

Congress of the United States
Washington, DC 20515

February 2, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

As Puerto Rico and the mainland continues to reel from a devastating hurricane season, we write with great concern on nationwide drug shortages. The lack of medicines and medical supplies since Hurricane Maria devastated Puerto Rico is creating immense anxiety for hospitals, providers, and, most importantly, the patients they serve.

Puerto Rico plays an important role in supporting American public health. Nearly 80 pharmaceutical companies in Puerto Rico manufacture approximately 10 percent of all drugs consumed by Americans, and this sector represents an important part of the commonwealth's economy. Hurricane Maria threatened the supply of critical therapies to treat HIV, cancer, rheumatoid arthritis and other drugs and medical devices only produced in Puerto Rico. There also are numerous reports of drastic and ongoing national shortages of Sodium Chloride 0.9 percent Injection Bags (IV fluid bags), amino acids, as well as other IV fluids. These shortages have underscored Puerto Rico's critical role after major manufacturing facilities were damaged or temporarily closed in the wake of Hurricane Maria. In light of this, we urge you to use all tools at your disposal to address these dire shortages.

We understand Puerto Rico's recovery is ongoing and will take time. We commend the FDA's ongoing efforts to provide a swift response to the complex challenges faced by the island's drug manufacturers and welcome the opportunity to assist in your endeavors to ensure the IV fluid shortages are rectified in a timely fashion. The ongoing shortage of medical products manufactured in Puerto Rico, specifically small volume IV fluid bags, has created a nationwide public health scare during the height of a severe flu season.

As you know, a shortage of IV fluids was documented by the FDA and has persisted since January 2014. As of October 2017, no drug or medical product manufacturers in Puerto Rico were operating at higher than 70 percent capacity. Baxter is one of only three U.S. companies that manufacture IV bags, and the last of their facilities in Puerto Rico were only recently reconnected to the fragile power grid.

To avoid any further harm to consumers, we request that the FDA use every authority at its disposal to address this crisis and present a plan to ensure immediate and sustained production of IV bags that also provides sufficient guidance to mitigate cost increases.

We understand the FDA has taken steps to attempt to remedy this crisis by allowing the importation of saline products from other countries and by also approving new saline

products. However, providers in our states have voiced concerns over the uncertainty of when these products will become available and when a long-term solution to this shortage will be implemented. We also respectfully request answers to the following questions:

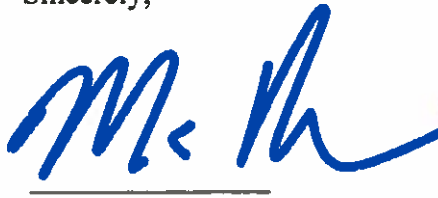
1. What steps has the FDA taken to prevent new shortages of other medical products manufactured in Puerto Rico?
2. Is the approval of new suppliers of saline permanent or temporary, and what would trigger a change in this status as current suppliers eliminate shortages?
3. When does the FDA expect these products to become widely available?
4. Does the FDA have the tools necessary to increase the nation's supply of saline and other IV fluids?
 - a. If not, will you please provide detailed ways in which Congress can assist?
5. What steps is the FDA taking to ensure manufacturers are creating contingency strategies to avoid future shortfalls?
6. Is the FDA coordinating with other agencies aiding in Puerto Rico's recovery to ensure the rebuilding of its critical infrastructure adequately address the operational needs of pharmaceutical and medical device manufacturers?

Thank you for your attention to this matter as your important work in Puerto Rico continues. We appreciate that the FDA recognizes the health of our nation and look forward to working with you to resolve this issue.

Sincerely,



Richard Blumenthal
U.S. Senator



Marco Rubio
U.S. Senator



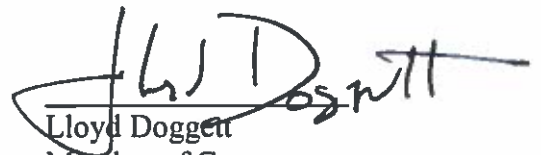
Marcy Kaptur
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Bill Nelson
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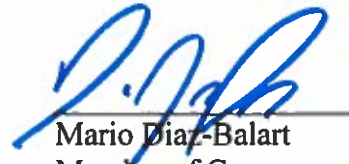
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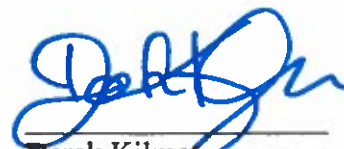
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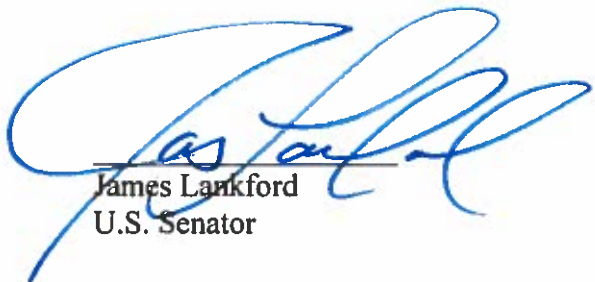
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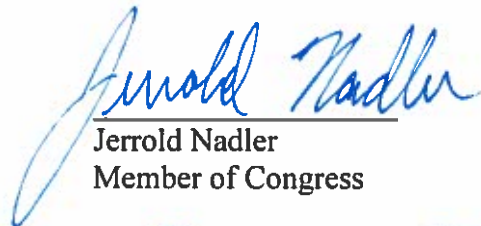
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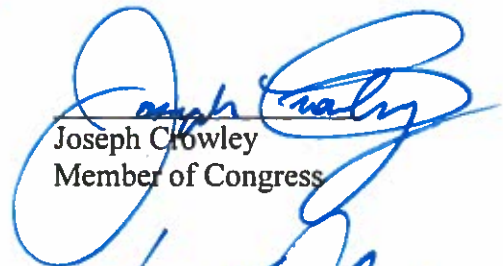
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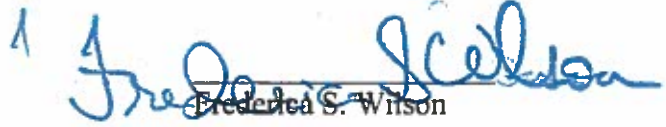
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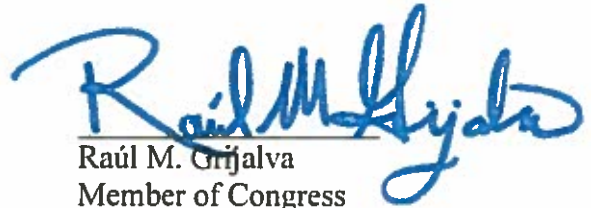
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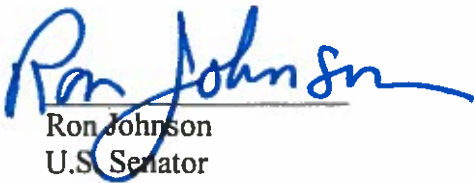
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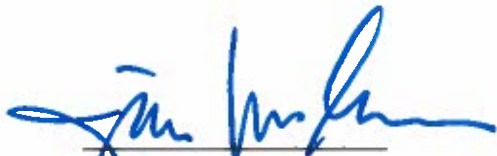
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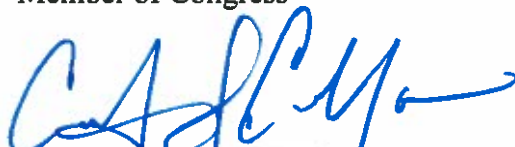

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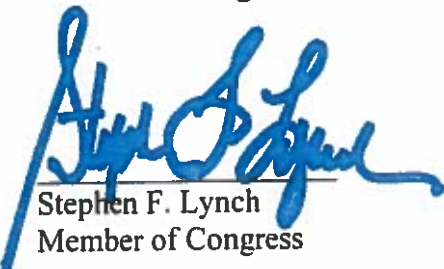
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