

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

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August 21, 2019

Dr. Norman Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Acting Commissioner Sharpless:

I am writing to express my concern regarding ongoing drug shortages throughout the United States and to request information about current and planned actions by the Food and Drug Administration (FDA) to address this serious public health concern. New and active drug shortages in the United States are at their highest levels in almost five years. The number of active shortages in the first half of 2019 alone, 282, already exceeds the number of active shortages at any point in 2018 according to the American Society of Health-System Pharmacists (ASHP).¹

Drug shortages are causing devastating health and economic consequences for patients, hospitals, and consumers.² For patients, the impact on care is significant, as shortages cause delays when receiving emergency medications, undergoing medical procedures, and obtaining needed prescription drugs.³ The worst case scenario is now a reality in some instances. For example, the recently reported shortage of intravenous immune globulin (IVIG), a critical drug used to treat a growing number of immune disorders, has resulted in rationing and cancelation of infusions for some patients, leaving them to cope with elevated risks of infection and increased severity of symptoms.⁴

¹ University of Utah Drug Information Service, Drug Shortages Statistics, National Drug Shortages: Active Shortages by Quarter (<https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>) (accessed August 12, 2019). The University of Utah Drug Information Service is generally recognized as the most comprehensive source of drug shortage information. See U.S. Government Accountability Office: *GAO's 2014 Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability* (GAO-14-194) (Feb. 2014).

² Drug shortages can include pill and intravenous based drugs, biologics, and biosimilars.

³ Vizient, *Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals* at 10, (June 2019), https://newsroom.vizientinc.com/sites/vha.newshq.businesswire.com/files/doc_library/file/Drug_Shortages_Labor_Cost_Report_Vizient.pdf.

⁴ Peter Loftus, *Drug shortage leaves patients without immune-disorder treatment*, The Wall Street Journal (August 9, 2019), <https://www.wsj.com/articles/drug-shortage-leaves-patients-without-immune-disorder-treatment-11565343023>.

Hospitals are also severely impacted by drug shortages. Eighty percent of the almost 4,000 community hospitals surveyed in a 2019 report by the National Opinion Research Center (NORC) at the University of Chicago said drug shortages contributed to a significant increase in spending.⁵ Nationally, hospitals spend over \$359 million annually on labor costs alone to manage the impacts of drug shortages.⁶ These and other costs can often result in added expenses and increased risks for patients, including more expensive hospital stays, greater risk of error, and delays in care.⁷ Critical infrastructure and national security concerns are also implicated by expansive and ongoing drug shortages in the United States.

As Ranking Member of the Homeland Security and Governmental Affairs Committee, I have directed my staff to examine the harm current drug shortages and drug pricing practices are causing to patients, hospitals, and consumers as well as efforts by the U.S. Department of Health and Human Services and the FDA to address and mitigate this harm. As part of this effort, my staff have met with numerous stakeholders impacted by this issue, all of whom have raised concerns over the growing risks created by drug shortages and drug pricing practices. These include reallocation of resources and therapeutic alternatives by hospitals and pharmacies forced to respond to drug shortages, nontransparent and predatory drug price increases by some pharmaceutical companies, and decisions by manufacturers to not produce certain inexpensive drugs with low profit margins.

Unfortunately, shortages are particularly prevalent for inexpensive drugs with low profit margins. These include generic medications, often in an injectable form, that have been in existence for many years and are critical to patient care in hospital settings. The top five drug classes currently experiencing active shortages are: central nervous system depressants and stimulants; antimicrobials; cardiovascular drugs; chemotherapy agents; and electrolytes, fluids, and nutrition products.⁸

As one example, sodium bicarbonate, an injectable drug regularly used in critical care, is currently in short supply. Commercial production of this injectable drug began over half a century ago and the raw materials to make this product are simple: it is essentially a sterilized version of the same baking soda that can be found on every supermarket shelf in America. Despite the simplicity of the product and its critical importance to patient care, there are now insufficient quantities of sodium bicarbonate for patients at hospitals across the country.⁹

⁵ NORC at the University of Chicago, *Recent Trends in Hospital Drug Spending and Manufacturer Shortages*, Presented to American Hospital Association, Federation of American Hospitals, and American Society of Health-System Pharmacists (January 15, 2019), <https://www.aha.org/system/files/2019-01/aha-drug-pricing-study-report-01152019.pdf>.

⁶ See *Supra* n.3 at 5.

⁷ American College of Emergency Physicians, Letter to Dr. Scott Gottlieb, Former Commissioner of the FDA at 3 (January 10, 2019), <https://www.acep.org/globalassets/new-pdfs/advocacy/acep-comments-on-fda-meeting-on-drug-shortages.pdf>.

⁸ University of Utah Drug Information Service, Drug Shortages Statistics, National Drug Shortages: Active Shortages Top 5 Drug Classes (as of June 30, 2019) (<https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>) (accessed August 12, 2019).

⁹ FDA, Drug Shortages List, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm> (accessed August 12, 2019) (noting the status of “Sodium Bicarbonate Injection, USP” as “currently in shortage”); See also Katie Thomas,

Pharmaceutical companies cite “increased demand,” “manufacturing delays,” and “run[ning] out of stock” as reasons for the shortage.¹⁰ As a result, the FDA recently resorted to allowing the temporary importation of certain sodium bicarbonate injections from a manufacturing facility in Australia until U.S. manufacturers are able to resume production.¹¹

In the wake of the drug shortage crisis in 2011, where the number of new annual shortages grew to 267, Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA), amending the Federal Food, Drug, and Cosmetic Act (FFDCA).¹² The FDASIA, in relevant part, expands the FDA’s regulatory authority to help prevent and mitigate drug shortages, and also requires that the FDA submit an annual report to Congress on drug shortages not later than March 31 of each calendar year.¹³ The FDA has said that it is in the final stages of issuing the current report, despite its March 31 deadline. Hospitals, healthcare systems, and the public benefit from timely delivery of this information. The report provides information including: (1) the number of manufacturers that submitted a shortage notification; (2) actions taken by the FDA to mitigate drug shortages; (3) the FDA’s coordination with the Drug Enforcement Agency (DEA) on efforts to reduce drug shortages; and (4) the names of manufacturers that were issued noncompliance letters for failing to notify the FDA of a disruption (permanent or temporary) in manufacturing under § 506c(f) of the FFDCA, as amended.

I appreciate and recognize the measurable steps the FDA has taken to address drug shortages, including the prevention of 145 drug shortages in 2017, expanded and expedited review and approval processes for drugs that are in shortage, public disclosure of drugs that are off-patent and lack generic competition, and implementation of the Agency Drug Shortages Task Force. Though laudable, these efforts are unfortunately not sufficient, given the current state of rising drug shortages in our nation. In addition to the concerns identified above, I am increasingly concerned the FDA may not have the data it needs to adequately assess and mitigate drug shortages.

A vital drug runs low, though its base ingredient is in many kitchens, The New York Times (May 21, 2017) https://www.nytimes.com/2017/05/21/health/sodium-bicarbonate-solution-critical-shortage-hospitals.html?_r=0.

¹⁰ American Society of Health-System Pharmacists, *Sodium Bicarbonate Injection* (August 3, 2019), <https://www.ashp.org/drug-shortages/current-shortages/Drug-Shortage-Detail.aspx?id=293> (accessed August 8, 2019).

¹¹ *Id.*

¹² Pub. L. No. 112-144, 126 Stat. 993 (2012). In October 2011, Executive Order No. 13588 directed the FDA to use “all appropriate administrative tools . . . to require drug manufacturers to provide adequate advance notice of manufacturing discontinuances that could lead to shortages of drugs that are life supporting or life sustaining, or that prevent debilitating disease . . . [and to] expedite its regulatory reviews of new drug suppliers, manufacturing sites, and manufacturing changes . . .”; *See also* University of Utah Drug Information Service, Drug Shortages Statistics, National Drug Shortages: Annual New Shortages by Year from January 2001 to June 30, 2019 (<https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics>) (accessed August 12, 2019).

¹³ 21 U.S.C. § 356c-1(a). The original act required FDA’s drug shortages report to be submitted at the end of each calendar year; however, the passage of the 21st Century Cures Act amended the report deadline to March 31 so that data from the entire preceding year could be included.

To better understand how the FDA is working to improve its efforts to address this public health crisis, I request your response to the following questions by September 6, 2019.

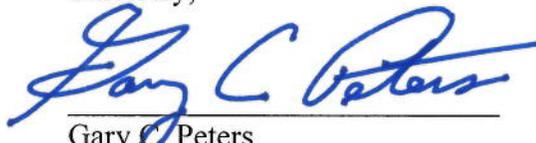
1. Please provide the estimated date of publication for the FDA's Report on Drug Shortages for Calendar Year 2018. Please also provide the Committee with a copy of the report upon its release as well as information regarding how the FDA intends to ensure timely filing of future annual drug shortage reports pursuant to § 356c-1 of the Federal Food, Drug, and Cosmetic Act, as amended.
2. Please discuss the follow-up actions taken as a result of the November 27, 2018 public meeting held by the FDA to address root causes of drug shortages and enduring solutions. Please also detail all actions the Agency Drug Shortages Task Force has taken since July 2018 to mitigate drug shortages as well as future plans and goals to address ongoing drug shortages.
3. Please provide a description of planned and anticipated impacts, as well as safety considerations, under Pathway 1 and Pathway 2 of the FDA's Safe Importation Action Plan with respect to steps to allow importation of drugs from foreign markets to address drug shortages for patients, consumers, and hospital systems throughout the United States.¹⁴ Please also discuss any anticipated impact these proposals will have within the next year on consumers.
4. Beyond the statutorily required manufacturer notifications in the Drug Shortages Report, please provide a description of the information manufacturers voluntarily provide to the FDA as part of its efforts to address underlying causes of drug shortages. Please also state whether manufacturers provide the FDA with the following: information about industry consolidation; decisions by manufacturers to limit production of inexpensive drugs with low profit margins; manufacturers' location, duration of shortages; sources of raw materials; and causes of shortages.
5. Please provide a description of any limitations in your current authority as Acting Commissioner, including but not limited to statutory and/or regulatory limitations that prevent you from fully exercising the authorities of the FDA Commissioner. Please also specify any nondelegable duties of the FDA Commissioner, including those relevant to addressing and mitigating drug shortages.

¹⁴ U.S. Department of Health and Human Services and Food and Drug Administration, Safe Importation Action Plan (July 31, 2019), pursuant to Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. §§321, 801(d), 804).

The Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate “the efficiency, economy, and effectiveness of all agencies and departments of the Government.”¹⁵ Additionally, Senate Resolution 70 (116th Congress) authorizes the Committee to investigate “the efficiency and economy of operations of all branches of the Government.”¹⁶

Thank you for your prompt attention to this request. If you have any questions about this request, please have your staff contact Megan Petry at Megan_Petry@hsgac.senate.gov or (202)-224-0392. Thank you for your attention to this matter.

Sincerely,



Gary C. Peters
Ranking Member
Committee on Homeland Security
and Governmental Affairs
United States Senate

¹⁵ S. Rule XXV(k)(2) (B); *see also* S. Res. 445, 108th Cong. (2004).

¹⁶ S. Res. 70, 116th Cong. §12(e)(1)(A) (2019) (enacted).