APOTEX
Global Health Company

May 6, 2025

U.S. Department of Commerce
Bureau of Industry and Security

Re: Docket No. 250414–0065
Rule Identification Number: XRIN 0694-XC120

Apotex Response to Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Apotex, a global health company and one of the world's leading generic pharmaceutical manufacturers, is pleased to respond to the U.S. Department of Commerce's Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.

EXECUTIVE SUMMARY

Apotex is aligned with the Trump Administration's goal to strengthen the resilience of the domestic pharmaceutical supply chain and improve access to affordable and innovative medicines and health products for all Americans. Apotex strongly supports the Administration's commitment to accelerating competition for high-cost prescription drugs, and its recent call for accelerating approval of generics, biosimilars and combination medications to enable greater access to lifesaving drugs for Americans.

Generic pharmaceutical products from Apotex and other manufacturers in Canada support these objectives. They are high quality, affordable, safe, secure, and essential to Americans' health and U.S. national security. Tens of millions of Americans rely on Apotex products to effectively and affordably manage their health. Apotex supplies more than 125 different product lines to the U.S. market, treating a wide range of health conditions. Apotex is the third largest U.S. supplier of generic oncology medicines.

Unfair trade practices by overseas governments put these benefits at risk. They create an uneven playing field and undermine the viability of the North American generic pharmaceutical industry. Generic drugmakers already face significant challenges competing against foreign companies, which are often able to offer lower cost drugs due to subsidies from their governments and less stringent environmental standards. Consequently, North American manufacturers will be unable to absorb the cost of any new tariffs, they will need to raise drug prices, and some may shutter plants and eliminate products altogether. Each of these outcomes will undermine public health and the overall resilience of the U.S. healthcare system by creating new drug shortages and exacerbating existing ones, as well as increasing the price of prescription drugs in the United States.

Further, as Canada was identified by the Department of Defense (DoD) as the most trusted partner to the U.S. in provision of pharmaceuticals and their inputs with the lowest level of security risk, second

only to the U.S. itself, any tariffs on generic pharmaceuticals from Canada will result in greater reliance on overseas drug companies, weakening U.S. national security.

Apotex recommends three critical actions to strengthen the U.S.'s pharmaceutical supply and help lower drug costs:

1. **Exempt USMCA compliant generic pharmaceutical imports from Canada from tariffs.** In the immediate term, doing so will continue to ensure availability of critical generic medications, as well as avoid drug shortages and higher costs for U.S. patients.
2. **Minimize national security risks by working with allies.** Work with Canada and other U.S. allies to better utilize and strengthen existing production capacity for generic pharmaceuticals and active pharmaceutical ingredients (API).
3. **Work with pharmaceutical companies to reshore production to North America.** Develop a strategic, long-term plan that considers the viewpoints of government, industry, and other stakeholders, that encourages North American API production.

These recommendations, if implemented, would encourage our industry to invest to reshore/nearshore manufacturing facilities, reducing dependence on prescription drugs from China and other foreign countries.

APOTEX IS A LEADING MANUFACTURER OF GENERIC MEDICINES

Apotex's global headquarters are in Toronto, Canada, with our U.S. headquarters in Weston, Florida. We are owned by SK Capital Partners, a U.S. private equity firm based in New York that manages several pharmaceutical manufacturing facilities across the U.S and Canada through its portfolio companies, including U.S.-based Noramco, an API manufacturer, and U.S.-based Woodstock Sterile Solutions.

With world class, large-volume manufacturing finished dosage and API facilities in North America, Apotex is extremely well-positioned to play a leading role in the U.S. effort to reduce dependence on and the concentration of prescription drugs from China and other overseas suppliers.

The U.S. enjoys the benefit of securing generic drugs from Canada, a close ally, which are under compliance with the United States-Mexico-Canada Trade Agreement (USMCA). Our manufacturing facilities in Toronto can produce up to 19 billion oral solid and specialty generic product doses annually. They include a Class 3 potent oral solid dose facility with a 200 million dose capacity and 75-80 million units of sterile and non-sterile liquids, along with a 10 billion dose packaging facility, an API manufacturing facility, and a large-scale warehousing and distribution facility.

Apotex products are delivered daily by truck from our manufacturing campus in Toronto to our U.S. distribution center in Plainfield, Indiana. Approximately 95% of the volume (5.5 billion doses) and prescriptions Apotex supplies annually to the U.S. market are manufactured at our high-quality sites in Toronto, guaranteeing a safe and secure supply for generic pharmaceutical products.

Apotex is consistently recognized by U.S. regulators, quality organizations, and customers for our high levels of operational excellence, ability to meet market demands, and help in alleviating drug shortages. Recent examples include the U.S. Pharmacopeia's (USP) Champion of Quality award for our industry-leading role in helping launch USP's Pharmaceutical Product Quality Testing Program, to be

announced on May 7, 2025, and our 2023 receipt of the U.S. Food and Drug Administration's (FDA) Drug Shortage Assistance Award for our work to alleviate a shortage of varenicline tablets.[1]

OVERSEAS PRODUCTION, ESPECIALLY FROM ASIA AND PARTICULARLY CHINA, HINDERS NORTH AMERICAN MANUFACTURING RESHORING

The current financial incentive for manufacturers to invest in new or existing U.S. or North American manufacturing facilities is very low. The increase in low-cost foreign products that today saturate the U.S. supply of generic pharmaceutical products – particularly antibiotics – has created conditions that prohibit a sustainable return on investment.

Apotex has direct experience in this respect. Due to the unsustainable economics of cephalosporins and penicillins fueled by hidden Chinese and Indian government subsidies for their own domestic manufacturers, along with other unfair trade practices, Apotex offshores production of these antibiotics to partners abroad. This allows us to meet reimbursement requirements for price and continue to make these critical medicines available in the U.S. market. Absent this approach, Apotex would have no choice but to exit the U.S. market within this product category.

While Apotex would prefer to transfer the production of these antibiotics to North America, it is not economically feasible due to the flood of lower priced products from overseas. Apotex manufactured penicillin in Toronto until 2019, and previously had Facility Establishment Identification (FEI) numbers from FDA. However, with aging equipment, increasing costs and decreasing demand, Apotex made the difficult decision to close the facility and transfer production overseas. With no possibility of economically sustainable production, the facility was demolished last year.

Had sufficient incentives been available, Apotex would have been willing to invest in the facility and ensure the availability of North American produced antibiotics. However, the inability to compete with overseas antibiotic manufacturers made any such investment unfeasible. [redacted]

TARIFFS WILL WEAKEN NATIONAL SECURITY, REDUCE DRUG SUPPLIES, AND MAKE DRUG PRICES LESS AFFORDABLE

Apotex shares the Administration's intent to enhance access to affordable and innovative medicines and health products for all Americans, and its goal to strengthen the resilience of the domestic pharmaceutical supply chain. We are committed to remaining a trusted partner for U.S. healthcare professionals and patients by prioritizing the continuity of supply and ensuring widespread access to high-quality medications for all.

While Apotex supports the effort to strengthen U.S. production, increasing tariffs on Canadian generic drug suppliers will compromise national security, decrease consumers' access to critical medication, and impose higher costs for healthcare systems and patients.

1 U.S. Food & Drug Administration, Drug Shortage Assistance Award to Apotex, April 4, 2023

Tariffs on Canadian suppliers will cause the U.S. to rely more on overseas lower cost imports – not less – weakening national security

Imposing tariffs on Canadian generic pharmaceutical imports will compromise U.S. national security readiness by impeding the effort to increase the ability to obtain essential generic medicines from secure and trusted sources with a common border. With Canadian manufacturers already struggling to compete with cheaper drugs from China and India, tariffs will further cause the price of Canadian generic drugs to rise, and cause the U.S. to import more drugs from foreign manufacturers outside of North America.

Currently, the U.S. does not have the manufacturing capabilities to produce enough API and Key Starting Material (KSM) to meet its drug supply needs. According to an April 17, 2025, published report from USP, only 12% of the API for U.S. generic drugs is sourced domestically (likely driven by Schedule 2 drugs requiring U.S. production), while India provides 35%, the European Union provides 18%, and China provides 8%.[2] China dominates the world supply of KSM.[3]

Further, China supplies 90% of the raw materials for antibiotics[4] and 40% to 50%[5] of the KSMs for API. India, which is also heavily reliant on China for KSM, supplies 35%[6] of the API for generic medicines in the U.S. and 47% of the U.S.'s generic prescriptions.[7] The API Innovation Center documented that "more than four out of five of the top 100 generic medicines consumed in the U.S. have no U.S. source of their API."[8]

With generic pharmaceuticals accounting for 90% of all prescriptions filled in the U.S., such a high level of dependency on just two countries for such a large swath of the market leaves U.S. drug supplies highly susceptible to major disruptions caused by triggering events – such as geopolitical crises, public health emergencies and natural disasters.

Meanwhile, imposing tariffs on Canadian generic drugs would raise the cost of pharmaceutical products manufactured by a close ally and further drive the U.S. healthcare system to rely on lower cost imports from overseas countries that do not share the same national security objectives as the United States.

A November 2023 Pharmaceutical Supply Risks report from the DoD underscored the national security risk resulting from overreliance on China and India, noting that the DoD currently "has a high dependence on foreign material and trade agreements to maintain pharmaceutical capabilities."[9] The report further found that 54% of the drugs reviewed are from API sources that the DoD considers "high" or "very high" risk, TAA non-compliant, or unknown.[10]

Ensuring the safety of the U.S. pharmaceutical supply – particularly for the military, but also for the public – is a central goal of the Administration's efforts to strengthen domestic manufacturing and

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2 Marta Wosinska and Stephen Colvill, Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union, *Quality Matters*, U.S. Pharmacopeia, April 17, 2025

3 DrugPatentWatch, Sourcing the Key Starting Materials (KSMs) for pharmaceutical Active Pharmaceutical Ingredients (APIs), March 28, 2025; Victor Suarez, Statement to U.S. Senate Committee on Armed Services Subcommittee on Personnel, April 17, 2024

4 Drew Endy, Strange Competition: A Statement of Evidence Written in 2025, Bio-Strategies & Leadership, Hoover Institution, Stanford University, February 6, 2025

5 DrugPatentWatch, Sourcing the Key Starting Materials; Suarez, Statement to U.S. Senate Committee

6 IQVIA, U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System, IQVIA Institute for Human Data Science, April 30, 2024

7 Wosinska and Colvill, Over half of the active pharmaceutical ingredients (API)

8 The API Innovation Center, Building a Resilient Domestic Drug Supply Chain: The Path to National Security, March 25, 2025

9 U.S. Department of Defense, Report on the Department of Defense Pharmaceutical Supply Chain Risks, Office of the Under Secretary of Defense for Acquisition and Sustainment, November 2023, p. 4

10 Ibid., p. 4

supply chain resiliency. Accomplishing those goals requires manufacturing infrastructure, as well as the adoption of policies to incentivize and fund the purchase of products manufactured in North America.

Apotex believes that relying on allies both in the near and long term to meet the domestic pharmaceutical supply chain security objectives must be core to the U.S. tariff strategy from the beginning. Doing so will ensure the transition will occur more securely and quickly than seeking to source products only from sources in the U.S., which does not have the capacity to meet demand.

In a May 2024 Pharma Manufacturing article titled *Mining pharma's reshoring rush*, health care economist Marta Wosinksa said: "There's an opportunity for the government to be much more strategic about this. Think about which supply chains, which players, and how to think holistically about not only infrastructure but follow on. If it's not systemic, the government can easily end up spending a bunch of money and accomplishing very little."[11]

To that end, in a February 2024 American Affairs article, Foreign Government Subsidies and FDA Regulatory Failures Are Causing Drug Shortages in the United States, Here's How to Fix It, Nick Iacovella and Jon Toomey recommend how the U.S. government can incentivize and facilitate the purchase of domestically manufactured products through federal programs and agencies including Medicare, Medicaid, the Children's Health Insurance Program, the Department of Veterans Affairs, the Department of Health and Human Services Strategic National Stockpile, and the Department of Defense's Defense Health Agency:[12]

> According to data from the Centers for Medicare and Medicaid (CMS), more than sixty-five million Americans are enrolled in Medicare, and nearly 90 million Americans are enrolled in Medicaid and Children's Health Insurance Program (CHIP)," they note. "This is a massive customer base that the US government should leverage to realign federal government health care programs to support domestic manufacturers.
>
> At a minimum, the federal government should provide priority to domestic manufacturers when federal agencies are procuring drugs directly. The Department of Veterans Affairs, the Department of Health and Human Services' Strategic National Stockpile, and the Department of Defense's Defense Health Agency should all prioritize signing long term contracts with domestic manufacturers to give them the confidence of knowing that they will have a buyer for multiple years."

Apotex agrees with this approach, and believes it must be a part of a holistic plan to ensure that adequate demand will be in place to sustain reshored North American generic pharmaceutical manufacturing in perpetuity. **Any such incentive programs should include preferential purchasing incentives for products from allied countries, which Congress last year directed the DoD to examine for its pharmaceutical purchases.**[13]

In their submission to this docket, the Association for Accessible Medicines (AAM) proposes a means by which Medicare can support this objective, utilizing a condition of participation requiring providers to prioritize and health plans to cover, generics and biosimilars from resilient suppliers, which are either: (1) Suppliers that finish manufacturing in the United States, its Free Trade Agreement partners, or its World Trade Organization Pharmaceutical Agreement Partners (including any future partners of those

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11 Karen Langhauser, Mining pharma's reshoring rush, *Pharma Manufacturing*, May 29, 2024

12 Nick Iacovella and Jon Toomey, Foreign Government Subsidies and FDA Regulatory Failures Are Causing Drug Shortages in the United States, Here's How to Fix It, *American Affairs*, February 20, 2024

13 Joint Explanatory Statement to FY 2025 National Defense Authorization Act (PL 118-159), Requirement to procure domestically produced generic drugs, January 2025

agreements); or (2) Resilient suppliers with a significant domestic presence through predictable long-term, value-based contracts. AAM also recommends that long-term, fixed-volume contracts should be prioritized for all federal procurements with resilient suppliers. Apotex supports these proposals and the other actions that AAM recommends the Administration take to strengthen the resiliency of the U.S. pharmaceutical supply chain.

Tariffs on Canadian generic drug suppliers will lead to shortages in the U.S.

Proposed tariffs on Canadian generic drug imports will exacerbate existing drug shortages, cause new ones, and lead to ongoing discontinuations of products. Given existing global price pressures, tariffs on Canadian generic drug manufacturers will cut into already razor-thin margins for companies like ours and force manufacturers to evaluate strategic options. For some companies, the added cost of tariffs will reduce the economic viability of products and prompt them to discontinue production – quickly reducing the supply of generic pharmaceuticals.

At the same time, demand for these drugs will continue to grow. One set of drugs that is particularly vulnerable to discontinuation: generic sterile injectables, which are used to treat life-threatening diseases such as cancer and manage chronic conditions such as diabetes and autoimmune disorders, and are already prone to recurrent shortages.

Any reduction in supply will drive drug prices higher for Americans, leading to hoarding and causing more shortages. This will result in fewer medicines for those in need, declining health outcomes across the population, inflationary pressures from expensive drugs, and economic harm. Collectively, these effects will further undermine trust in the U.S. healthcare system.

A recent study published in the Journal of the American Medical Association found that 79% of the drugs imported into the U.S. from Canada were generics. Furthermore, among 3,099 drugs, 52 depended on Canada for at least 50% of the supply, including 28 with no alternative suppliers.[14] Of these 52 drugs, 23 were rated as clinically significant and 27 have a history of shortages.[15]

The profit margin on generic pharmaceutical products is extremely thin, particularly in markets that have been genericized for a long period of time. As such, the lack of sustainable margin on many of these products is a driving factor in causing drug shortages, especially in sterile injectables, as noted by the FDA.[16]

In addition to the likelihood of price increases, there are other market dynamics that will create U.S. drug shortages and discontinuances of certain critical medicines because the ability to increase the price of products is limited. Such examples include the 340B program and Medicaid CPI penalties. Of the products that Apotex manufactures, 168 National Drug Codes are at risk for deletion if a tariff is levied. These products include treatments for infectious diseases, oncology, heart attack and stroke prevention and treatment, and non-opioid pain management.

Tariffs on Canadian suppliers will cause price increases and compromise patient care by accelerating the pharmacy closure crisis

14 Mina Tadrous, et al., Trade Tariffs on Canadian Pharmaceuticals—Implications for US Drug Supply and Costs, *Journal of the American Medical Association*, March 31, 2025

15 Ibid.

16 FDA, Drug Shortages: Root Causes and Potential Solutions, February 2, 2020

Tariffs will raise prices across a broad range of products. More expensive drug prices and more expensive medical insurance both work against the Administration's goal of lowering the costs of prescription drugs.[17]

As noted above, generic drugs are sold just above the cost of production, and there is very little room for manufacturers to absorb the added cost of the tariffs. Should manufacturers not outright discontinue products due to the added costs, leaders in the pharmaceutical industry have said, "pricing increases will be passed on to payers and ultimately to patients," which is not "in the interest of patients or health care generally in the U.S."[18]

President Trump has made clear that his goal is to deliver lower prescription drug prices to Americans. In the Executive Order he signed on April 15, 2025, he noted that during his first term, his administration had encouraged "the development of generic and biosimilar alternatives to higher cost brand name prescription drugs and biologics" to "increase access to affordable medicines."[19] Tariffs will instead effectively force manufacturers to raise the cost of products they continue to offer in the U.S. market if they do not exit such products altogether.

Imposing tariffs on Canadian generic drug suppliers will also reduce patient access to medicines by exacerbating the ongoing pharmacy closures. Since 2019, more than 7,000 independent and major chain pharmacies across the U.S. have closed.

One of the key drivers of the pharmacy closure crisis is inadequate reimbursement from payers, which forces pharmacies to choose between dispensing products at a loss or removing products altogether from pharmacy shelves. Price increases that generic manufacturers will implement to offset the costs of tariffs for products that remain in the market will create an immediate disparity between acquisition costs and pharmacy reimbursement.

The disconnect from price increase to reimbursement increase can be between 6-18 months, straining pharmacy cash flows and forcing pharmacies to choose between losing money on each dispensed drug or not serving patients. Further, the accelerated financial shock will accelerate pharmacy closure rates, further compromising the quality of patient care that is already eroding in communities with healthcare access issues, such as the rural United States.

THE ADMINISTRATION CAN STRENGTHEN SUPPLY AND LOWER DRUG COSTS

Apotex recommends three critical actions to strengthen the U.S.'s pharmaceutical supply and help lower drug costs:

1. **Exempt generic pharmaceutical imports from Canada from tariffs.** In the immediate term, ensure availability of critical generic medications, as well as avoid shortages and higher costs for U.S. patients.
2. **Minimize national security risks.** Work with U.S. allies (including Canada) to reinforce the production capacity and availability of generic pharmaceuticals and API from appropriate supply chains.
3. **Work with pharmaceutical companies to reshore production to North America**. Develop a strategic, long-term plan that considers the viewpoints of government, industry, and other

17 The API Innovation Center, Building a Resilient Domestic Drug Supply Chain

18 Paula Doenecke and Ashleigh Furlong, US Tariffs Will Raise Prices for US Patients, Sandoz CEO Says, *Bloomberg*, March 5, 2025

19 Donald Trump, Lowering Drug Prices By Once Again Putting Americans First, Executive Orders, Presidential Actions, The White House, April 15, 2025

stakeholders, and that would encourage North American API production, which would enable companies to make long-term investments in the United States.

1. Exempt Apotex and other Canadian generic drug manufacturers from tariffs, which is critical to maintaining the security of the U.S. drug supply chain

While Apotex supports the onshoring of manufacturing facilities to North America, it will take years and billions of dollars to do so. To achieve the goal of strengthening U.S. pharmaceutical supply chain resiliency more quickly and securely, the U.S. must rely on close allies, particularly Canada.

A May 2022 report from the National Forum to Secure America's Supply Chain for Essential Medicines recommended pursuing such a path, noting that it is critical to "develop a complete essential medicine supply chain and manufacturing model – from precursor materials to finished products – that more fully leverages both on- and ally-shored resources and suppliers."[20]

The report further noted that a multi-year strategic plan would be needed to accomplish this goal to avoid unintended consequences. This plan would first focus on essential medicines, working to obtain them from allies while investments in manufacturing could be made. The plan would then expand to a larger group of drugs. The report underscored that the government would need to prioritize a list of medications and develop a plan to avoid shortages during the process. Any approach that is not carefully planned could result in life-threatening shortages of medications for the American people.

A September 2024 article in Chemical & Engineering News also concluded that onshoring manufacturing would take years, and much larger government support than has been brought to bear to date would be required.[21]

Apotex shares this view, and believes this model will require a stable, long-term partnership between government, regulators, and industry that makes private sector investment financially viable and provides novel incentives to unlock American ingenuity, all in the service of U.S. patients. We would readily embrace the opportunity to meet with U.S. and Canadian governments to find a solution that would benefit the U.S. and North America more broadly, given Apotex's unique assets that have served U.S. patients with high quality and accessible products for close to 50 years.

Apotex has demonstrated its commitment and ability to provide large-scale manufacturing to support the U.S. market and avert drug shortages, which is a core element of our company's mission. For example, at one period not long after the onset of generic competition to Pfizer's Lipitor (atorvastatin), Apotex supplied 70% to 80% of atorvastatin demand in the U.S. due to issues faced by other suppliers. This amounted to billions of dosages and ensured patients continued to have a supply of the best-selling and most widely used cholesterol drug of all time.

Apotex has significant experience supplying a multitude of dosage forms covering a wide range of therapeutic areas in a consistent and high-quality manner, which is essential in helping to reduce drug shortages and to ensuring access to medication for patients. U.S. regulators, customers, and quality organizations have consistently recognized Apotex for its high levels of quality, operational excellence, and ability to meet market demands and to help alleviate drug shortages.

20 Advanced Regenerative Manufacturing Institute (ARMI), Essential Medicines Supply Chain and Manufacturing Resilience Assessment, May 23, 2022

21 Aayushi Pratap, The unfulfilled dream of drug reshoring, *c&en*, September 28, 2024

Apotex currently markets eight (8) products on USP's list of the 100 drugs most vulnerable to shortages in the U.S. due to supply chain issues.[22] Further, Apotex currently markets four (4) products in the U.S. on FDA's drug shortage list, helping ensure availability of the drugs for patients.

In 2023, FDA recognized Apotex with the Drug Shortage Assistance Award for working with the agency to mitigate a shortage of varenicline tablets in the U.S. following a recall of Pfizer's Chantix, which was prior to the onset of generic competition.[23] In that case, FDA exercised its waiver authority to allow Apotex to import the product made for the Canadian market into the U.S. and alleviate the varenicline tablet shortage, illustrating the critical importance of Canadian manufacturers during a supply disruption.

To ensure Apotex can continue to play a significant role in helping prevent and mitigate drug shortages in the U.S., Apotex recommends that the Administration continue to exempt USMCA compliant products from any tariffs on generic pharmaceuticals. Doing so would simply be a continuation of an existing policy and would not require the Administration to act.

2. Minimize national security risks by working with U.S. allies to boost production capacity and availability of generic pharmaceuticals and API

Canada's pharmaceutical industry offers the U.S. the most secure option for unimpeded access to high-quality generic medicines. Over the last few years, many legislative and executive branch actions have underscored the critical role that Canadian generic pharmaceutical manufacturers can play in strengthening domestic supply chain resilience and meeting U.S. national security goals.

In the last Congress, for example, the Senate's version of the Fiscal Year 2025 National Defense Authorization Act (NDAA) included a provision that required DoD to purchase defense-relevant domestically manufactured generic drugs with API and KSM sourced domestically or from countries designated under the Trade Agreements Act of 1979.[24] The language included a waiver allowing DoD to acquire products outside the requirements when the identified drugs could not be secured in sufficient quantities to meet military needs or when needed at U.S. market prices.

In its score of the legislation, the Congressional Budget Office (CBO) identified the Defense Production Act (DPA) as a potential mechanism for effectuating the domestic generic drug purchasing requirement.[25] CBO noted that "The President declared essential medicines are critical to national defense and therefore eligible for special procurement authorities under the DPA. Among those authorities are the use of purchase commitments, grants, and other support."[26] Since 1992, Canada has been considered a domestic U.S. source under the DPA.

The final enacted version of the FY2025 NDAA [PL 118-159] did not include the domestic purchasing requirement. However, in lieu of that provision, the bill required DoD to "develop a plan to improve access by members of the Armed Services to safe, high quality pharmaceutical products, and eliminate or mitigate risks in the pharmaceutical supply chain of the Department of Defense."[27]

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22 USP, USP publishes Vulnerable Medicines List to inform efforts to reduce risk and increase supply chain reliability for patients, U.S. Pharmacopeia, March 4, 2025

23 Apotex, Apotex Receives FDA's Drug Shortage Assistance Award, April 19, 2023

24 118th Congress, S. 4638: Fiscal Year 2025 National Defense Authorization Act (NDAA), The United States Senate, July 8, 2024

25 Congressional Budget Office, Cost Estimate, S. 4638, National Defense Authorization Act for Fiscal Year 2025, July 8, 2024

26 Ibid.

27 118th Congress, H.R. 5009 - To authorize appropriations for fiscal year 2025 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes., The United States House of Representatives, December 23, 2024

In the joint explanatory statement accompanying the bill, the House and Senate Armed Services committees directed DoD to provide a briefing, not later than May 1, 2025, on several issues regarding the supply chains for pharmaceutical products necessary for warfighter readiness, including "the feasibility of establishing an acquisition preference to encourage domestic or **allied sourcing** of pharmaceutical products, to include what the framework could look like."[28] [emphasis added]

In a November 2023 "Report on the Department of Defense Pharmaceutical Supply Chain Risks" required by the FY2023 NDAA [PL 117-263], the Defense Logistics Agency (DLA) found that the U.S. has several vulnerabilities in its supply chain and used the result of its assessment to develop a Hierarchy of Drug Security.[29]

The report stated that, "Given no other limitations, DLA's preference for all drugs, APIs, and key ingredients would come from the following sources in the priority/order presented:[30]

1. U.S. domestic sources
2. Sources in the Americas (Canada and Mexico)
3. TAA-compliant sources outside the Americas
4. Non-TAA compliant sources except for China
5. China

The U.S. government declared that Canada has the lowest level of security risk, second only to the U.S. itself.

As it relates to the quality of Apotex's generic pharmaceutical products, manufacturing facilities in Canada are readily accessible to FDA and its inspectors. In the last two years, Apotex has had, among others, six (6) successful inspections by the FDA and 15 by Health Canada, demonstrating our ongoing commitment to providing high quality and safe products to U.S. patients.

In comparison, it is well documented that inspecting facilities in countries such as China and India has long been challenging for Western government agencies and continues to be a challenge for the FDA, resulting in a significantly higher risk of these imports not meeting FDA quality and safety standards.

Indeed, just one month ago, U.S. Senator Rick Scott, the chairman of the Senate Aging Committee, wrote to FDA Commissioner Martin Makary in the latest example of long-running congressional concern about this matter.

> "The Food and Drug Administration (FDA) is widely considered to be the global standard for drug quality, however, due to discrepancies with domestic and foreign inspections there are concerns with quality disparities between domestic and foreign drugs. **We are especially concerned with the quality of drugs coming from foreign countries like China and India** … Our nation's current reliance on foreign made drugs and pharmaceutical ingredients necessitates thorough quality assurance processes and routine inspections to ensure that American standards are being met for all products entering our country. Unfortunately, this is not the case for a number of products made by Chinese and Indian manufacturers. **Drug and API manufacturers in China and India have received the most warning letters for violations** … Incidents involving poor drug quality have resulted in injury and even death, such

28 Ibid.

29 U.S. Department of Defense, Report on the Department of Defense Pharmaceutical Supply Chain Risks, Office of the Under Secretary of Defense for Acquisition and Sustainment, November 2023

30 Ibid.

> as three tragic deaths that occurred due to contaminated eye drops from an Indian manufacturer in 2023."[31] [emphasis added]

Leaders of the House Energy and Commerce Committee conveyed the same concerns two years ago in a July 18, 2023, letter to then-FDA Commissioner Robert Califf, writing:

> "[W]e are worried that the United States is overly reliant on sourcing from foreign manufacturers with a demonstrated pattern of repeatedly violating FDA safety regulations. The Committee is not alone in voicing concerns. The Department of Defense recently announced that it will begin independently testing the quality and safety of imported generic drugs."[32]

Apotex's support for the type of independent testing program for generic pharmaceutical quality DoD is carrying out underscores the critical importance of maintaining unimpeded access to the U.S. market for Canadian generic pharmaceuticals. For example, last year, Apotex partnered with USP to launch the Pharmaceutical Product Quality Testing Program (PPQT), a pilot program to test the quality of generic pharmaceuticals in the United States.

In late 2024 through early 2025, USP tested the quality of 10 Apotex oral solid dose products it secured directly from the market. Apotex was the first participant in the program, supplying supporting data and documentation to USP. The results, which verified the quality of Apotex products based on compendial monograph specifications and FDA-approved drug applications, will be published on the USP website and shared with Apotex customers. For our pioneering leadership in this effort, USP recognized Apotex with its Champion of Quality Award.

As our leadership in assuring the quality of medicines we supply to the U.S. market demonstrates, generic pharmaceutical imports from Apotex and other Canadian manufacturers provide the quality and reliability sought by the Administration to mitigate supply chain vulnerabilities and address national security concerns across North America.

3. Work with pharmaceutical companies to reshore production to North America

Unfair trade practices undercut North American competitiveness. The causes and impact of China and India's command of the generic pharmaceutical and raw material markets have been extensively documented by a wide variety of sources over the last decade. These sources include numerous U.S. executive branch and congressional studies, and assessments by academia, think tanks, and industry.

The causes and impact of the U.S.'s dependence are clear. China and India benefit from a range of cost advantages that allow them to sell products at extremely low prices that U.S. domestic manufacturers cannot match.

As one expert U.S. source, the API Innovation Center, stated in its March 25, 2025 publication titled Building a Resilient Domestic Drug Supply Chain: The Path to National Health Security:

> "Massive subsidies by foreign governments, lower production costs and lax government regulations have driven pharmaceutical companies to offshore API production and manufacturing."[33]

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31 United States Senate Special Committee on Aging, Chairman Scott, Sens. Moody and Justice Ask FDA to Prioritize Foreign & Domestic Drug Quality and Protect Seniors, The United States Senate, Press Release, April 1, 2025

32 United States House of Representatives Committee on Energy and Commerce, Letter to FDA Commissioner Robert M. Califf, The United States House of Representatives, July 18, 2023

33 The API Innovation Center, Building a Resilient Domestic Drug Supply Chain

Separately, the American Affairs journal published an in-depth analysis of Indian government subsidies for its pharmaceutical industry in a report titled: Foreign Government Subsidies and FDA Regulatory Failures Are Causing Drug Shortages in the United States: Here's How to Fix It.[34]

These factors described in these reports have created an uneven playing field in the U.S. for domestic, Canadian, and other Western generic pharmaceutical manufacturers because they operate in locations with higher production costs and stricter quality and environmental frameworks.

For example, Apotex manufactures and supplies to the U.S. market the drug olanzapine, one of the 227 products on the essential medicines list prepared by the FDA in response to President Trump's August 6, 2020, Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States (EO 13944).[35] There are at least 11 other essential medicines on the list that could be produced at an Apotex API site in Ontario, Canada.

Each of these 11 APIs has been produced as a generic drug for several years. As such, there are many global API manufacturers producing them at very low prices. Due to unfair trade practices, foreign countries such as China can bring these APIs to market at a much lower price than what Apotex or any U.S. manufacturer can offer. While Apotex is willing to invest in substantial research and development to generate the API processes and secure the necessary commercial and regulatory approvals, very low-cost foreign competition diminishes the business case for this investment.

Without incentivizing investment in North American manufacturing, customers will continue to purchase less expensive alternatives from countries such as China and India. Efforts already underway provide valuable insight into the time and approach that will be needed to accomplish the goal.

In its analysis of the proposal in the Senate version of the FY 2025 NDAA that would have required DoD to purchase domestically manufactured generic drugs, CBO found that for the 25% of DoD's purchases that are critical to national security objectives, it would take five (5) years before the Department of Defense could begin to purchase more pharmaceuticals from domestic sources, and that the cost of those products would be double the cost of products sourced from non-TAA compliant countries, such as China and India.

The report concluded that "by 2034, CBO estimates direct spending would increase $300 million annually, and the total increase in direct spending would be about $1 billion over the phase-in period." That figure only accounts for DoD purchases that are critical to national security objectives and does not include other drugs purchased by the military, civilians on private insurance, or through government programs such as Medicare and Medicaid.

Dependence on foreign suppliers manipulating the market with subsidies poses a threat to U.S. national security readiness and U.S. public health – as has been concluded repeatedly by the U.S. government, patient advocacy organizations and other analysts.

Continued reliance on low-cost imports from China and India in particular is a risk to North America at large. With Canada closely aligned with the U.S., the Administration should evaluate how these dynamics are impacting security across the continent.

34 Iacovella and Toomey, Foreign Government Subsidies and FDA Regulatory Failures

35 Donald Trump, Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, Executive Orders, Presidential Actions, The White House, August 6, 2020

CONCLUSION

In conclusion, Apotex respectfully requests that the U.S. Department of Commerce exempt Canadian generic pharmaceutical imports from any tariffs imposed under the Section 232 National Security Investigation. Apotex is committed to supporting the resilience of the U.S. pharmaceutical supply chain and ensuring access to high-quality, affordable medications for all Americans.

Tariffs on Canadian generic pharmaceuticals will undermine U.S. national security, exacerbate drug shortages, and increase healthcare costs, ultimately harming the health and wellbeing of the American people. By partnering with trusted allies like Canada and incentivizing domestic API production in North America, the U.S. can achieve its goals of strengthening supply chain resilience and reducing dependence on foreign suppliers.

We appreciate the opportunity to provide our perspective and recommendations on this critical issue. Apotex remains dedicated to being a reliable partner in the U.S. healthcare system and looks forward to working collaboratively with the Administration to enhance the security and affordability of pharmaceutical products for all Americans.

REQUEST FOR CONFIDENTIAL TREATMENT

Pursuant to 5 U.S.C. § 552(b)(4), Apotex respectively requests confidential treatment of bracketed business confidential information in the attached submission. We certify that the information contained in brackets, or is otherwise identified as confidential, is confidential in its entirety. The information for which business confidential treatment is requested pertains to sensitive commercial information of Apotex that would not customarily be released to the public. Disclosure of this information would cause substantial harm to Apotex's competitive and commercial positions or limit our ability to provide the Department with similar information as part of this and future investigations.

Sincerely,

Christine Baeder

Christine Baeder
President, Apotex Corp.

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