March 16, 2012

The Honorable Tom Harkin
731 Hart Senate Office Building
Washington, DC 20510

Dear Senator Harkin:

The organizations listed below represent clinicians, health care facilities, drug manufacturers and patient advocacy groups that are united on an issue that has quickly become a national health crisis – drug shortages. We are writing to urge you to address drug shortages now, before delays and disruptions in patient care become even more widespread. Look no further than the recent methotrexate shortage as evidence that this issue can no longer be ignored, as children with otherwise treatable cancer face being without treatment options. Activities by the Food and Drug Administration (FDA) and manufacturers may have addressed the methotrexate issue, but if Congress acts now, it would allow the FDA and manufacturers to respond more quickly in the future, before another case like this occurs.

We realize the entire drug-shortages crisis cannot be solved through Congressional action, but there are things Congress can do now, while longer term solutions continue to be examined. For example, Congress can authorize the FDA to develop an early warning system that requires manufacturers to notify the agency when they experience a production disruption or discontinue a product. Using a voluntary and confidential reporting system, FDA has established a track record of success avoiding 195 shortages in 2011 by working behind the scenes with other manufacturers to ramp up production. While this represents a major success, required reporting would assist in addressing the 267 other drug shortages that have occurred in 2011. In addition, Congress can require manufacturers to develop contingency plans to line up alternate suppliers of raw materials, or encourage redundancies in manufacturing. In order to streamline this process, FDA could establish criteria to determine whether a drug is vulnerable to a shortage, and work with manufacturers to develop contingency plans or promote redundancies.

Further, we urge Congress to require FDA and the Drug Enforcement Administration (DEA) to work collaboratively to provide flexibility in the development of production and raw material quotas to ensure that manufacturing capacity is not compromised due to limits that prevent additional manufacturing of a controlled substance drug. This would help manufacturers of controlled substance drugs ramp up production when another company's production line goes down.

Finally, we urge Congress to consider the establishment of appropriate incentives for manufacturers. Among other options, Congress could consider a generic user fee program in the upcoming Prescription Drug User Fee Act (PDUFA) reauthorization to allow FDA to leverage fees as economic incentives for manufacturers, and to speed the application process for these products. For example, the agency could offer reduced application fees for products in short supply, or discounted fees if a company demonstrates that its contingency plans are sufficient to reduce the risk of a shortage if production is halted. While this policy option does rest within the PDUFA reauthorization process, we believe

appropriate mechanisms such as a generic user fee program could provide a crucial economic tool for FDA to provide incentives to manufacturers, and should be enacted as quickly as possible.

We appreciate your attention to this critical issue and are pleased that public hearings have been held in both houses of Congress. However, the time to take action is now as our patients simply cannot wait any longer.

Sincerely,

ADVOCACY ALLIANCE

Susan G. Komen for the Cure

ASCA Ambulatory Surgery Center Association

FAAEM always means board certified

American Academy of Emergency Medicine Resident and Students Association

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

accp American College of Clinical Pharmacy

American College of Surgeons

Inspiring Quality: Highest Standards, Better Outcomes

American Hospital Association

AMA American Medical Association

American Pharmacists Association®

Improving medication use. Advancing patient care.

APhA


AMERICAN PSYCHIATRIC ASSOCIATION
1844


aspen
LEADING THE SCIENCE AND PRACTICE OF CLINICAL NUTRITION
American Society for Parenteral and Enteral Nutrition


American Society of
Anesthesiologists


ASCO
American Society of Clinical Oncology


ASHP
American Society of
Health-System Pharmacists


ACCC
Association of Community Cancer Centers


Children's
Healthcare of Atlanta


CHILDREN'S
HOSPITAL
ASSOCIATION


Cleveland Clinic


HOPA
Hematology/Oncology
Pharmacy Association


Hospira
World's leading provider
of injectable drugs
and infusion technologies


ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES


JOHNS HOPKINS
MEDICINE


Lancaster General Health

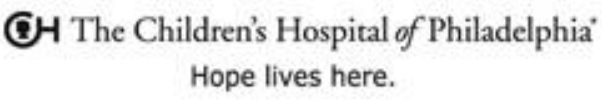

LIVESTRONG


MUSC
Children's Hospital


NCPA
NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION


NYU Langone
MEDICAL CENTER


Society of
Critical Care Medicine
The Intensive Care Professionals


The Children's Hospital of Philadelphia
Hope lives here.


University of Michigan
Hospitals and
Health Centers


UNIVERSITY OF UTAH
HEALTH CARE