THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

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Sidney M. Wolfe, M.D., Director
Michael A. Carome, M.D., Deputy Director
Sarah Sorscher, J.D., M.P.H., Attorney
Public Citizen Health Research Group
1600 20th Street N.W.
Washington, DC 20009

Dear Drs. Wolfe and Carome, and Ms. Sorscher:

This letter is in response to your letter regarding the November 14-15 congressional testimony of Dr. Margaret Hamburg and the Food and Drug Administration's (FDA) proposal for a new framework of regulatory oversight over compounding pharmacies.

As Dr. Hamburg testified, current law tries to draw a line between traditional pharmacy compounding and typical manufacturing. In fact, pharmacy operations have evolved and now represent a continuum of activities, from traditional compounding based on a prescription from a licensed prescriber for an individual patient with a medical need for a compounded medication, to compounding larger volumes of drugs in advance of receiving a prescription for an individual patient, to pharmacies that operate outside the scope of traditional pharmacy compounding by producing drugs for health care entities without receiving any prescriptions. As Dr. Hamburg testified, some of these activities pose greater risks and require greater oversight than others to protect the public health. As well, FDA has learned from meetings with a wide variety of interested parties and with representatives of the 50 states at a meeting on December 19, 2012, that there continues to be a wide spectrum of views on where the compounding continuum ends and typical manufacturing begins.

This issue is quite complex, and simply drawing a line between compounding and typical manufacturing may not be the best solution to regulate an industry that has evolved over the past twenty years. Hospitals, other health care entities, and their patients have come to depend on certain facets of the industry to perform services that may be better carried out by appropriately regulated entities.

As Dr. Hamburg noted in her testimony, there are issues with FDA's current authority. Compounding pharmacies generally are not required to register with FDA. As well, when FDA conducts for-cause inspections, the agency's ability to inspect records has been challenged because of the exemption under section 704 of the Federal Food, Drug, and Cosmetic Act that exempts certain pharmacies from having to produce records – records that are often needed to determine whether the pharmacies' activities comply with federal law. Furthermore, unlike typical drug manufacturers, compounding pharmacies generally are not required to report to FDA adverse events related to their products of which they have knowledge.

Given the number of interested parties involved and the need to clarify federal and state roles over an activity that will almost certainly remain jointly regulated to some extent, we need legislation for the development of an oversight system to better regulate pharmacy compounding. In addition, we feel strongly that other changes are necessary to FDA's authority to strengthen its ability to appropriately regulate compounding, such as clarification of FDA's inspection authority so that FDA can consistently and efficiently gather the necessary information about the scope of a pharmacy's operations and determine how to regulate them under the new regulatory paradigm. Dr. Hamburg's testimony sought to explain why additional legislation is needed to provide appropriate and efficient oversight of this evolving industry, something she could not do without highlighting the shortcomings of existing law.

Notwithstanding our belief that legislation is necessary, FDA intends to use its existing authority to the extent possible under a risk-based approach to the oversight of pharmacy compounding in an effort to prevent future tragedies. In addition, FDA is evaluating what it knows about compounding pharmacies from historical data, such as warning letters and adverse event reports, to ensure that its inspection and enforcement resources focus on the compounding operations that pose the greatest risks.

We expect to continue to engage in a robust dialogue with you and other interested parties, including state governments and Congress, to determine what steps to take to reduce the risks of future tragedies such as the recent outbreak. In moving forward, we would like to enlist your support to put in place an effective federal regulatory scheme that operates in concert with state oversight of traditional pharmacy practice and protects the public health. I look forward to working together with you to address this important public health issue.

Sincerely,

Kathleen Sebelius

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