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May 23, 2012

Secretary Kathleen Sebelius
United States Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

Regularly, I am hearing from physicians and health care providers requesting assistance in addressing current drug shortages. As you know, this issue is quickly becoming a national crisis, truly affecting doctors' ability to treat their patients.

Later this month, Congress is expected to consider the FDA Reform Act (H.R.5661), which will likely contain a provision encouraging the Food and Drug Administration (FDA) to apply accelerated approval and "fast-track" designations to facilitate the development and review of treatments for serious or life-threatening diseases.

It is my hope that Congress and the FDA will act to develop a long-term solution to alleviate drug shortages in this country; however, I remain concerned about the doctors and patients who require life-saving medications prior to legislation being signed into law and regulations being issued by the Administration.

Emergency providers, who staff the nation's roughly 4,500 Emergency Departments and care for over 120 million patients annually, must daily contend with critical drug shortages, many of which are potentially a matter of life or death for their patients. Specific Emergency Department drug shortages include, but are not limited to, the following:

- Diazepam injection
- Etomidate injection
- Ketorolac injection
- Lorazepam injection
- Metoclopramide injection
- Sodium Bicarbonate injection
- Phytonadione (Vitamin K) injectable
- Methotrexate injection

In the meantime, what temporary solutions are available to the Department, and ultimately the FDA, that can be undertaken in order to address this serious issue? From 2010-2011, the FDA utilized options such as requesting other companies to increase production and expedite review of other sources in addressing 127 drug shortages. More recently, to accommodate for a shortage of a drug to treat pediatric leukemia, methotrexate was successfully imported from Australia. Are additional drugs, currently listed on the FDA's shortage list, being imported from other countries as well? If so, which drugs are being imported and from which countries? If not, has this option been deemed unfeasible for other drugs currently in short supply?

Particularly for those drugs that are in shortage and there is no alternative, can the FDA utilize temporary importation of unapproved foreign drugs? To date, has the FDA evaluated any foreign-approved drugs for possible use in the U.S. market?

Finally, there have been reports of drugs being sold on the "gray market." It is extremely troubling to hear of third-parties purchasing these critical drugs, seeking to profit from doctors and hospitals desperate to have medication for their patients. Are there regulations and safeguards in place at the Department and the FDA to ensure that medication, and particularly those drugs in shortage, are sold directly from the manufacturer to the health care provider? The presence of a gray market is only exploiting the drug shortage crisis – selling drugs to the highest bidder – rather than ensuring that patients are afforded the medication needed to treat their disease or injury.

We must ensure that health care providers have access to critical medications needed to treat their patients. I look forward to hearing from you as to ways we can work to end these drug shortages in an expeditious manner.

Sincerely,



J. RANDY FORBES
Member of Congress