



**UNIVERSITY OF MARYLAND**  
**SCHOOL OF PHARMACY**

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Representative Jim McDermott, Chairman  
Subcommittee on Income Security and Family Support  
Committee on Ways and Means  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative McDermott:

Thank you for the opportunity to participate in the Ways and Means hearings on foster care. The following discussion responds to your May 23, 2008 questions concerning foster care children and psychotropic medication.

**Question #1. *What are the reasons for the increase in psychotropic medication in youth?***

Some of the factors that may account for the increased utilization are: 1) more social acceptance of medication treatment of children by their parents; 2) an end to the moratorium on direct-to-consumer prescription drug advertising in 1997; 3) the shift, since the 1980s in psychiatric theory from a biopsychosocial treatment model to biological psychiatry which seems to have produced a greater emphasis on somatic (drug) therapy; 4) the evolution of the Diagnostic and Statistical Manual (DSM) categorization of mental disorders. This is reflected in the widening of diagnostic categories into spectrum disorders, e.g., autism; 5) the profound involvement of academic psychiatrists (thought leaders) in drug company-sponsored clinical trials and company consultation endeavors producing potential conflicts of interests. Ironically, the New York Times today provided us with yet another example (see Harris and Carey, 06/08/08, front page, Researchers Fail to Reveal Full Drug Pay). 6) fewer uninsured children permit more health services to be accessed.

**Question #2. *How has this affected the methods that are used to treat children in foster care?*** Foster care youth have more developmental, social and behavior problems which increases their likelihood of being candidates for behavioral and psychiatric interventions including psychotropic medication treatment. Virtually all such youth are Medicaid-insured and they generally receive more medication than commercially insured youth. In addition, Medicaid prescriptions have fewer co-payment restrictions.

**Question #3. *Why are foster children more likely to be prescribed these medications?***

Foster care children have significantly more emotional and behavioral problems as their Medicaid-insured non-foster care counterparts and they receive psychotropic medication at a rate 3-4 times that of youth enrolled in TANF or SCHIP. In addition, oversight of Medicaid "appropriateness" of use is woefully inadequate so that as many as 5 concomitant

psychotropic drugs do not trigger an exception report. And, exception reports generally have little or no impact on changing physician prescribing behavior.

**Question #4. *Why are they more likely to be treated with 2 or more classifications of medications, many of which are “off-label” drugs?***

Concomitant medication use has contributed to the increased prevalence of psychotropic medication. Physicians tend to add medications when the response to treatment is inadequate, although discontinuation or switching may be more useful. Another factor responsible for multiple classes of medication use in psychiatry is the tendency of the DSM system to emphasize the co-occurrence of several diagnoses which then justifies several medications. The off-label status of such combinations creates serious uncertainty of either effectiveness or safety. Managing complex pharmacologic therapy is particularly challenging where continuity of care is not possible. Off-label use is common in children because the pharmaceutical industry has had (until recent Best Pharmaceuticals for Children Act (BPCA) legislation and exclusivity incentives) little interest in financing clinical trials to assess efficacy in children. Consequently, physicians tend to generalize from adult experience which unfortunately has been shown to be inadequate for major psychotropic classes. Examples include atypical antipsychotics, selective serotonin reuptake inhibitor (SSRI) antidepressants and anticonvulsants used as mood stabilizers.

**Question #5. *Do you believe that states are conducting the appropriate level of oversight and evaluation of the use of these drugs for children in foster care?***

The level of oversight by state officials appears to be severely limited for child psychotropic drug use since the criteria adopted by many states were created by a group of experts having little or no empirical basis for their review criteria. There are few/unknown consequences to practitioners with exceptions to the criteria. Also, many association-based clinical guidelines tend to be consensus recommendations among leading practitioners and, thus far, lack attempts to relate revised criteria to either physician behavior or patient outcome. Recently, there are several efforts to improve the oversight for foster care, in particular, in Illinois, Tennessee, Texas, and Massachusetts. Illinois stands out because the model they have adopted uses a single academic-based expert as the clinical reviewer for all psychotropic drug prescriptions for youth in state custody. This arrangement heightens accountability and also permits exchange of information between medical peers. This is a model I favor based on my 9-year experience within the New York State Office of Mental Health system. There, I worked with the automated exception reporting system of oversight of psychotropic medications for severely mental ill individuals hospitalized in state psychiatric centers.

**Question #6. *What is the general consensus within the medical community on the use of anti-psychotic drugs to treat children with behavioral and emotional problems?***

The leaders in academic child psychiatry and at the NIMH and FDA tend to support the existing evidence that antipsychotic medications are useful for seriously disruptive youth. The potential adverse effects from these drugs can be serious. For example, the atypical antipsychotics carry risks of drug-induced diabetes and lipid abnormalities but the

community standard implies that the benefits outweigh the potential risks. Additional study of the risks and benefits in community-treated populations is warranted.

Please contact me if you have additional questions. On a personal note, I congratulate you on bringing your professional training well beyond the individual child to the most vulnerable population among U.S. children today.

Sincerely,

A handwritten signature in cursive script that reads "Julie M. Zito". The signature is written in black ink and is positioned above the typed name.

Julie M. Zito, PhD  
Professor of Pharmacy and Psychiatry