



Regulatory Education and Action for Patients

● *Seeking Common Ground*

November 8, 2011

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Patient Principles on Drug Shortages

Dear Dr. Hamburg:

On behalf of Regulatory Education and Action for Patients (REAP), we thank you for your commitment to addressing the drug shortage crisis that is impacting the patients whom we represent. REAP is an umbrella coalition comprised of 45 patient advocacy groups whose mission is to communicate the challenges patients face in accessing care to Federal and State policymakers. REAP's collective voice assures a wide range of patient concerns are considered in policy development to maximize care access and improved outcomes as well as minimize unintended consequences upon implementation. REAP, through its member entities, contributes information and perspectives regarding important health care decisions to a degree that has not been possible heretofore by health care advocacy groups in the regulatory arena.

In light of President Obama's Executive Order on Drug Shortages, as well as the recently released corresponding FDA and HHS reports, REAP is pleased to submit the attached document which conveys the patient perspective on the drug shortage crisis. The document highlights three principles essential to patients that merit consideration when examining potential resolutions to the issue: adequate communication, the necessity of creative short and long term solutions, and active enforcement against abusive practices. Each principle is accompanied by a list of relevant specific actions that may be taken by the Federal government.

We again thank you for your continued efforts to ensure patient access to necessary therapies. REAP members stand ready to answer questions and provide any additional information about the patient groups for whom we advocate and we hope you will call on us to be involved in future drug shortage deliberations.

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www.reapforum.org

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NPAF Founding Organization

Sincerely,

Alpha-1 Association
Alpha-1 Foundation
American Brain Tumor Association
C-Change
Colon Cancer Alliance
COPD Foundation
Fight Colorectal Cancer
Friends of Cancer Research
Hypertrophic Cardiomyopathy Association
Kidney Cancer Association
Leukemia Lymphoma Society
LIVESTRONG
Lymphoma Research Foundation
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure
Susan G. Komen for the Cure Advocacy Alliance
Us TOO International Prostate Cancer Education and Support Network
Y-ME National Breast Cancer Organization
ZERO – The Project to End Prostate Cancer



PATIENT PRINCIPLES ON DRUG SHORTAGES **Potential Actions for Consideration**

- **ADEQUATE COMMUNICATION IS ESSENTIAL:** Patients, physicians and the general public are entitled to receive meaningful advance warning of potential drug shortages and to be told when an anticipated shortage has materialized, how long that shortage is expected to last and the treatment implications of the shortage.
 - Manufacturers should notify the FDA and their supply chain partners promptly when a shortage situation appears to be developing.
 - Manufacturers, their distributors, and/or the FDA should notify physicians of foreseeable and actual drug shortages using press releases, web postings and other generalized communications tools coupled with more targeted, personalized communications such as “Dear Doctor” letters, notices included with drug shipments and in medical journals and, if applicable, field sales or national account representative messaging.
 - Physicians and other providers should advise patients of anticipated and actual drug shortages and discuss the implications of the shortage with them in the context of their personal treatment options and risks.
 - No patient should be started on therapy with a drug that is or is expected to be in short supply without first being told about the situation and the potential consequences of possible treatment interruptions or delays.
 - If the treatment protocol of choice for a patient must be altered because of a drug shortage, the patient should be advised of the required change, told about any anticipated differences in outcome or side effects and given the opportunity to ask questions about other options.
 - In the case of clinical trials, investigators should be notified of any shortages and, in turn, communicate any changes in treatment protocols to patients.

- **CREATIVE MULTI-FACETED SHORT AND LONG-TERM INTERVENTIONS ARE NEEDED:** Because numerous factors contribute to the growing drug shortage problem, the Administration, Congress and industry should work together cooperatively to develop and expeditiously implement creative, multi-faceted, short and long-term solutions that will encourage enhanced production of shortage-prone products at reasonable prices. We are sure you will agree that patients have a right to expect rapid bipartisan support for a package of legislative initiatives addressing recognized key drivers of the critical

drug shortage issues that are putting lives at risk. A range of possible solutions to be considered include:

- Explore tax and/or other regulatory incentives to upgrade production lines and encourage the manufacturing of low cost, less profitable products subject to shortages, such as fast-tracking FDA approval for profitable drug products for those manufacturers who continue to produce less profitable products subject to shortages
 - Anticipate patent expirations as well as market demand and their impact on shortage creation potential
 - Enhance FDA resources to support inspections of Active Pharmaceutical Ingredient (API) producers and more rapid resolution of manufacturing issues
 - Revise drug reimbursement formulas that prevent manufacturers from raising prices sufficiently to support production of drugs prone to shortages
 - Explore mechanisms by which medically necessary drugs are identified and maintained in ready supply in event of an overall shortage
 - Utilize pharmacies that are created for the purpose of expediting drugs in need.
 - Streamline current Good Manufacturing Practices (cGMP) regulations to reduce regulatory burden without sacrificing drug quality
 - Review and assess additional recommendations as set forth by proposed bipartisan legislation and HHS recommendations
- **ACTIVE ENFORCEMENT AGAINST ABUSIVE PRACTICES IS REQUIRED:** Severe penalties should be established and consistently imposed to discourage the hoarding of drugs in short supply, to protect patients and their healthcare providers from price gouging, and eliminate the distribution of adulterated or counterfeit products in response to orders for drugs with limited availability.
 - If necessary, laws establishing severe penalties for individuals and companies that attempt to profit through price-gouging from drug shortages should be quickly enacted.
 - An accessible, well-publicized nationally available system that allows patients and providers to report suspected instances of hoarding, price gouging or counterfeit drugs should be established and adequately staffed so that law enforcement can quickly be apprised of situations requiring investigation.
 - Enforcement of laws designed to prevent abuses associated with drug shortages should be given top priority by authorities and the courts and convictions should be well publicized to deter others from engaging in abusive practices.