

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641
June 13, 2019

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

Dear Acting Commissioner Sharpless:

Pursuant to Rules X and XI of the U.S. House of Representatives, as part of its broader examination of the opioid crisis, the Committee is continuing to investigate the public health threat of fentanyl. Fentanyl is a synthetic opioid that is 50 times more powerful than heroin, and is now among the leading causes of opioid deaths. The Committee has been examining this issue for more than two years; since February 2017, the Committee has sent six bipartisan letters related to fentanyl and held a hearing in March 2017 at the Subcommittee on Oversight and Investigations.¹

The Centers for Disease Control and Prevention (CDC) released data showing that in 2017, there were over 70,000 drug overdose deaths in the United States,² including over 47,000 involving opioids.³ Over 28,000 of these deaths involved synthetic opioids such as fentanyl – an increase of nearly 47 percent from the previous year.⁴ CDC reports that we are now in the “third

¹ See, e.g., Letter from Rep. Greg Walden, Chairman, and Rep. Frank Pallone, Jr., Ranking Member, *et al.*, House Committee on Energy and Commerce, to Kemp Chester, Acting Director, Office of National Drug Control Policy (Feb. 23, 2017); House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, *Fentanyl: The Next Wave of the Opioid Crisis*, 115th Cong. (Mar. 21, 2017).

² Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999–2017* (Nov. 2018).

³ Centers for Disease Control and Prevention, *Opioid Overdose: Drug Overdose Deaths* (www.cdc.gov/drugoverdose/data/statedeaths.html) (accessed May 13, 2019).

⁴ Centers for Disease Control and Prevention, *Opioid Overdose: Fentanyl* (www.cdc.gov/drugoverdose/opioids/fentanyl.html) (accessed May 13, 2019).

wave” of the opioid epidemic, with “significant increases in overdose deaths involving synthetic opioids – particularly those involving illicitly-manufactured fentanyl.”⁵

The Drug Enforcement Administration (DEA) previously reported to the Committee that China is the primary source of illicit fentanyl, with pure fentanyl shipped through the mail from China to the United States.⁶ Mexican drug cartels also receive shipments of fentanyl and its precursors directly from China where it is usually adulterated with heroin or other powdered forms of narcotics, and then shipped into the United States.⁷ Earlier this year, China announced that it would schedule all fentanyl-related drugs as controlled substances.⁸ However, concerns remain about China’s enforcement of these provisions and its efforts to stop illicit fentanyl exports.⁹

Last year, H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the Act), which passed through this Committee, was signed into law. Among other things, the Act gave the Food and Drug Administration more tools to intercept illicit drugs coming through our nation’s international mail facilities, including fentanyl shipped to the United States by mail from China. The Act also places new responsibilities on the U.S. Postal Service and the U.S. Customs and Border Protection related to tracking shipments of controlled substances.¹⁰

As overdose deaths involving fentanyl continue to rise, we remain concerned about the impact of this epidemic on the public health, and we are committed to identifying further solutions to stop the flow of deadly illicit fentanyl into our communities. Therefore, to assist the Committee’s investigation, please provide a briefing on these issues to Committee staff.

⁵ Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic* (www.cdc.gov/drugoverdose/epidemic/) (accessed May 13, 2019).

⁶ House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, testimony of Louis J. Milione, DEA Assistant Administrator, *Fentanyl: The Next Wave of the Opioid Crisis*, 115th Cong. (Mar. 21, 2017).

⁷ Senate Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations, statement of Gregory C. Nevan, Deputy Assistant Director, Illicit Trade, Travel, and Finance Division, Homeland Security Investigations, U.S. Immigration and Customs Enforcement, U.S. Department of Homeland Security, *Combating the Opioid Crisis: Exploiting Vulnerabilities in International Mail Security*, 115th Cong. (Jan. 25, 2018).

⁸ *China Bans All Types of Fentanyl, Fulfilling Pledge to Trump*, New York Times (Apr. 1, 2019).

⁹ *U.S.-China fentanyl pact is not expected to produce immediate results*, Washington Post (Dec. 3, 2018).

¹⁰ SUPPORT for Patients and Communities Act, Pub. L. No. 115-271 (2018).

Dr. Norman E. Sharpless, M.D.

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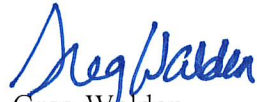
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If you have any questions regarding this request, please contact Kevin McAloon of the Majority Committee staff at (202) 225-2927 or Alan Slobodin of the Minority Committee staff at (202) 225-3641.

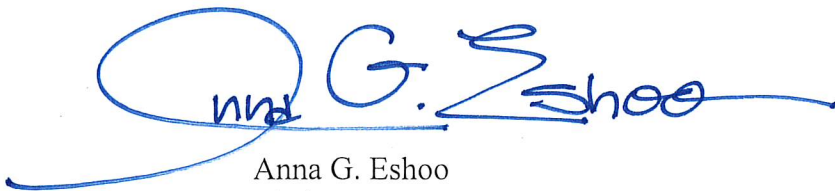
Sincerely,



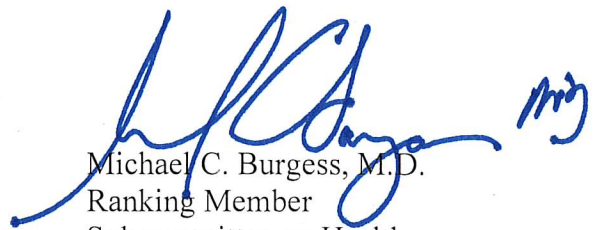
Frank Pallone, Jr.
Chairman



Greg Walden
Ranking Member



Anna G. Eshoo
Chairwoman
Subcommittee on Health



Michael C. Burgess, M.D.
Ranking Member
Subcommittee on Health



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