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United States Senate

WASHINGTON, DC 20510

April 18, 2012

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993

Dear Dr. Hamburg:

As you know, drug shortages pose a serious risk to the health of countless Americans. Drug shortages are a pervasive problem affecting all aspects of care – from enteral nutrition, to cancer treatments, to anesthetics. One solution is to provide health systems with the ability to extend the supply of certain medications.

Given the Food and Drug Administration's (FDA) role in regulating pharmaceuticals, it is imperative that your agency take every action necessary to alleviate the burden of these shortages on patients, providers, and health care systems. One such action that can help address this problem is to allow hospitals to repackage drugs – a process by which a pharmacist divides larger vials of medication into smaller containers – and send them to other hospitals within the same health care system.

Recent communications with your agency indicate that the FDA may be inclined to allow a hospital pharmacy to repackage drugs and deliver them to affiliated hospitals. However, these same communications also refer to the Compliance Policy Guide titled "Hospital Pharmacies – Status as Drug Manufacturer," which does not allow such actions. The Policy Guide states that a hospital may repackage drugs for use within that hospital, but is required to register as a drug manufacturer and meet FDA Good Manufacturing Practices (GMP) in order to distribute the repackaged drugs to affiliated hospitals within the same medical system. The GMP requirements are simply too burdensome for health systems. The result is that some hospitals lack access to much-needed medications even though other hospitals in the same system may have those medicines in supply.

It is my belief that the FDA has the authority to permit such repackaging. Accordingly, I urge the FDA to take immediate action to enable health systems to extend the supply of vital, life-saving pharmaceuticals by issuing guidance allowing hospital pharmacies to repackage drugs and distribute them to affiliated hospitals. If you believe the FDA is unable to accomplish this administratively and that a legislative solution is required, please let me know as soon as possible as I have drafted legislation to allow health system repackaging.

Sincerely,

Sherrod Brown

Sherrod Brown
United States Senator