Prescription Psychotropic Drug Use Among Children in Foster Care

Testimony of Julie Magno Zito before the U.S. House of Representative, Committee on Ways and Means, Subcommittee on Human Resources, *Prescription Psychotropic Drug Use Among Children in Foster Care.* Washington, DC, May 8, 2008.

My name is Julie Magno Zito. Thank you for the invitation to testify today. I am a Professor of Pharmacy and Psychiatry at the University of Maryland, Baltimore. I have received more than 4 million dollars in NIH and foundation support. This support has allowed me to pursue pharmacoepidemiologic research as a specialty in the area of psychiatry, with a focus in the area of child mental health. Our team of specialists includes child psychiatrist and pediatrician researchers, pharmaceutical computing experts and epidemiologists and together we have published nearly 100 research papers on population-based medication use for the treatment of emotional and behavioral conditions. Prior to this position, I was a research scientist at the Nathan Kline Institute in New York where I developed guidelines for physician prescribing of psychotropic drugs for severe mental disorders (Zito, 1994). In 2006, Carole K. Strayhorn, Comptroller of the state of Texas requested an independent analysis of psychotropic medication patterns for foster care children in Texas which we agreed to conduct with data supplied by the Texas Department of Health and Human Services and analyzed at the University of Maryland. The results of that analysis are the focus of my report today.

OBJECTIVES FOR THE PREPARED TESTIMONY

My objective for the prepared testimony is to present and support four major points.

- ***Need for Community-based Studies on Outcomes of Psychotropic Treatment.*** Since 1990, the **expanded use of psychotropic medication** to treat emotional and behavioral problems in U.S. youth has caught the attention of the media without adequately informing the public of evidence of beneficial and appropriate use. To address this important gap in our knowledge base on the benefits and risks of such treatments requires sustained study in community-based youth populations—not just in clinical trial volunteers. Post-marketing studies are particularly important to identify and describe patient outcome in terms of academic performance, social development and avoidance of negative outcomes, e.g. crime, substance abuse and school failure—in other words, beyond symptom control. In the current U.S. research environment, most medication research focuses on symptom improvement in short-term clinical trials which is necessary but not sufficient information to establish the role of medication in community-based pediatric populations. Therefore, **we recommend outcome studies of community-treated youth**—for all youth, but particularly in foster care and disabled youth because they have the greatest likelihood of receiving complex, poorly evidenced, high cost medication regimens. Cooperation between the state agency responsible for oversight of child welfare and the Medicaid administration would permit databases to be linked so that the continuity of care and outcome in foster care can be assessed according to the type of placement setting.

- ***High Foster Care-specific Prevalence of Psychotropic Medication Use.*** Among community-based populations, **foster care youth** tend to receive psychotropic medication as much as or more than disabled youth and 3-4 times the rate among children with Medicaid

coverage based on family income [temporary assistance for needy families (TANF) or state-Children's Health Insurance Program, (s-CHIP)]. For example, in 2004, 38% of the 32,000+ Texas foster care youth less than 19 years of age received a psychotropic prescription (Zito et al., 2008). When 2005 data were disaggregated by age group the 2005 annual prevalence of psychotropic medication was: 12.4% in 0-5 year olds; 55% in 6-12 year olds; and 66.5% in 13-17 year olds. When two-thirds of foster care adolescents receive treatment for emotional and behavioral problems, far in excess of the proportion in non-foster care population, we should have assurances that the youth are benefiting from such treatment. Relatively high annual prevalence of psychotropic medications also has been reported for foster care youth in Minnesota (Hagen & Orbeck, 2006), Maryland (dosReis, Zito, Safer, & Soeken, 2001; Zito, Safer, Zuckerman, Gardner, & Soeken, 2005), Delaware (dosReis et al., 2005), California (Zima, Bussing, Crecelius, Kaufman, & Belin, 1999), and Pennsylvania (Harman, Childs, & Kelleher, 2000). Collectively, these patterns raise questions but do not address appropriateness and the role of medication in this vulnerable and needy population. Whether medication addresses the social, environmental and developmental needs of youth where unstable family structures are the norm is unknown.

Data for descriptive utilization studies are readily available through the Center for Medicaid and Medicare (CMS), and are relatively inexpensive to organize and analyze but as yet there is no **national reporting of foster care treatment.** Questions about why, typically foster care youth exceed the use of psychopharmacologic drugs observed in disabled youth deserve to be explored from a broader, societal perspective as well as from a clinical perspective. Poverty, social deprivation, and unsafe living environments do not necessarily justify complex, poorly evidenced psychopharmacologic drug regimens.

- ***Concomitant Psychotropic Medication Patterns in Foster Care with Little Evidence of Effectiveness or Safety.*** Combinations of medication are prescribed in order to address multiple symptoms. The sparse data on such practice patterns suggest that it is increasing (Safer, Zito, & dosReis, 2003). To assess concomitant psychotropic classes in the Texas foster care data, we selected a one month cohort of youth in July 2004 and found 29% (n=429) received one or more classes of these medications. Of these psychotropic-medicated youth, 72.5% received two or more psychotropic medication classes and 41.3% received 3 or more such classes. In such combinations, more than half the medicated youth had an antidepressant (56.8%); a similar proportion (55.6%) had an ADHD medication (a stimulant or atomoxetine) dispensed, and 53.2% had an antipsychotic dispensed. Most psychotropic combinations lack adequate evidence of effectiveness or safety in youth. Typically, they are adopted based on knowledge generalized from adult studies or assume that the combination is as safe and effective as each component of the regimen. Such assumptions, however, are not warranted because data reveal that children and adolescents differ from adults in adverse drug reactions to psychotropic medications (Safer, 2004; Safer & Zito, 2006). In addition, pediatric research shows that increasing the number of concomitant medications increases the likelihood of adverse drug reactions (Turner, Nunn, Fielding, & Choonara, 1999; Martinez-Mir et al., 1999). Long-term safety and drug-drug interactions are also more problematic. Data show that poorly evidenced regimens tend to increase in complexity over the age span suggesting that polypharmacy is not effective in managing the multiplicity of problems of foster care youth and others with serious social, behavioral and mental health problems who are often referred to as treatment-resistant or

difficult to treat (Lader & Naber, 1999). This is particularly true when observing youth with repeated hospitalizations. In the Texas cohort, 13% had a psychiatric hospitalization in the study year and 42% of these had a psychiatric hospital diagnosis of bipolar disorder. As younger age youth receive psychotropic medications, the early introduction of medications to the developing youth (12% of preschoolers in these data from Texas), suggests the need for drug safety studies. Drug safety studies require access to large community-based data sets, formation of cohorts for longitudinal assessment over successive years and epidemiologic methods for conducting observational safety studies. Yet, funding and training of clinical scientists for this type of research is quite modest (Klein, 1993; Klein, 2006) while the FDA is largely focused on the pre-marketing assessment of new drugs (APHA Joint Policy Committee, 2006).

Concomitant medication with antipsychotics and anticonvulsant-mood stabilizers is referred to as **"off-label' usage**, i.e., lacking FDA approved labeling for either the age group or the indication for treatment, e.g. an antipsychotic for ADHD or disruptive disorders. In the Texas foster care data, most antidepressant use was also off-label. Moreover, when the drug class use was compared among the leading diagnostic groups, there was little evidence of specificity. In youth with 3 or more medication classes, antipsychotic medications were used in 76.1% of those with an ADHD diagnosis; 75.8% of those with adjustment or anxiety diagnoses; and 84.1% of those with a depression diagnosis. If medication regimens increase the risk of adverse events without robust evidence of benefits (outcomes), prudence suggests that oversight programs monitor and review therapeutic interventions in professionally competent, individualized, and caring assessments.

- ***Foster Care Oversight, Quality Assessment and Public Health-oriented Prescriber Education.*** Quality assurance programs for psychopharmacologic treatments aim to review and assess the appropriateness of therapy. Such programs are understandably weak because: 1) record reviews are not always accurate; 2) multiple prescribing physicians may account for prescriptions that are not actually in use; 3) computerized systems that trigger automatic warning letters frequently have no impact (Soumerai, McLaughlin, & Avorn, 1990) in part because there are no consequences for prescribing outside the guidelines. In the Texas Medicaid system, the Texas Department of State Health Services panel produced practice guidelines for youth in Medicaid in 2005 (Texas Dept of State Health Services, 2005). They concluded that a department review should be required if antipsychotic agents and antidepressants were prescribed for youth under 4 years of age, stimulants under 3 years of age, if 2 or more drugs from the same class were prescribed concomitantly, and if ***5 or more different classes*** of psychotropic medication were prescribed concomitantly. Five months after promulgating these criteria, there was a 31% drop in use of 5 or more psychotropic classes among foster care youth (Texas Health and Human Services Commission, 2006). Illinois and Tennessee foster care programs have implemented oversight based on a central or regional academic reviewing process that is intended to keep prescribing physicians up to date on current practice and to discourage unnecessary or potentially unsafe regimens. This is a laudable step in the direction of more nuanced, comprehensive reviews and allows for a patient-specific, individualized review. If such programs are evaluated formally, they can provide valuable information on the feasibility and success of this approach to improve the quality of psychotropic medications for foster care.

We recommend that **the criterion for triggering an individualized patient record review is the dispensing of 3 or more concomitant psychotropic medication classes** in youth given that such drug use lacks supportive evidence and systematic safety studies, and is off-label in almost all instances. Essentially, 3-drug class regimens have inadequate evidence for a therapeutic benefit and safety in youth. Additional appropriate triggers include young age (antipsychotic or antidepressant in <4 year olds) and 2 or more drugs used concomitantly within the same class.

BACKGROUND

Increased Psychotropic Medications for Youth: Good News or Bad News?

Medicaid insurance covers vulnerable pediatric populations including youth with disabilities and those in foster care, as well as youth qualifying by low family income [temporary assistance to needy families (TANF) and state-Children's Health Insurance Program (s-CHIP)]. The treatment experience of Medicaid youth is accessible for population-based research because the Center for Medicaid and Medicare Services (CMS) is a repository of detailed administrative data on outpatient visits and medication dispensings along with demographic data including race/ethnicity and enrollment characteristics. These data enable researchers to create yearly trends in health service use including psychotropic drugs across states.

Since 1990, psychotropic medication use in children and adolescents has increased dramatically across all insured youth (Zito et al., 2003). Among more than 900,000 youth with either Medicaid or HMO insurance coverage, administrative claims data from the community showed the use of a psychotropic medication was 2-3 times greater in 1996 than 10 years earlier. In general, Medicaid youth receive more mental health services including psychotropic medications than commercially-insured youth because they have more impairments (Shatin, Levin, Ireys, & Haller, 1998). Data on Medicaid-insured youth in a northeastern state showed 8.9% of youth less than 19 years old received a psychotropic medication in 2007 (Pandiani & Carroll, 2008). Remarkably, antipsychotic use increased approximately 6-fold between 1997 and 2007. While the rising use affects all age groups, the rise is particularly notable in preschoolers. Medicaid-insured preschoolers from 7 states were 5-times more likely to received an antipsychotic and twice as likely to receive an antidepressant in 2001 compared with 1995 data from 2 other states (Zito et al., 2007). The trend toward increased prevalence of psychotropic medication is similar in commercially-insured youth although the annual rate is lower. This trend is illustrated by national parent survey data [Medical Expenditure Panel Survey, MEPS] for the 1987-1996 decade and showed similar growth (Olfson, Marcus, Weissman, & Jensen, 2002). In summary, population-based analyses of psychotropic usage patterns for youth show variations in use according to region, race/ethnicity, type of insurance, as well as clinically relevant differences in age group, gender and type of condition (Zito, Safer, & Craig, 2008). When the 30% of U.S. youth with Medicaid insurance are analyzed according to eligibility, foster care is likely to be the group receiving the highest rates of psychotropic medication relative to the disabled (eligible by Supplemental Security Income) and those with income eligibility.

Foster Care Psychotropic Medication Use

Demographic Profile of Foster Care Youth in the United States. In 2005, 514,000 youth were in publicly supported foster care—less than 1% (0.7%) of the 74 million youth less than 18 years of

age (Administration for Children Youth and Families, 2008). Data from 2000 showed gender is equally split. A majority is 6-15 years old: 11-15 year olds (29%); 6-10 year olds (25%); 1-5 (24%); 16-18 year olds (16%); and the remainder are less than 1 and over 18. In FY 2000, African-American youth represented the largest share of children in foster care (41%) followed by White (40%), Hispanic (15%) and Native American (2%). These race/ethnicity characteristics are disproportionately high relative to the U.S. population of African-Americans (15%) and Native Americans (1%). Length of stay data indicate that 55% of youth are in foster care for less than 2 years. As children age, their chances of reaching optimal residency (permanency goal) diminishes. A large majority of youth in foster care live in a non-relative foster home (47%) or in a relative foster home (25%). Most youth return to parental care (57%) while adoption or living with relatives occurs in 27% of cases. Against this statistical demographic profile, we will explore the medical treatments for behavioral and psychiatric conditions with a focus on psychotropic medications.

Psychotropic Prevalence in Foster Care. Among the 32,135 Texas foster care Medicaid enrollees less than 20 years old in the study year September 2003 to August 2004, 37.9% of youths had a psychotropic medication dispensing (Zito et al., 2008). This figure contrasts with 25.8% (CI 25.0-26.6) annual prevalence from a Mid-Atlantic foster care population in 2000 (Zito et al., 2005). In 1998, 34% of youth ages 3-16 in St. Louis County, Minnesota Family Foster Care had at least 1 psychotropic medication dispensing. This compared with 15% of youth receiving a psychotropic medication in the general population (Hagen et al., 2006).

Among Medicaid enrollees less than 20 years old in a populous suburban county of a mid-Atlantic state in 1996, psychotropic treatment prevalence rates for foster care youths were 1.7 (95% CI=1.4,2.2) times higher than those for SSI youths and 18 (95% CI=14.9,22.7) times higher than those for youths in the other aid group (dosReis et al., 2001). Other aid refers primarily to eligibility based on income or medical need.

In FY 1995, Medicaid claims from foster care youth 5-17 continuously enrolled youth in Southwestern Pennsylvania showed these children were 3 to 10 times more likely to receive a mental health diagnosis. They were 7.5 times more likely to be hospitalized for a mental health condition than children covered by AFDC. Prevalence of psychiatric conditions was comparable between foster care and disabled youth (Harman et al., 2000).

Foster care youth with a diagnosis of autism spectrum disorder (ASD) were twice as likely to receive concomitant drug therapy (defined as 3 or more medication classes overlapping for more than 30 days in the year 2001) compared with their counterparts eligible by low family income. Findings from this large national sample suggest that factors unrelated to clinical presentation may account for these prescribing practices and warrant further research ((Mandell et al., 2008).

Concomitant Psychotropic Medications: more than one in the same class or between classes
A recent review of the sparse literature on concomitant psychotropic medication use in youth revealed that this treatment regimen was rarely used in children in the late 1980s (Safer et al., 2003). Bhatara et al. showed concomitant use for the treatment of attention deficit hyperactivity disorder (ADHD) based on national ambulatory medical care survey (NAMCS) data increased 5-

fold from 1993 through 1998 (Bhatara, Feil, Hoagwood, Vitiello, & Zima, 2002). Across all conditions, there was an increase of 2.5-fold from 4.7% to 11.6% using MEPS data that was observed by Olfson et al. for the period from 1987 through 1996 (Olfson et al., 2002). In general, this review suggests that concomitant use of psychotropic medications in youth is a recent phenomenon. Common combinations include stimulants and clonidine (Zarin, Tanielian, Suarez, & Marcus, 1998) and stimulants and antidepressants (Zito et al., 2002).

Concomitant use is likely to be greater in populations treated by psychiatrists than those treated by pediatricians. (Bussing, Zima, & Belin, 1998) showed that in a Florida school district-wide sample of elementary school age special education youth, concomitant psychotropic use occurred in 48% of psychiatrist-treated youth compared with 6% of pediatrician-treated youth.

In the Texas study, in a one month cohort (July 2004), 72.5% of the *medicated* youth received concomitant medications (Zito et al., 2008). Among the medicated youth, 41.3% received ≥3 psychotropic medication classes concomitantly, 15.9% received ≥4, and 2.1% received ≥5 classes. The rank order of the most common concomitant psychotropic class combinations was as follows: antipsychotics with ADHD medications, antipsychotics with antidepressants, antidepressants with ADHD medications, and anticonvulsant-mood stabilizers with antidepressants (Zito et al., 2008). Generally, psychotropic treatment by medication class was not specific relative to the leading diagnostic groups (Depression; ADHD; Adjustment/Anxiety). To illustrate, 76 to 84% of youth with 3 or more concomitant classes had antipsychotic dispensings *regardless* of the diagnostic group and the vast majority reflected behavioral and emotional symptoms, i.e. non-psychotic use. At the time of the study, all antipsychotic and anticonvulsant-mood stabilizer use was off-label use, i.e. without FDA-approved labeling for an indication, dose or age group (Roberts, Rodriguez, Murphy, & Crescenzi, 2003).

Foster Care Oversight for Medication Quality of Care

Clinical guidelines on foster care services have been produced by professional organizations, e.g. The American Academy of Child and Adolescent Psychiatry (American Academy of Child and Adolescent Psychiatry, 2008). Their standards focus on minimal and ideal recommendations. The recommendation on requests by the prescribing physician for consultation with child and adolescent psychiatry experts is only initiated by the requesting physician. The American Academy of Pediatrics statement on health care of young children in foster care recommends more frequent monitoring of the health status of children in placement than for children living in stable homes with competent parents (American Academy of Pediatrics, 2002).

Clinical education teams working the public sector are known as academic detailers and have been shown to be effective (Soumerai & Avorn, 1990). Ideally, a team of clinical pharmacists led by a psychopharmacologist in child psychiatric drug therapy could work to balance drug information originating from proprietary-funded thought leaders. Such an approach could lead to a balance between a marketing perspective and a long-term public mental health perspective.

Another concern of Medicaid treatment is cost. In the Texas data we analyzed, very expensive psychotropic medications were prescribed, including antipsychotic agents (averaging

$22/month) and anticonvulsant-mood stabilizers (averaging $110/month). In fact, over 50% of the Medicaid expenditures for the foster care youth in FY 2004 were for antipsychotic medications (Strayhorn, 2006). In light of the vast public expenditures and services related to medication use, public-interest academic detailing should be encouraged.

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