abbvie

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Stephen Astle
Director, Defense Industrial Base Division
Bureau of Industry and Security
Office of Strategic Industries and Economic Security
U.S. Department of Commerce
1401 Constitution Avenue, NW
Room 3876
Washington, D.C. 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Director Astle:

On behalf of AbbVie Inc. ("AbbVie"),[1] we appreciate the opportunity to comment on the investigation of imports of pharmaceuticals and pharmaceutical ingredients initiated under section 232 of the Trade Expansion Act of 1962, as amended (the "Section 232 Investigation").[2] AbbVie is a U.S. company committed to discovering and delivering transformational pharmaceutical and biopharmaceutical medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care.[3] Innovation is the lifeblood of our company—our investments in U.S. research and development ("R&D") reflect our commitment to innovation in

[1] On October 19, 2011, Abbott Laboratories announced a plan to separate into two publicly traded companies. As part of this effort, Abbot spun off its research-based pharmaceutical manufacturer division. That spin-off company, named AbbVie, was formed in April 2012, and the separation was fully effective January 1, 2013. AbbVie is listed on the New York Stock Exchange under ticker symbol ABBV. Abbott Laboratories continues to exist as a separate company that sells medical devices, diagnostics, branded generic medicines, and nutritional products. It is listed on the New York Stock Exchange under ticker symbol ABT.

[2] 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).

[3] Biopharmaceuticals are drugs produced from biological sources, such as living cells, tissues, or microorganism. Pharmaceutical drugs, on the other hand, are typically synthesized from chemicals. U.S. International Trade Administration, *Pharmaceuticals and Biopharmaceuticals*, available at https://www.trade.gov/pharmaceuticals-and-biopharmaceuticals.

this country across a wide array of pharmaceuticals and disease states. Since AbbVie became an independent company in 2013, we have invested more than *$63 billion* in research to discover, develop, and deliver new medicines to patients. Over 90 percent of our employees involved in discovery research are located in the United States.

AbbVie supports the Trump Administration's objectives of revitalizing and expanding U.S. pharmaceutical production. As described in more detail below, AbbVie supports strengthening and expanding incentives to support a U.S.-driven pharmaceutical market—from early innovation, through manufacturing and supply. As part of this effort, AbbVie recently announced our plan to invest $10 billion in the United States over the next 10 years, with plans to add four new manufacturing plants to our network, expanding our production for active pharmaceutical ingredient ("API"), drug product, peptides, and devices in the United States.[4]

Section 232 provides that if the President concurs with the finding of the Secretary of Commerce ("Secretary") that an article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, then the President shall determine the nature and duration of the action that must be taken to adjust the imports of the article and its derivatives so that such imports will not threaten to impair the national security.[5] In making any such determination, both the Secretary and the President should have practical, up-to-date information on what measures will lead to a stronger U.S. pharmaceutical industry—and thereby support our national security. The Administration should also be aware of what type of measures would undermine domestic production and thereby weaken our national security. We address both categories below.

As shown in this submission, the following policies can strengthen U.S. national security by ensuring that the United States continues to lead the world in pharmaceutical innovation. These policies would also have the practical effect of building a stronger domestic drug industry and thereby adjusting import volumes[6]:

- First, the Administration should tailor any proposed measures to account for the necessary and critical time needed to bring domestic pharmaceutical manufacturing online. Failure to adopt this principle could lead to supply disruptions and severe harm to American patients.

- Second, the Administration should support U.S. tax policies that encourage domestic pharmaceutical manufacturing, the domestic labor force, and other domestic investments,

[4] *See* AbbVie, Q1 2025 Earnings Call Transcript (Apr. 25, 2025), available at https://www.msn.com/en-us/money/companies/abbvie-inc-nyse-abbv-q1-2025-earnings-call-transcript/ar-AA1DFfYk?ocid=finance-verthp-feeds ("Q1 Earnings Call Transcript").

[5] *See* 19 U.S.C. § 1862(c)(1)(A)(ii).

[6] Section 232 plainly intends for the Administration to consider policies that could strengthen domestic production as part of its overall approach to adjusting imports. *See* 19 U.S.C. § 1862(d) (providing that the Secretary and the President shall give consideration to the requirements of growth of domestic industries and such supplies and services including "the investment, exploration, and development necessary to assure such growth").

and that ensure a level playing field for companies like AbbVie that are headquartered in the United States. Such policies should create incentives for innovative manufacturing and other systems involved in the research, development, and manufacturing of pharmaceuticals, and should remove disincentives that discourage innovation.

- Third, the Administration should take a careful and targeted approach to imposing any additional measures to adjust imports. Any such measures should be tailored in a manner consistent with Section 232 national security concerns and should consider differences in market factors and national security concerns for generic and biosimilar products versus innovator products.

Taken as a whole, our comments provide a clear and practical path to increased domestic production, while avoiding measures that could disrupt domestic supply and otherwise undermine patient care.

I. AbbVie Has a Deep Commitment to U.S. Production of Innovative Pharmaceuticals

Twelve years ago, AbbVie was spun off from Abbott Laboratories, which was founded in Illinois in 1888. Today, AbbVie is a leading U.S.-based pharmaceutical company. AbbVie represents a long tradition of investing in U.S. pharmaceuticals and protecting U.S. national security.[7] AbbVie's commitment to the United States was further demonstrated when it bought Allergan plc ("Allergan") in 2020. AbbVie's acquisition of Allergan, then an Irish-headquartered company, brought the worldwide base of Allergan's profits back into the U.S. taxing regime.[8]

With a presence in all 50 states and Puerto Rico, AbbVie employs 28,000 employees in the United States, with a total impact on employment estimated to be nearly five times that amount through direct and indirect business activity.[9] AbbVie employs more than 6,000 American workers in U.S. manufacturing of pharmaceutical and biopharmaceutical products.[10] AbbVie also continues to invest and increase our footprint in the United States, with $10 billion dollars in planned U.S. capital investment and four additional U.S. plants in the next decade.[11]

[7] Abbott, *Our Heritage*, available at https://www.abbott.com/about-abbott/our-heritage.html. For example, in 1916, Abbott produced its first synthetic medicine, Chlorazene, a breakthrough antiseptic developed by British chemist Dr. Henry Dakin to treat wounded soldiers in World War I. Likewise, in 1942, Abbott joined a consortium of pharmaceutical makers, at the behest of the U.S. Government, to ramp up production of penicillin for wartime use. The consortium increased U.S. production more than 20,000 percent. *Id.*

[8] *See* Q1 Earnings Call Transcript.

[9] Q1 2025 Earnings Call Transcript; *see* PhRMA and TEConomy Partners, LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* (May 2024), available at https://cdn.aglty.io/phrma/global/blog/import/pdfs/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf, at 20.

[10] Q1 Earnings Call Transcript.

[11] *Id.*

As part of AbbVie's commitment, we focus on investments that provide a reliable and secure supply chain, ensuring availability of medicines for patients in the United States. AbbVie continues working to maximize use of U.S. source materials to ensure continuous availability of our medicines for American patients.

II. Pharmaceutical Manufacturing Production Process

As shown above, AbbVie shares the Administration's concerns about having a strong and successful pharmaceutical industry in the United States. Indeed, AbbVie is aligned with the Administration's goal of increasing U.S. manufacturing of pharmaceutical products. As a practical matter, however, achieving this goal will require policies that account for the complexity of this industry. To provide the Administration with more information on this vital topic, we provide below a brief discussion of pharmaceutical manufacturing, with a focus on the timeline, process, and regulatory requirements involved in building a manufacturing facility that can be approved by the Food and Drug Administration ("FDA"). We also discuss the necessary timeline to ramp up production at such a facility.

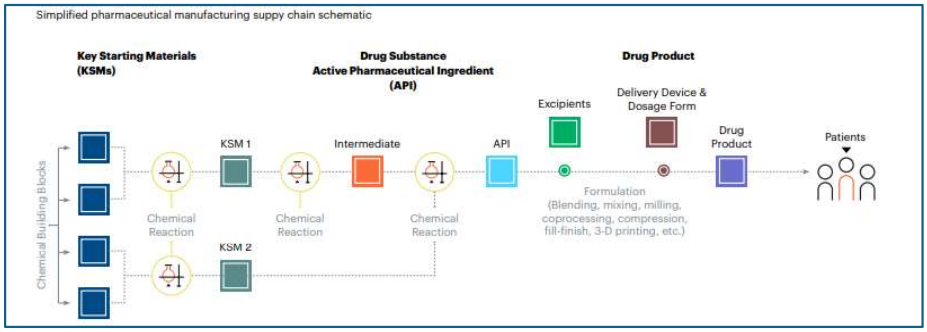
A. Pharmaceutical Manufacturing is Complex and Highly Regulated

All drug and biological products regulated by FDA must establish manufacturing and controls that ensure safety and effectiveness from the original starting material of a product, through production of the API and any drug substance intermediates, to the drug product in its finished dosage form.[12] Furthermore, drug production must then be scaled up for commercial production to satisfy patient demand.[13] The following figure represents a high-level schematic of pharmaceutical manufacturing (which is separate from biopharmaceutical manufacturing that requires different, additional steps and complexity).[14]

[12] *See, e.g.,* 21 U.S.C §§ 351, 355, 356a; *see also* 21 C.F.R. Parts 210, 211 and 600-680.

[13] PhRMA, *Biopharmaceutical Manufacturing*, available at https://phrma.org/policy-issues/research-development/manufacturing-supplychain#:~:text=Setting%20up%20the%20manufacturing%20capacity,comply%20with%20various%20regulatory%20requirements.

[14] USP, USP Annual Drug Shortages Report: Economic factors underpin 2023 shortages (June 2024), available at https://www.usp.org/supply-chain/drug-shortages, at 11. Please note that excipients are ingredients in medications other than the API.



The specific steps in this process will vary for different types of drug and biological products. However, in all cases, each step must be robustly validated and verified as complying with current good manufacturing practices and other regulatory requirements.[15] Each step requires strict operational procedures, organizational structures, and adherence to quality standards.[16] In addition, each step requires highly specialized equipment, personnel, training, and facilities. FDA will approve a drug or biological product *only* if the manufacturer of that product adequately demonstrates control over an established, consistent manufacturing process. Furthermore, this approval will typically require a pre-approval or pre-license inspection.[17] At each step during this process, both the drug producer and the regulators at FDA must comply with detailed rules and regulations under U.S. law.

Each finished drug product has a unique manufacturing process and formulation. The manufacturing process will be tailored to the specific finished product and range in difficulty, with biologic drugs being some of the more difficult and complex drugs to make.[18] Drug products may come in solid oral dosage forms, sterile injectable dosage forms, or specialized dosages forms. For example, sterile injectables are made with very different machinery than oral dosage form products. Sterile injectables must also be manufactured under complex environmental monitoring and other controls to ensure sterility.[19] Combination drug products, such as antibody-drug conjugates, add still more complexity and are therefore even more challenging to produce.[20]

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[15] *See* 21 C.F.R. Parts 210-211, 600-680; *see also* FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* (Apr. 2004), at Sec. VI (outlining general considerations for manufacturing site changes); FDA, *Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations* (Sept. 2006); FDA, *Draft Guidance for Industry Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products Questions and Answers* (Jul. 2024).

[16] *See, e.g.*, 21 C.F.R. § 211 Subpart B (setting forth organization and personnel requirements); *id.* at Subpart F (setting forth production and process controls); *id*. at Subpart J (setting forth requirements concerning records and reports).

[17] 21 C.F.R. §§ 314.105(c), 601.20(d).

[18] *See generally* Amar S. Prashad, et al., *From R&D to Clinical Supplies*, ACS Publications (Mar. 2017), available at https://pubs.acs.org/doi/full/10.1021/acs.oprd.7b00020 ("Prashad").

[19] FDA, *Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice* (Sept. 2004), available at https://www.fda.gov/media/71026/download, at 19.

[20] Antibody-drug conjugates are a type of targeted cancer therapy that combines a monoclonal antibody, which binds to specific proteins on cancer cells, with a potent chemotherapy drug. *See* Oliver Marcq, *Innovations for Next-*

B. Building A Pharmaceutical Manufacturing Facility is a Multi-Year Process

To build an FDA-approved pharmaceutical manufacturing facility, a company needs specialized expertise, validation of each step in the process, and regulatory approval. The regulatory approval itself includes numerous steps, each of which requires thoughtful planning and due diligence. We discuss this process in more detail below.

First, site selection and site identification require the producer to find a suitable site that has available manufacturing capacity, including sterile capacity, as needed. Furthermore, the facility must adhere to the *Pharmaceutical Manufacturing Effluent Guidelines* and other regulations by the Environmental Protection Agency.[21] Any pharmaceutical manufacturing facility must also register with the FDA.[22] Additionally, the relevant state government will require a pharmaceutical manufacturer to obtain a state license, as well as meet local zoning ordinances, including requirements for industrial zoning and potential impact on environmentally sensitive areas. Of course, these state and local requirements will vary significantly across U.S. jurisdictions. But obviously, no construction on a new U.S. facility can move forward unless the appropriate laws and regulations have been satisfied.

Second, the manufacturer seeking to build a new facility in the United States must prepare and submit information regarding utilities, equipment, and processes used for the manufacturing process, as well as identify critical process parameters and product quality attributes. If the manufacturer is shifting production of a drug from a different facility, a technology transfer is necessary—whether the shift is taking place from one U.S. facility to another or from another country to the United States. The manufacturer must hire and train new employees, establish manufacturing processes (and have those processes validated by the appropriate officials), and prepare the operating principles for the new facility.[23] Once this work has been completed, the manufacturer must make validation batches of the drug to successful completion, and again win the approval of regulators. Of course, when a manufacturer changes locations for making a particular drug, it must satisfy regulators that the pre- and post-change versions of the drug are comparable.[24]

Generation Antibody-Drug Conjugates (May 2018), available at https://link.springer.com/chapter/10.1007/978-3-319-78154-9_6#Sec21, at 113-161.

[21] *See, e.g.*, U.S. Environmental Protection Agency, *Pharmaceutical Manufacturing Effluent Guidelines*, available at https://www.epa.gov/eg/pharmaceutical-manufacturing-effluent-guidelines (citing 40 C.F.R. Part 439).

[22] 21 U.S.C. § 360; *see also* FDA, *Registration Requirements*, *available at* https://www.fda.gov/industry/fda-basics-industry/if-i-am-required-register-my-drug-facility-and-list-my-drug-product-how-do-i-proceed.

[23] *See generally* FDA, Guidance for Industry: *Process Validation: General Principles and Practices* (Jan. 2011); FDA, Guidance for Industry: *Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA* (Oct. 2022).

[24] FDA, *Guidance for Industry: Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA* (Oct. 2022), at 15, 21-22.

Third, the manufacturer must prepare and submit a manufacturing supplement to the approved new drug or biologics license application, including internal preparation and coordination with the FDA. Again, this step is required by current FDA regulations.[25] The FDA must approve and inspect manufacturing and may require additional time for inspection of the new facility. Of course, the FDA may raise concerns and responding to those concerns will require additional time.[26] One review of FDA letters issued to manufacturers regarding finished drug product manufacturing concerns found, "it takes anywhere from four months to four years to resolve the issues" raised by the regulator.[27]

Expert observers who have analyzed this process have concluded that building a fully functional new pharmaceutical manufacturing facility in the United States will likely take from three to seven years,[28] with variations depending on the complexity of the product.

Of course, merely building the facility is not sufficient to truly serve the U.S. market. After the facility has won regulatory approval, the manufacturer must increase production enormously to make enough drugs to supply its customers.[29] In AbbVie's experience, the length of time needed to make pharmaceuticals ranges significantly, depending on the drug. Thus, even after the multi-year process of building a manufacturing facility is complete, the ramping up of production can add significantly to the time frame before the facility is fully functional. For example, even after

[25] *See* 21 C.F.R. Parts 210-211, 314, 600-680.

[26] 21 C.F.R. §§ 314.70, 601.12; *see* FDA, Guidance for Industry: *Changes to an Approved NDA or ANDA, FDA* (Apr. 2004), at sec. VI; FDA, Guidance for Industry: *Manufacturing Site Change Supplements: Content and Submission* (Dec. 17, 2018), at sec. V(A).

[27] Ann M. Thayer, *The complete response letter: the mail no one wants to receive*, Chemical & Engineering News (May 15, 2017), available at https://cen.acs.org/articles/95/i20/complete-response-letter-mail-one.html.

[28] *See, e.g.*, Merck, *Press Statement: Merck to Construct New Facility in the United States to Expand Manufacturing Capacity for TICE® BCG* (Jan. 2021), available at https://www.merck.com/news/merck-to-construct-new-facility-in-the-united-states-to-expand-manufacturing-capacity-for-tice-bcg/ ("completing construction, inspection and regulatory approvals of a manufacturing facility may take approximately *five to six years in total*") (emphasis added); Hearings on the Causes of Drug Shortages and Proposals for Repairing these Markets Before the S. Comm. on Oversight and Gov't Reform Subcomm. on Healthcare, 112th Cong. (Nov. 2011) (statement of Scott Gottlieb) ("It can take *as long as seven years*, from start to finish, to stand up a new manufacturing facility for sterile injectable drugs. The divergent, and sometimes outdated specifications required by FDA is one reason why we see a number of drug makers manufacturing their generic parenteral products only for sale outside the U.S.") (emphasis added); PhRMA, *Website: Biopharmaceutical Manufacturing*, available at https://phrma.org/policy-issues/research-development/manufacturing-supply-chain#:~:text=Setting%20up%20the%20manufacturing%20capacity,comply%20with%20various%20regulatory%20requirements ("Setting up the manufacturing capacity and all the pieces that go with it is a complex and lengthy process. Building a new manufacturing facility, for example, can cost up to $2 billion and take 5 to 10 years before it is operational, including the time and costs related to comply with various regulatory requirements.").

[29] Juliette Heraud, et al., *Managing agile ramp-up projects in manufacturing – Status quo and recommendations*, CIRP Journal of Manufacturing Science and Technology (Oct. 2023), available at https://doi.org/10.1016/j.cirpj.2023.06.002.

the manufacturing facility is complete, it can take roughly 16 additional months to produce a monoclonal antibody (a biologic), from initiation of manufacturing to fill-finish.[30] In other words, assuming that it takes five years to build and obtain approval of a manufacturing facility for a monoclonal antibody, the first output of drug product from that facility would not be available for almost *six and a half years* after the facility was first announced.

As described above, the delays at issue are almost entirely the result of regulatory requirements or the inherent complexity of making the type of advanced and innovative drugs that we produce. Under these circumstances, putting more pressure on pharmaceutical companies will not be sufficient to immediately increase U.S. drug production—and in the meantime, restrictions on imports could lead to significant shortages of vital drugs on which American patients rely.

III. AbbVie Supports Policies that Would Encourage Investments in U.S. Pharmaceutical Innovation and Manufacturing

Notwithstanding the difficulties described above, AbbVie is committed to producing innovative drugs in the United States and has made enormous investments to support that effort. Furthermore, as we have previously explained, AbbVie supports policies that would encourage investments in U.S. pharmaceutical innovation and manufacturing. In crafting such policies, the Administration should take the following points into account:

- There are significant differences between the U.S. market for generic and biosimilar drugs and the U.S. market for innovative drugs, such as those made by AbbVie.[31] While innovators have already invested in U.S. manufacturing, significant challenges exist for a domestic supply chain for generic drugs.[32] Thus, to the extent the United States faces a national security challenge with respect to pharmaceuticals, that challenge overwhelmingly relates to the production of generic drugs, not innovative drugs.

- To the extent the Administration wants to encourage more production of innovative drugs in the United States, it should consider changing elements of U.S. tax policy that currently put U.S. companies at a disadvantage compared to companies headquartered in jurisdictions outside the United States.

[30] *See* Prashad, *supra* note 18. In drug manufacturing, "fill-finish" refers to the final stages of production where the drug substance is formulated, sterile filtered, and filled into its final container (such as a vial or syringe).

[31] Throughout this submission, in accord with industry practice, we use the term "innovator drug" to refer to the first drug containing a specific active ingredient to be approved for use, and we use the term "generic drug" to describe a later version that contains the same active ingredient and is typically less expensive. Innovator drugs are often protected by patents, while generic drugs are manufactured after the patent has expired.

[32] Fraiser Kansteiner, *Tariff hits to generic drugs could 'blow back on everybody' without supply chain resilience, says USP chief*, Fierce Pharma (Apr. 23, 2025), available at https://www.fiercepharma.com/manufacturing/tariff-hits-generic-drugs-could-blow-back-everybody-says-usp-chief-call-increased.

Given these facts, the Administration should adopt practical policies that will lead to increased production in this country and should avoid policies that would lead to shortages or other supply difficulties.

A. The Administration should recognize the significant differences in market conditions between innovator drugs and generic drugs

As outlined below, AbbVie—as a U.S. manufacturer of innovative drugs—has focused on policies that contribute to development of innovation in the pharmaceutical sector in the U.S. The policies and issues that affect innovators differ significantly from those for generics and biosimilars.[33]

To properly address the relevant policy issues here, the Administration must distinguish between innovators on the one hand, and generic and biosimilar products on the other hand. Market factors and national security concerns for generic and biosimilar drugs and innovator products are very different. Generic drugs account for more than 90 percent of prescription drugs dispensed in the United States.[34] The regulatory paradigm for generic drugs is completely separate from that applied to innovator products.[35] Perhaps most significantly, while the United States has a very robust industry that makes innovator drugs, generic drugs are increasingly manufactured outside the United States—and particularly in India or China.[36] There are multiple reasons why generic drug production has largely left the United States—including the lower costs of production abroad, the lack of reliable intellectual property and differing product liability frameworks that are seen as less stringent and providing safe harbor for generic drugs.[37] As AbbVie's focus is on innovator drugs, our comments relate primarily to that aspect of pharmaceutical production. Nevertheless, it should be obvious that, to the extent there are national security concerns about imported drugs, those concerns relate almost exclusively to generic drugs, not innovative drugs.

Indeed, by contrast to generic drug producers, innovator producers like AbbVie already engage in significant *on*shore production.[38] They rely on highly skilled domestic workers and are engaged in the relatively complex work of establishing manufacturing processes from the beginning.

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[33] The term "biosimilar" refers to drugs that are similar to, but not exact copies of, brand-name biologic medications, such as those made by AbbVie. *See* 42 U.S.C. § 262(i)(2).

[34] Marta Wosińska, *Will Pharmaceutical Tariffs Achieve Their Goals?*, Brookings (Mar. 27, 2025), *available at* https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/ ("Wosińska").

[35] *See* 21 U.S.C. § 355(j).

[36] Wosińska, *supra* note 35.

[37] Richard G. Frank, et al., *The Evolution of Supply and Demand in Markets for Generic Drugs*, Milbank Q. 99(3):828-852 (Sept. 2021), available at doi: 10.1111/1468-0009.12517.

[38] Wosińska, *supra* note 35 (stating "most FDF [finished dosage form] volume for brands is already produced in the U.S.").

A few key facts underscore the differences between generic and innovator drugs. A recent study found that U.S. imports of generic drugs tend to come largely from China and India, with over 60 percent of solid oral generic drugs by volume imported from India.[39] By contrast, over 80 percent of solid oral innovator drugs by volume are produced in either the United States or the European Union ("EU"), with at least 50 percent already being produced in this country.[40] Furthermore, generic drugs tend to rely on API that is manufactured entirely overseas, while innovator products tend to ensure consistent supply of API with multiple sources across the United States and the EU.[41] These facts further show that national security issues associated with production of generic drugs are much more significant than any such issues with innovator products.

The Administration should also recognize that most medicines regarded as "essential" have been genericized. In his first Administration, President Trump directed the FDA to identify essential medicines, medical countermeasures, and critical inputs that should be available in the United States at all times.[42] The twin objectives of that action were aligned with the purpose of Section 232: (1) to seek sufficient and reliable, long-term domestic production of essential medicine products; and (2) to minimize supply chain risks by reducing dependence on foreign manufacturers of those products.[43] Similarly, last year, Commerce's Bureau of Industry and Security ("BIS") —the same agency responsible for administering Section 232 investigations— conducted a survey into the U.S. Active Pharmaceutical Ingredient Industrial Base. That survey focused on medicines essential to the "critical medical infrastructure" of the United States.[44] Both the FDA analysis in 2020 and the BIS analysis in 2024 show that the medicines generally regarded by the U.S. government as "essential" consist primarily of generic drugs. Once again, this fact indicates that the Administration's focus here should be on generic drugs, not innovator drugs.

Because AbbVie makes innovator drugs, not generic drugs, our comments here do not address how to increase the production of generic drugs in the United States. Instead, we will

[39] *Id.*

[40] *Id.*

[41] U.S. Pharmacopeia ("USP") compiled public information on the API manufacturing landscape that indicates the majority of innovator, or branded, pharmaceutical API manufacturing is in the United States and the EU. *See* Vimala Raghavendran, et al., *Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union*, Supply Chain Blog (Apr. 17, 2025), available at https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european.

[42] 85 Fed. Reg. 49929, EO 139844: Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States (Aug. 6, 2020).

[43] 19 U.S.C. § 1862; 15 C.F.R. § 705.11.

[44] Bureau of Industry and Security, *BIS To Conduct Assessment of U.S. Active Pharmaceutical Ingredient Industrial Base* (July 9, 2024), available at bis.gov/press-release/bis-conduct-assessment-u.s.-active-pharmaceutical-ingredient-industrial-base (expected publication by summer 2026).

discuss how the Administration could support policies that would lead to increased production of innovator drugs in the United States.

B. Recent changes in U.S. tax policy have undermined incentives to create innovative drugs in the United States

To the extent the Administration wants to increase U.S. production of innovative drugs—a goal AbbVie strongly supports—it should focus on changing U.S. tax policy. In the pharmaceutical sector, innovation depends on capital investment spending for R&D. Traditionally, the U.S. government has encouraged innovation with two types of tax incentives: (1) output-based tax incentives, such as lower tax rates that apply to profits generated by innovation; and (2) input-based tax incentives, such as tax deduction and credits for R&D expenditures. However, certain policies currently enacted in U.S. tax law *discourage* innovation in the United States.

Consider what has happened to output-based tax incentives. In 2004, the Domestic Production Activities deduction ("DPAD") was enacted as part of the American Jobs Creation Act.[45] The DPAD afforded a deduction to U.S. companies that recognize certain income attributable to qualifying manufacturing and production activities performed in the United States. In 2017, as part of tax reform under the Tax Cuts and Jobs Act, the DPAD was repealed and replaced with a modified deduction for individuals and specified agricultural activity, as well as a deduction for income recognized by domestic companies related to eligible profits derived from foreign exports, called the Foreign Derived Intangible Income ("FDII") deduction.[46]

Both the DPAD and the FDII deduction have encouraged innovation by lowering the tax rate for eligible income associated with innovative activities. However, the DPAD has been repealed, and the allowed FDII deduction is scheduled to decline next year.[47] These developments discourage U.S. innovation. Restoring an updated version of the DPAD while also enhancing benefits under the FDII regime would encourage companies to invest in both U.S. manufacturing and U.S. R&D.[48] We further note that President Trump has proposed a 15 percent corporate income

[45] Pub. L. No. 108-357.

[46] Pub. L. No. 115-97, § 13305.

[47] 26 U.S.C. § 250(a)(3) (reducing the deductions from 37.5 to 21.875 percent and from 50 to 37.5 percent, as applicable, for taxable years after 2025).

[48] One proposal to enhance the benefits under the FDII regime would involve eliminating the qualified business asset investment ("QBAI") exemption that pertains to FDII. Under the current framework, the QBAI exemption decreases the amount of a domestic corporation's income eligible for the FDII deduction. As a result, investments in tangible property within the U.S. reduce the overall tax benefit available under FDII. Eliminating the QBAI exemption would allow Congress to promote investment within the U.S. The QBAI exemption also applies to reduce the global intangible low-taxed income ("GILTI") inclusion for U.S. taxpayers. A proposal to eliminate the QBAI exemption from FDII may prompt discussions to eliminate it from GILTI as well. *See, e.g.,* CRS, *GILTI: Proposed Changes in the Taxation of Global Intangible Low-Taxed Income* (Nov. 25, 2024), available at https://www.congress.gov/crs-product/IF11943.

tax rate for companies that manufacture in the United States.[49] This proposal would effectively create another output-based tax incentive that would encourage increased pharmaceutical production in the United States.

Next, the Administration should consider input-based tax incentives. Historically, the United States has provided two main input-based tax incentives for innovation, an R&D deduction and an R&D credit. As shown in more detail below, however, both of these incentives are currently being undermined.

R&D Deduction. Section 174 of the Internal Revenue Code (21 U.S.C. § 174), that was first established in 1954, has for decades permitted companies to claim the current and present value of R&D as a tax deduction on a yearly basis. In 2022, a change in the law required companies to capitalize and amortize R&D expenditures over a longer five-year or 15-year period.[50] This change significantly reduced the present value of the tax benefit and increased the tax burden of U.S. companies. Furthermore, this change made the U.S. market less attractive in comparison to foreign jurisdictions where R&D expensing is allowable and incremental benefits—such as patent box regimes and refundable R&D credits—are also available. Recent research shows that in response to the reduction in R&D deductions, research-intensive companies cut R&D investments in 2022 alone by $12.2 billion.[51] Meanwhile, other countries, such as China and certain EU members, are passing tax policies that provide additional benefits for innovation.[52]

R&D Credit. In the United States a tax credit is available for qualifying R&D spending. To qualify for this credit, the spending must pass a four-part test as defined by Section 41(d) of the Internal Revenue Code. That test requires R&D products to: (1) eliminate uncertainty; (2) discover previously unknown technological information; (3) include a new or improved business component; and (4) involve a process of experimentation (such as a process through which hypotheses are formulated, tested, and subsequently refined). However, the last Administration agreed to a Global Minimum Tax that would undermine the potential value of this credit. [53] The

[49] Adam N. Michel & Joshua Loucks, *The Case for Trump's 15 Percent Corporate Tax Rate* (Jan. 8, 2025), available at https://www.cato.org/blog/case-trumps-15-percent-corporate-tax-rate#:~:text=Cut%20the%20Corporate%20Rate%20As%20Low%20As%20Possible&text=Figure%203%20shows%20the%202024,tax %20rate%20to%2019.6%20percent.

[50] 21 U.S.C. § 174(a)(2).

[51] Mary Cowx, et al., *The Consequences of Limiting the Tax Deductibility of R&D*, Stanford University Graduate School of Business Research Paper No. 4998845 (July 23, 2024), available at https://ssrn.com/abstract=4998845.

[52] Stanford Report, *The tax code oversight causing innovation to falter* (Oct. 22, 2024), available at https://news.stanford.edu/stories/2024/10/american-innovation-got-slammed-temporary-end-key-tax-incentive?source=email.

[53] Under the Global Minimum Tax guidelines, the U.S. R&D credit is classified as a non-refundable credit. This means it is treated as a reduction in tax expense rather than an increase in income, which would apply if it were considered a refundable credit. As a result, companies utilizing the R&D credit may become more susceptible to the top-up tax, formally referred to as the "undertaxed profits rule."

current Administration has expressed skepticism about the Global Minimum Tax, and we urge the Administration to resist any change that would undermine the historic tax credits for R&D in the United States.

While AbbVie supports tax policies that will encourage increased U.S. manufacturing of pharmaceuticals, we believe that restricting trade in innovative pharmaceutical and pharmaceutical ingredients could cause significant harm to the U.S. industry and U.S. patients, while frustrating the Administration's objectives of encouraging more U.S. manufacturing and building a more resilient supply chain.[54]

C. A program to increase production of innovative drugs in the United States should have the following elements

a. Revised tax policies to encourage innovative production in the United States

AbbVie encourages the Administration to focus on tax policies that incentivize U.S. R&D manufacturing activities. In particular, we support the following reforms: (1) restoring a complete deduction of R&D expenses on a yearly basis;[55] (2) providing favorable tax rates for domestic manufacturing and production activities; and (3) combating foreign tax policies that undermine U.S. taxation rights.

Each of these measures would be much more effective than any restriction on trade in innovative drugs. As explained above, reinstating current expensing of R&D would encourage U.S. pharmaceutical manufacturing by reducing after-tax costs and enhancing the global competitiveness of domestic production.[56] Similarly, reducing U.S. corporate income tax rates associated with domestic manufacturing, and expanding federal tax incentives, such as enhanced R&D tax credits, would further strengthen U.S. pharmaceutical manufacturing. AbbVie also supports President Trump's proposal for a 15 percent corporate income tax rate for companies that manufacture in the United States.

In sum, reforms in U.S. tax policy could offer powerful incentives to encourage pharmaceutical companies to manufacture products domestically.

b. Provide additional incentives for domestically produced goods and pharmaceutical innovation

AbbVie further encourages the Administration to strongly consider other policies that would encourage investments in U.S. pharmaceutical innovation.

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[54] Marc L. Busch, *Trump's pharmaceutical tariffs will risk the lives of American patients*, The Hill (Apr. 25, 2025), available at https://thehill.com/opinion/healthcare/5265790-pharmaceutical-tariffs-national-security.

[55] *See supra* note 53.

[56] *Id.*

For example, we support the Administration's interest in removing disincentives created by the Inflation Reduction Act, such as removal of the so-called "pill penalty,"[57] which disproportionately penalizes non-biological drug products by subjecting them to price controls after only 7 years, compared to 11 years for biological products.[58]

The Administration should also explore policies to further develop the skilled workforce needed for U.S. pharmaceutical manufacturing. Increases in domestic pharmaceutical manufacturing will require additional skilled workers,[59] an area where there are already reports of a lack of such workers.[60] Job training programs, including partnerships with the private sector, and skilled worker incentives will help provide the labor force necessary for complex pharmaceutical manufacturing. Significantly, other countries such as Japan and Europe are already making substantial investments in such programs.[61] For example, AbbVie supports the President's effort to modernize American workforce programs to prepare workers for high-paying skilled trade jobs in the future.[62] In general, a bachelor's degree and specialized training is required for skilled workers involved in pharmaceutical manufacturing. We also urge the Administration to tailor any measures to account for the lengthy time needed to develop a more robust workforce.

AbbVie also supports incentives and regulatory optimization to ramp up API development in the United States, particularly as there is a lack of such incentives at present.[63] Incentives such as tax relief for companies that invest in new API manufacturing capabilities—particularly those that use more efficient advanced manufacturing technologies and/or repurpose underutilized domestic manufacturing capacity—would provide much-needed encouragement for increased API production in the United States. So too, would regulatory incentives, such as priority review for

[57] 90 Fed. Reg. 14273, EO 14273: Lowering Drug Prices by Once Again Putting Americans First (Apr. 15, 2025).

[58] Pub. L. No. 117-169, § 11001 (amending 42 U.S.C. 1320f-1).

[59] *See, e.g.*, Angela Gabriel, *Massive Investment in US Manufacturing Triggers Wave of Career Opportunities*, BioSpace (Apr. 24, 2025), available at https://www.biospace.com/job-trends/massive-investment-in-us-manufacturing-triggers-wave-of-career-opportunities.

[60] *See* Scott Fotheringham, *Addressing the shortage of skilled workers*, ISPE (May/June 2023), available at https://ispe.org/pharmaceutical-engineering/may-june-2023/addressing-shortage-skilled-workers; Alliance for Regenerative Medicine, Workforce Report: Gap Analysis for the Cell and Gene Therapy Sector (Mar. 2023), available at https://alliancerm.org/wp-content/uploads/2023/03/ARM-Workforce-Gap-Analysis.pdf.

[61] *See* PhRMA, *The Biopharmaceutical Industry Boosts the U.S. Economy* (2022), available at https://www.phrma.org/policy-issues/research-development/economy-workforce.

[62] 90 Fed Reg. 17525, EO 14278: Preparing Americans for High-Paying Skilled Trade Jobs of the Future (Apr. 23, 2025) (highlighting the Bureau of Labor Statistics' projection that there will nearly half a million vacant open skilled trade jobs annually over the next decade).

[63] *See* API Innovation Center, *Building a Resilient Domestic Drug Supply Chain: The Path to National Security* (Mar. 25, 2025) available at https://apicenter.org/wp-content/uploads/2025/03/APIIC-White-Paper-2025-Building-a-Resilient-Domestic-Drug-Supply-Chain.pdf, at 2 (highlighting the lack of incentives for U.S. drug makers to produce API domestically).

drug manufacturers using domestically manufactured API. Of course, these programs will necessarily require time to have their full effect.

The Administration should also consider additional FDA reforms that would result in faster approvals of drug products and ease regulatory burdens for new manufacturing. For example, the Administration should explore whether an accelerated program can be established for reputable manufacturers that invest in new domestic manufacturing capability. Such a program would help address, at least in part, the lengthy timeline that currently exists.[64] Similarly, extensions of (or even establishment of new) exclusivity periods for companies that move manufacturing, including production of API, to the United States, would help to offset the time and significant financial investment needed to shift pharmaceutical production to this market. The Administration should also consider a program that would allow manufacturers to include, at the time of submitting a New Drug Application or Biologics License Application to the FDA, a pre-established plan for onshoring production that would eliminate the need for approval of regulatory manufacturing supplements when new domestic production is brought online.

c. Phase in changes to account for the necessary time frame of any shifts in pharmaceutical manufacturing production

To the extent that the Section 232 Investigation concludes that any additional measures are necessary to achieve national security objectives, AbbVie urges the Administration to phase in such action to allow time for new investments in U.S. production to come online. This approach would protect vital materials used in R&D and would allow crucial time for manufacturers to make investments, establish supply chains, and gain necessary regulatory approvals. A phase-in period would also avoid price spikes and potential disruptions in supply that are likely to occur with immediate imposition of additional measures such as tariffs.

The complex challenges outlined above in Section II.B., which require a multi-year timeline to build and bring on-line pharmaceutical manufacturing facilities in the United States, justify a phased-in approach to any additional measures considered by Commerce to address national security concerns in the pharmaceutical sector. Like the phased-in approach adopted by the Administration in the recent investigation involving Chinese shipbuilding, the Administration should give careful consideration to the timing of any additional measures affecting the pharmaceutical sector.

The Administration should also prioritize onshoring of U.S. production of essential medicines as identified by FDA and BIS.[65] Focusing on essential medicines is the most effective

[64] *See supra* note 28.

[65] FDA, *Drug and Biologic Essential Medicines, Medical Countermeasures, and Critical Inputs for the List Described in Section 3(c) of the Executive Order 13944*, last updated Oct. 30, 2020, available at https://www.fda.gov/media/143406/download?attachment; Bureau of Industry and Security, "BIS To Conduct Assessment of U.S. Active Pharmaceutical Ingredient Industrial Base," (July 9, 2024) (expected publication by summer 2026).

way to address national security concerns related to risks associated with supply chain concentration and possible weaponization of supply chains by other nations.

In the short term, restrictions on trade in innovative drugs will potentially undermine existing U.S. manufacturing by causing R&D to slow and prices to rise, either through higher insurance costs or reduced access to products.[66] Such an outcome would certainly harm the very patients who need innovative medicines most.[67] Indeed, such restrictions are likely to create shortages of critical inputs or segments in the market.[68] Restrictions could also reduce the ability of manufacturers to create the redundancy in sourcing necessary to ensure consistent supply for American patients.[69] Given these facts, government officials should proceed with great caution in considering programs that could limit American patients' access to drugs.

Finally, the Administration should avoid measures that would harm companies seeking to increase drug production in the United States. For example, if U.S. drug companies are forced to pay tariffs on their imports, they will have less funding available for R&D, and they would also have to face increasing costs of product that they need to develop new drugs. Such an outcome would make U.S. companies less competitive and would hinder Administration efforts to obtain more drug production in the United States.

IV. Unfair non-tariff barriers harm U.S. companies, American patients, and American leadership in innovative medicines, and should be separately investigated and confronted outside of Section 232

The Commerce Department's request for comments specifically seeks information on the economic impact of foreign unfair trade practices.[70] U.S. pharmaceutical manufacturers have consistently expressed concern about many foreign countries limiting market access for innovative therapies, including compulsory and non-transparent pricing and reimbursement procedures such

[66] Letter to Ambassador Greer and Secretary Lutnick by Members of Congress (Apr. 9, 2025), available at https://matsui.house.gov/sites/evo-subsites/matsui.house.gov/files/evo-media-document/20250409_letter-to-ustr-and-commerce-on-tariffs-on-essential-medical-supplies.pdf.

[67] KS Lee, et al., *Factors Impacting Pharmaceutical Prices and Affordability: Narrative Review*. 9(1):1-12 Pharmacy (2023), available at https://doi.org/10.3390/pharmacy9010001; Matthias Bauer & Philip Lamprecht, *How Tariffs Impact Access to Medicines*, Geneva-Network.com (June 2021).

[68] Wall Street Journal Editorial Board: *Trump's Good-Bad Pharma Agenda, Faster generic approvals make sense, but tariffs will counter the gains* (April 28, 2025), available at https://www.wsj.com/opinion/donald-trump-pharma-executive-order-drugs-innovation-tariffs-beecdbcb.

[69] For example, a Baxter North Carolina intravenous (IV) fluids plant impacted by Hurricane Helene caused shortages of IV fluids with almost 90 percent of providers reporting shortages from damage to just the one manufacturing site. AMA, Fixing IV fluid shortage only a start in addressing drug supply (Oct. 30, 2024), available at https://www.ama-assn.org/delivering-care/public-health/fixing-iv-fluid-shortage-only-start-addressing-drug-supply#.

[70] 90 Fed. Reg. at 15952.

as clawbacks, utilization caps, access delays, and reference pricing.[71] Together, these compulsory practices disproportionately impact U.S. innovator manufacturers, whose products make up a majority of those launched in the EU and unfairly shift the burden of innovation expenses to the U.S.[72] We describe some of the most market-distorting practices below.

Clawbacks. One such coercive practice is clawbacks, which mandate pharmaceutical manufacturers to pay back a share of their net revenues to the local government if the utilization of their therapies exceeds a pre-specified budget threshold. Currently, approximately two thirds of the 27 EU member states utilize some form of clawback to fund their national healthcare services using pharmaceutical company revenues.[73] Further, the United Kingdom mandates companies to bear the full risk of drug budget overshoots, which has resulted in average annual contributions equal to approximately 25 percent of net revenue over the last several years.[74] Clawbacks effectively operate as a double tax and, in some EU jurisdictions, are explicitly regulated as taxes.[75]

Artificial price limits. Foreign countries also use procurement tools such as mandatory recurrent price cuts. For example, Japan engages in annual price revisions for pharmaceuticals, mandating price cuts without substantial negotiation.[76] More egregiously, international reference pricing (sometimes referred to as "IRP") is another harmful practice used by many foreign countries including many EU member states, Canada, Brazil, and China. IRP is often implemented based on arbitrary criteria plainly designed to force drug prices below true market levels, discouraging innovation and reducing competition.

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[71] Many of these are reflected in USTR's 2022 National Trade Estimate on Foreign Trade Barriers. United States Trade Representative, *2022 National Trade Estimate Report on Foreign Trade Barriers* (Mar. 2022), available at https://ustr.gov/sites/default/files/2022%20National%20Trade%20Estimate%20Report%20on%20Foreign%20Trade%20Barriers.pdf (referencing clawbacks in Greece and Poland).

[72] *See, e.g.*, Mario Draghi, *The Draghi report on EU competitiveness* (Sept. 9, 2024), at 189-190 ("[o]f the top ten best-selling biological medicines in Europe in 2022, two were marketed by EU companies, while six (including the top four) were marketed by US-based companies.").

[73] Generic Medicines, Market Review – European Generic Medicines Market (2023), available at https://www.medicinesforeurope.com/wp-content/uploads/2023/06/Market-Review-2023-29-06.pdf.

[74] Abpi, *Delivering a voluntary scheme for health and growth* (Mar. 2025), available at https://www.abpi.org.uk/media/t4ih3u0o/abpi-vpag-report-20-march-2025.pdf.

[75] Act 98 of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products (Drug Economy Act); *see also* Baker McKenzie, *Hungary: Tax relief for pharmaceutical sector windfall tax published* (July 23, 2023); Government Emergency Ordinance No. 77, Romania (Sept. 21, 2011) (establishing certain contributions for financing expenses in the medical field); Paul Ciprian Radu, et al., *Drug Policy in Romania*, Value in Health Regional Issues 16C (2018), at 28-32.

[76] PhRMA, *Special 301 submission 2025* (Jan. 27, 2025), available at https://cdn.aglty.io/phrma/global/resources/import/pdfs/PhRMA_2025%20Special%20301%20Review_Comment.pdf.

Failure to follow rules. EU member states routinely ignore the EU Transparency Directive requiring member states to make reimbursement decisions on new therapies within 180 days of approval by the European Medicines Agency ("EMA") to reduce spending on innovative therapies. In 2024, industry research shows the average time between licensing and patient access was actually 531 days[77]—almost three times the time required by the EU's own Directive. Multiple EU member states also artificially limit competition by only providing restricted reimbursement covering a smaller population of patients than the product labeling approved by the EMA defines as eligible for treatment. According to available data for 2024, approximately 40 percent of drugs available in Europe were reimbursed only for limited patient sub-groups within the scope of their EMA-approved label.[78]

Lack of intellectual property protections. Several trading partners, such as Brazil, China, Mexico and India, also deny predictable and effective intellectual property ("IP") protection for pharmaceutical innovation, *e.g.*, by restricting patentability criteria, denying effective regulatory data protection, and lacking effective patent or other IP enforcement mechanisms to resolve disputes.[79] Many of these measures are inconsistent with global norms and reflect a failure to implement either bilateral agreements with the United States (*e.g.*, pharmaceutical-related IP provisions contained in the U.S.-China "Phase One" Agreement and in the U.S.-Mexico-Canada Agreement), and/or long-standing obligations undertaken in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), which, among other things, requires protection from "unfair commercial use" for pharmaceutical regulatory data.[80] These practices unfairly limit the ability of U.S. innovators to compete in non-U.S. markets. Meanwhile, innovative drug producers in those same countries have the ability to take advantage of robust IP protection in the U.S. market.

These unfair practices serve as non-tariff trade barriers, lower the value of U.S. exports from some of our most innovative companies, reduce revenue streams into the United States from foreign trading partners, and harm the ability of U.S. pharmaceutical companies to maintain our global leadership, U.S. investments, and improvements in care for American patients.

While AbbVie certainly urges the Administration to address these unfair practices, any actions taken must not harm U.S. innovator companies or limit patient access to necessary therapies. For this reason, AbbVie does not believe that broad-based tariffs on pharmaceuticals or restrictions on imported pharmaceuticals would be an effective approach. Instead, AbbVie

[77] EFPIA, *New data from EFPIA reveals multiple factors leading to unequal access to medicines for patients across Europe* (June 12, 2024), available at https://efpia.eu/news-events/the-efpia-view/efpia-news/new-data-from-efpia-reveals-multiple-factors-leading-to-unequal-access-to-medicines-for-patients-across-europe/.

[78] *Id.*; *see also* IQVIA, *EFPIA Patients W.A.I.T. Indicator 2023 Survey* (June 2024), available at https://efpia.eu/media/vtapbere/efpia-patient-wait-indicator-2024.pdf.

[79] *See generally* Office of the U.S. Trade Representative, *2025 Special 301 Report* (2025), available at https://ustr.gov/sites/default/files/files/Issue_Areas/Enforcement/2025%20Special%20301%20Report%20(final).pdf

[80] *See* World Trade Organization, TRIPS Article 39.3.

supports efforts by the Administration to address these practices through trade negotiations and other country-specific tools such as Section 301 of the Trade Act of 1974.[81]

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As shown throughout this submission, AbbVie supports the Administration's goals to expand manufacturing in the United States but recognizes that such expansion will take time. We urge the administration to consider a careful, phased approach to imposition of any restrictions on trade in pharmaceuticals, and to couple any such restrictions with much-needed incentives for additional domestic production and investment in pharmaceutical innovation.

Thank you again for considering AbbVie's comments. AbbVie welcomes continued dialogue on this crucial topic to provide long-term incentives to move manufacturing to the United States.

Sincerely,

Scott T. Reents
Executive Vice President, Chief Financial Officer
On behalf of AbbVie Inc.

[81] 19 U.S.C. § 2411 et seq.