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December 5, 2017

Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
White Oak Building One
10903 New Hampshire Avenue, Room 2217
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

I greatly appreciate the Food and Drug Administration's (FDA) work to implement the Drug Quality and Security Act (DQSA). I was the author of H.R. 1919, the Safeguarding America's Pharmaceuticals Act, which was integrated into DQSA under Title II. As we approach deadlines by which manufacturers and re-packagers must serialize products, I believe we should examine ways that FDA can utilize this law to ensure opioid pills are not diverted from the supply chain.

In 2013, DQSA created a uniform national standard for security of the drug supply chain in order to protect Americans against counterfeit and otherwise illegitimate drugs. As the author of Title II of this Act, I believe the traceability requirements will not only make the supply chain more secure but also has the ability to prevent opioid diversion. We are losing 91 Americans every day from opioid overdoses, and prescription opioids are a driving factor of this devastating trend with nearly half of all these overdose deaths involving a prescription opioid. Furthermore, in my home state of Ohio we are seeing some of the highest overdose death rates in the nation. In 2016, Ohio had a 32 percent increase in deaths from the previous year with at least 4,050 people losing their lives from unintentional drug overdose.

Due to this nationwide crisis, I urge FDA to review ways to better prevent and identify both the diversion of prescription drugs, including opioids, from the U.S. drug supply chain and the introduction of illegitimate prescription drugs (e.g., counterfeit opioids) into the supply chain. As part of that review, I would like FDA to consider the following questions:

1. Does FDA have the necessary tools to identify diverted prescription drugs, including prescription opioids?

2. Would FDA recommend Congress provide additional authority to the Administration to effectively track and trace diverted prescription drugs?

3. What changes should be made to ensure consumers are being protected and prescription drugs are not falling into the wrong hands?

4. Has FDA considered using blockchain or other technologies to monitor prescription drugs within the supply chain as well as drugs that have been diverted?

Thank you for your consideration of these comments and questions. Should you have any questions, please contact Rachel Schwegman on my staff at 202-225-6405 or rachel.schwegman@mail.house.gov.

Sincerely,

Robert E. Latta
Member of Congress