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COMMITTEE ON THE BUDGET

July 2, 2019

The Honorable Norman E. "Ned" Sharpless, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

I write concerning last week's announcement that the Food and Drug Administration (FDA) is investigating a multistate outbreak of *Salmonella* Uganda infections that have been linked to papayas imported from Mexico. I have serious concerns that the Agency did not provide consumers with necessary information regarding this outbreak in a timely manner, which ultimately put lives at risk.

A leading publication for the fresh fruit and vegetable industry posted a story about the outbreak at 10:58 AM on Friday, June 28, 2019<sup>1</sup>. However, it was not until almost five hours later that the first government agency, the Centers for Disease Control and Prevention, first published a *Food Safety Alert* at 3:30 PM<sup>2</sup>. Another hour would go by before the FDA posted an outbreak notice to its own website and subsequently sent the details of the outbreak investigation to its e-mail distribution list<sup>3</sup>. As a result, most major media outlets did not begin reporting on the outbreak until late afternoon.

When it comes to announcing an ongoing outbreak, where consumers potentially have contaminated food in their homes, minutes matter.

The FDA is a regulatory agency whose first priority should be that of ensuring and protecting public health. The Agency has an obligation to notify consumers of possible food safety threats as soon as possible. Based on the aforementioned timeline, I do not feel that occurred in this case.

<sup>1</sup> See, <https://www.thepacker.com/article/updated-fda-links-mexican-papaya-outbreak-asks-halt-sales>.

<sup>2</sup> See, <https://www.cdc.gov/salmonella/uganda-06-19/index.html>.

<sup>3</sup> The FDA's outbreak investigation notice did not appear to be published before 4:30 PM on Friday, June 28, 2019. Additionally, an FDA email first announcing the outbreak was sent at 4:42 PM on the same day.

While the current outbreak is responsible for at least 62 infections, including 23 hospitalizations, across eight states, foodborne illnesses related to imported papayas are not a new occurrence. In fact, there have been *Salmonella* outbreaks tied to papayas in five out of the last nine years. In total, these outbreaks have resulted in 418 confirmed infections, 113 hospitalizations, and three deaths since 2011<sup>4</sup>.

Moreover, results from the investigation of the 2017 outbreak showed widespread contamination. Because of additional border screening conducted by the FDA after the outbreak began, the Agency identified *Salmonella* strains from three additional farms that matched illnesses from other outbreaks<sup>5</sup>.

Since 2011, the FDA has had in place an import alert on papayas that relies primarily on third-party testing to demonstrate the fruits are free of contamination before being admitted at the border. Undoubtedly, this current screening approach appears to be woefully inadequate, and it is failing to stop imports of contaminated fruit from reaching the tables of families across the United States.

Therefore, I request an immediate, written response to the following questions:

- 1) Does the FDA believe that the Agency publicly announced the outbreak in a timely manner consistent with safeguard public health? Was FDA aware of public reporting on the outbreak by an industry publication early in the day on Friday, June 28, 2019? Had anyone at FDA been in contact with anyone from that outlet? What explains the FDA's hours long delay in public confirmation and notification of the outbreak?
- 2) What is the current status of FDA's outbreak investigation? What is the most up to date count of illnesses, hospitalizations, and deaths resulting from this outbreak?
- 3) During the 2017 Mexican papayas outbreaks, FDA identified four farms in Mexico that had produced the contaminated papayas. Were FDA officials able to visit all of those farms to inspect for food safety issues? If not, what were the barriers that prevented such inspections from taking place? For the farms that were visited, what food safety issues were identified? Did FDA officials visit those farms a second time to confirm that the issues had been corrected?
- 4) The FDA's 2011 Import Alert on papayas relies on third-party *Salmonella* testing to verify that shipments are free of *Salmonella*. Have FDA officials visited any of the laboratories that are providing such testing to ensure that procedures used have been appropriately validated? Are these labs required to be accredited? Firms on the "Green List" do not have to provide such testing. In order to get on the "Green List," do

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<sup>4</sup> U.S. Centers for Disease Control and Prevention, *National Outbreak Reporting System*.

<sup>5</sup> See, <https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigates-multiple-salmonella-outbreak-strains-linked-papayas>.

importing firms have to take any additional steps beyond showing five consecutive clean test results from an unaccredited third-party laboratory?

- 5) Following the 2017 outbreak, the FDA increased screening of papayas at the border, including by directly testing incoming shipments rather than relying solely on third-party testing. How long did this enhanced screening continue? What other steps, if any, has the FDA taken since 2017 to strengthen requirements for imported papayas? What other steps, if any, has the FDA considered taking as a result of the ongoing outbreak?
- 6) Are all papaya importers currently required to comply with the FDA's foreign supplier verification program (FSVP) rule? What activities does the FDA consider to be adequate to verify that a papaya supplier has controlled *Salmonella* hazards? Is the importer required to verify that the farm supplying the fruit has been audited by a third party under the FDA's produce safety rule?
- 7) Does the FDA have any plans to carry out risk-based food safety inspections of papaya farms in Mexico or any other foreign country moving forward?
- 8) Does the FDA have any additional plans to stop papayas imports from Mexico if these risks cannot be controlled moving forward?

Should you have any questions regarding this request, please contact Christian Lovell of my staff at (202) 225-3661 or [christian.lovell@mail.house.gov](mailto:christian.lovell@mail.house.gov).

Thank you for your attention to this urgent matter.

Sincerely,



ROSA L. DeLAURO  
Member of Congress