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Erick Longnecker
Deputy Assistant Secretary for Technology Security
U.S. Department of Commerce
Bureau of Industry and Security
Office of Strategic Industries and Economic Security
1401 Constitution Avenue NW, Room 3876
Washington, DC 20230

RE: Padagis LLC Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [BIS-2025-0022; XRIN 0694-XC120]

Dear Deputy Assistant Secretary Longnecker:

Padagis LLC (“Padagis”) welcomes the opportunity to submit comments regarding the Section 232 national security investigation of pharmaceuticals and pharmaceutical ingredients.¹ To the extent the Administration determines that a trade action is warranted to address imported pharmaceuticals and pharmaceutical ingredients, we urge the Administration to defer actions that could adversely impact the nation’s ability to confront the fentanyl and opioid crisis through imports of critical overdose reversal medication Naloxone.

Padagis is a leading global provider of high-quality generic pharmaceuticals headquartered in the United States. Padagis produces in both the U.S. and in Israel, a key U.S. ally and source of safe, fairly traded active pharmaceutical ingredients (“API”), finished generic drug products, and other inputs critical to the pharmaceutical industry.

Padagis is committed to innovation and excellence, driven by the vision that every patient deserves affordable access to the medication that best serves their needs. To achieve that goal, Padagis is expanding its portfolio and its domestic production of finished dosage products including generic naloxone² nasal spray to combat the opioid crisis—designated a national emergency by President Trump in his first term and renewed as a focus of the Administration’s efforts in February 2025.³

¹ *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15951 (Apr. 16, 2025).

² See Naloxone Drug Facts, National Institutes of Health National Institute on Drug Abuse (Jan. 2022) (“Naloxone is a medicine that rapidly reverses an opioid overdose. ... Examples of opioids include heroin, fentanyl, oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, and morphine.”), available at <https://nida.nih.gov/publications/drugfacts/naloxone>.

³ See Fact Sheet: President Donald J. Trump Imposes Tariffs on Imports from Canada, Mexico and China, The White House (Feb. 1, 2025) (“The extraordinary threat posed by illegal aliens and drugs, including deadly fentanyl,

As Padagis progresses in its established plans to expand domestic production of finished dosage naloxone nasal spray, it is critical that any trade action resulting from this investigation intended to buttress domestic production against imports not inadvertently hamper the Administration's efforts to relieve the opioid crisis. In these comments, Padagis will highlight the importance and feasibility of increasing domestic capacity for pharmaceuticals including naloxone nasal spray; the extent to which domestic production can meet the country's needs now and in the future; and the impact of current trade policies on domestic production of the life-saving drug naloxone.

I. U.S. PRODUCTION OF NALOXONE NASAL SPRAY IS NOT SUFFICIENT TO MEET DOMESTIC DEMAND FOR OPIOID OVERDOSE-FIGHTING DRUGS

In 2016, over 64,000 Americans died from drug overdoses, leading President Trump to declare the opioid crisis a public health emergency in October 2017.⁴ This figure rose to 87,000 in 2024.⁵ In February 2025, President Trump reiterated his concerns regarding the public health emergency caused by the flow of opioids, specifically fentanyl, across the U.S. border.⁶

As shocking as the 2024 opioid overdose death figures are, they represent a significant decline from 2023, when opioid overdose deaths reached 114,000.⁷ Government partnerships with public safety organizations in every state have proven one of the key factors in identifying emerging drug threats and providing rapid responses to opioid overdoses.⁸ Unfortunately, despite this national decline in opioid overdose deaths, overdose remains the leading cause of death for Americans aged 18-44.⁹

Naloxone is the front-line defense in fighting the opioid crisis. Naloxone is a life-saving medicine and when formulated as an easy to use, single-dose, prepackaged nasal spray, it allows emergency personnel, first responders, and even bystanders without medical training to aid a person experiencing an opioid overdose.¹⁰ It is, bar none, the most effective and immediate tool to prevent opioid overdose fatalities.

constitutes a national emergency under the International Emergency Economic Powers Act (IEEPA). ... During his first term as President of the United States, President Trump established the President's Commission on Combating Drug Addiction and the Opioid Crisis and declared the Opioid Crisis a public health emergency.”), available at <https://www.whitehouse.gov/fact-sheets/2025/02/fact-sheet-president-donald-j-trump-imposes-tariffs-on-imports-from-canada-mexico-and-china/>.

⁴ Ending America's Opioid Crisis, The White House, available at <https://trumpwhitehouse.archives.gov/opioids/>.

⁵ Provisional Drug Overdose Death Counts, 12 Month-ending Provisional Number of Drug Overdose Deaths by Drug or Drug Class, U.S. Centers for Disease Control and Prevention National Center for Health Statistics, available at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm?>.

⁶ See *supra*, note 3.

⁷ CDC Reports Nearly 24% Decline in U.S. Drug Overdose Deaths, U.S. Centers for Disease Control and Prevention (Feb. 25, 2025), available at <https://www.cdc.gov/media/releases/2025/2025-cdc-reports-decline-in-us-drug-overdose-deaths.html>.

⁸ *Id.*

⁹ *Id.*

¹⁰ Naloxone for Opioid Overdose: Life-Saving Science Policy Brief, National Institutes of Health National Institute on Drug Abuse (Mar. 2017), available at <https://archives.nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science>.

The FDA has approved two delivery forms of naloxone: injectable and single-dose prepackaged nasal spray,¹¹ and approved the nasal spray for over-the-counter use in March 2023.¹² More than 2.1 million naloxone prescriptions were dispensed from retail pharmacies in 2023¹³, and millions more have been provided to local and state governmental agencies and other harm-reduction groups for use in impacted communities. However, despite the best efforts of both producers and state organizations, nearly every state falls short of the quantity of naloxone needed for 80 percent of witnessed overdoses.¹⁴

In recent years, the U.S. government has allocated over \$34 billion to improve the U.S. pharmaceutical supply chain, recognizing the national security and public health threat posed by the domination over pharmaceutical production by a small number of producers concentrated in a few countries, with India and China together accounting for 61 percent of all global API drug master files (“DMF”) filings.¹⁵ When looking at *new* API drug master filings, the contrast is even more striking: India’s API DMF filings rose from 20 percent in 2020 to 62 percent in 2021; China’s rose from 4 percent in 2020 to 23 percent in 2021.¹⁶ Over the same period, new API DMF filings by the U.S. and E.U. decreased: U.S. filings fell from 15 percent in 2020 to a mere 4 percent in 2021.¹⁷ Europe experienced an even more dramatic decline, from 49 percent in 2020 to 7 percent in 2021.¹⁸

Fortunately, unlike some other pharmaceuticals and APIs, the production of naloxone is not monopolized by producers in India or China—domestic producers like Padagis can source fairly traded naloxone API from the E.U. and the United Kingdom, and is seeking to source appropriate API from U.S. producers.

Padagis estimates that the total U.S. naloxone market is approximately 18 million units and the U.S. is currently importing around 35 percent of that volume. As the studies cited above have shown, current domestic need outpaces the domestic supply of naloxone. Without additional

¹¹ Naloxone Drug Facts, National Institutes of Health National Institute on Drug Abuse (Jan. 2022).

¹² FDA Approves First Over-the-Counter Naloxone Nasal Spray, U.S. Food & Drug Administration (Mar. 29, 2023), available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray>.

¹³ Naloxone Dispensing Rate Maps, U.S. Centers for Disease Control and Prevention (Nov. 7, 2024), available at <https://www.cdc.gov/overdose-prevention/data-research/facts-stats/naloxone-dispensing-rate-maps.html>.

¹⁴ New Study Shows Major Shortage of Naloxone in Nearly Every U.S. State, Brandeis University (Feb. 11, 2022), available at <https://heller.brandeis.edu/news/items/releases/2022/traci-green-lancet-naloxone.html>. See also Michael A. Irvine, Ph.D., Declan Oller, Ph.D., Jesse Boggis, MPH, Brian Bishop, Pharm.D., Prof. Daniel Coombs, Ph.D., Eliza Wheeler, MPA, et al., Estimating Naloxone Need in the USA Across Fentanyl, Heroin, and Prescription Opioid Epidemics: A Modelling Study at Fig. 1, *The Lancet* (Mar. 2022), available at [https://www.thelancet.com/article/S2468-2667\(21\)00304-2/fulltext](https://www.thelancet.com/article/S2468-2667(21)00304-2/fulltext) (henceforth, “Estimating Naloxone Need in the USA”).

¹⁵ Geographical Concentration of Pharmaceutical Manufacturing: USP Medicine Supply Map Analysis, USP (May 18, 2022), available at <https://qualitymatters.usp.org/geographic-concentration-pharmaceutical-manufacturing>.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

domestic naloxone production capacity, medical personnel and community health programs will lack the most essential weapon in the fight to combat the opioid crisis.

II. PADAGIS IS ACTIVELY INCREASING ITS DOMESTIC PRODUCTION OF NALOXONE TO FIGHT THE OPIOID CRISIS, BUT RELIES ON IMPORTS IN THE INTERIM

Padagis is on fast track to join three existing domestic producers of naloxone nasal spray. All domestic naloxone nasal spray producers currently rely on imports of key components of their naloxone devices such as the cartridges used for the intranasal and injectable administration of naloxone.¹⁹ Without insufficient finished dosage naloxone nasal spray available pending Padagis's ramp-up of domestic finished dosage production, and without any domestic production of the raw material inputs for that drug, imports serve as a critical stopgap without which tens of thousands of lives will be lost needlessly every year due to opioid overdoses.

Padagis recognizes the significant threat to U.S. national security posed by over-reliance on imported pharmaceuticals and has invested substantial capital into increasing its domestic production of naloxone despite the availability of reliable supply from Israel. Padagis plans to have its domestic naloxone production lines operational by early 2026. To this end, Padagis has invested or will invest at least \$8.0 million to purchase and install the necessary equipment in Padagis's Minnesota manufacturing facility. Upon installation, Padagis will undertake the strenuous process of testing and qualifying the equipment and then seeking appropriate regulatory approval to commence U.S. production of its generic naloxone nasal spray. The production line for this product is highly specialized and requires a significant investment of resources—both time and monetary—to become operational at full capacity.

Padagis is committed to accelerate installation and qualification of its U.S. based production lines to every extent possible. However, until its production lines are fully operational at capacity, Padagis requires reliable access to imports of naloxone nasal spray. For this reason, Padagis respectfully requests that the Administration delay any trade action, including tariffs on imports of *finished naloxone in applicators*, until 2026 when Padagis anticipates that its domestic production lines will be operating at full capacity.

III. TRADE ACTIONS TO ADDRESS THE NATIONAL SECURITY THREAT POSED BY CERTAIN COUNTRIES' DOMINANCE OF THE PHARMACEUTICAL INDUSTRY SHOULD BE TARGETED AND CIRCUMSCRIBED TO PREVENT HARM TO DOMESTIC PHARMACEUTICAL COMPANIES

Padagis supports the Administration's efforts to address trade imbalances in the pharmaceutical sector that pose national security and public health risks to Americans. In implementing trade actions to address this threat, Padagis strongly urges the Administration to utilize targeted trade

¹⁹ Though Padagis does not have access to the identification of each API supplier used in naloxone nasal products from other producers, it is Padagis's belief that little to none of the API used in these products is manufactured within the U.S.

remedies that allow domestic pharmaceutical manufacturers like Padagis to access fairly traded API and other pharmaceutical inputs from allies such as Israel and Europe.

As noted above, Padagis and other domestic producers of naloxone rely on imports of the API used to formulate naloxone, as well as the cartridges in which finished naloxone is distributed. To Padagis's knowledge, there is limited domestic capacity to manufacture either of those essential inputs for finished naloxone production or distribution. Accordingly, Padagis respectfully requests that the Administration implement trade actions that target pharmaceutical bad actors without harming domestic pharmaceutical manufacturers and their fair trade suppliers.

If tariffs on imports of finished pharmaceuticals, APIs, and other inputs are applied broadly, generic naloxone will become more expensive per dose. Given the budgetary constraints faced by many community and public health programs, every additional dollar spent purchasing naloxone may mean another life lost due to an opioid overdose—a death that may have been prevented but for lack of funding to purchase sufficient naloxone. Consequently, Padagis urges the Administration to consider exempting naloxone APIs and inputs like naloxone delivery cartridges from tariffs or other Section 232 trade action, at minimum until the earlier of (1) the Administration's determination that domestic production capacity for such ingredients is sufficient to meet the needs of domestic finished dosage naloxone producers or (2) the conclusion of the opioid crisis resulting in diminished need for finished dosage naloxone. Doing so will support the continued expansion of domestic naloxone production capabilities and capacity, while further incentivizing the establishment of naloxone API manufacturing in the U.S. insofar as nascent domestic producers will have the security of protectionary action upon ramp-up of production.

* * *

Padagis appreciates the Administration's efforts to solicit stakeholder feedback on the national security threats posed by certain imports of pharmaceutical goods. As a domestic producer of generic pharmaceutical products critical to combatting the opioid crisis—including generic naloxone nasal spray, the most effective, user-friendly, and immediate tool to prevent opioid-related overdose deaths—Padagis looks forward to working with the Administration to increase domestic production of these life-saving drugs and ensuring that domestic producers like Padagis have a continuous supply of fairly traded pharmaceutical inputs to support their domestic generic pharmaceutical manufacturing operations.

Sincerely,



Landon Clark
Senior Vice President & General Counsel
Padagis LLC