(i) The Current and Projected Demand for Pharmaceuticals and Pharmaceutical Ingredients in the United States

The current demand for pharmaceuticals and pharmaceutical ingredients in the United States can be measured by looking at different indicators. Whatever matrix you choose to use to indicate the demand, all show the same result of consistent growth with billions of prescriptions for pharmaceuticals written every year. Increasing demand is expected as we have an increasing aging population and increasing life expectancy, in part due to the success of these pharmaceutical interventions. With the demand for pharmaceuticals increasing, the demand for pharmaceutical ingredients to make those pharmaceuticals is also increasing. Absent the unknown and yet not invented technology or therapy the demand trend is expected to continue. With more products and more patients, the projected demand is expected to increase at an exponential rate.

(ii) The Extent to Which Domestic Production of Pharmaceuticals and Pharmaceutical Ingredients Can Meet Domestic Demand

Domestic production of pharmaceuticals and pharmaceutical ingredients could meet domestic demand; however, there has been a void of investment in this market segment for decades as businesses capture savings from emerging markets. The result is the current domestic production can not meet the domestic demand. As a nation we are dependent on foreign supply of pharmaceutical ingredients to meet the domestic demand for pharmaceuticals. To meet the domestic demand and accomplish an end goal of pharmacological independence a significant amount of time and capital is required.

While certain pharmaceutical segments maintain stronger domestic production capabilities, particularly novel branded medications and biologics, the overall ecosystem cannot sustain American pharmaceutical needs independently. Without significant policy interventions and strategic investments in manufacturing infrastructure, the gap between domestic pharmaceutical demand and production capacity will continue to widen, further increasing America's dependency on international sources for essential medicines.

(iii) The Role of Foreign Supply Chains in Meeting United States Demand for Pharmaceuticals and Pharmaceutical Ingredients

With nearly all of our generic pharmaceuticals being manufactured outside the United States and the vast majority of active pharmaceutical ingredients being manufactured outside the United States, foreign supply chains are critical to meet the current demand for pharmaceuticals and pharmaceutical ingredients. Areva can directly attest to foreign dependency, with its specialized therapeutic areas such as oncology. The case of a critical leukemia drug manufactured by a domestic pharmaceutical company illustrates vulnerabilities. In 2020, only two global suppliers of the necessary API existed—one in Israel and another in Wuhan, China. When this essential ingredient for gene therapy, stem cell transplants, and other advanced cancer treatments faced acute shortages, the remaining supplier exploited their market position by **quadrupling** prices, knowing domestic manufacturers had no alternatives. Despite expedited FDA approval for API sourcing changes, the shortage created significant disruptions, with major pharmaceutical companies like Johsnon&Johnson, Gilead, and Bristol Meyers Squibb unable to secure sufficient

supplies for their gene therapy patients. This meant that patients that could have survived with the therapy available did not survive because of our dependence on a foreign supply of materials.

There is a broader strategic vulnerability created by concentrated API supply chains: foreign suppliers can effectively control both availability and pricing of critical medications, potentially compromising patient care at a whim or during global crises and creating significant economic leverage over the United States healthcare system. Without strategic diversification, these dependencies will continue to present profound challenges to America's pharmaceutical supply.

(iv) The Concentration of United States Imports of Pharmaceuticals and Pharmaceutical Ingredients from a Small Number of Suppliers and the Associated Risks

The United States has experienced a profound transformation in pharmaceutical supply chains over the past decade, with significant implications for national security, patient care, and economic stability. Traditional Western suppliers from Germany, Austria, Poland, and France have largely exited the pharmaceutical ingredients market, creating a vacuum that has been filled predominantly by a small number of suppliers from India and China. This shift is starkly visible at major industry gatherings like CPHI, where Indian and Chinese companies now dominate the supplier landscape.

- The statistical evidence of this dependency is compelling: approximately 72% of active pharmaceutical ingredients (APIs) used in the United States drug supply are manufactured across more than 150 countries, with two nations—India (48%) and China (13%)—controlling the majority of this supply. Even more concerning is the acceleration of this trend, with United States imports of Chinese pharmaceuticals surging by 485% between 2020 and 2022, growing from $2.1 billion to $10.3 billion. *Wilson Center, "Strengthening US-Mexico Quality Pharmaceutical Supply Chains," 2023*.
- *Atlantic Council, "The US is relying more on China for pharmaceuticals — and vice versa," April 21, 2023*.
- Based on specific case information provided by Areva Pharmaceuticals regarding their fludarabine API sourcing challenges in 2020.

The concentration creates the possibility for these nations or suppliers to leverage our dependency and arbitrarily set price for necessary ingredients or refuse to supply. Furthermore, our dependency restricts the freedom of our leaders to exercise desired foreign policy out of fear for retaliation in the supply chain. The United States faces critical national security vulnerabilities due to the extreme concentration of pharmaceutical ingredient suppliers, particularly in oncology treatments where innovative therapies rely on a foundation of established medications. Essential cancer-fighting APIs—including Fludarabine, Cytarabine, Fluorouracil, Cladribine, Carboplatin, Etomidate, and Methotrexate—are predominantly sourced from nations that maintain adversarial relationships with the United States, creating significant supply chain risks.

Smaller pharmaceutical manufacturers like Areva face substantial challenges accessing these critical ingredients, despite having developed domestic production plans. While the technological expertise exists to manufacture these cancer APIs within the United States at competitive costs, companies require substantial capital investment to establish continuous manufacturing processes

that begin with basic starting materials and implement new more efficient technologies into the manufacturing process. This capital gap represents a significant barrier to reducing America's dangerous dependency on foreign suppliers.

The concentration risk extends beyond mere supply chain disruptions. When essential medications are controlled by a limited number of foreign entities, treatment protocols for millions of American patients become vulnerable to geopolitical tensions, trade disputes, and deliberate market manipulation. This vulnerability was demonstrated during recent oncology drug shortages when limited supplier options resulted in treatment delays and suboptimal care for cancer patients nationwide.

Areva has developed comprehensive plans—including detailed blueprints, schematics, financial models, and manufacturing technology—to reestablish domestic production of these key cancer APIs. These plans represent a strategic opportunity to address a critical national security vulnerability while strengthening America's pharmaceutical manufacturing base. With appropriate capital investment and policy support, this model could serve as a template for reducing dependency across other vulnerable therapeutic categories.

(v) The Impact of Foreign Government Subsidies and Predatory Trade Practices on United States Pharmaceuticals Industry Competitiveness

As already illustrated China and India are filling the supply vacuum. This is possible because of the Chinese and Indian government support for their pharmaceutical sectors creating unnatural price advantages that domestic companies cannot match through efficiency alone. This reality was illustrated when a Chinese API vendor admitted to an American pharmaceutical company that they could readily secure multi-million dollar government loans for pharmaceutical manufacturing—a level of financial support unavailable to their United States counterparts. This disparity was underscored by a German manufacturer's admission that their input costs exceeded Chinese competitors' selling prices, revealing the impossibility of competing through legitimate market mechanisms alone.

These predatory pricing practices have particularly severe consequences in critical therapeutic areas with limited suppliers. When Areva Pharmaceuticals had no alternative but to qualify a Chinese vendor as one of only two global sources for a critical cancer therapy ingredient, this created a situation of extreme vulnerability. The Chinese supplier, recognizing the irreplaceable nature of their product in essential treatment protocols, gained significant leverage over pricing and supply terms.

Areva Pharmaceuticals possesses superior technological capabilities, including advanced fermentation techniques that could simplify manufacturing processes currently used in China and implement continuous processing from raw material to API to finished pharmaceuticals. However, without government support similar to our competitors it is not possible to deploy these innovations and America's technological advantages remain theoretical rather than practical resulting in continuous decline of domestic manufacturing increasing dependence on foreign supply. This disconnect between American innovation and production capacity represents a strategic vulnerability that foreign competitors continue to exploit through government-backed

predatory practices, systematically undermining domestic pharmaceutical manufacturing competitiveness across critical therapeutic categories.

(vi) The Economic Impact of Artificially Suppressed Prices of Pharmaceuticals and Pharmaceutical Ingredients Due to Foreign Unfair Trade Practices and State-Sponsored Overproduction

The domestic pharmaceutical market faces systematic price distortions through coordinated dumping strategies employed by Chinese and Indian manufacturers, each leveraging distinct competitive advantages to undermine American production capacity. These practices create complex economic ripple effects throughout the domestic healthcare system beyond the immediate displacement of domestic manufacturing. In fact they make creating the alternative of domestic production nearly impossible as they can simply over produce while we begin domestic manufacturing, stock pile until we are ready to enter the market, and then dump the excess product on the market when we are ready to supply domestic products resulting in catastrophic price drops causing massive losses to the domestic producer.

Chinese manufacturers excel in large-scale API production, leveraging significant economies of scale and state support to produce pharmaceutical ingredients at artificially low prices. Their distribution approach typically relies on networks of brokers and agents, creating an illusion of market competition when multiple vendors in fact represent the same manufacturing source. While China's pharmaceutical export strategy has historically focused on raw materials, there are clear indicators of strategic intent to develop finished product capabilities that would further intensify market pressures on domestic manufacturers.

Indian pharmaceutical companies employ a more sophisticated market penetration strategy by vertically integrating their operations—manufacturing both APIs and finished dosage forms like tablets, capsules, and injectables. Their approach involves strategic partnerships with major domestic pharmaceutical wholesalers like Cencora, McKesson, and Cardinal Health. This arrangement facilitates a particularly damaging form of market manipulation: Indian manufacturers provide artificially low-priced finished pharmaceuticals to these distributors, who then apply extreme markups of 6,000-8,000%, creating an economic incentive structure that benefits both the foreign manufacturer and the American distributor while systematically undermining domestic production capacity.

This complex web of artificially suppressed input prices, predatory distribution arrangements, and strategic market manipulation creates structural barriers for domestic pharmaceutical manufacturing revival. The economic damage extends beyond lost manufacturing jobs to include diminished innovation incentives, reduced quality control, increased supply chain vulnerability, and ultimately higher costs for the domestic healthcare system despite the appearance of cheap imports. Without addressing these unfair trade practices and state-sponsored overproduction, efforts to rebuild domestic pharmaceutical manufacturing capacity will face persistent, artificial economic barriers.

(vii) The Potential for Export Restrictions by Foreign Nations, Including the Ability of Foreign Nations to Weaponize Their Control Over Pharmaceuticals Supplies

A foreign nation may choose to restrict the supply of materials resulting in a large scale shortage of necessary medications resulting in widespread loss of life. Furthermore, as the industries in these countries are often financed or otherwise sponsored by the respective government, those entities have little leverage and must do as they are instructed. As our dependence increases and foreign adversaries control more and more of the supply, the risk of our dependence being used against us in conflict rises. While explicit pharmaceutical export restrictions have not been widely implemented, they are certainly possible, especially in retaliation for tariffs. What we commonly see are subtler forms of supply manipulation which represent a clear and present threat to national security and public health. Foreign suppliers, particularly from China, employ strategic manufacturing delays and capacity limitations that function as de facto export controls. These disruptions—often extending to 18 months or longer for critical APIs—cannot be explained by legitimate manufacturing constraints and demonstrate how supply chains can be weaponized without formal policy declarations.

The vulnerability is particularly acute for widely used medications that Americans take for granted. In a conflict scenario with China, even basic over-the-counter products like Tylenol could face severe shortages, as China controls a substantial portion of the global acetaminophen raw material supply chain. This dependency extends across numerous therapeutic categories, creating multiple points of vulnerability that could be exploited during geopolitical tensions.

Historical precedent for such weaponization exists across other strategic sectors where foreign nations have restricted exports of critical materials during diplomatic conflicts. The pharmaceutical sector's vulnerabilities are particularly concerning given the direct impact on public health and the extended timeframes needed to develop alternative sourcing or domestic production. Unlike consumer goods, where substitutes may be readily available, medication shortages directly threaten patient survival, making pharmaceutical dependency an especially powerful leverage point in international relations.

(viii) The Feasibility of Increasing Domestic Capacity for Pharmaceuticals and Pharmaceutical Ingredients to Reduce Import Reliance

It is feasible to immediately increase domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance. If you could find a company with existing business plans, schematics for facilities, technology and know-how to manufacture, and experience in manufacturing and distributing pharmaceuticals and API, and a history of success with the FDA you would have a perfect partner to meet the domestic demand (the “Perfect Partner”). From the moment funding reaches a Perfect Partner until the moment an FDA approved batch of API enters the supply chain it is likely 5 years. The time is required because a facility would have to be constructed or retrofit, that facility would need to be approved by the FDA, then the approved facility would produce a batch of API which has to be approved by the FDA, and only then can the manufacturer begin to scale up manufacturing of API to meet domestic demand.

The FDA role in the process can be the biggest rate limiting factor and should we have cooperation from the FDA the 5 year time period could be dramatically shorter.

While increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients will reduce import reliance the situation is so dire it is simply too much to do all at once. We must start somewhere and how far we get is dependent upon how much capital is allocated and identifying capable companies ready, willing, and able to implement a plan for manufacturing API and capital to execute on those plans. Areva is a Perfect Partner and stands ready, willing, and able to execute on an existing plan to manufacture API. Areva will require assistance with capital to execute on those plans. Areva can execute this plan immediately and completion will depend in large part on the FDA approval process of the facility. Rebuilding domestic pharmaceutical manufacturing capacity represents a viable strategic imperative with demonstrated models for implementation. Areva Pharmaceuticals has developed a comprehensive, shovel-ready approach to reestablish domestic production of critical cancer APIs on their 14-acre project site in Indiana. This initiative exemplifies the feasibility of targeted reshoring in strategic therapeutic areas.

The Areva proposal includes complete financial modeling, technological specifications, and documented support from federal and state representatives—demonstrating the readiness of this approach for implementation. As an FDA-approved pharmaceutical company with established expertise in oncology products, Areva brings critical domain knowledge and regulatory experience essential for successful API manufacturing restoration.

The economics of domestic pharmaceutical ingredient production become increasingly favorable when accounting for the true costs of foreign dependency, including supply chain disruptions, quality control issues, and national security risks. Advanced manufacturing techniques, including continuous processing, can significantly enhance the competitiveness of domestic production while reducing environmental impacts and improving quality consistency.

Strategic government support through procurement guarantees, tax incentives, and innovation partnerships can further enhance the viability of domestic pharmaceutical manufacturing. By focusing on critical therapeutic areas with clear national security implications, rather than attempting to reshore all pharmaceutical production, the United States can develop a targeted, economically sustainable approach to reducing its most dangerous supply chain vulnerabilities. Once we have reduced our reliance on foreign supply enough options like tariffs become viable again to protect the cultivated domestic manufacturing.

(ix) The Impact of Current Trade Policies on Domestic Production of Pharmaceuticals and Pharmaceutical Ingredients, and Additional Measures to Protect National Security

Current trade policies have not sufficiently addressed the critical vulnerability in pharmaceutical supply chains. Furthermore, the use of tariffs or similar measures under the current system of reliance is reckless and poses an unreasonable risk to the pharmaceutical market as we have no alternative supply. When a nation is as dependent upon foreign supply as we have become, we can not even use trade policies to assist domestic production as the risk of supply interruption across the market is too significant.

We are decades behind where we need to be in domestic production. Rather than pursuing a comprehensive reshoring of all API manufacturing—which would be economically impractical targeted strategic approach is needed. The United States should prioritize developing domestic manufacturing capabilities in key therapeutic segments including cancer drugs, anti-infectives, analgesics, and other critical medications where supply chain disruptions pose significant national security risks.

This focused approach leverages America's existing scale advantages, as our domestic market is large enough to sustain production in these strategic segments. Furthermore, American pharmaceutical manufacturing could serve dual strategic purposes: ensuring national self-sufficiency in critical medications while establishing the United States as a trusted global supplier of high-quality pharmaceuticals.

Expanding pharmaceutical export markets, particularly in regions like Africa where concerns about the quality of pharmaceuticals from countries like India and China exist, represents both an economic opportunity and a diplomatic advantage. By supplying higher-quality alternatives to developing nations, the United States can build stronger international relationships while improving global health outcomes. Once established domestic supply chains are meeting domestic demands there is significant export opportunity.

Additional trade measures, including targeted tariffs, quotas, or incentives for domestic production, may be necessary to protect these strategic pharmaceutical sectors from market distortions caused by foreign subsidies and predatory pricing. However, these should be implemented as part of a comprehensive policy framework that balances immediate security concerns with long-term industrial development goals and international trade relationships and must be made with great caution as we should not disrupt the supply through these means until we have ability to supply domestically as the alternative of no medications is simply not an acceptable outcome.

(x) Any other relevant factors

Areva stands ready willing and able to assist the Secretary of Commerce on their investigation under section 232 of the Trade Expansion Act (19 U.S.C. 1862) to determine the effects on national security of imports of pharmaceutical ingredients, and their derivative products. As a manufacturer Areva is particularly well informed and can speak of its first hand experiences and challenges. Should additional information be desired please reach Vic Swaminathan, CEO, Areva Pharmaceuticals at info@arevapharma.com or call 855-853-4760.