

Opening Remarks - Mitigating Emergency Drug Shortages Act of 2019
Senator Susan M. Collins
November 5, 2019

Well, good morning everyone, and thank you, Blair. I'm delighted to join you today to increase awareness of drug shortages and to highlight the new legislation that I've introduced with Senator Tina Smith, the *Mitigating Emergency Drug Shortages or MEDS Act*. My staff spends a great deal of time coming up with catchy acronyms for our bills, and we managed in this case to achieve that. I also want to recognize Brian Marden, the chief pharmacy officer for MaineHealth in Maine, who will be sharing his expertise on this issue in just a few minutes. I know I'm standing between you and the panel of experts, so let me just make a few points.

First, as Blair has mentioned, the MEDS Act has the support of more than 50 organizations. I will tell you that when this speech was first drafted, we had 10. So, I love that support is growing and that's due to a lot of people in this room who have worked very hard, and I believe that it will continue to grow. These groups represent hospitals, patients, physicians, pharmacists, suppliers and many others. And I know that many of these organizations are represented here today. The broad support for the MEDS bill is indicative of how serious the problem is. And this is a problem that is growing. When I was talking earlier to Brian, I mentioned that five years ago it was rare for us to hear from a hospital, a patient, a supplier, or a pharmacist about this issue. Then five years ago, it seemed to have taken off and we were constantly hearing from people about drug shortages. I often hear from people, whether it's hospitals or pharmacists or physicians, who find themselves caught in the middle of a drug shortage with very little idea of how or when the problem is going to be resolved.

One example is a cancer patient who called my Portland office about a shortage of a drug that he had used successfully to treat his bladder cancer. Because of the shortage of this drug he has been denied additional treatments and naturally he's living in constant fear of his cancer returning and whether or not he's going to be able to get access to the drug that he needs. A former nurse told me of how shortages of I.V. Benadryl and EpiPens had left her family feeling helpless. She was incredulous that shortages like this were occurring in our country. Another Maine hospital called me to report a shortage of injectable morphine, clearly essential for this hospital. Now, I know that physicians and hospitals and pharmacists are trying to manage these shortages behind the scenes, but they are understandably very frustrated.

Drug shortages add \$230 million a year to U.S. drug costs and \$216 million a year in increased labor costs to address the shortages. One of our hospitals in Maine, Northern Lights, has had to add additional staff just to work on drug shortages. I'll never forget during the government shutdown last year, hearing from a physician practice that could not get answers about the status of a shortage of a critical endocrinology drug because the FDA was shut down due to the government closure. That was really frustrating.

Let me give you yet another example to illustrate how widespread this problem is. Earlier this year, MaineHealth, which is our largest health care operation in Maine, was experiencing eleven critical shortages and 30 less critical ongoing shortages. For one drug, the hospital had to

switch to a more expensive alternative that cost ten times more than the drug that was no longer available.

The MEDS Act, which we've introduced, would take several crucial steps to help with this problem. First, it would require pharmaceutical companies to disclose to the FDA the causes and expected duration of shortages. In addition, manufacturers would have to develop contingency and redundancy plans to ensure the ongoing supply of essential medications. Another provision of the bill would give the FDA the authority to prioritize review of new drug applications and manufacturing inspections of drugs that are in shortage.

The MEDS Act also directs HHS to develop recommendations to incentivize manufacturers that entered the market for drugs that are experiencing shortages. Our bill also requires HHS and the Department of Homeland Security to conduct a risk assessment of national security threats associated with the shortages of certain drugs. Just last week, the Director of the Center for Drug Evaluation and Research at the FDA testified that as of this August, only 28 percent of the manufacturing facilities making active pharmaceutical ingredients, or APIs, for our market are located in our country. Think about that - only 28 percent. Of the remaining 72 percent of overseas APIs manufacturers rely upon, 13 percent are in China. I don't like hearing that at all. Finally, our legislation requires the Secretary to improve consumer notification of drug shortages. That absence of information is so frightening to consumers and frustrating for their health care providers. We need to get past the notion that this is a temporary problem that sometimes occurs when there's a hurricane in Puerto Rico. That can be a factor and indeed has been a factor, but this is a far more complicated problem with root causes that we need to address.

I am delighted that this briefing is being held today to help illustrate the stubbornness and seriousness of this problem for patients, physicians, pharmacists, hospitals, suppliers, and everyone involved from the manufacturer to the patient. And I am particularly grateful for your support for the MEDS Act. Working together, I am hopeful that we can get it put on the agenda for a markup by the HELP committee and get this bill passed.

Now, I also want to end by telling you that, fortunately, I just happen to have a meeting coming up with the new nominee, Dr. Hahn, to be the head of FDA, and I want to assure you that this will be very high on our agenda. This gives us an opportunity to talk with the new head of the agency and to make sure that he is aware of this problem and committed to backing the MEDS Act and doing all that FDA can do to solve this problem. Again, thank you so much for your support. And again, I thank the panelists and Blair for organizing this event. Thank you.

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