



November 8, 2019

Mr. Phillip L. Zweig, M.B.A.
Executive Director/Co-founder
Physicians Against Drug Shortages
plzweig@aol.com

Dear Mr. Zweig,

Thank you for your September 27, 2019 email to Dr. Norman Sharpless, Acting Commissioner of Food and Drugs. I am responding on behalf of Dr. Sharpless, myself, and my colleagues at the U.S. Food and Drug Administration who also received your inquiry.

One of the FDA's top priorities is to ensure that Americans have access to safe and effective medicines. As such, we are greatly concerned about drug shortages, which can harm patients and burden health care providers and the overall healthcare delivery system. In response to a request from Congress, in 2018, FDA convened an inter-agency Drug Shortages Task Force to study the problem, identify the root causes, and recommend enduring solutions. On October 29, 2019, FDA released the Task Force report, Drug Shortages: Root Causes and Potential Solutions. The report identifies economic factors, including three primary factors, as the root causes of drug shortages and provides three recommendations for enduring solutions. The report is available on the FDA website at <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>.

In your email and earlier comments for the Task Force, you raised the issue of the role of "safe harbor," in drug shortages. Specifically, safe harbor, created in section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, exempted group purchasing organizations, and later pharmacy benefit managers, from criminal prosecution for taking "kickbacks" from suppliers. The Drug Shortages Task Force did not find evidence that the safe harbor provision is contributing to drug shortages. FDA also heard from stakeholders that the contracting practices of group purchasing organizations are contributing to lower profits on generic drugs, thereby reducing the incentive for drug companies to invest in quality management systems or market these drugs. I encourage you to review our report, including our analysis of the problem and proposed solutions. Thank you for writing to express your concerns about drug shortages.

Sincerely,

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research