Public Citizen Calls for Independent Investigation of FDA' s Failure to Regulate Pharmacy Practice at Heart of Meningitis Outbreak

FDA Statements in Aftermath Appear Deliberately Misleading on Agency' s Authority to Regulate

WASHINGTON, D.C. – The U.S. Department of Health and Human Services (HHS) Office of Inspector General should open an independent investigation into how the Food and Drug Administration (FDA) failed to use its established regulatory authority to protect the public from the dangerous practice of large-scale drug compounding that led to the widening fungal meningitis outbreak caused by tainted steroid injections, Public Citizen said today in a letter addressed to HHS Secretary Kathleen Sebelius.

Citing statements made by an FDA official during a teleconference with journalists reported by The Washington Post, Public Citizen strongly condemned the FDA for making misleading statements to the public; in particular claiming to lack " clear authority to take action earlier against" the New England Compounding Center (NECC), the company that produced large quantities of the contaminated steroid drug linked to the ongoing meningitis outbreak. In addition to other unnamed officials, the article quoted Deputy FDA Commissioner for Global Regulatory Operations and Policy Deborah M. Autor as saying it was " really unfortunate that it sometimes takes a tragedy" to bring about change and calling for a " new regulatory scheme that appropriately controls the risk."

" This attempt by one of the most senior figures within the FDA to deflect criticism for FDA failures that contributed to the meningitis outbreak is deeply troubling," said Dr. Michael Carome, deputy director of Public Citizen' s Health Research Group. " The claims by agency officials that the FDA lacks authority to properly regulate compounding pharmacies is contradicted by a long history of remarkably consistent statements and enforcement actions asserting the agency' s legal authority over such pharmacies."

Prior warning letters from the FDA to several compounding pharmacies over the past decade, including one to the NECC in 2006, indicate that the agency considered these pharmacies to be engaged in drug manufacturing. The pharmacies were therefore

considered by the FDA to be subject to the safety and effectiveness standards required for approval of new drugs, as well as the rigorous manufacturing standards designed to ensure that drugs are sterile and uncontaminated with such germs as bacteria or fungi before being sold and distributed.

“ Given its attempts to dodge responsibility in this matter, the FDA is clearly incapable of conducting an objective evaluation of its own policy, oversight, and enforcement decisions, which no doubt contributed to this ongoing preventable tragedy,” Carome said. “ An independent investigation must be conducted and should identify all agency officials whose actions and decisions contributed to the FDA’ s failure to prevent this public health catastrophe.”

###