CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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May 7, 2025 submitted via www.regulations.gov

Bureau of Industry and Security
Office of Strategic Industries and Economic Security
United States Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15951 (April 16, 2025); Docket No. 250414-0065

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to submit comments on the above-captioned request for comments, published by the Bureau of Industry and Security (BIS) in the Federal Register on April 16, 2025.

For 144 years, CHPA has served as the leading voice working to ensure that Americans have access to nonprescription, or over-the-counter (OTC) medicines, OTC medical devices, and dietary supplements. Our over 70 member companies manufacture and market consumer healthcare products, providing millions of Americans with safe, effective, directly accessible health products to treat and prevent many common ailments and conditions – all available without a prescription and without the need for an intervention by a healthcare profession.

While OTC medicines and dietary supplements are regulated by the U.S. Food and Drug Administration under the federal Food, Drug, and Cosmetic Act, both are distinct from prescription medicines. OTC drugs have a number of overlapping regulatory requirements with prescription drugs, while dietary supplements are a subset of foods. But both OTC medicines and dietary supplements have many ingredients under Harmonized Tariff Schedule of the United States (HTSUS) headings in Chapters 29 and 30.

I. Executive Summary

- We are concerned about the impact of tariffs on consumer healthcare products by increasing the risk of out-of-stock shelves, price inflation, and unintended impacts that increase risks of counterfeit or substandard products being introduced into the United States market (where counterfeits are already a risk the Administration has correctly identified). Out-of-stock shelves could even be exacerbated by pantry loading.

- Given the significant impact tariffs could have on American consumers of OTC products and dietary supplements, we encourage that any tariff actions be phased, flexible, proportional, and targeted to clearly identified national security risks rather than broad application of

pharmaceutical tariffs to these products. Instead, incentives could be used to increase capacity and production in the United States.

- OTC medicines and dietary supplements are high volume, low margin products purchased directly by consumers without the intervention of a healthcare professional. These products are invaluable assets that allow Americans to take control of their health, treat common ailments, and help prevent chronic conditions – all while being accessible and affordable.

- These products help to reduce costs in the U.S. healthcare system: every dollar spent on OTC medicines saves the U.S. healthcare system over seven dollars in healthcare spending. Dietary supplements play a crucial role in filling nutritional gaps and supporting overall health, in turn helping prevent chronic diseases and boosting immune functions.

- A significant majority of OTC medicines and dietary supplements sold in the United States are finished in North America. We welcome opportunities in increase United States manufacturing capacity, but onshoring to a new facility can be a five to seven year process.

- There are fundamental differences in import reliance and sourcing between consumer healthcare products and prescription drugs. Consumer healthcare products comprise less than 12% of "pharmaceutical" imports, and the supply chains and leading sources of imports are substantially different.

- A number of OTC or dietary supplement manufacturers made good faith investments in production in Canada and Mexico over the past several years, in reliance on the provisions of the United States-Mexico-Canada Agreement (USMCA). We therefore welcome duty-free entry on USMCA-compliant goods.

- It is important to recognize that not all ingredients for our industry's products can be manufactured in the United States due to a multitude of reasons.

II. Comments in Depth

A. OTC Medicines and Dietary Supplements in the Larger US Healthcare Context

Consumer healthcare products today provide strong value to Americans and help reduce costs to the American healthcare system. Access to dietary supplements and OTC medicines empowers consumers to take greater control over their health and provides considerable public health benefits. Indeed, regular use of dietary supplements and OTC medicines can help reduce risks and incidence of illnesses – up to 50% in some instances.

For OTC medicines**,** a 2022 study commissioned by CHPA found each dollar spent on OTC medications saved the United States healthcare system $7.33 in healthcare spending.[1] The overall savings to the

[1] "The Power of OTCs to Provide Consumer Value." IRI and Consumer Healthcare Products Association, November 2022, https://www.chpa.org/sites/default/files/media/docs/2022-11/The-Power-of-OTCs-to-Provide-Consumer-Value.pdf.

U.S. healthcare system totaled $167.1 billion in 2021 compared to alternatives. Savings from drug costs totaled $56.8 billion, which was generated by the lower prices of OTC medicines as compared to more expensive branded or generic prescription medicine alternatives to treat conditions that can be self-managed. The remaining $110.3 billion in annual savings came from avoided clinical visits. These savings are the result of consumers making the decision to self-treat with OTCs rather than making a visit to the doctor's office for treatment.

In addition to providing value through cost savings, OTC medications also help reduce the burden on the United States healthcare system, ensuring that scarce health care provider resources are reserved for more serious conditions that cannot be self-treated. The same study estimated that 82% of consumers who treat a condition with an OTC medicine would seek professional medical treatment if OTCs were not available in the marketplace. It is clear the United States health system would not be able to absorb additional office visits from the millions more of consumers seeking treatment or prescriptions for mild conditions they can self-treat.

For dietary supplements**,** including vitamins, minerals, omega-3 fatty acids, probiotics, and others, as more and more Americans look for ways to improve their overall health and wellness, these products play a key role in optimizing people's self-care plans. In 2023, the U.S. Centers for Disease Control and Prevention (CDC) found that nearly 60% of American adults and more than one-third of children and adolescents had taken a supplement in the past month. And reliance on supplements continues to grow.

Dietary supplements play a crucial role in filling nutritional gaps and supporting overall health. Dietary supplements help individuals maintain optimal levels of essential nutrients, which can prevent chronic diseases and boost immune function. By incorporating these products into daily routines, individuals can proactively safeguard their health and well-being.

Consistent use of health and wellness products, including a number of dietary supplements, can reduce the incidence of certain illnesses by up to 50%, underscoring their importance in maintaining public health. For instance, a recent clinical trial found that people ages 60 and older who took a daily multivitamin showed an estimated three fewer years of memory loss than those who took a placebo.[2] The role of folic acid for women of reproductive age to help prevent neural tube defects in babies is another well-established example. And in a country where less than five percent of people get enough fiber from the foods they eat,[3] supplements can help support digestive and heart health.

Further evidence on the use of key dietary supplements looked at potential reductions in costs associated with coronary heart disease (CHD) in the United States among those at a high risk. Results found that the potential avoided hospital utilization costs related to the use of omega-3 supplements at preventive intake levels among the target population can be as much as $2 billion a year, with use of folic acid, B6, and B12 at preventive intake levels providing further benefits and savings.[4] Thus, targeted dietary supplement regimens are recommended as a means to help control rising societal

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[2] See Brickman, et al., as reported at https://www.nih.gov/news-events/nih-research-matters/daily-multivitamin-may-enhance-memory-older-adults.

[3] Quagliana, et al., Closing America's Fiber Intake Gap, Am J Lifestyle Med. 2016.

[4] Shanahan, et al., From Science to Finance – A Tool for Deriving Economic Implications from the Results of Dietary Supplement Clinical Studies, Journal of Dietary Supplements, 2016.

health care costs, and as a means for high-risk individuals to minimize the chance of having to deal with potentially costly events and to invest in increased quality of life.

Both dietary supplements and OTC medicines also provide value beyond economics: They empower individuals to take charge of their health. In an era where healthcare systems are often overwhelmed, these products offer a first line of defense, enabling people to manage common health issues without the need for a doctor's visit. For instance, over-the-counter medications for pain relief, allergies, and digestive issues provide quick and accessible solutions, reducing the burden on healthcare providers and allowing individuals to address their symptoms promptly. This freedom and choice in managing one's health fosters a sense of responsibility and confidence, ultimately leading to better health outcomes.

In short, consumer healthcare products are invaluable assets that promote self-care, preventive health, accessibility, and autonomy. They empower individuals to take control of their health, prevent diseases, and manage minor ailments effectively, all while being accessible and affordable. These high volume, low margin products purchased directly by consumers at retail are a distinct market from prescription medicines.

B. Challenges and Limitations of International Trade Data

Tariff Classification. There are several challenges and limitations applying the Harmonized System (HS) tariff nomenclature and goods classification to consumer healthcare products and prescription drugs. For some products, it is necessary to apply 10-digit statistical reporting numbers in the Harmonized Tariff Schedule of the United States (HTSUS), while for others it is necessary to apply broader "basket" categories containing other goods, even at the 10-digit level. Throughout these comments, CHPA has attempted to carefully apply the correct classifications; however, the data are not as "clean" as we would like, as for some products the trade data overstate imports and exports by including goods beyond those regulated by FDA as OTC medicines or dietary supplements.

Scope of Consumer Healthcare Products and Prescription Drugs. Pharmaceuticals, pharmaceutical ingredients, and consumer healthcare products are classified throughout the U.S. tariff schedule. Annex II of Executive Order 14257 of April 2, 2025 (Annex II),[5] lists the goods exempted from reciprocal tariffs. Some of the 1,000 plus lines in Annex II are applicable to pharmaceuticals and pharmaceutical ingredients and presumably provide the basis for the initial draft list of products subject to this Section 232 investigation. The trade data for consumer healthcare products and prescription drugs presented in these comments were extrapolated from Annex II. CHPA is prepared to assist BIS in any request to clarify the list of tariff lines applicable to consumer healthcare products or pharmaceutical use.[6]

According to CHPA's analysis, within Annex II, consumer healthcare products and related chemical precursors and other inputs are classified in five HS Chapters, 29 4-digit tariff headings, 82 6-digit subheadings, and 299 10-digit statistical reporting numbers.

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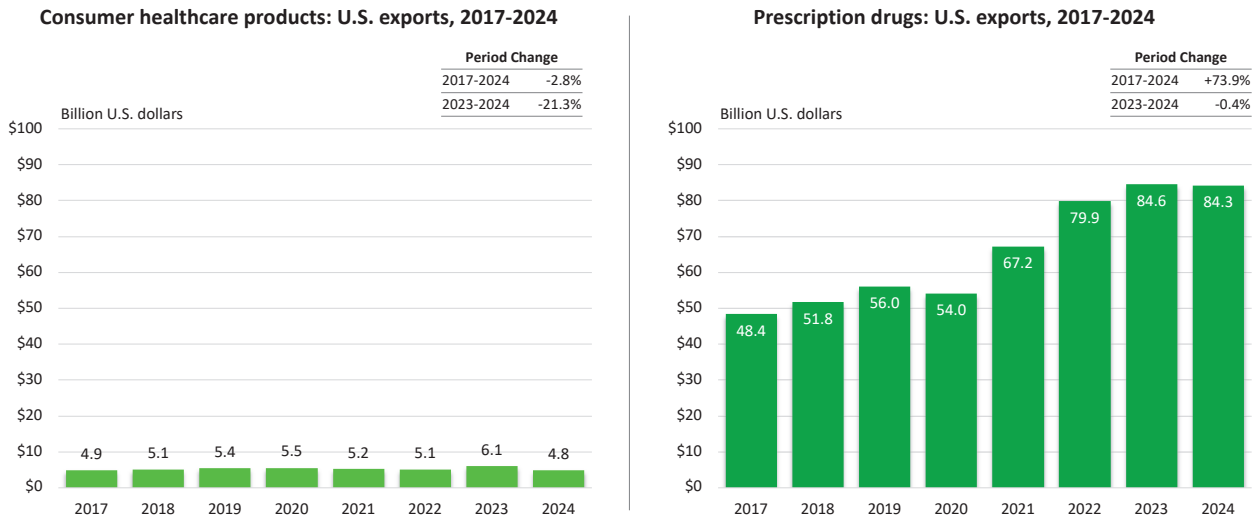
[5] Regulating Imports With a Reciprocal Tariff To Rectify Trade Practices That Contribute to Large and Persistent Annual United States Goods Trade Deficits, April 7, 2025, 90 FR 15041.

[6] CHPA notes that some of the chemicals cited in Annex II, in particular chemicals in Chapter 38 (Miscellaneous chemical products), Chapter 39 (Plastics and articles thereof), and Chapter 40 (Rubber and articles thereof) do not appear to be applicable to pharmaceuticals or pharmaceutical ingredients.

Figure 1 presents U.S. exports of Annex II listed consumer healthcare products and prescription drugs. Using the methodology described above, the United States exported $4.8 billion of consumer healthcare products in 2024, a decrease of 2.8 percent from $4.9 billion in 2017. The United States exported $84.3 billion of prescription drugs in 2024, an increase of 73.9 percent from $48.4 billion in 2017. Consumer healthcare products accounted for 5.4 percent of U.S. exports of pharmaceuticals listed in Annex II.

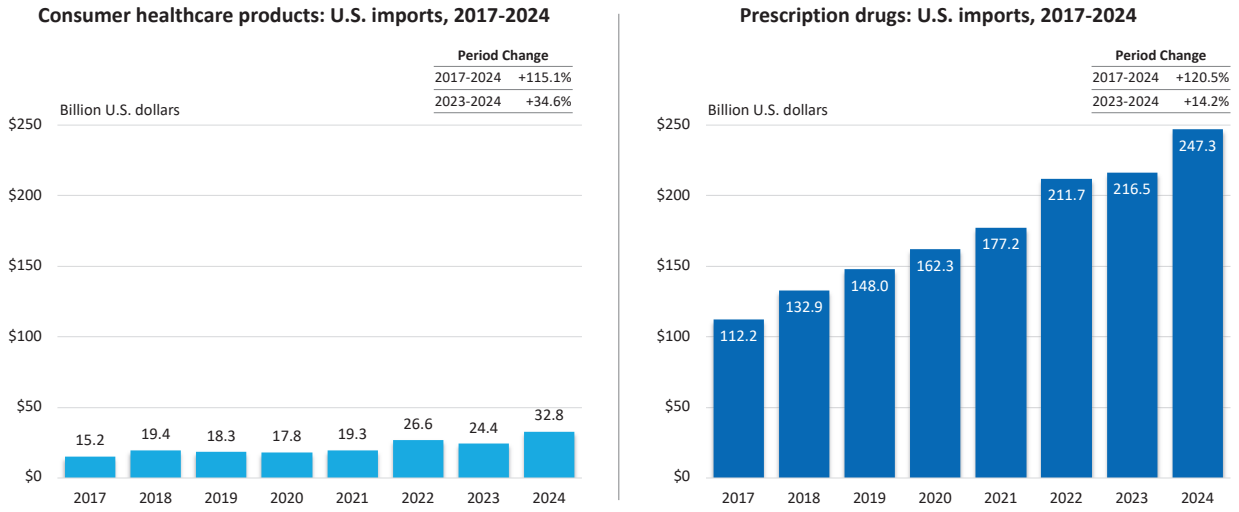
Figure 1. U.S. exports of consumer healthcare products and prescription drugs to the world, 2017-2024



Source: Compiled from U.S. Census Bureau data.

Figure 2 presents U.S. imports of Annex II listed consumer healthcare products and prescription drugs. The United States imported $32.8 billion of consumer healthcare products in 2024, an increase of 115.1% from $15.4 billion in 2017. The United States imported $247.3 billion of prescription drugs in 2024, an increase of 120.5% from $112.2 billion in 2017. Consumer healthcare products accounted for 11.7% of U.S. imports of pharmaceuticals listed in Annex II.

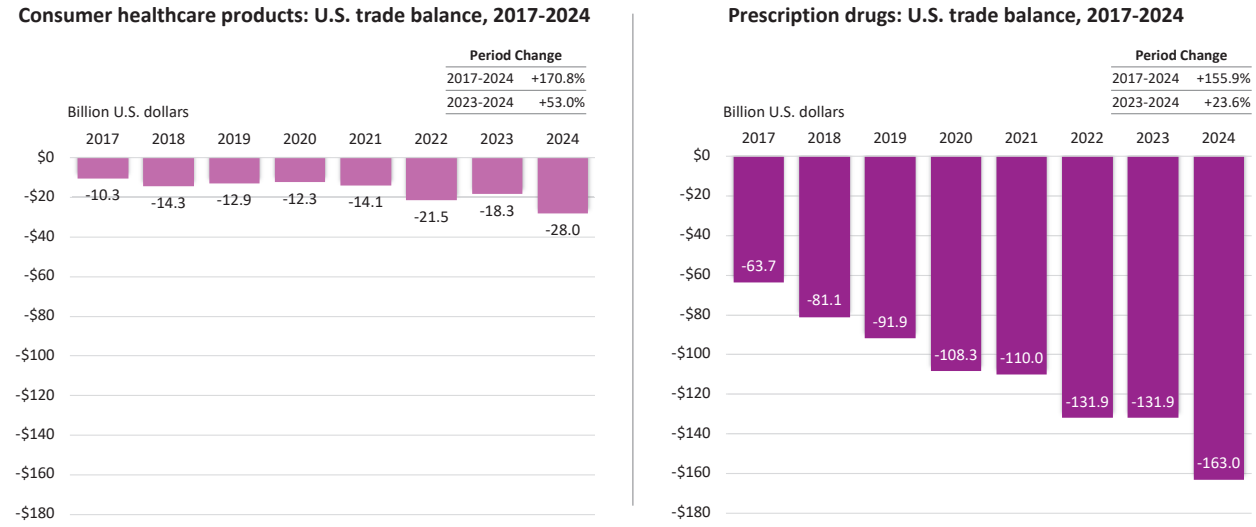
Figure 2. U.S. imports of consumer healthcare products and prescription drugs from the world, 2017-2024



Source: Compiled from U.S. Census Bureau data.

Figure 3 presents the U.S. trade balance of Annex II listed consumer healthcare products and prescription drugs. The United States had a trade deficit of $28.0 billion of consumer healthcare products in 2024, an increase of 170.8 percent from $10.3 billion in 2017. The United States had a trade deficit of $163.0 billion of prescription drugs in 2024, an increase of 155.9% from $63.7 billion in 2017. Consumer healthcare products accounted for 14.7% of the U.S. trade deficit of pharmaceuticals listed in Annex II. Consumer healthcare products accounted for 2.3% of the overall U.S. goods trade deficit in 2024, while prescription drugs accounted for 13.5% of the overall U.S. goods trade deficit in 2024.[7]

Figure 3. U.S. trade balance in consumer healthcare products and prescription drugs with the world, 2017-2024

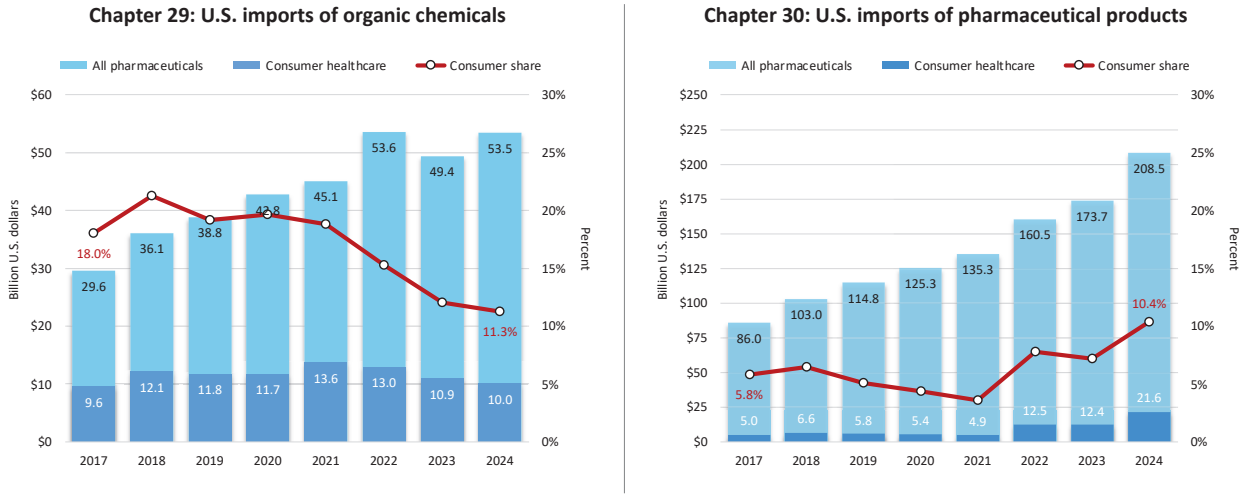


Source: Compiled from U.S. Census Bureau data.

[7] The United States had a $1,203 billion trade deficit in goods with the world in 2024.

Figure 4 presents consumer healthcare products and prescription drugs as a share of U.S. imports of Chapter 29 (chemical products) and Chapter 30 (pharmaceutical products) listed in Annex II.[8] Consumer healthcare products accounted for 11.3% of U.S. imports of Annex II listed Chapter 29 chemical products in 2024, down from 18.0% in 2017. Consumer healthcare products accounted for 10.4% of U.S. imports of Annex II listed Chapter 30 pharmaceutical products in 2024, up from 5.8% in 2017. Prescription drugs accounted for 88.7% of Annex II listed Chapter 29 imports and 89.6 percent of Annex II listed Chapter 30 imports in 2024.

Figure 4. U.S. imports of Annex II listed HS Chapter 29 (chemical products) and HS Chapter 30 (pharmaceutical products), by end use, 2017-2024



Source: Compiled from U.S. Census Bureau data.

III. Responses to BIS Specific Topic Areas for Comment:

(i) The current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States.

Addressing solely the market for OTC medicines and dietary supplements, not prescription drugs, demand is free-market driven, with United States retail sales at approximately $82 billion in 2024, up 4% from the previous year, and consistent with a roughly 5% annual increase over the past four years.[9] Much of this modest but steady growth is driven by increasing interest by Americans in nutrition and personal care. Another driver of shifts in the market is increased consumer attention to healthy aging and to wellness. Market research firm Circana estimates self-care will continue to show steady growth, with dietary supplements, oral care, and women's health all key growth areas, along with more holistic need states associated with sleep and stress.

[8] CHPA believes that some of the tariff lines listed in Annex II as pharmaceutical goods are not, in fact, used in consumer healthcare products or prescription drug manufacturing. CHPA is willing to work with BIS to identify which tariff lines are actually used in the production of consumer healthcare products and prescription drugs.
[9] Source: Circana, April 2025.

(ii) The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand.

CHPA members have invested significantly in U.S. manufacturing facilities over the past decade. However, there are certain impediments to onshoring that remain. The global supply chain for these products is very complex and increasing domestic production would require collaboration between industry, federal, state, and local governments to address all aspects and phases of the pharmaceutical manufacturing process.

Pharmaceutical manufacturing can be divided into four main phases. As the product moves through these phases, the level of technical complexity and production costs decrease. Each phase plays a crucial role in the production and distribution of pharmaceutical products. The major phases of pharmaceutical manufacturing are:

- **Synthesis** of active pharmaceutical ingredients (APIs), which is highly technical, requiring specialized skills and production facilities
- **Formulation** of APIs with other inactive ingredients, e.g. excipients, and converting them into finished pharmaceutical products (FPPs)
- **Packaging** of the final pharmaceutical products
- **Distribution** and logistics, e.g., of bulk FPPs that may be packaged elsewhere

Approximately 75% of the downstream process phases (formulation, packaging and distribution) of OTC medicines occurs within the U.S. However, a significant number of APIs are imported for various reasons. One critical reason is that APIs may be synthesized from key starting materials (KSMs) and locally mined raw materials. For example, nickel, cobalt and iron-based catalysts, mined outside of the U.S., facilitate chemical reactions during API synthesis. API manufacturers' proximity to these raw materials and KSMs lead to exclusive sourcing (discussed further under topic (iii)).

Nearly 64,000 metric tons of API used in the top 13 OTC medicines were imported in 2024 alone (Tables 1-2). These imports valued at $3.9 billion were from over 62 countries highlighting the complexity of the OTC medicines supply chain. Less expensive APIs are especially important for OTC medicines which have lower margins than prescription medicines.

Table 1 presents the top 13 OTC API imports by country. **Table 2** presents the top 13 OTC API imports by active ingredient. In 2024, the U.S. imported 64,000 metric tons of the top 13 APIs valued at $3.9 billion from 62 countries, highlighting the complexity of the OTC medicines supply chain.

The 13 OTC API imports in this example represent a small fraction of those used in the thousands of OTC medicines used by Americans to manage illnesses of all types daily. For example, aspirin, acetaminophen, and ibuprofen, which makeup three of the top four imports on this list, are also included on the FDA's "List of Essential Medicines, Medical Countermeasures, Critical Inputs Required by Executive Order"[10].

[10] Essential Medicines, Medical Countermeasures, and Critical Inputs

Table 1. U.S. imports of top 13 OTC APIs, by partner, 2020-2024

		General U.S. Imports					Share	Period Change
	Partner	2020	2021	2022	2023	2024	2024	2023-24
		Customs Value (U.S. dollars)					Percent	Percent
1	Singapore	591,209,035	997,114,950	1,065,932,102	1,704,754,330	922,393,301	23.7%	-45.9%
2	India	239,192,205	243,746,583	287,774,049	298,956,363	704,838,521	18.1%	135.8%
3	Germany	60,818,496	59,661,946	40,278,601	39,429,891	568,451,900	14.6%	1341.7%
4	United Kingdom	325,546,380	58,262,304	290,378,106	61,780,440	227,084,854	5.8%	267.6%
5	Canada	219,864,637	99,105,274	117,970,708	166,864,539	217,041,502	5.6%	30.1%
6	Israel	37,272,601	30,767,966	22,657,739	19,766,091	195,916,632	5.0%	891.2%
7	Italy	43,779,179	61,252,096	47,272,965	54,874,815	156,597,512	4.0%	185.4%
8	China	210,384,262	196,531,086	241,294,854	184,182,325	150,023,165	3.9%	-18.5%
9	Japan	24,024,639	23,600,369	23,926,824	17,698,665	132,479,285	3.4%	648.5%
10	Mexico	59,883,410	42,887,912	83,424,757	108,718,201	127,920,826	3.3%	17.7%
11	Belgium	49,635,904	122,675,357	127,399,944	152,492,673	127,104,901	3.3%	-16.6%
12	Taiwan	3,800,936	1,234,484	3,750,952	4,579,475	72,956,178	1.9%	1493.1%
13	Spain	38,940,845	41,362,223	40,956,862	32,947,008	72,052,430	1.8%	118.7%
14	France	132,358,025	35,314,755	70,485,780	63,837,873	70,343,917	1.8%	10.2%
15	Switzerland	33,519,125	43,423,302	47,706,928	85,716,197	55,464,362	1.4%	-35.3%
	All other	135,445,224	308,324,378	161,096,206	57,765,990	94,177,864	2.4%	63.0%
	TOTAL	**2,205,674,903**	**2,365,264,985**	**2,672,307,377**	**3,054,364,876**	**3,894,847,150**	**100.0%**	**27.5%**

Source: Compiled from U.S. Census Bureau data.

Table 2. U.S. imports of top 13 OTC APIs, by HTSUS heading, 2020-2024

			General U.S. Imports					Share	Period Change
	HTS10	Description	2020	2021	2022	2023	2024	2024	2023-24
			Customs Value (U.S. dollars)					Percent	Percent
1	3004909259	MEDICAMENTS PRIMARILY AFFECTING THE DIGESTIVE SYSTEM	--	--	--	--	1,497,857,000	38.5%	--
2	2937220000	HALOGENATED DERIVATIVES OF ADRENAL CORTICAL HORMON	633,922,612	1,037,243,857	1,316,781,043	1,707,175,413	1,075,544,504	27.6%	-37.0%
3	3004909276	COUGH AND COLD PREPARATIONS PUT UP IN MEASURED DOSI	303,290,410	184,812,486	306,681,009	373,799,486	374,298,771	9.6%	0.1%
4	2933394100	DRUGS CONTAINING AN UNFUSED PYRIDINE RING (WHETHER	557,671,987	498,262,231	347,285,670	374,355,533	347,965,252	8.9%	-7.0%
5	3004909280	ANTIHISTAMINES PUT UP IN MEASURED DOSES OR IN FORMS O	336,149,363	266,781,450	290,166,967	267,999,129	310,219,410	8.0%	15.8%
6	2939300000	CAFFEINE AND ITS SALTS	86,319,817	100,504,347	142,069,061	125,405,310	106,202,608	2.7%	-15.3%
7	2918993000	AROMATIC DRUGS	57,342,369	66,261,419	43,656,354	40,234,370	40,145,975	1.0%	-0.2%
8	2922190900	AROMATIC DRUGS OF AMINO-ALCOHOLS, OTHER THAN THOSE	92,883,963	89,216,641	91,813,029	33,850,763	34,921,623	0.9%	3.2%
9	2916391500	IBUPROFEN	67,619,962	57,175,407	53,604,788	31,016,870	26,790,377	0.7%	-13.6%
10	2933592100	ANTIHISTAMINES, INCLUDING THOSE PRINCIPALLY USED AS	19,585,454	21,764,239	15,369,592	14,404,911	19,327,467	0.5%	34.2%
11	3004909227	ANALGESICS, ANTIPYRETICS AND NONHORMONAL ANTI-INFLA	--	--	--	--	17,355,762	0.4%	--
12	2918221000	ORTHO-ACETYLSALICYLIC ACID (ASPIRIN)	13,965,224	13,594,974	13,844,953	11,682,618	15,414,734	0.4%	31.9%
13	2924296210	ACETAMINOPHEN	15,241,558	14,734,220	29,710,540	51,572,811	10,989,804	0.3%	-78.7%
14	2937210020	HYDROCORTISONE	11,491,360	10,710,863	9,661,329	10,614,931	10,315,381	0.3%	-2.8%
15	2909490500	GUAIFENESIN	10,190,824	4,202,851	11,663,042	12,252,731	7,498,482	0.2%	-38.8%
16		**TOTAL**	**2,205,674,903**	**2,365,264,985**	**2,672,307,377**	**3,054,364,876**	**3,894,847,150**	**100.0%**	**27.5%**

Source: Compiled from U.S. Census Bureau data.

The complexity of producing APIs is cost prohibitive for domestic manufacturers to onshore production without significant investments, especially APIs used for OTCs which operate on smaller margins. For example, Novartis who produces higher value Rx products announced a $23 billion investment in U.S. based infrastructure to ensure key Rx medicines for United States patients are made domestically[11]. This single capital expenditure alone is nearly 25% of the entire U.S. OTC medicine and dietary supplement market. While relatively smaller investments may be needed to onshore an OTC medicine's production, the scale of investments to build infrastructure to meet U.S. demands will be significantly challenging.

[11] Novartis plans to expand its US-based manufacturing and R&D footprint with a total investment of $23B over the next 5 years | Novartis United States of America

Where there may be more flexibility for large Rx companies to onshore production, OTC medicines manufacturers may be limited to only the highest value products due to smaller margins. Not only will significant domestic capacity be needed for onshoring, but product expansions for a single facility would take five to seven years to meet current demand. Therefore, meeting increasing future demands will take even longer.

Currently, foreign manufacturers may provide much of the U.S. supply employing conventional or less efficient manufacturing processes. Before OTC medicines and dietary supplements manufacturers could determine the feasibility of onshoring, there are several costly, time-consuming preliminary steps that must be taken with an unknown probability of success. Manufacturers must determine the feasibility of modernizing production processes to increase efficiency for specific products, but there is no guarantee that this would be possible for individual medicines or dietary supplements. Experts in API manufacturing efficiency recommend various strategies to upgrade processes aimed at increasing domestic production[12]. However, the most critical OTC drug products must be identified followed by creating new synthesis processes, finding domestically sourced raw materials alternatives, developing new formulations, investigating and implementing automation, artificial intelligence, and other technology upgrades to fit domestic production environments. This preliminary work would add an unknown amount of time to the approximate five to seven years' investment needed to implement an established manufacturing process.

The U.S. FDA acknowledges advanced manufacturing technologies like continuous manufacturing and 3D printing as approaches to improve drug quality, address shortages, and reduce costs[13] for onshoring. These technologies have a smaller facility footprint, lower environmental impact, and require fewer humans for operation. Due to the upfront costs, technological upgrades may limit the adoption to a few larger manufacturers. Although there is potential to apply new technologies for process efficiency there is a likelihood that only a few, if any, higher value OTC medicines and dietary supplements could leverage new technologies domestically due to a lower return on investment, built-in needs for raw materials inaccessible in the United States (discussed in response to topic (iii)), technical feasibility and others. Experts have pointed out the necessity for chemical and manufacturing technology upgrades for domestic production. However, this approach may not be viable for many OTC medicines and dietary supplements.

Much of the discussion has been about (APIs), or upstream, manufacturing. Downstream processes are also affected by the need for imports as well as exports. Some raw materials that can only be procured abroad are used to manufacture finished products domestically and then exported to other countries from the United States. One CHPA member company stated that their final products are exported to over 20 countries from United States facilities. Tariffs on raw materials exclusively found in other countries will not only impact imports, but also United States production – and exports - of OTC medicines and dietary supplements that support manufacturing jobs.

Some critical excipients (inactive ingredients used as API carriers) are used in formulations to provide different drug delivery functionalities that are crucial for a medicine's effectiveness. Excipients are added to delay drug release over time as appropriate for the specific treatments. Critical formulation

[12] Overcoming-Global-Risk-to-the-Pharmaceutical-Supply-Chain_061824.pdf

[13] https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019

ingredients like imported ion exchange resins imported from Germany, China, and India extend the release of medications. Other topical medicine formulations, e.g. menthol, capsaicin, also employ unique excipients. A wide range of starting materials for API synthesis as well as inactive, but important, ingredients are listed in chapters 29 and 30 and directly impact OTC medicine and dietary supplement functionality.

Further downstream in the manufacturing process, some packaging and labeling materials are also imported. Packaging and label service providers produce packaging materials e.g. blister packages, labels etc. Aluminum packaging materials e.g. bauxite, a precursor to alumina that is then smelted into aluminum is sourced countries like Australia, Guinea, China, and Brazil. Bauxite is mined in the United States, but at significantly smaller quantities than the other countries. Coltan (Tantalum) and rare earths used in radiofrequency identification (RFID) tags are mined in Democratic Republic of Congo (coltan) and China (rare earths). Some plastic bottles for liquid products are lined with rubber seals (preferred in some food-grade applications) and made of natural rubber from trees grown in Thailand, Indonesia, and Vietnam.

In summary, a few larger OTC medicines manufacturers may be able to increase domestic capacity to meet the demands through needed expansions across all phases of manufacturing. The greatest opportunity will be the higher value OTC medicines or dietary supplements that demonstrate feasibility after techno-economic assessments where technical issues, economics, and risks are weighed to determine if onshoring will be viable long-term. However, this would take many years of intense capital with no promise of a return on investment. Manufacturing processes may be reworked to meet United States market requirements using locally available raw materials, but the industry will remain reliant upon foreign sources until, if ever, alternate starting materials can be discovered domestically. The pharmaceutical industry is dependent on other industries e.g. chemical, petroleum and mining for access to domestic raw materials from API synthesis, formulations and packaging. Since OTC products manufacturers procure relatively smaller amounts of the same raw materials consumed in larger quantities by heavy industries, OTC products manufacturers indirectly rely on other sectors within the United States for some raw materials. Meanwhile, the OTC medicines and dietary supplements industry are reliant on importation of many raw materials.

OTC medicines and dietary supplements are comprised of a wide range of ingredients. One role that the United States government could play is to assure any tariffs on the range consumer healthcare products within chapters 29 and 30 are phased, flexible, proportional, and targeted to clearly identified national security risks rather than broad application of pharmaceutical tariffs to prevent risks of product shortages and increased costs for consumers.

(iii) The role of foreign supply chains, particularly of major exporters, in meeting U.S. demand for pharmaceuticals and pharmaceutical ingredients.

As stated in topic (ii), the U.S. imported 64,000 metric tons of API imports for the top 13 OTC medicines from over 62 countries in 2024. These imports represent a small fraction of many OTC products used by Americans to treat common illnesses. Sourcing from abroad permits United States manufacturers to adapt swiftly to market changes, safeguard against supply disruptions, maintain cost competitiveness, adjust to unexpected changes, leverage the benefits efficiencies of foreign manufacturers with proximity to raw materials, and other benefits.

One significant reason that OTC manufacturers must rely on imports is the need for naturally occurring materials or are only available within certain countries and cannot be obtained from sources within the United States (Table 3). For example, certain metal-based catalysts discussed earlier are commonly used during the synthesis of some APIs and the metals are primarily mined outside of the United States. As stated under topic (ii), formulations and packaging may contain exclusive imported materials and components. Similarly, bismuth, used in the antidiarrheal and upset stomach ingredient bismuth subsalicylate, is an active almost exclusively mined in China with no source in the United States. Additionally, some materials may be patented in foreign countries and cannot be used commercially within the United States.

Many dietary ingredients or drug active ingredients are derived from plants. Many plants will not grow in the United States due to unfavorable climate and environmental conditions. For example, Psyllium used as a bulk laxative and dietary supplement comes from a plant only grown in the northern India. Attempts to grow psyllium in the United States have proven unsuccessful. Lutein and Zeaxanthin are also grown in India. Even within India, attempts to grow these plants elsewhere requires 4-6 years of pre-planning.

These are just a few examples of a long-term reliance on certain countries for critical ingredients. Even in situations where another source may be or become available, a change to a supplier requires long lead times. For example, change in supplier of API or other chemicals for drugs can take an average of 2-3 years (Rx) or 1-2 years (OTC). A change of supplier for dietary supplement materials can take up to one year. This lead time is due to identifying a new supplier, performing stability testing, regulatory filing and approvals, etc.

Table 3. Examples of imported materials not available in U.S. or where the U.S. is a smaller supplier

Imported Material	OTC Medicines Uses	Country Imported
Bismuth	antidiarrheal agent	Mining-China
Lutein	eye supplement nutrient	Plants – India
Zeaxanthin	eye supplement nutrient	Plants – India
ketotifen hydrogen fumarate	Ophthalmic active ingredient	Switzerland, Iran
naphazoline hydrochloride	Ophthalmic active ingredient	Vietnam, Chile, India, Turkey, South Korea, Russia, and Singapore
pheniramine maleate	Ophthalmic active ingredient	India, China
brimonidine tartrate	Ophthalmic active ingredient	India
Psyllium	laxative/dietary supplement	Plants-Northern India
ion exchange resins	Formulations	Germany, India, China
Nickel	API synthesis catalysts	Mining-Indonesia, Philippines, Russia, Canada, Australia
Cobalt	API synthesis catalysts,	Mining-Democratic Republic of the Congo, cAustralia, Cuba, Philippines, Russia
iron-ore	API synthesis catalysts; Stainless steel parts used in pharmaceutical grade equipment	Mining-Australia, China, Brazil, India, Russia

Zinc	Stainless steel parts used in pharmaceutical grade equipment	Mining-China, Australia, Peru, India
rare earths	RFID	Mining-China
Coltan	RFID packaging chips	Mining-Democratic Republic of Congo (coltan)
Bauxite	Aluminum blister packaging	Mining-Australia, Guinea, China, Brazil
natural rubber	Liquid bottle liners and seals	Trees - Thailand, Indonesia, Vietnam

In addition to raw materials and active ingredients used in medicines, specialized equipment and materials of construction are at risk. For example, iron-ore used in the construction of stainless-steel tanks, piping etc. that are commonly used in pharmaceutical manufacturing is primarily mined in Australia, China, Brazil, India, and Russia.

Foreign companies have entry and exit points throughout all phases of OTC medicines and dietary supplements manufacturing. It may be possible to leverage new technologies and novel chemistry to lower costs. Replacement of certain raw materials with domestically sourced ones can be researched, but there's uncertainty if they can be replaced. Advanced technologies can be identified but must be a technical and economic match for the specific OTC products to be implemented. To be cost competitive, domestic suppliers cannot rely on conventional production methods. For all these reasons, United States manufacturers will likely maintain a high level of reliance on global suppliers for raw materials to meet domestic demands.

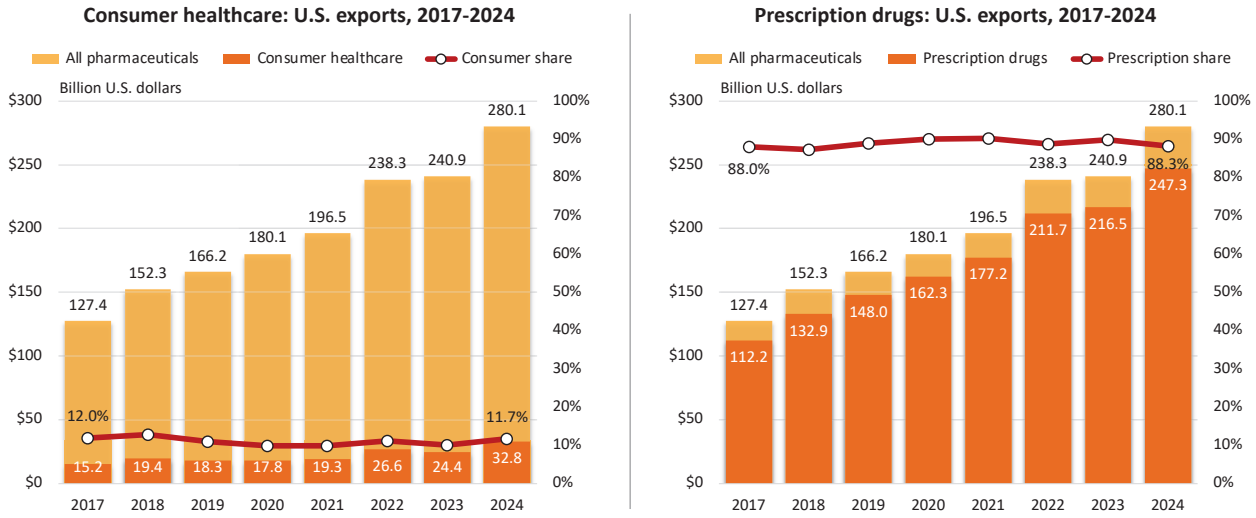
(iv) The concentration of U.S. imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks.

There are significant differences in import reliance and sourcing between consumer healthcare products and prescription drugs. Consumer healthcare products comprise less than 12% of "pharmaceutical" imports, and the supply chains and leading sources of imports are substantially different.

Figure 5 presents United States imports of consumer healthcare products as a share of total pharmaceutical imports.[14] The United States imports $32.8 billion of consumer healthcare products in 2024 compared with $247.3 billion of prescription drugs.

[14] Total pharmaceutical imports are based on pharmaceutical-related products in Annex II exclusions from reciprocal tariffs.

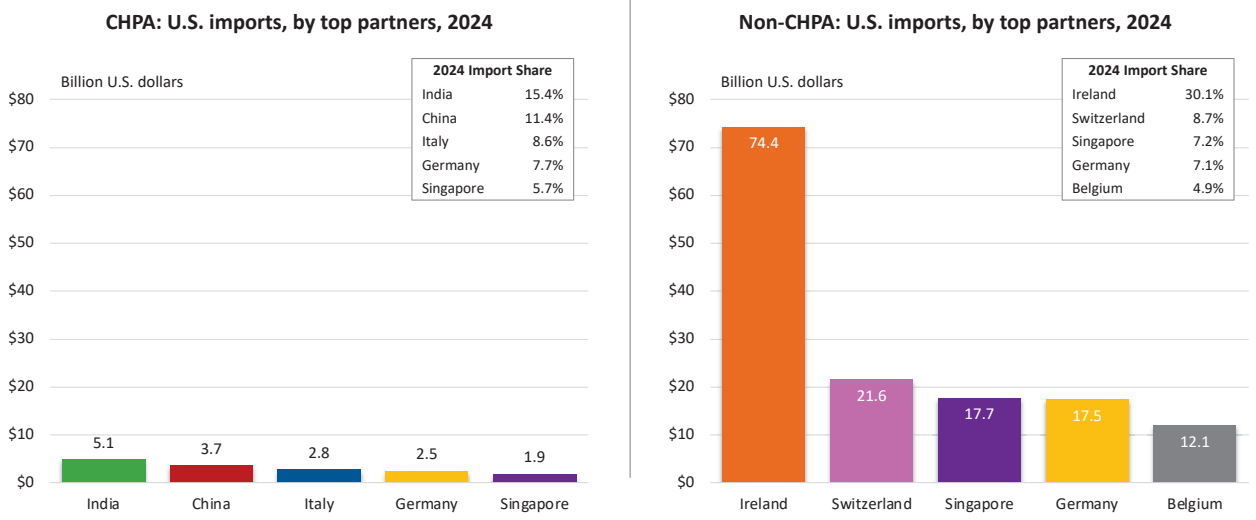
Figure 5. U.S. imports of consumer healthcare products vs. prescription drugs from 2017 to 2024



Source: Compiled from U.S. Census Bureau data.

Figure 6 presents the leading sources of United States imports for consumer healthcare products and prescription drugs. For consumer healthcare products, the leading United States import sources in 2024 were India ($5.1 billion), China ($3.7 billion), Italy ($2.8 billion), Germany ($2.5 billion), and Singapore ($1.9 billion). For prescription drugs, the leading United States import sources in 2024 were Ireland ($74.4 billion), Switzerland ($21.6 billion), Singapore ($17.7 billion), Germany ($17.5 billion), and Belgium ($12.1 billion).

Figure 6. Leading U.S. import sources for consumer healthcare products vs. prescription drugs

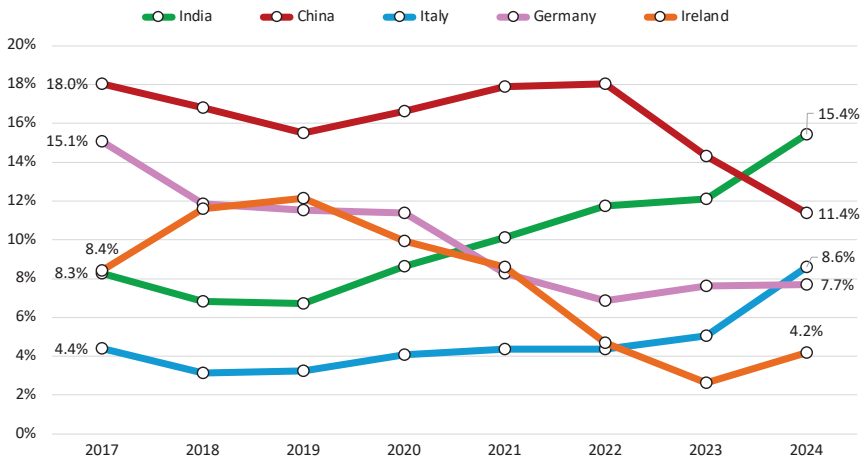


Source: Compiled from U.S. Census Bureau data.

Figure 7 presents U.S. imports of consumer healthcare products by leading import sources from 2017 to 2024. The sources of U.S. imports of consumer healthcare products are diversifying, with significantly less reliance on China, which declined from 18.0% of U.S. imports in 2017 to 11.4% in 2024. U.S. imports of consumer healthcare products from India – now the leading U.S. import source -- have

increased from 8.3% of United States imports in 2017 to 15.4% in 2024. U.S. imports of consumer healthcare products from Italy also have increased from 4.4% in 2017 to 8.6% in 2024. Notably, the share of United States imports of consumer healthcare products from Ireland decreased from 8.4% in 2017 to 4.2% in 2024.

Figure 7. U.S. imports of consumer healthcare products by leading import sources, 2017-2024



Change from 2017 to 2024

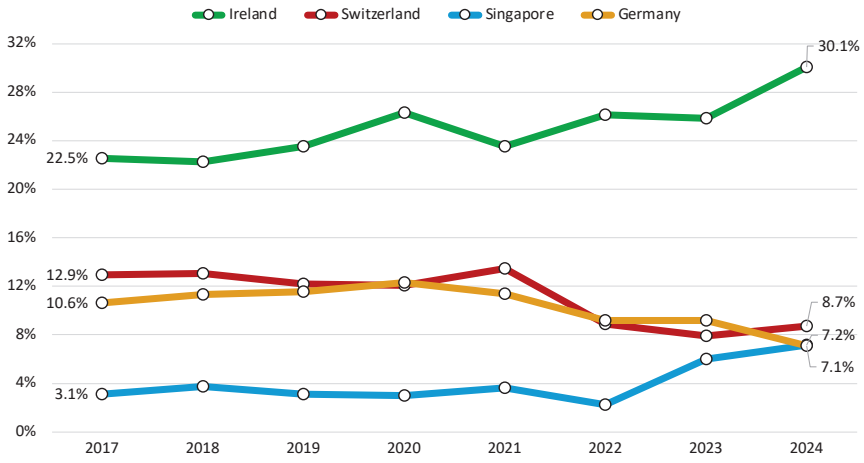
Partner	U.S. imports	U.S. import share
	U.S. dollars	*Percentage points*
India	3,795,251,978	+7.2
China	981,293,406	-6.6
Italy	2,153,791,575	+4.2
Germany	227,044,040	-7.4
Singapore	1,078,080,866	+ 0.5
Switzerland	608,528,256	-0.9
Ireland	90,796,720	-4.2
Slovenia	1,323,814,589	+4.0
Belgium	1,111,671,664	+2.8
France	603,869,292	+0.1
All other	4,050,125,287	+0.7
TOTAL	**17,543,252,018**	

Source: Compiled from U.S. Census Bureau data.

Figure 8 presents U.S. imports of prescription drugs by leading import sources from 2017 to 2024. Unlike consumer healthcare products, which have been diversifying, the sources of U.S. imports of prescription drugs have become less diversified, with greater reliance on Ireland and Singapore, while other sources have been relatively flat or declining. Ireland now accounts for 30.1% of U.S. imports of prescription drugs, up from 22.5% in 2017.[15] U.S. imports of prescription drugs from Singapore increased from 3.1% of U.S. imports in 2017 to 7.2% in 2024.

[15] Ireland accounts for only 4.2 percent of United States imports of consumer healthcare products, down from 8.4 percent in 2024.

Figure 8. U.S. imports of prescription drugs by leading import sources, 2017-2024



Change from 2017 to 2024

Partner	U.S. imports	U.S. import share
	U.S. dollars	*Percentage points*
Ireland	49,106,355,031	+7.5
Switzerland	7,077,271,854	-4.2
Singapore	14,202,533,934	+4.0
Germany	5,606,465,832	-3.5
Belgium	10,224,179,412	+3.2
China	7,012,940,439	+1.0
India	3,619,394,192	-1.7
Italy	4,966,736,916	-0.4
Canada	3,240,325,691	-1.6
Japan	4,685,709,124	-0.1
All other	25,373,334,951	-5.5
TOTAL	**135,115,247,376**	

Source: Compiled from U.S. Census Bureau data.

With respect to domestic drug manufacturing, we also highlight the diversity of the OTC and dietary supplement market. Overall, for both OTC and Rx medicines, FDA calculates 42% of drug manufacturing sites are in the United States [16] Among these, approximately 1600 of the over 4,800 FDA-registered drug manufacturing sites are OTC facilities registered under FDA's OTC monograph user fee program.[17]

Also worth noting are instances where a consumer healthcare product manufacture utilizes other countries for certain raw materials and single-source APIs, the finished products produced in the U.S. are exported to other countries. For example, one of our larger manufacturers notes they export finished dietary supplements and OTC medicines to over 20 countries. Inability to obtain those raw materials and product final products in the U.S. would place these exports in jeopardy.

(v) The impact of foreign government subsidies and predatory trade practices on U.S. pharmaceuticals industry competitiveness;

and

(vi) The economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state- sponsored overproduction.

As highlighted in the April 29, 2025, Office of the United States Trade Representative's 2025 Special 301 Report on the adequacy and effectiveness of United States trading partners' protection and enforcement of intellectual property rights, there are certainly issues of counterfeiting and sale of

[16] FDA Center for Drug Evaluation and Research FY2023 Report on the State of Pharmaceutical Quality. (A breakdown of dietary supplement facilities within human food facilities is not available.)

[17] OTC medicines are on the market through either new drug applications (including abbreviated new drug application), the same product licensing system as for prescription drugs, or under OTC monographs established by FDA. OTC monographs cover FDA reviews of active ingredients by therapeutic category, rather than product-by-product reviews. (See federal Food, Drug, and Cosmetic Act Sec. 505G.) Thus, there are fewer barriers to entry for OTC monograph drugs in the US. A significant majority of OTC medicines are regulated through monographs.

diverted or substandard products, particularly out of China. This is true not only for prescription products, but for OTC medicines and dietary supplements as well, where the rise of e-commerce platforms globally is making it increasingly easier for counterfeiters or diverters to take advantage of online marketplaces where monitoring and regulation are more challenging.

For instance, a 2023 Michigan State Study found that counterfeit products were most commonly purchased via e-commerce websites (39%) and social media (39%). Of the consumers who bought counterfeits on social media, 68% did so on Facebook.[18] Among common markets for counterfeit pharmaceutical and consumer healthcare products are:

- Alibaba Group Platforms (China): Alibaba platforms like AliExpress and Taobao have been reported to sell counterfeit or substandard healthcare products.

- DHgate (China): Another Chinese online platform where counterfeit and substandard healthcare products, including pharmaceuticals and medical devices are listed.

- Supply Leader (Hong Kong): This site represents themselves as "Wholesale supply for e-commerce business" and provides metrics alongside the items they sell, indicating their primary target audience to be e-commerce third-party sellers. Low pricing and direct connection to China are high risk factors for counterfeiting. Test purchases from this site have resulted in receipt of counterfeit versions of healthcare and personal care products.

- Shopee (Latin American and Southeast Asia): Certain seller patterns (quantity numbers that appear random or odd) suggest the possibility that various third-party sellers are connected through one entity. Shopee also offers a Product Liability Protection Program for sale to shoppers in Southeast Asian countries that often accompany counterfeit products. The program allows consumers the ability to file a claim for medical coverage if they experience an adverse event, indicating that the product is not legitimate and potentially normalizing counterfeit products.

In short, we agree that online enforcement against counterfeiting remains a global concern impacting American consumers and legitimate producers. Counterfeit products make their way from China and other source countries directly to online purchasers around the world, including the United States. As tariffs increase the costs of consumer healthcare products in the United States, the risk of foreign counterfeits or substandard products in turn only grows.

Separately, we also note that OTC medicines and dietary supplements have complete price transparency in the US: These products are available at-shelf in hundreds of thousands of retail outlets and online with prices displayed so that consumers can select the consumer healthcare products they need at the value-point selected by the purchasing consumer. As noted at the outset of these comments, consumer healthcare products exist in a highly competitive market that also provides value beyond economics: They empower individuals to take charge of their health. These open market-driven products offer a first line of defense, enabling people to manage common health issues through quick

[18] https://msutoday.msu.edu/news/2023/msu-survey-7-in-10-consumers-deceived-into-buying-counterfeit-products-online

and accessible solutions, reducing the burden on healthcare providers and allowing individuals to address their symptoms promptly.

(vii) The potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies.

As discussed in topics (ii) and (iii), the U.S. imported 64,000 metric tons of API imports for the top 13 OTC medicines from over 62 countries in 2024. These imports represent a small fraction of many OTC products used by Americans to treat common illnesses. Sourcing from abroad permits United States manufacturers to adapt swiftly to market changes, safeguard against supply disruptions, maintain cost competitiveness, adjust to unexpected changes, leverage the benefits efficiencies of foreign manufacturers with proximity to raw materials and other benefits.

(viii) The feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance.

There are many critical factors to consider in determining the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients. Considerations include the current supply chain interdependencies, domestic capacity, federal, state and local regulatory landscape e.g. EPA, FDA, DEA and others, workforce capacity (skills, numbers), and others.

One hurdle for companies is to be able to produce enough API for OTC medicines for domestic use and exporting globally. Onshoring API manufacturing requires a significant investment into research and development, capital and time. Despite these challenges some CHPA members are onshoring production. As just one example, a CHPA member companies, Reckitt, is increasing their domestic production footprint by opening their largest OTC manufacturing facility within the United States in December 2024[19]. Several other CHPA member companies are similarly expanding U.S. or North America capacity.

As stated under topic (ii), global OTC supply chains are largely interdependent as demonstrated by the large number of countries (33) supplying the United States with the top 13 OTC APIs. Currently it may be more feasible to import some products due some countries' exclusive access to certain raw materials and other factors that result in access to low cost, quality and safe OTC medicines in the United States.

Barring regulatory and other hurdles, at a minimum it is estimated to take up to five to seven years to establish a single OTC medicines manufacturing facility (Table 4)[20]. Dietary supplement manufacturers would be similarly impacted. Rapidly increasing manufacturing to scale to meet demands for many of the critical medicines would be a challenge and require interventions beyond the manufacturers' control. Toward this end, we welcome the President's May 5, 2025 Executive Order on Regulatory Relief to Promote Domestic Production of Critical Medicines. As discussed under topic (iii), there is a dependence on importation of KSMs, APIs and raw materials exclusive to other regions of the world. A steady supply of these materials is required to initiate and sustain production. In some instances,

[19] Reckitt opens its largest OTC manufacturing facility in the UNITED STATES | Reckitt.com

[20] Fact Sheet: President Donald J. Trump Announces Actions to Reduce Regulatory Barriers to Domestic Pharmaceutical Manufacturing – The White House

alternatives may be found through research and development, skills that may not exist within many OTC companies. Manufactures may hire contract drug manufacturing organizations (CDMOs) and organizations[21,22] who focus on updating API synthesis approaches using alternate materials for domestic self-reliance, cost, workforce and other efficiencies. However, the time and costs can be significant. If unsuccessful, there would still be a need to rely on imports.

Table 5. General tasks and timing to onshore OTC medicines manufacturing

Tasks	Estimated Timeframe
Staffing & Contracting	24 months
Regulatory & Design	12–18 months
Facility Construction & Commissioning	18–36 months
Sourcing & Equipment Procurement	6-12 months
Technology Transfer & Validation	9-12 months
Regulatory Approval	12–18 months
Post-Construction Activities	6-10 months
Production Launch	2 months
Total (with overlap)	5-7 years

If technically feasible, stricter United States environmental regulations may impact constructing new API facilities[23]. Synthesis often requires large volumes of hazardous solvents, storage tanks, and effluent treatment plants (ETPs) for treatment of wastewater prior to reuse or disposal into the environment. Manufacturing facilities are permitted only in certain areas for public safety. Governmental agencies including the United States Environmental Protection Agency (EPA), state, and local entities play a critical role in enabling the establishment of API manufacturing facilities. They must have a workforce commensurate with the demand for approvals. Similarly, the FDA must be appropriately staffed and focused on expediting API manufacturer related approvals. Other agencies like the United States Drug Enforcement Agency (DEA) would have similar considerations when controlled substances are produced. Since many of the regulatory agencies are independent, coordination and alignment at all levels of government would expedite onshoring.

In summary, the OTC medicines and dietary supplement industries have technical, workforce, supply chain and regulatory challenges to address before extensive onshoring can be accomplished. The technical challenges of redesigning manufacturing processes can be cost prohibitive for OTC and dietary manufacturers and may be inapplicable for many medicines and supplements. In lieu of redesigning processes, technology can be transferred from abroad but still requires a high level of skill that must also be on shored especially for API synthesis. In the interim, existing manufacturers would continue to import critical tariffed raw materials that are not available in the United States for API synthesis and formulating in the finished products.

The timelines and scale of onshoring efforts must match the capacity of federal, state and local regulatory agencies. All factors mentioned must be addressed ahead of large-scale expansion to

[21] Medicines for All Institute - College of Engineering- Virginia Commonwealth University
[22] Phlow Corp. | Providing a Resilient and Reliable Supply of Life Changing Medicines
[23] Fact Sheet: President Donald J. Trump Announces Actions to Reduce Regulatory Barriers to Domestic Pharmaceutical Manufacturing – The White House

substantially meet the domestic demand. Considering timing, technical, raw materials, workforce and other needs, the feasibility of significantly increasing domestic capacity for OTC medicines, dietary supplements and ingredients appears low.

(ix) The impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security.

Rather than enhancing or protecting national security, we are concerned that, absent sufficient phasing, proportionality, and flexibility in any introduction of tariffs, placing consumer healthcare products under tariffs will inevitably create stresses and risk to complex supply chains. This could lead to shortages on some consumer healthcare products. It is in no one's interest to constrict American consumers' ability to choose their preferred products due to empty store shelves, in turn, forcing Americans to settle for alternatives they either don't want or that might not work as well for their specific needs.

Considering the low margins on consumer healthcare products, we are also concerned that any production cost increases as a result of tariffs must be passed on to the consumer in order for manufacturers to continue producing these products. It is important to take into consideration that consumers are sensitive to cost – even small increases in price can result in purchasing shifts. While many of these medicines are produced in the United States, resilient global supply chains are needed to continue sourcing the ingredients that go into them.

A third consideration speaks to the overlap between the US-Mexico-Canada Agreement on trade and any pending Section 232 action. Several CHPA members have expanded manufacturing capacity in Canada and Mexico since 2017, shifting capacity there from other parts of the world. They did so in reliance on the USMCA agreement, where they have been manufacturing for North America or all of the Americas. In one CHPA member company example, dosage forms are finished in Canada or Mexico, and then placed in final packaging and labeled in the United States (i.e., no tariff shift despite the value-added in the United States). This has allowed that manufacturer to invest over $350 million in its United States production facilities in the last five years, supporting an increase in United States jobs.

Given the significant impact tariffs could have on American consumers and our healthcare system, we ask that any tariff actions be phased, flexible, and proportional, and targeted to clearly identified national security risks rather than broad application. We encourage the Administration provide a process for relief and to carefully consider the consequences of imposing tariffs that would burden Americans with out-of-stock retail shelves or higher costs every time they need to purchase a safe, beneficial, and affordable option to care for themselves or their families. Protecting access to these essential products must remain a priority. Keeping these products accessible for Americans aligns with the Administration's commitment to foster self-reliance. Limiting supply chains could have the opposite impact: disrupting access and reducing choices.

(x) any other relevant factors.

Even in scenarios such as those described under topic (viii), and with a number of companies currently expanding United States finished product manufacturing capacity, this could be accelerated by means such as:

- Accelerated depreciation of capital investment expenses
- Workforce training credits
- Investment tax credits to spur relocation
- Production tax credits for three to five years to incentivize rapid expansion
- Assistance in identifying and reducing some of the permitting barriers to building or expanding facilities, or at least expediting permitting process. We welcome the President's May 5, 2025, Executive Order, Regulatory Relief to Promote Domestic Production of Critical Medicines, to accelerate this effort.[24]
- Offsets on duties imposed on ingredients and other key inputs for products finished in the U.S.
- Providing tariff relief in bilateral agreements with trading partners
- Continuing duty-free entry on USMCA-compliant goods.

These means would address the most critical bottlenecks facing our industry and manufacturing here in the U.S. more directly and viably than broad-based tariffs.

III. Conclusion

Looking ahead, CHPA member manufacturers welcome opportunities to increase manufacturing capacity in the United States. As noted under topic (viii), a number of manufacturers are already actively working to boost their United States manufacturing capacity. But such investments are not made overnight, and there is a reliance interest in recent capacity expansions under USMCA. Expanding capacity typically takes multiple years. While such transitions take place, American consumers must continue to have access to consumer healthcare products to get and stay healthy.

Given the significant impact tariffs could have on American consumers and our healthcare system, we ask that any tariff actions be phased, flexible, and proportional, targeting clearly identified national security risks rather than broad application. We urge the Administration provide a process for relief and to carefully consider the consequences of imposing tariffs that would burden Americans with out-of-stock retail shelves or higher costs for safe, beneficial, and affordable consumer healthcare options. Protecting access to these essential products must remain a priority. Keeping these products accessible for Americans aligns with the Administration's commitment to foster self-reliance. Limiting supply chains could have the opposite impact: disrupting access and reducing choices.

Our members look forward to continuing to provide American families with safe, beneficial, and affordable healthcare products to treat and prevent many common ailments and conditions. We hope to be able to do so with market-driven solutions that take into account global, complex supply chains,

[24] We acknowledge this has federal, state, and local aspects beyond this investigation.

encourage a long-term shift to more domestic production, and continue to provide access and choice to American consumers.

We appreciate the opportunity to provide our views. We are available to provide additional information, data, and analysis, if requested.

Sincerely,

David Spangler

David C. Spangler
Senior Vice President, Legal, Government Affairs & Policy

Fred Meadows

Fred Meadows, Ph.D.
Senior Director, Quality, Technical & Regulatory Affairs

CHPA-Sec232_pharmaceuticals_investigation_comments-May2025