects than the older antipsychotics (haloperidol, chlorpromazine, fluphenazine). Gradually, the newer medications are replacing the older ones.

In addition to the increasing use of the atypical antipsychotic medications in an outpatient setting to control aggression and behavioral disorders in children and adolescents (an off-label use), they are commonly used with this population in an inpatient setting, where the symptoms are more severe and persistent. There is growing evidence that these medications, especially risperidone, are effective in treating aggressive behavior across different psychiatric conditions, particularly in children and adolescents of below average intelligence. Additionally, there is some evidence that aripiprazole (Abilify) is effective in treating pediatric bipolar disorder and is "well tolerated."[55] However, all of the supporting data are from short-term, not long-term, studies. Most researchers underscore how little is known about the long-term effects of these powerful medications, and all of them call for more caution and research into their use.[56]

Aside from the use of risperidone, which some have recommended as a first-line treatment for aggression and impulsivity in children and adolescents, little is known about the efficacy of this class of medications in a younger cohort. In that light, treatment guidelines call *first* for treating primary psychiatric disorders involving "clear and persistent aggression" with psychosocial and educational interventions. If these treatments fail, then "clinicians should consider treatment with an atypical antipsychotic, using a conservative dosing approach and routine assessment of treatment effects and medication side effects."[57]

Meanwhile, more physicians, especially those in primary care settings, are prescribing the atypical antipsychotics for a younger population. Clearly, there is a divergence here between clinical research findings and recommendations and actual real world practice.

Risks

The atypical antipsychotic medications are not FDA-approved for use with children and adults, and are therefore off-label. One of the reasons they are increasingly prescribed, however, is that they have a lower risk profile than the earlier antipsychotics. That is not to say there is no risk: side effects include weight gain and new onset diabetes. Other reported side effects across the range of antipsychotics, although low in incidence, include extrapyramidal symptoms (EPS), tardive dyskinesia (TD), neuroleptic malignant syndrome, hyperglycemia, hyperlipidemia, cardiovascular abnormalities, and hyperprolactinemia.[58]

On the whole, little is known about the potential risks involved in the use of the atypical antipsychotics among children and adolescents. That alone should warrant caution in their use. Also, because antipsychotics are often prescribed for non-psychotic disorders, such as aggression, some call for more consideration of non-pharmacological treatments, such as behavioral therapy and psychoeducation, which have been shown to be beneficial in treating aggression.

But then, alternative approaches take time, and time is in short supply for many providers. Pharmaceuticals, meanwhile, are abundant.

Sociodemographic *Characteristics*

Differences in the need for, and use of, health care services generally based on race, income, age, geographical location and family structure are widely noted in the literature. Much less is reported, however, on sociodemographic aspects of psychotropic medication use by children and adolescents, although what is cited confirms patterns of disparity established for other aspects of health care services.

A 2005 study[59] utilizing the DISC Predictive Scale instrument for assessing psychiatric symptoms noted the following:

- **RACE/ETHNICITY** African-Americans reported more psychiatric symptom clusters than Whites and White Hispanics. They have a relatively high risk for anxiety clusters compared to other ethnic groups. Rates of OCD (Obsessive-Compulsive Disorder) clusters among African-Americans were twice as high as among Whites; they were also higher for specific anxiety and agoraphobia clusters.
- **AGE** Younger adolescents had higher rates in the anxiety cluster than older adolescents. Conversely, older adolescents had higher risks in the affective cluster. Middle adolescents had the highest risk for attention deficit and behavioral problems.

- **INCOME** Adolescents from lower income families were more likely to meet the criteria for at least one psychiatric symptom cluster than those from higher income families.
- **OTHER** Compared to non-metropolitan areas, adolescents in the largest metropolitan areas were at "reduced risk for most psychiatric problems, including anxiety and affective domains, SUD [Substance Abuse Disorder] and co-occurring problems. U.S.-born adolescents had higher risk for SUD and disruptive behavior problems in comparison with immigrant adolescents."

With regard to the use of psychotropic medications themselves:

- White children are more likely to receive prescriptions for psychotropic drugs than African-American children, with the discrepancy largest for psychostimulants and antidepressants.[60]
- In 2004, rates of treatment for depression among adolescents were higher among Whites (44.9%) than among White Hispanics (36.8%) or African-Americans (28.9%).[61]
- Health insurance makes a difference: Adolescents who had health insurance in 2004 were more likely to be treated for depression (41.2%) than those who did not have health insurance (26.9%).[62]

Parent surveys report similar prevalence and use trends across sociodemographic descriptors, although at lower percentages than reported by researchers using psychometric evaluation instruments. Highlights from a 2003 survey:[63]

- Parents report more severe emotional and behavioral difficulties for boys than for girls – a 6% compared to 3% prevalence average across all age categories.
- Household income is a factor: 8% of children living below the federal poverty level had definite or severe difficulties, compared to 6% of children in near-poor families and 5% in non-poor families (200% or more of federal poverty level).
- Family structure is a factor: Percentages reporting difficulties:
  - Children not living with either parent – 9%
  - Children living with mother only – 7%
  - Children living with father only – 4%
  - Children living with two parents – 4%

In a 2004 survey[64] focused on the willingness of parents to have psychotropic medications prescribed for their children, researchers reported that rates of antidepressant use among children increase with the mother's education and are higher for boys and children with private health insurance. However, the researchers found few consistent sociodemographic predictors of willingness to prescribe psychotropic medications for children, and concluded that the "strongest predictors of willingness to give psychiatric medications to children were trust in personal physicians, general attitudes towards psychiatric medications (in essence, perceived efficacy), and the respondent's willingness to take psychiatric medications herself or himself."

What Is 'Normal' Behavior?
The Threshold of Medicalization and Medication

The rising rates of mental and behavioral disorders among children and adolescents, and the use of psychotropic medications to treat them, occurs within the larger context of the increasing *medicalization* of all aspects of modern life: defining a problem in medical terms, employing a medical framework to understand it, and using a medical intervention to treat it.[65]

The central contention, in its simplest terms, is that much of what was formerly considered "normal" behavior in childhood – temper tantrums, excitable behavior, sporadic swings in mood and behavior – is increasingly diagnosed as "mental" or "behavioral" conditions that are amenable to medical intervention, usually pharmaceuticals. For example, a child who is repeatedly hostile and defiant in the face of parental and school authority may eventually be diagnosed as having oppositional defiant disorder (ODD) and treated with psychotherapeutic intervention, medication or both. As more of these diagnoses are made, and as more parents and providers become comfortable responding with ever more medical products and services to treat it, the medical "disorder" can become the de facto framework for interpreting an ever wider range of so-called "normal" behavior.

In this way, the threshold of what is viewed as 'normal' shrinks as the threshold of the triggers of medical intervention expands.

As the ability to predict and control more aspects of modern life increases, the public's tolerance for a range of symptoms and problem behavior decreases.

Changing Definitions of Risk

Changing thresholds of normalcy are hardly limited to mental and behavioral disorders:[66]

- **HYPERTENSION** The onset of hypertension has gradually decreased from systolic/diastolic blood pressure (BP) of 160/100 to 140/90, and even 130/90. Lowering the BP adds 14 million people in the U.S. who need "treatment."
- **HYPERCHOLESTEROLEMIA** Lowering the cholesterol threshold from 240 to 200 added almost 43 million people to the at-risk category. They, too, need medical treatment.
- **OVERWEIGHT** Lowering the body mass index for being overweight from 27 to 25 added almost 30 million people to the "problem" side of the equation. If it gets to 23, even the thin will be fat.

Taken to extremes, we will all eventually be classified "at-risk" and in need of medical treatment. This is the standard critique of a profitable medical industry that seeks to expand the definition of the problem in order to sell more products and services. But as emotionally appealing as it is to blame the pharmaceutical industry and greedy providers as the "bad guys" stoking our addiction to pills and high tech procedures, this visceral condemnation masks a more complex picture:

- ✔ As the ability to predict and control more aspects of modern life increases, the public's tolerance for a range of symptoms and problem behavior decreases. In emotional and behavioral symptoms in children and adolescents, the tolerance is limited to a shrinking range around the mean.
- ✔ This decreasing tolerance is perceived by many at a social and cultural level, but not always on the personal level. So, while public opinion does not support medicalized definitions of child behavior and affirms the view that "we prescribe far too many drugs to treat what are normal behaviors in children," many parents nonetheless readily assent to prescribing such medications for their own children when faced with what they perceive to be "problem" behavior. It's well known that people often behave differently than their response on an opinion poll would predict.

- ✔ As tolerance for problem behavior decreases, expectations for solutions and cures increase – all with a low tolerance for risk. The hype of science and technology engenders the dream of perfection and control. Everything can be "fixed" – there is less tolerance of failure. When it shows up – as it invariably does – blame is assigned, usually to groups and interests other than one's own.
- ✔ Many groups are instrumental in creating and perpetuating specific diagnoses and treatments, ranging from parents, self-help and advocacy organizations to pharmaceutical companies, clinicians and researchers.[67] It is tempting to see this all as "medical imperialism," but the process is more inclusive and collaborative than that. Scientific categories, too, are socially constructed. Successful claims are the product of years of complex interaction between a wide variety of motivated parties.
- ✔ The debate over medicalization generally, and in the mental and behavioral health of children specifically, has greatly accelerated over the past several decades through increased media and political attention. As more diagnoses, treatments and cost-benefit claims are made, more are subject to public scrutiny in a shrill, often politicized environment, where the sheer noise of competing assertions arguably has the net effect of solidifying entrenched positions and makes any bridging dialogue difficult. The recent spate of pronouncements by the FDA on the safety of certain psychotropic medications for use by children is a case in point. When knowledge is inconclusive, the certainty of fixed belief is all the more attractive. Ironically, the more time it takes for research and clarification, the shorter the public's attention span becomes.

Symptoms, Disorders *and the DSM*

It is common to hear the phrase, "we treat symptoms, but not the disease."

Applied across a broad spectrum of physical and social ills, this refers to the American pragmatic predilection – some would say obsession – to define every problem, name it, and solve it by addressing its root causes. Americans pride themselves on being problem-solvers – hence we tend to frame everything as a problem that is amenable to a solution if only we had the will, resources and time to find it.

In behavioral and mental health, the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) is the official repository of defined and named problems – mental disorders – that is used by mental health professionals (psychiatrists, psychologists, primary care physicians, social workers, counselors, etc.) to make diagnoses across a wide variety of settings (inpatient, outpatient, primary care, social service systems, etc.). The DSM consists of three major components: the diagnostic classification, the diagnostic criteria sets and the descriptive text. Initiated in 1952, the DSM has undergone three subsequent revisions, with the DSM-IV issued in 1994 and a text revision (TR) of the DSM-IV published in 2000. The next revision is scheduled for 2011.

Science and *Special Interests*

Disorders enter the DSM via a vetting process involving over 1,000 individuals and various professional organizations. Ideally, this involves the independent and objective consideration of scientific research and evidence-based practice, but it also reflects the tug of war between different theoretical perspectives – primarily the psychoanalytic versus the "biology-based" approach – and the real world consideration of applying the DSM codes in actual practice settings, where providers are reimbursed by health plans based on making specific diagnoses.

Predictably, the idea of what constitutes a legitimate mental disorder in the DSM often takes a back seat to the political and economic exigencies of the moment. Some believe that the DSM is not a "scientific document" but is rather a "mix of social values, political compromise, scientific evidence and material for insurance forms."[68] Others point out financial ties between psychiatrists who worked on the DSM-IV and the pharmaceutical industry, and question the integrity and transparency of what purports to be an independent process free of special interests.[69] Since the FDA will not approve a drug to treat a mental condition that is not listed in the DSM, the process of its development is obviously of importance to pharmaceutical manufacturers.

Since the FDA will not approve a drug to treat a mental condition that is not listed in the DSM, the process of its development is obviously of importance to pharmaceutical manufacturers.

Still others, most notably the Church of Scientology, claim that mental disorders don't exist at all, and the DSM is a "fraud" perpetrated on the American public to push dangerous, life-threatening drugs. Even critics of various aspects of the construction of the DSM point out that such extreme views have no basis in medical fact, but that has not stopped the Church of Scientology's war on modern psychiatry to find its way into state legislatures in the form of bills to regulate various aspects of research into, and use of, psychotropic medications in children and adolescents.

In this climate of mistrust, suspicion and, in the most extreme cases, outright hysteria, what can we reasonably conclude about the legitimacy and use of the DSM in mental health practice for children and adolescents?

- The evolution of the DSM reflects the contentious development of the field of psychiatry itself, moving from a theoretical framework grounded in psychoanalysis to one grounded in a more biological-based and categorical approach to diagnosis. What continues to be in dispute today in the professional literature (to say nothing of the popular media) is the scientific basis of the complex interplay between genetic, biochemical and environmental factors in the manifestation of emotional states and behavior. The dominant biochemical paradigm, which tracks the "disease" model of modern allopathic medicine, is questioned by some as an overly reductionist approach that substitutes an allegedly "evidenced-based" diagnosis for a more "comprehensive" examination of social and environmental factors that do not easily lend themselves to "intellectual shortcuts."[70] A more nuanced diagnosis that takes family systems and individual psychodynamics into account is recommended.

- The DSM is often the scapegoat for diagnoses driven more by the demands of clinical practice than by applying a specific set of symptom and impairment criteria. For example, the DSM-IV requires that a diagnosis of ADHD have a sufficient number of 18 related behavioral symptoms that persist for at least six months; symptom onset before seven years of age; functional impairment in at least two separate settings; and no other mental, medical or environmental explanation for the symptoms.[71] In actual practice, however, there is considerable variability in how

these criteria are applied. The leap from the identification of symptoms to making a specific diagnosis based on DSM criteria is often too quickly made. Who, for example, has the time to be sure that "no other mental, medical or environmental explanations" are involved? Certainly not physicians whose reimbursement is tied to how many 15-minute sessions they can squeeze in the day.

The DSM will continue to evolve along with the development of scientific knowledge and clinical practice, and it's reasonable to predict that not every diagnosis in the system today will necessarily be there tomorrow. For example, many clinicians doubt that there is any real substance to the diagnoses of conduct disorder (CD) or oppositional defiant disorder (ODD) in children and adolescents, which are known to have many causes and have a high rate of co-morbidity with other diagnoses (anxiety disorders, bipolar disorder, etc.). In the words of one child and adolescent psychiatrist we talked to, "CD and ODD will probably go away once funding for them dries up." In the meantime, however, the tendency to make a quick diagnosis and attach a label to the child may do more harm than good, especially if it masks other causal factors that are amenable to treatment.

There is some force to the argument that the DSM is overly influenced, either directly or indirectly, by the pharmaceutical industry. On the face of the evidence, it is reasonable to conclude that some researchers are unduly influenced by pharmaceutical companies that may pay them for various consulting services. As in all aspects of what has become a profitable *industry* in every sense of the word, the development of new "disorders" can be the tail chasing the pharmaceutical dog: resources and interests follow the line of profitable expansion into new markets, which are legitimated in the DSM as new "disorders."

But who is surprised by this? It is the logical consequence of the commoditization of health care services. Mainline professional health organizations and researchers are well aware of the dangers, and are now calling for more transparency of ties between researchers and pharmaceutical manufacturers, including required public acknowledgement of all potential conflicts of interest. This should be encouraged on a voluntary basis among a collaboration of professional, public and private interests. More regulation may be necessary, but it should be the court of last resort, not the first. The goal is to encourage more independent research into the identification, causes and effective treatment of mental disorders without that research being hijacked by special interests and private gain.

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a profitable *industry* in every sense of the word,
the development of new "disorders"
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The Street:
The Real-Time World of Diagnosis and Use

It is on the "street" – the real-time world of clinical practice – where the rubber of careful and measured criteria of diagnosis and prescription meets the road of increased demand for services within a vast and growing health care industry.

On the street, the pressures of time and business often trump evidence-based criteria of practice. This is what accounts for the disparity one often sees between what *ought* to happen in prescribing psychotropic medications for children and adolescents, and what in fact *does* happen. The measured advice and diagnostic guidelines of groups such as the American Psychiatric Association, or the calls for caution and adherence to professional standards of clinical judgment by education and advocacy groups such as the National Alliance on Mental Illness (NAMI) do not necessarily reflect how many clinicians actually practice.

Business Practices

For better or worse, health care has become an *industry*. Many of the problems associated with treating children and adolescents with significant mental and behavioral disorders begin and end there.

The Logic of Supply and Demand

The rise of managed care "carve-out" plans for behavioral health in the 1980s and 90s occurred in tandem with the growing domination of the "business" model of health care generally and the search for more predictable revenue streams and "profitable" service lines. Eventually, a handful of behavioral health carve-out companies grew by consolidation to dominate the industry and ratchet down costs by shifting treatment from inpatient to outpatient settings (made possible, in part, through the use of new psychotropic medications), negotiating discounted hospital and professional fees, and using various management techniques to limit unnecessary services.

This worked for awhile, but eventually high demand and market saturation fueled unsustainable "bottom feeding" and "low balling" business practices that, coupled with consolidation on the provider side of the equation, resulted in a standoff between payers and providers, and higher costs being passed on to employers and consumers.

The situation is a bit different today. To be effective in controlling costs and "directing" care, managed care companies need an adequate supply of providers – ideally, an excess – who will absorb the discounted rates and still provide care. Today, there is a shortage of psychiatrists and other mental health providers willing to work for reduced fees, put up with administrative hassles or have limited treatment options. Many of those who are left are voting with their feet and leaving managed care plans to practice on their own in a fee-for-service environment where there is more than an adequate supply of consumers willing and able to pay the bill.

"It is important to balance the increasing market pressures for efficiency in psychiatric treatment with the need for sufficient time to thoughtfully, correctly, and adequately assess the need for, and the response to, medication treatment. Monitoring ongoing use of psychoactive medications requires sufficient time to assess clinical response, side effects and to answer questions of the child and family. AACAP opposes the use of brief medication visits (e.g. 15-minute medication checks) as a substitute for ongoing individualized treatment. The role of psychosocial interventions, including psychotherapy, must be evaluated, and such interventions must be included in the treatment plan."

American Academy of Child and Adolescent Psychiatry Policy Statement

Low reimbursement rates mean that physicians have to cram more visits into the day simply to stay in the game.

The 15-Minute Meds Management Visit

Faced with a lack of resources, managed care companies are compelled to redefine the "episode of care" in ever more narrowly defined and "efficient" treatment inputs. Instead of the luxury of taking, say, an hour to make a differential diagnosis based on a careful evaluation of the patient's physical and social history, the physician's encounter with the patient is reduced to a 15-minute "medication" visit, where all of the incentives are lined up to focus on quickly identifying symptoms most in need of attention and treating them as quickly and efficiently as possible. This situation is compounded for psychiatrists who specialize in treating children and adolescents, because the reimbursement rates don't cover the extra time it takes to interview parents, caretakers, teachers and others familiar with the child's behavior.

Low reimbursement rates mean that physicians have to cram more visits into the day simply to stay in the game. Many psychiatrists know that patients will do much better with a combination of psychotherapy and medication management – and all of the professional guidelines underscore the importance of a complete differential diagnosis and the use of medications as only one part of a well-rounded treatment plan – but the time and expense for this simply isn't in the managed care playbook of cost effective – i.e., profitable – treatment.

A Two-Tiered System

This drives talk therapy into its own separate system, which is the province of psychologists and a variety of master-level clinicians. The result is a two-tiered system. Patients who can afford to pay up front or have a rich benefit plan can see psychiatrists and Ph.D. psychologists; middle and lower income patients get the split treatment plan of talk and medication in different systems. Since physicians increasingly don't get paid for talk, there is a predictable lack of communication and coordination between different parts of the system. Children can be placed on a medication regimen without any counseling component at all. This is not considered to be a "best practice" strategy, but with a shortage of clinicians, lack of time, low reimbursement rates and little integration between the medical and behavioral health systems, it is often the only recourse available.

Pharmacy Benefit Management Companies

The use – or not – of psychotropic medications across all classes of patients is also influenced by pharmacy benefit management companies (PBMs), which psychiatrists and other physicians see "as an affront to their medical capabilities and as an enormous administrative burden."[72] Physicians may find that medications they consider to be the best course of treatment are on one formulary but not another, and simply keeping track of what's available for any given patient "can be a real hassle." Local interviews with Arizona physicians confirmed that PBMs are a significant issue in their practice, and another reason

why neither administrative efficiency nor effective treatment options are always well served in today's bottom-line oriented health care industry.

And we haven't even mentioned the issue of psychiatrists and other physicians having to deal with utilization reviews conducted by "lesser-trained" clinicians. To say that many physicians are upset with the way they are treated in the industry – as *labor*, not as *professionals* – is to put it mildly.

The Disease v. Developmental Model

The dominant model in American health care is the **Disease Model**: the diagnosis and treatment of disease, illness and pathology. Applied to children and mental health, this translates into the classification of symptoms into mental and behavioral disorders, and their treatment primarily through biologically-based interventions.

Alternatively, a **Developmental Model** stresses the stages of a child's physical, mental and social development over time. In addition to investigating the biological substrate of behavior, it links that substrate to environmental and social factors that impact stages of development as noted and defined through epidemiologic studies.

Although we don't get into it here, it would be interesting to speculate on how a developmental approach to diagnosis and treatment of behavioral health problems in children might differ from a disease-based approach – or if this distinction is valid in the first place. For example, if we had more developmental pediatricians treating children, would we see less use of psychotropic medications? How would diagnostic and treatment modalities change, if at all? Would outcomes differ?

Social-Cultural Factors

On the street, healthcare services shape, and in turn are shaped by, a number of larger social-cultural factors that mitigate against the adoption of what are considered to be "best practices" of care with regard to the use of psychotropic medications in children and adolescents.

An Ego-Centric Culture

Despite paying lip service to the importance of family and community in raising children ("It takes a whole village to raise a child."), American values and institutions reflect a singular, almost obsessive focus on the concepts of freedom and individualism, which find their fullest expression in fulfilling unlimited needs and desires through a competitive, market-driven system of economic transactions. It is the ideal of the autonomous individual as self-legislator and self-actualizer – not the ideal of the development of the social self within a responsive community – that dominates American culture and sets expectations of "useful" behavior: the acquisition of skills and attitudes that enable the individual to *compete* in the "emerging global marketplace."

The Psychiatrist Shortage Issue

One study commissioned by the American Academy of Child and Adolescent Psychiatry (AACAP) in 2003[73] found, on average, one child psychiatrist for every 15,000 youths under 18 – a caseload of 750 children per physician. In Arizona, there were 134 child psychiatrists practicing in 2004, with five counties having no child psychiatrists at all.[74] Various studies project a "crisis" in having enough child psychiatrists to meet future demand, although the track record of workforce projections based on "needs" is dubious at best. In the end, "we need, or demand, what we can pay for, individually and collectively."[75]

While dissecting the psychiatrist shortage question is outside the scope of this report, the following summary points set the critical context for workforce capacity issues that impact the use of psychotropic medications among children and adolescents:

Considering the realities of doing business in this "commodity-driven" climate, it's little wonder that there is a growing shortage of psychiatrists generally, and psychiatrists who specialize in treating children and adolescents specifically.

- There is a continuing decline in the number of medical students who choose to become psychiatrists. Based on recent surveys, this isn't projected to change anytime soon.
- Less interest in medical students studying psychiatry parallels a declining interest in primary care. Historically at least, both are "integrative" specialties – making a differential diagnosis based on physical, mental, social and environmental factors – and both make considerably less money than the "proceduralists" (surgery, dermatology, radiology, cardiology, etc.). In the industrial model of medical care, standardized algorithms of diagnosis and treatment, coupled with ever more focused and powerful procedures, are arguably destined to replace the "professional judgment" of individual physicians based on years of experience and transcend the integrative specialties in the process. More medical students will gravitate to the high tech, proceduralist fields.
- With increased demand for, and growing acceptance of, the use of psychotropic medications in children and adolescents, there is an increase in the number of referrals to psychiatrists. With fewer child and adolescent psychiatrists, however, the slack is taken up by pediatricians, psychiatric nurse practitioners, primary care physicians, general nurse practitioners and, in a few states, by psychologists who have sought and received prescription privileges. One might foresee a broadening of scope of practice for professionals in related fields and a refocusing of psychiatry on more complex psychobiological disorders and eventually into a tighter biological orbit around the cognitive neuroscience specialties generally. Exactly how this might impact *quality* of care, of course, is a central issue.
- The shortage of psychiatrists able to *take* referrals is compounded by a shortage of family therapists and other specialized clinicians to take referrals *from* psychiatrists. Based on our interviews and anecdotal evidence in Arizona at least, it is hard for psychiatrists to find qualified therapists able to fill out an integrated team to deal with both the biological and social aspects of serious emotional and behavioral disorders.
- One of the perverse results of increased service demand and a limited supply of providers is the increasing number of youth with serious mental disorders who are "turned over" to the state simply so they can get treatment. Lower income families who cannot afford to see physicians and therapists in private practice (who are backlogged to begin with) — and even higher income families who are at their wit's end with a mentally ill child — often find that their best option is to make the child a ward of the state. It's incredible but true: prisons, juvenile justice and foster care systems are major providers of services for both children and adults with mental illness and behavioral disorders.

So it is that social policies and practices are framed in terms of the individual's rights and needs – the *ego-centric model* – rather than duties and responsibilities – the *communal model*. So it is that children, who are utterly dependent upon adults well into their second decade, must be "prepared" for the modern workplace in order to compete successfully as *consumers*.

The Pressure Cooker of Over-Stimulation

The excesses and problems associated with a culture and social structure that glorifies the individual and competition in all of its varied forms are well known: unstable family structures, high rates of psychosocial problems (crime, substance abuse, violence, anxiety, unhappiness, etc.) and growing economic and social inequality. Every breathless pronouncement of high rates of mental and behavioral disorders among children and adolescents in "advanced Western democracies" has its genesis in an over-stimulated society, where media-saturated images of individual self-fulfillment, happiness and the acquisition of consumer goods and services to satisfy a plethora of "lifestyles" conspire to create a pressure cooker of often unrealistic expectations for adults and children alike.

Children who do not conform to ever more restrictive and socially acceptable standards of behavior and control, whether defined by their parents, schools or the wider community, become "problems" that need to be addressed, lest they become even bigger problems to society later on. In this view, the cost of treating these children now will pale in comparison to the cost of treating them later as adults with behavioral disorders, high rates of substance abuse, poor education and the like.

The New Drugs of Choice

Among adolescents and young adults, the use of illicit street drugs such as cocaine and marijuana is on the decline, while the illicit use of prescription drugs is on the rise.

That's according to the annual Monitoring the Future survey sponsored by the National Institute on Drug Abuse since 1975. As reported in a recent article in the *New England Journal of Medicine*,[76] the proportion of teens who said they had used an illicit drug during the past year declined by as much as one-third among 8th graders and by 10% among 12th graders. Conversely, 7.2% of high school seniors reported the non-medical use of sedatives, up from 2.8% in 1992. Alcohol, however, remains the most widely used drug.

But here's a key difference: Whereas teens stated they used illicit drugs for "recreation," they turn to prescription drugs for "practical effects" – hypnotic drugs for sleep, stimulants to enhance school performance, and tranquilizers to decrease stress. Many characterize their use of these medications as "responsible, controlled and safe." And why not? They see these medications portrayed in a blitz of mass market advertising as a beneficial aspect of everyday living. They see their parents using them, they hear physicians extolling their virtues, they pay little attention to the safety warnings and adverse side effects in the fine print.

It's becoming a way of life. Asked to comment on why the use of "calming" prescription drugs by teens is on the rise, while the use of stimulants is decreasing, one teen stated, "We're living in a time that seems decidedly more apocalyptic, especially since 9/11 and all the recent natural disasters. Maybe we need something to slow down."

Fix This

The pressure cooker of over-stimulation that engenders high expectations of control and performance is inversely proportional to the time and resources available to address the child's needs. Clinicians report that parents and other caregivers, in search of respite and quick relief, will often demand that the child be put on psychotropic medications to "fix" the immediate symptoms while they buy some time to "figure out what's really going on."

"What is the child trying to tell us?" a well-trained clinician might say. Best practice guidelines developed by pediatricians, psychiatrists and psychologists all stress that it takes investigative work to sort through the combination of biological, social and environmental factors impacting the problem behavior. But while some parents who have the skills and are willing to take the time to sort through the issues before turning to medications as one part of an overall program of treatment, others are perfectly content to get a prescription that provides immediate relief and deal with a recommended counseling component "later."

Later, of course, never comes. The symptoms are gone, behavior has improved. Problem solved – for now. The pressure this creates for physicians to prescribe medications for children, and to keep on prescribing them, is enormous.

Social Order and Control

Clearly, more than biological factors impact the ADHD diagnosis.

Ever higher levels of social wants, needs and desires in an over-stimulated, consumer-oriented society engender the need for greater social control. With regard to children, the dominant social institutions for this purpose remain the family and the school, but changes in both over the past 50 years have precipitated the greater use of medications as a quick – and often effective – means of managing the behavior of children.

Many **schools**, for example, are increasingly focused on tightly monitored and prescribed regimens of knowledge acquisition and skill development (time on task, frequent testing, etc.) that, coupled with high student-teacher ratios and limited time and resources for other outlets for learning and development (physical exercise, play, the arts), lower the threshold of unacceptable behavior. The teacher has limited time and patience to deal with a child who may be exhibiting, say, "oppositional-defiant" behavior. She calls in the counselor or school nurse for assistance, and sets in motion a process that may eventually lead to an ODD diagnosis and medication.

The social and environmental factors in schools that are associated with an ADHD diagnosis are a case in point. Recent research[77] shows that higher diagnosis rates are associated with schools subject to stricter state-level performance accountability laws, older teachers (less patience with aberrant behavior), summer birthdays (younger children in the classroom) and not living with a biological father. Clearly, more than biological factors impact the ADHD diagnosis.

Granted, medical guidelines call for a complete diagnosis considering all relevant factors and input from all involved parties (the child, teachers, parents, counselors), but this is the exception, not the rule, in a time- and resource-stressed climate. In one of several ironies here, policy leaders who are the most vocal in their allegations of spurious behavioral diagnoses in children and the misuse of psychotropic drugs to treat "normal" behavior are often the same ones who vote against educational appropriations to lower class size, increase extra-curricular resources and make investments in trained personnel and community-based programs that might provide effective alternatives to medications. It becomes easier to blame harried teachers and "poor parenting" than to look for constructive solutions.

The **American family**, too, is challenged by the disconnect between expectations of the child's "compliancy" in the structured regimen of schooling and socialization and the resources available to assure it. Good intentions aside, the increase in single-parent families, the demands of the workplace, the lack of time and money to take advantage of various strategies to help the child (counseling, recreational programs, spending more time together as a family, proper rest and nutrition, etc.) and the sheer amount of stress encountered in simply getting through the day make the use of medications the most immediately useful – and, for some families, even the only – cost- and time-effective choice.

On the other hand, families that have higher education and income levels, and which may in fact have the time to pursue other avenues of support for their children, may view psychotropic medications as a way to *enhance* academic and social performance in cases where the child is not meeting their expectations.

In one example related to us, upper income parents of an adolescent who was "highly excitable" but nonetheless a solid "B" student pressured their physician to prescribe a psychostimulant so the child could be an "A" student and have a shot at getting into the "right college." An anecdote does not a social trend make, but it underscores how perceived levels of behavioral impairment – and the use of medications to treat them – are influenced by social class and cultural expectations.

Ethical Issues

Many of the references in the literature to ethical considerations associated with the use of psychotropic medications among children and adolescents focus on the issue of conducting research into the efficacy of these medications among a population that is often unable to give its informed consent to treatment.

A young child lacks sufficient knowledge, experience and self-awareness to make an informed judgment about the use of such medications, and thus is at the mercy of parents, medical professionals and other adults to make those decisions for her. Critics of the use of psychotropic medications among the very young stress the strong ethical obligation parents and medical professionals have to protect the child from the possible deleterious effects of these medications on human growth and development. Given what they perceive to be lack of knowledge and agreement on the etiology of mental illness, diagnostic criteria, efficacy and serious side effects, they consider it morally reprehensible to prescribe psychotropic medications for any but the most severe and clear cut cases of need.

Which is better: to let the child suffer needlessly when medications to treat severe symptoms are available, or to use those medications to help promote development?

On the other side, medical professionals and parents of children with severe emotional disorders point out the ethical consequences of *not* using these medications, especially where other alternatives aren't available or haven't worked, and the child's ability to develop normally and exercise the full range of her abilities and interests is compromised. Which is better: to let the child suffer needlessly when medications to treat severe symptoms are available, or to use those medications to help promote development?

Rather than make a blanket moral pronouncement on the so-called evils of these medications in all cases, the ethically responsible course of action is to make an informed judgment of the cost-benefit equation in individual cases, and to leave those decisions in the hands of parents, caregivers and competent medical professionals.

Catch-22

Another contested issue is the ethics of indiscriminately applying the diagnostic categories and medication results from adult-based clinical trials to those of children in the absence of "qualified research" on children themselves. This is hugely ironic and a bit of a Catch-22: One can't very well complain that children are being inappropriately enrolled in clinical trials without informed consent, and then turn around to argue that these medications shouldn't be prescribed until we have "sound research" to support their safety and effectiveness. Medical researchers routinely find it difficult to enroll children in clinical trials for psychotropic agents, and it is not uncommon to see results reported on trials with as few as five to ten children in them. Yet the same parents and policy leaders who seek more "certainty" on the safety and efficacy of these medications are often unwilling to enroll their own children in the requisite research studies, and even go so far as to advocate for more restrictions on conducting that research in the first place.

The Fundamental Quandary

At a deeper level, however, all of the ethical issues concerning the use of psychotropic medications among the young are manifestations of a more fundamental quandary: the untold consequences of intervening in the human psyche for the development of the self and what it means to be fully "human."

On the one hand, there are clear cases where the intervention into the psyche of children with psychotropic medications might be considered medically necessary: "to restore the connection between lived experience and emotional effect, to correct chemical imbalances that lead to chronic misery and self-destructive behavior, or to give individuals the raw neurological ingredients necessary to feel happy in response to genuinely happy things."[78] There are children and adults who, through no fault of their own, lack those neurological connections, and these medications, given a proper diagnosis, administration and monitoring, can be enormously helpful.

On the other hand, there are other cases where the use of these medications might in fact *sever* the connection between lived experience and emotional effect: rather than go through the pain and discomfort of stressful moments, grief or thwarted needs and desires, we take medications to smooth the rough edges and sail through the day. The use of psychotropic drugs in this way by adults is one thing, but it is entirely another for children, whose concept of self and development of 'character' is in its formative stage. What are the consequences of raising a generation whose lived experience has been chemically mediated to the point where the very notions of 'self' and 'self-control' rest on a technological, and not a 'human,' construct?

Sentient Machines

Clearly, this begs the question of what it means to be 'human.' If all we are is "chemical wetware," as some biological reductionists might argue, then the chemical and technological enhancement of that wetware to improve adaptation and performance is not only beneficial but *necessary* in order to fully realize our *human* potential and evolve as "sentient machines."

This is a caricature of a complex position, surely, but it is both logically and historically consistent with the dominant frame of humans as consumers, health care as a commodity, and social progress as synonymous with industrial growth and development. In this ethical framework, our common *humanity* is enhanced to the degree that we are able to use the

fruits of science and technology to bring the natural world under our control. The development of psychotropic medications, which is still in its infancy, is only one of many possible interventions to increase control and improve performance that we can look forward to in the future.

Character and Lived Experience

But there is something in this view of what it means to be 'human' that doesn't *feel* right.

Feelings, which are an essential part of our moral life, are often difficult, if not impossible, to put into words, and to use feelings alone as the basis of moral argument is unacceptable where fundamental premises and conclusions are in dispute.

Nonetheless, many people might express their misgivings about the increasing use of psychotropic medications among children and adolescents in this way: To be fully human is to realize the breadth of possibilities and *limitations* from living in a natural world. It is to experience pain as well as joy, sorrow as well as happiness, barriers as well as opportunities. It is through the lived struggle of human experience that character is formed, and through the formation of character that life achieves its richest meaning and dignity. To the degree that the use of psychotropic medications may be prescribed in children as a substitute for that lived struggle, the development of character – and hence human meaning – is diminished.

This expression is based on humanistic faith, borne from experience. It rests at the foundation of all future discussions about bioethics and the application of new technologies to enhance and control human performance. It is at the interstice, and not the margins, of science and faith that this dialogue ultimately must proceed.

What does it mean to be 'human?'

Legislative and Policy Issues

All of the medical, social and cultural issues surrounding the use of psychotropic medications among children and adolescents come together in national and state policy discussions and legislative action. Most of the focus falls under the general headings of safety, the role of schools, mental health screening and clinical research involving children. (The large percentage of children in foster care who are prescribed psychotropic medications is also a flashpoint issue in state legislatures, but we do not cover it separately here.)

Safety

We previously noted the safety issues raised regarding the use of antidepressants and stimulants in children, and the controversy over whether specific classes of drugs deserve a "black box" warning or simply the inclusion of more comprehensive information leaflets for parents and patients. That debate will continue to play out as more research studies are completed, and more people become informed of the pros and cons of using specific medications to treat mental disorders in children.

Parents of children who are using psychotropic medications need to become more actively involved in advocacy efforts to strengthen, streamline and support the FDA drug approval and monitoring process.

FDA-Bashing

What is of concern here is the role of the FDA in the drug approval process. FDA-bashing has become a fashionable sport in the Washington beltway and among consumer and advocacy groups (too cozy with the pharmaceutical industry, lax oversight, too slow to approve drugs, too quick to approve drugs, etc.), but the truth of the matter is that while new responsibilities have been piled on, FDA's public funding has not kept pace. With limited funding from the government, fees from pharmaceutical companies now account for almost half of FDA's budget for drug evaluation and 12 percent of the agency's overall budget.[79] This compromises public perceptions of independence and objectivity.

In addition to the need for increased public funding attendant with increased responsibilities for determining efficacy and safety, other policy recommendations might include head-to-head comparison of new drugs with older drugs for the same purpose, more active monitoring of drugs among the target populations, development of an open clinical trial registry that would require drug companies to publicly share all of their trial data, and – the most controversial recommendation – banning direct-to-consumer marketing.[80]

At the very least, parents of children who are using psychotropic medications need to become more actively involved in advocacy efforts to strengthen, streamline and support the FDA drug approval and monitoring process.

The Role of Schools

The role of school personnel in the identification of children with mental disorders and the recommendation on the use of psychotropic medications to help these children adhere to standards of school performance and acceptable behavior has been a major flashpoint issue over the past decade. Much of the heat, so to speak, has come from the Citizens Commission on Human Rights (CCHR), established by the Church of Scientology in 1969, which has promulgated "model legislation" to essentially prohibit school personnel from either "identifying or diagnosing unwanted classroom behaviors or slow learning as disorders or suggesting or recommending psychotropic drugs for any child."[81]

This has produced a veritable hot bed of claims, counterclaims and legislation. At least 25 states have introduced bills, regulations and resolutions to limit the use of psychotropic agents among school children. The federal Child Medication Safety Act was passed in 2004 to prohibit school personnel from requiring a child to obtain a prescription for a federally controlled drug as a condition of attending school. CCHR lobbyists are prevalent in state legislatures, including Arizona. Together with lobbyists for mental health advocacy groups, physicians and educators, they fuel the flames of a contentious and protracted debate.

Do More With Less

Schools face the same predicament as the FDA: they are asked to do more and more with less and less. Expectations for high performance and "zero tolerance" for egregious behavior are usually inversely proportional to the resources available to achieve them. In the absence of school- and community-based resources to address the emotional and behavioral needs of children, medications often become a de facto first line of response. In that light, the propensity to address the increasing use of these medications among children and adolescents with more restrictive regulation *alone* on what school personnel can and cannot do lacks the force of both moral clarity and economic efficiency.

The question for policy leaders boils down to this: Given the growing prevalence of emotional and behavioral disorders manifested in schools, and given the reluctance to prescribe psychotropic medications, what resources *are* we prepared to invest in our schools and communities to address this issue?

Schools face the same predicament as the FDA: they are asked to do more and more with less and less.

Mental Health Screening

In its 2003 report, the President's New Freedom Commission on Mental Health (NFC) recommended, among other things, that both children and adults be screened for mental illnesses and emotional disturbances. Although the NFC never in fact recommended *mandatory* screening and subsequently stressed "programs that provide voluntary screening only with parental consent,"[82] the net effect of the report was to create a climate of suspicion stoked by opponents of mental health screening of any type who insinuated that "Big Brother" was watching America's children to ensure that they remained pliant and controllable through spurious diagnoses and prescription drugs – all of it a plot of Big Pharma.

Any program of mental health screening for children and adolescents soon came under suspicion, including TeenScreen, a national voluntary mental health and suicide risk screening program that is used in over 40 states and is just getting underway in Arizona. States began to consider and pass legislation regarding parental notification and consent. In Arizona, legislation (SB1324) was recently passed and signed into law in May 2006 requiring parental notification and consent for mental health screening in the schools.

From Screening to Diagnosis

The heated rhetoric of the policy debate on mental health screening masks two central issues. The first is the relationship between screening and diagnosis. As we noted previously, close to 60% of adolescents screen positive on the Diagnostic Interview Schedule for Children (DISC) instrument for various symptoms related to diagnosable mental disorders, but they have not been actually diagnosed by a trained mental health professional. It is not unreasonable to question the wisdom of allowing unqualified school personnel to conduct screenings for legitimate psychiatric disorders without oversight by psychiatrists or other trained health professionals, and certainly without the requisite resources to provide a

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thorough differential diagnosis in those cases that warrant it. The danger is that children who screen positive for certain disorders like depression and ADHD, and whose behavior may be noted by teachers and administrators as symptomatic, are often labeled with the disorder a priori, and that bias is subsequently introduced into a health care system that, as we previously noted, lacks the time and resources to do a complete differential diagnosis that either confirms or rejects the initial superficial assessment.

The result is that diagnostic labels attached by school personnel often stick in the absence of a legitimate diagnosis by a highly trained professional. And that's not good.

Parents Have Responsibilities, Too

The second issue is that of informed consent and human rights. One doesn't have to buy into the agenda and ideology of the Church of Scientology to affirm the basic human rights of all individuals, including children, and the rights of parents and caregivers to be both fully informed of, and to consent to, any screening and treatment for children under their charge. No one in the mental health community disputes this. What can be confusing, however, is what counts as 'notification' – passive notification with no requirement of signed parental consent, or an enforced formal system of signed consent – and how it translates into actual school practices. Different school systems can interpret and implement the same notification policy differently. In Arizona, we are not aware of school districts that do not require signed parental consent.

Regardless, the onus and responsibility should not lie with the schools alone. Parents and caregivers have responsibilities, too. They need to take steps to be fully informed and proactive in the lives of their children. Legislation alone will not accomplish this.

Clinical Research Involving Children

Arizona HB1477 was a stalking horse for efforts to limit the use of psychotropic medications generally, and among children specifically.

Much is made by critics of the use of psychotropic medications among children and adolescents, and of the lack of clinical research supporting efficacy and safety. Why, then, would they oppose the expansion of the requisite research?

The example of Arizona HB1477, recently passed by a Republican-controlled legislature and vetoed by a Democratic Governor, is illustrative. The purpose of the bill was to prohibit any state-funded institution or agency from testing the effects of a psychotropic medication on any person "without the voluntary and informed written consent of that person who volunteers for the test," followed by a list of prescribed conditions concerning 24-hour notification, listing of known side effects, etc.[83] Under the advice of health care associations, and given existing research and protocol oversight by the FDA, independent institutional review boards (IRBs) and standard clinical practice guidelines, the Governor vetoed the bill as "unnecessarily burdensome."

A Stalking Horse

This piece of legislation, like so many of the bills considered in state houses across the country, was a stalking horse for efforts to limit the use of psychotropic medications generally, and among children specifically. There are legitimate ethical issues concerning the enrollment of children, especially the very young, in clinical drug trials without rigorous oversight and careful research design, but the place to address these issues is through the

federal, institutional and professional research infrastructure already in place, and not through ad hoc state legislation that is often not only duplicative of existing safeguards, but impedes the development of sound clinical research to boot.

On one point, however, critics are on solid ground. This is the dominance of pharmaceutical companies in paying for a growing portion of "independent" clinical research and in establishing various financial and consultative relationships with clinical researchers themselves. But this is a national, not a state, issue.

We return to the same conclusion
again and again:
If we are concerned about the growing
and indiscriminate use of powerful medications
to treat young children,
but are enamored with the power
of "market forces" to address this and related issues
without providing sufficient public resources
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Conclusions and *Recommendations*

Children, adolescents and psychotropic medications is a flashpoint issue in American health care because it encompasses all of the incendiary triggers: the desire for perfection and control, the obsession with technological enhancement and the quick fix, the fragmentation of mind and body in two separate systems of care, misaligned financial incentives, the industrialization of medical care, the legitimacy of disorders and diagnoses, and changing conceptions of self, society and what it means to be fully human.

Ask somebody whether they think children should be taking psychotropic medications, and you will soon be deep into the psyche of American culture itself.

We have presented a 30,000 foot fly-over of some of these triggers here, each of which could be the subject of a more thorough and critical examination in its own right. Our intent has been to map the territory, not to mount an expedition.

All the same, we've reached some conclusions on where the fault points in the territory lie, and offer recommendations for policy and practice in the spirit of further inquiry and learning.

Prevalence

- The prevalence of serious emotional and behavioral disorders in children and adolescents should not be in dispute. The consequences of not attending to them, especially in the most severe and persistent cases, are devastating for both families and society. Based on behavioral indicators alone, a strong case can be made that these disorders are underreported and undertreated.

Disorders and Diagnoses

- What is in dispute – and legitimately so – are the factors that contribute to the disorder, the classification of symptoms as specific disorders, and the criteria for making a differential diagnosis. The medicalization of a wide range of behavior in children is clearly established, and researchers need to carefully delineate and account for it in the continuing evolution of the DSM.

- There is a major gap between best practice diagnostic recommendations of professional associations and actual medical practice. For reasons previously cited, many physicians prescribe psychotropic medications for children with a limited diagnosis or even no diagnosis at all. The result is overprescribing and the labeling of some children with specific disorders where they may not exist. A further result is the use of prescription drugs alone without the attendant psychotherapeutic interventions recommended in the best practice guidelines. Finally, underprescribing may also occur to the extent that physicians miss or shortchange the diagnosis.

Efficacy and Safety

- All conclusions about the efficacy and safety of using psychotropic medications to treat disorders in children assumes thorough diagnosis, treatment and monitoring by a highly trained and competent healthcare professional. If we can't guarantee this, these medications should not be used.

- On a comparative basis, the stimulants can be considered safe and effective, based on years of research. We know less about the newer antidepressants and antipsychotics, which should be prescribed with caution. We agree with others that more study is needed into the long-term efficacy and side effects of these agents, especially among children who are continuously medicated.
- We join others in advocating for more public support for *independent* research into the efficacy and safety of these medications in children, and for closely monitoring the influence of pharmaceutical companies on the classification of disorders, clinical research design and results. Good intentions aside, there is ample evidence to support the contention that researchers and practitioners are often unduly influenced by relationships with drug manufacturers. This demands a countervailing force.
- We concur with best practice medical guidelines that psychotropic medications should not be used as a first line defense of choice except in the sickest of children, and should generally not be prescribed in the absence of also providing psychosocial support. We understand the exigencies of societal demand and the perverse financial incentives that mitigate against following best practice guidelines, but at some point more physicians must to be willing to "just say no."

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Recommendations for Policy and Practice

In order to help close the gap between how physicians *ought* to practice based on diagnostic and prescription guidelines, and how they are often *forced* to practice within the industrial- and commodity-driven model of American health care, we support the following recommendations:

- ✔ **PARITY BETWEEN MENTAL HEALTH AND PHYSICAL HEALTH BENEFITS.** We don't limit the number of visits a child can have for complications from asthma or diabetes, and we shouldn't limit the number of visits for behavioral conditions either. This is not the expensive proposition critics make it out to be.[84] If physicians and other health professionals are reimbursed at competitive rates for providing psychosocial support as well as prescribing medications, we will conceivably see more balanced treatment plans and better outcomes.
- ✔ **INTEGRATION OF PHYSICAL AND MENTAL HEALTH SERVICES.** Behavioral health carve-outs may make sense for special populations such as the seriously mentally ill, but not for the millions of children and adults whose disorders may be less severe and more sporadic. Many come in through the primary care system, which lacks sufficient coordination and collaboration with behavioral health specialists and resources – and vice versa. There are signs that this is changing, but huge challenges of aligning financial incentives and overcoming issues of professional turf remain. We provide more specific recommendations on this topic elsewhere.[85]
- ✔ **EXPAND PROFESSIONAL SCOPE OF PRACTICE.** There is a shortage of psychiatrists, and psychiatrists who specialize in children and adolescents in particular. It's understandable that psychiatry wishes to define and control its professional boundaries and scope of practice, but with fewer medical students choosing to enter the profession, and with the demand for services growing, it's inevitable that other providers will enter the picture. Psychiatrists need to get out in front of this issue and become more proactive in establishing algorithms of care that can be extended, coordinated and monitored across a wider network of providers.

- ✔ **STRENGTHEN THE FDA'S ROLE IN DRUG APPROVAL AND MONITORING FOR SAFETY AND EFFECTIVENESS.** This means more public funding, and less reliance on pharmaceutical fees. We would even go so far as to suggest that direct-to-consumer advertising by pharmaceutical companies be banned, or at least revisited. In any event, policy makers cannot very well expect the FDA to be fast, thorough and effective without providing adequate financial resources.

- ✔ **STEP UP THE RESEARCH AGENDA.** Experts agree that we cannot safely extrapolate results from clinical trials of psychotropic agents with adults to children. It's very hard to recruit children for clinical trials, and harder still to find financial support for the long-term studies that are necessary to establish acceptable levels of efficacy and safety. We understand the rationale behind recent moves by the FDA to encourage pharmaceutical companies to conduct clinical trials with children, but this is a double-edged sword, given the perception of bias. We need more public funding, as well as greater sensitivity to the ethical issues.

- ✔ **EDUCATE, EDUCATE, EDUCATE.** There is no substitute for informed parents, teachers, school officials, health providers, policy leaders and other groups who are up to speed on the facts, fallacies and ambiguities concerning the use of psychotropic medications among children and adolescents. Professional advocacy and professional associations need to lead the way in a highly visible and carefully orchestrated campaign that is built on an open dialogue between contesting parties and views, and not on the "us versus them" framework that dominates the debate today. Other things that might be pursued: educating new teachers about these issues *before* they enter the classroom, introducing more medical students to behavioral health issues in practice rotations, and providing accessible, understandable information for parents and other caregivers to counter what may be perceived as biased information from drug companies and/or other special interest groups.

- ✔ **MORE CAUTION.** First, "do no harm." With many unanswered questions remaining about the efficacy, safety and long-term effects of the prolonged use of psychotropic medications among children, all of the institutional actors must put the "whole child" first. We should consider pharmacotherapy with caution, while acknowledging that medication is hardly ever a panacea or complete solution to the web of complex biochemical, social, physical and environmental factors that affect a child's development.

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To improve the health of people and their communities in Arizona, with an emphasis on helping people in need and building the capacity of communities to help themselves.

The purpose of *Arizona Health Futures* is to unravel an important health policy topic of relevance to Arizonans, provide a general summary of the critical issues, background information and different perspectives on approaches to the topic, tap into the expertise of informed citizens, and suggest strategies for action.

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