United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

April 18, 2018

The Honorable Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

The Committee on Homeland Security and Governmental Affairs is examining the Food and Drug Administration's (FDA) policy to request limits on packaging for loperamide. More commonly known as Imodium, loperamide is a drug that many consumers, including approximately 700,000 patients with Crohn's disease and the estimated 25 to 45 million Americans who suffer from Irritable Bowel Syndrome (IBS), use to manage gastrointestinal conditions.[1] We write to request information about the FDA's policy and the consequences it may have for people who rely on loperamide.

On January 30, 2018, the FDA announced plans to work with manufacturers to use blister packs or other single-dose packaging to limit the number of loperamide doses available over the counter in one package.[2] The FDA explained its desire to address potential safety concerns stemming from individuals mixing loperamide with other drugs to enhance euphoric effects or using loperamide to treat opioid withdrawal.[3] While these efforts are well-intentioned, the FDA's policy would limit over-the-counter packs to eight pills, which is enough to treat acute diarrhea for only two days.[4] This decision could have unintended consequences for the millions

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[1] *See FDA Drug Safety Podcast: FDA Limits Packaging for Anti-Diarrhea Medicine Loperamide (Imodium) to Encourage Safe Use,* U.S. Food & Drug Admin. (Feb. 6, 2018), https://www.fda.gov/Drugs/DrugSafety/DrugSafetyPodcasts/ucm595631.htm?utm_campaign=CDER%20New%202%2F7&utm_medium=email&utm_source=Eloqua&elqTrackId=1596f7ce5df34fcab7a1e197d3c06eb1&elq=efca437e8df248e395528cc7f50d6b65&elqaid=2358&elqat=1&elqCampaignId=1670; *see also FDA Drug Safety Communication: FDA Limits Packaging for Anti-Diarrhea Medicine Loperamide (Imodium) to Encourage Safe Use,* U.S. Food & Drug Admin. (June 7, 2018), https://www.fda.gov/Drugs/DrugSafety/ucm594232.htm; Abbvie, *Understanding Crohn's Disease*, Crohn's & Colitis.com, https://www.crohnsandcolitis.com/crohns (last visited Mar. 9, 2018); Int'l Found. for Functional Gastrointestinal Disorders, *Facts About IBS*, https://aboutibs.org/facts-about-ibs.html (last updated Nov. 24, 2016).

[2] U.S. Food & Drug Admin., *supra* note 1.

[3] *Id.*

[4] Graedon, Teresa and Jo, FDA's Imodium crackdown dismays patients with IBS-D Seattle Times (Mar. 4, 2018) https://www.seattletimes.com/life/wellness/fdas-imodium-crackdown-dismays-patients-with-ibs-d/ (last visited Mar. 13, 2018).

of Americans who use loperamide on a regular basis, including individuals suffering from Crohn's and IBS.

For example, the decision may increase the burden for Americans seeking to mitigate the effects of their chronic diseases. One individual suffering from IBS worried that "I have controlled my symptoms for years with one Imodium tablet per day. Without it, I need to be near a bathroom within 20 minutes of eating, and I need to stay seated for 10 to 20 minutes. Not fun. This has been a cheap and easily available drug for IBS-D sufferers. I guess I need to stock up now, before it becomes both expensive and hard to find."[5]

To help the Committee better understand the FDA's policy, we respectfully request that you provide the following information:

1. Describe the process, justification, and analysis underlying the FDA's decision to request limits on packaging for loperamide.

2. Provide the number of deaths that have resulted exclusively from overuse of loperamide between 2013 and 2017, the number of opioid overdose deaths to which the use of loperamide contributed during this same period, and any estimates, if available, of the number of Americans using loperamide to manage opioid withdrawal symptoms.

3. Describe whether the FDA sought or received comments from the millions of Americans who rely on loperamide, including individuals affected by Crohn's disease and IBS. If so, explain how the FDA weighed these comments against other public health considerations.

4. Please describe applications pending before the FDA, if any, for additional therapies or treatments for individuals suffering from Crohn's disease or IBS.

Please provide a response as soon as possible but no later than 5:00 p.m. on May 2, 2018.

The Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate "the efficiency, economy, and effectiveness of all agencies and departments of the Government."[6] Additionally, S. Res. 62 (115th Congress) authorizes the Committee to examine "the efficiency and economy of all branches of the Government including the possible existence of fraud, misfeasance, malfeasance, collusion, mismanagement, incompetence, corruption, or unethical practices . . . ."[7]

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[5] *Id.*
[6] S. Rule XXV(k); *see also* S. Res. 445, 108th Cong. (2004).
[7] S. Res. 62, 115th Cong. § 12 (2017).

If you have any questions regarding this letter, please ask your staff to contact Satya Thallam of the majority staff at (202) 224-4751 or Brandon Reavis of the minority staff at (202) 224-2627. Please send any official correspondence relating to this request to Rina Patel at Rina_Patel@hsgac.senate.gov. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Chairman

Claire McCaskill
Ranking Member