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March 14, 2013

Margaret Hamburg, MD
Commissioner
United States Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

Re: Public Comments for the Food and Drug Administration Drug Shortages Task Force and Strategic Plan. Docket Number: FDA-2013-N-0124

Dear Commissioner Hamburg:

The American Academy of Child and Adolescent Psychiatry (AACAP) appreciates the opportunity to provide comments to the Food and Drug Administration Drug Shortage Task Force.

AACAP is a medical membership association established by child and adolescent psychiatrists in 1953. Now over 8,500 members strong, AACAP is the leading national medical association dedicated to treating and improving the quality of life for the estimated 7-15 million American youth under 18 years of age who are affected by emotional, behavioral, developmental and mental disorders. AACAP's members actively research, evaluate, diagnose, and treat psychiatric disorders, and pride themselves on giving direction to and responding quickly to new developments in addressing the health care needs of children and their families.

The issue of medication shortages, especially stimulant shortages, is one that has greatly affected members of AACAP and the patients that they serve. AACAP applauds the passage of the Food and Drug Administration Safety and Innovation Act and submits the following comments regarding its implementation.

Section II. 3 Are there other actions that FDA can take under its existing authority to address impending drug shortages?

Once notified of a potential or actual drug shortage, the FDA should allow the importation of drugs from Canada and Mexico. While the FDA has allowed this for some drug shortages, specifically the importation of methotrexate, it has not allowed it as a remedy for the shortage of stimulant medications.

In regard to the shortage of schedule II drugs the FDA and the Drug Enforcement Agency (DEA) should develop an interagency agreement that is triggered whenever a schedule II

drug is identified as being in short supply. This agreement would require the two agencies to develop a plan and take action to address the shortage within 30 days.

Elements of this plan may include the following:

- A request for information to the manufacturers of a drug in shortage to assess available inventory, manufacturing problems, supply disruption, or any other factor thought to be contributing to the shortage;
- A streamlined, 30 day review process for supplemental request for an active pharmaceutical ingredient (API);
- A waiver of some regulatory requirements during a drug shortage such as the need for multiple prescriptions when a 30 day supply of a schedule II drug is not available. Currently, when a pharmacy has insufficient medication to fill a prescription for a controlled drug and gives a patient only a partial amount they are prohibited from filling the remainder of the prescription without a second prescription.

Section II 4. Are there other communication tools that FDA should use or additional information the Agency should share to help health care professionals, and others manage shortages more effectively?

In addition to posting information regarding potential or actual drug shortages to the FDA web site, the FDA should contact as well as forward drug shortage bulletins directly to national, state, and local medical societies, and pharmacies. These bulletins should include any known geographical areas that may have a surplus of a drug in shortage, along with a list of alternative pharmacological therapies that may be substituted for a drug in shortage.

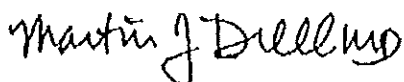
Section II 5. What impact do drug and biological product shortages have on research and clinical trials?

Drug shortages have had a significant impact on research and clinical trials. Drug shortages have led to the temporary suspension of clinical trials underway. The suspension of these trials has increased the difficulty in finding subjects to participate in the trial and has caused unnecessary hardships for those already participating.

Section II 5. What action can FDA take to mitigate any negative impact of shortages on research and clinical trials?

FDA can take the proactive step of ensuring that drugs have been pre-allocated ahead of time to research and clinical trials. The FDA should also engage in ongoing dialog with companies during a trial, part of this dialog should include ensuring that companies have the needed supply of drugs to complete their trials. In addition to this, if a research or clinical trial is negatively affected by a drug shortage then the expiration date of the trial should be extended to reflect the time lost due to drug shortages.

Sincerely,



Martin J. Drell, M.D.
President