

Congress of the United States
Washington, DC 20510

February 7, 2018

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

We are writing today regarding the “unprecedented” challenges facing hospitals and medical centers in Massachusetts as nationwide drug and device shortages strain the already scarce resources of medical providers in the aftermath of Hurricane Maria. We are particularly concerned by reports from Massachusetts hospitals that shortages of intravenous (IV) bags, saline, and emergency products have strained their capacity and required them to develop time-consuming strategies to address these shortages. While we appreciate the actions taken by the U.S. Food and Drug Administration (FDA) to address these shortages, we continue to be concerned by the reports of shortages and associated problems from Massachusetts facilities.

Drug and medical device manufacturing in Puerto Rico is critical to the stability of our nation’s medical product supply chain. According to a recent FDA analysis, Puerto Rico produces \$40 billion in pharmaceutical products a year—more than any other U.S. state.¹ Almost ten percent of the country’s pharmaceutical expenditures are for the more than 1,000 drug products manufactured in Puerto Rico—including HIV medications, oncology drugs, glucose monitors, and other critical medical devices.

On September 20, 2017, Hurricane Maria hit Puerto Rico—devastating the island and crippling its pharmaceutical and medical device manufacturing capabilities. The hurricane cut power to most of the island, leaving drug and medical device factories with limited electricity and preventing Puerto Rican employees from getting to work.² One month after the hurricane, you told Congress that manufacturing in Puerto Rico was “running at minimal levels, and certainly far from full production.” An FDA survey of the island found that “reports of manufacturing running below 50 percent [was] common,” with “no firm operating above 70

¹ U.S. Food and Drug Administration, *Securing the Future for Puerto Rico: Restoring the Island’s Robust Medical Product Manufacturing Sector* (November 6, 2017) (online at <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm584019.htm>).

² Katie Thomas, U.S. Hospitals Wrestle With Shortages of Drug Supplies Made in Puerto Rico,” *New York Times* (October 23, 2017) (online at <https://www.nytimes.com/2017/10/23/health/puerto-rico-hurricane-maria-drug-shortage.html>).

percent of their normal operation.”³ In response to the hurricane, the FDA began monitoring shortages of over 40 drug products and 50 medical devices.⁴

Four months after Hurricane Maria, drug and device shortages caused by the hurricane in Puerto Rico continue to challenge medical providers.⁵ We are particularly concerned that shortages of IV bags, saline, amino acids, and emergency medications like epinephrine and norepinephrine have forced hospitals to alter their care practices, compound their own medications, and ration devices and drugs amidst an increasingly severe flu season.⁶ The FDA has taken a number of steps to mitigate these shortages, such as asking companies with additional capacity to expand product production and extend product expiration dates; approving products from companies unaffected by the hurricane; and permitting the temporary import of impacted products.⁷ We applaud the FDA for its efforts.

However, we continue to hear from hospitals and medical centers in Massachusetts that bear the brunt of these shortages. According to the Massachusetts Health & Hospital Association, hospitals across the Commonwealth are utilizing “conservation and adaption strategies” to preserve limited supplies—such as “using larger IV bags instead of smaller bags, which, in turn, has caused a shortage of the larger bags.”⁸ Hospitals are reporting shortfalls of potassium chloride, lorazepam, and anesthetics like lidocaine or bupivacaine. While our state hospitals continue to provide the highest-quality medical care to patients, addressing these shortages is costly and time-consuming.

³ U.S. Food and Drug Administration, *Testimony of Scott Gottlieb, M.D., Commission of Food and Drugs, Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives* (October 24, 2017) (online at <http://docs.house.gov/meetings/IF/IF02/20171024/106530/HHRG-115-IF02-Wstate-GottliebMDS-20171024.pdf>).

⁴ U.S. Food and Drug Administration, “Statement by FDA Commissioner Scott Gottlieb, M.D. on medical device manufacturing recovery in Puerto Rico” (October 20, 2017) (online at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm581436.htm>).

⁵ Stephanie Armour and Thomas M. Burton, “Hospitals Wrestle With Shortage of IV Bags, Linked to Hurricane,” *Wall Street Journal* (January 7, 2018) (online at <https://www.wsj.com/articles/hospitals-wrestle-with-shortage-of-iv-bags-linked-to-hurricane-1515349271>).

⁶ Stephanie Armour and Thomas M. Burton, “Hospitals Wrestle With Shortage of IV Bags, Linked to Hurricane,” *Wall Street Journal* (January 7, 2018) (online at <https://www.wsj.com/articles/hospitals-wrestle-with-shortage-of-iv-bags-linked-to-hurricane-1515349271>); U.S. Food and Drug Administration, “FDA Commissioner Scott Gottlieb, M.D., updates on some ongoing shortages related to IV fluids” (January 16, 2018) (online at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592617.htm>); U.S. Food and Drug Administration, “Statement by FDA Commissioner Scott Gottlieb, M.D., update on recovery efforts in Puerto Rico, and continued efforts to mitigate IV saline and amino acid drug shortages” (January 4, 2018) (online at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm591391.htm>); Communication between the Boston Medical Center and the staff of U.S. Senators Elizabeth Warren and Ed Markey.

⁷ U.S. Food and Drug Administration, “FDA Commissioner Scott Gottlieb, M.D., updates on some ongoing shortages related to IV fluids” (January 16, 2018) (online at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592617.htm>); U.S. Food and Drug Administration, “Statement by FDA Commissioner Scott Gottlieb, M.D., update on recovery efforts in Puerto Rico, and continued efforts to mitigate IV saline and amino acid drug shortages” (January 4, 2018) (online at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm591391.htm>); U.S. Food and Drug Administration, “FDA works to help relieve the IV fluid shortages in the wake of Hurricane Maria” (November 14, 2017) (online at <https://www.fda.gov/Drugs/DrugSafety/ucm585052.htm>).

⁸ Communication between the Massachusetts Health & Hospital Association and the staff of U.S. Senator Elizabeth Warren.

For example, at Boston Medical Center (BMC), the largest safety-net provider and busiest Level One Trauma Center in New England, upwards of twenty staff from across pharmacy, supply chain, operations, nursing, and IT have been devoting twenty hours per week to address drug shortages. With the fluid shortages, BMC has had to move some compounding activities in-house, adding significantly to staff workload and increasing waste as a result of shortened shelf life for these products. BMC has resorted to having its nurses dilute antibiotics with sterile water on the floor and administer by IV push – a practice replaced close to twenty years ago in order to reduce administration time and increase patient safety. Hospital officials have expressed concern that the shortages could lead manufacturers to increase prices, which would further burden BMC.⁹

Meanwhile, Massachusetts General Hospital (MGH) has initiated its Hospital Incident Command System to “ensure efficient communication with the staff about how to cope with the shortage as it changes day to day.”¹⁰ Nurses at MGH are using the “IV push” method to provide patients with antibiotics and fluids—a process that takes up to 35 minutes—and pharmacists are compounding medications in-house.¹¹ According to MGH’s Chief Medical Officer, “If the influenza virus or catastrophic event breaks out, that would stress [the hospital] more. In some ways, it’s unprecedented... It raises fear we may have to make choices about not doing some things and delaying elective procedures.”¹²

At a recent hearing at the Senate Committee on Health, Education, Labor, and Pensions, you acknowledged the shortages of “saline solution and amino acids, as well as the cascading increase in demand for other medical products, such as empty IV containers” as a result of Hurricane Maria. You told the Committee that the FDA “continues to be focused on storm-related shortage issues,” and “has been in direct communication with manufacturers, distributors, hospitals, and other health care providers.”¹³ We appreciate the steps that the agency has already taken to combat these drug shortages, and look forward to working with you on additional steps to ensure that medical centers in Massachusetts and across the nation have the resources and supplies they need.

We appreciate that FDA has acted rapidly to attempt to address this shortage. However, we are concerned about continuing reports of problems at medical facilities in the state. To help us better understand these challenges, as well as the steps that the FDA has taken and additional

⁹ Communication between the Boston Medical Center and the staff of U.S. Senators Elizabeth Warren and Ed Markey.

¹⁰ Carey Goldberg, “Mass. General Hospital Raises Red Flag About National Shortage of IV Fluids,” *WBUR* (December 18, 2017) (online at <http://www.wbur.org/commonhealth/2017/12/18/mass-general-hospital-iv-fluids>).

¹¹ Stephanie Armour and Thomas M. Burton, “Hospitals Wrestle With Shortage of IV Bags, Linked to Hurricane,” *Wall Street Journal* (January 7, 2018) (online at <https://www.wsj.com/articles/hospitals-wrestle-with-shortage-of-iv-bags-linked-to-hurricane-1515349271>).

¹² Stephanie Armour and Thomas M. Burton, “Hospitals Wrestle With Shortage of IV Bags, Linked to Hurricane,” *Wall Street Journal* (January 7, 2018) (online at <https://www.wsj.com/articles/hospitals-wrestle-with-shortage-of-iv-bags-linked-to-hurricane-1515349271>).


¹³ U.S. Food and Drug Administration, *Testimony of Scott Gottlieb, M.D., Commissioner of Food and Drugs, Before the Committee on Health, Education, Labor & Pensions, United States Senate* (January 17, 2018) (online at <https://www.fda.gov/NewsEvents/Testimony/ucm592774.htm>).

steps that the FDA could be taking to resolve these problems, we request a staff briefing no later than February 23, 2018.

Sincerely,



Elizabeth Warren
United States Senator



Edward J. Markey
United States Senator



Richard E. Neal
Member of Congress



James P. McGovern
Member of Congress



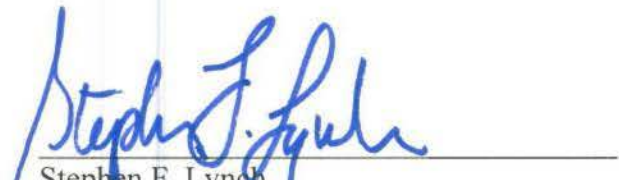
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Joseph P. Kennedy III
Member of Congress



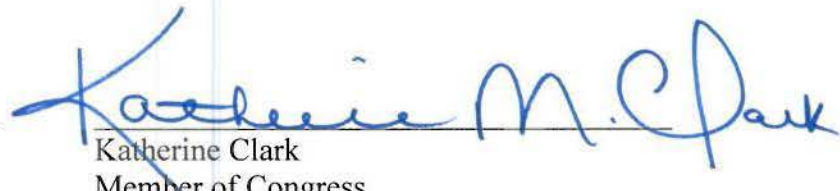
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