Testimony of Christine Baeder
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Senate Special Committee on Aging
"Leveling the Playing Field: Restoring America's Edge in Generic Drug Manufacturing"
September 23, 2026

Chairman Scott, Ranking Member Gillibrand, and members of the Committee, thank you for holding this critically important hearing. My name is Christine Baeder. I am the President of Apotex Corp., a leading North American supplier of generic essential medicines. We are proud to supply high-quality, lifesaving innovative and generic medicines to millions of people in the United States and around the world. Globally headquartered in Toronto, we are the top provider of generic prescriptions in Canada and a top ten supplier in the U.S. and Mexico.

I am grateful to the Committee for dedicating this hearing to an issue that is so essential to all of us—securing a resilient, domestic supply of generic medicines for current and future generations. The data is clear—for a variety of reasons, the United States generic pharmaceutical supply chain has become increasingly reliant on overseas active pharmaceutical ingredients (API), key starting material (KSM), and other important inputs. Given that generic pharmaceuticals account for nearly 90 percent of all prescriptions filled in the United States,[1] the potential consequences of this overreliance are stark. Simply stated, the Committee is right to consider mechanisms to reshore the generic supply chain, especially API and KSM, and ensure uninterrupted patient access to our essential medicines – and provide the public with transparency about where the medicines and the ingredients they are composed of come from as proposed by the Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Listings (CLEAR LABELS) Act. Apotex strongly supports the CLEAR LABELS Act and encourages Congress to pass a final version of the bill that requires the most granular level of information possible regarding the location of both the finished dosage form and API manufacturing sites to be disclosed in drug labeling. We applaud the Committee's unwavering commitment to strengthening the U.S. generic pharmaceutical supply chain and its continued focus on this issue of paramount importance to our patients and U.S. national security.

Today's hearing represents a unique opportunity to discuss policy mechanisms to help restore resiliency and bring generic manufacturing back to the United States. As I explain

[1] AAM, *2026 U.S. Generic & Biosimilar Medicines Saving Report*, at 9-10 (Sept. 2026), https://accessiblemeds.org/wp-content/uploads/2026/09/AAM-2026-Generic-Biosimilar-Medicines-Savings-Report-WEB-v3.pdf ("AAM Savings Report").

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in my testimony, a variety of factors have contributed to generics leaving the United States, including "race-to-the-bottom" pricing pressures, patent abuse by brand-name manufacturers, and the lack of meaningful incentives for generic manufacturers to produce medicines in the United States and North America. The last factor is the most critical—successful onshoring efforts will depend heavily on creating robust incentives to reward domestic manufacturing of generic medicines. Absent those incentives, domestic manufacturing will merely be an oft-discussed but never realized concept. The economics of our industry will not permit another outcome.

Importantly, we do not need to look far for incentives to onshore generic medicines. One such incentive—180-day exclusivity—is already an essential pillar of the Hatch-Waxman Act, the statutory framework that created the modern generic industry. 180-day exclusivity is the so-called "brass ring" of the industry because it is the singular incentive for generic manufacturers to challenge brand patents and bring their generic products to market as quickly as possible. Absent the incentive that 180-day exclusivity provides, generic manufacturers may well wait until brand patent expiry to market their lower-cost medicines, delaying patient access to lower-cost medicines and keeping brand drug prices higher for longer. ***Because 180-day exclusivity is so fundamental to the generic market, it is the obvious and best candidate to use as a policy lever to encourage generic onshoring.***

The value that 180-day exclusivity provides is straightforward: the first generic applicant who submits a substantially complete abbreviated new drug application ("ANDA") challenging brand patents as invalid or not infringed (a "paragraph IV" certification) is eligible for 180 days of market exclusivity.[2] During that period of market exclusivity, the Food and Drug Administration (FDA) cannot approve a subsequent ANDA with a paragraph IV certification that references the same brand drug, meaning that subsequent ANDAs cannot be legally marketed. Exclusivity therefore rewards the "trailblazing" first generic applicant who bears the cost and risk of invalidating or designing around the brand patents that increasingly create steeper obstacles to market competition. It is not an understatement to say that 180-day exclusivity is a major driver of virtually every major decision that generic manufacturers make. And the savings to patients from the incentive cannot be overstated—by accelerating generic competition, the 180-day incentive saved the U.S. healthcare system nearly $20 billion in one year alone.[3]

The Trump Administration has recognized the importance of this policy lever in FDA's FY 2027 legislative proposals. Congress should embrace this proposal to use the 180-day exclusivity incentive to "help repatriate the U.S. pharmaceutical supply chain" by

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[2] FDA, Small Business Assistance | 180-Day Generic Drug Exclusivity (Oct. 26, 2023), https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-180-day-generic-drug-exclusivity.

[3] AAM, *The Hatch-Waxman 180-Day Exclusivity Incentive Accelerates Patient Access to First Generics*, https://accessiblemeds.org/resources/fact-sheets/the-hatch-waxman-180-day-exclusivity-incentive-accelerates-patient-access-to-first-generics/ ("AAM Fact Sheet").

rewarding domestic manufacturers.[4] FDA has correctly focused on a type of 180-day exclusivity that has been significantly diluted since the passage of Hatch-Waxman and would substantially benefit from a legislative recalibration to restore its value and create a strong incentive for domestic manufacturing. I am referring to 180-day exclusivity for brand "new chemical entities" or "NCE's."[5] NCE simply refers to the fact that the brand drug contains no "active moiety" (the portions of the drug responsible for its physiological or pharmacological action) that has been previously approved by FDA. In other words, it represents the first brand approval of a drug.

Generics are subject to very specific timing requirements for NCE's that underscore the opportunity for legislative adjustments incentivizing onshoring. If an ANDA contains a paragraph IV certification, it can be submitted on the so-called "NCE-1" date. Brand NCE exclusivity lasts for five years, and NCE-1 simply refers to the fact that an ANDA with a paragraph IV certification can be submitted at year 4.[6] This creates a specific timing dynamic—multiple first applicants may submit on exactly the same "NCE-1" day and all share 180-day exclusivity.[7] Notably, FDA made this change—submissions on the same day resulting in shared exclusivity—in response to generic applicants "camping out adjacent to an FDA building for periods ranging from 1 day to more than 3 weeks" hoping to be the first applicant in the door.[8]

Because multiple first applicants can share the exclusivity, 180-day exclusivity for NCE's has been substantially diluted. Indeed, it is not uncommon for there to be 20+ shared first applicants for NCE's such as Eliquis®, a drug subject to Medicare price negotiation because of its high prices. Similar examples include Tecfidera® (29 first applicants), Aubagio® (21 first applicants), Farxiga® (20 first applicants), and Entresto® (18 first applicants). The impact on the incentive is obvious: with 20+ shared first applicants, no individual first applicant has a particularly strong incentive to "trailblaze." The proliferation of shared exclusivity for NCE's amongst many first applicants has therefore substantially changed the calculus for generic manufacturers on these high-priced, first-time brand approvals. This devaluing of the 180-day exclusivity incentive has contributed to the shift to overseas manufacturing, including for critical inputs.

For all these reasons, Apotex strongly supports legislation to recalibrate 180-day exclusivity for NCE's to reshore generic medicines, especially API and KSM, and restore value to 180-day exclusivity for NCE's. Apotex wishes to highlight several key principles of a recalibration of 180-day exclusivity that are particularly critical to ensure a realistic

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[4] Department of Health and Human Services, *FDA Fiscal Year 2027 Justification of Estimates for Appropriations Committees*, at 17 (Apr. 2026), https://www.fda.gov/media/191778/download?attachment.

[5] 21 C.F.R. § 314.108 (2026).

[6] 21 U.S.C. § 355(j)(5)(F)(ii).

[7] Erika Lietzan & Julia Post, *The Law of 180-Day Exclusivity*, 71 FOOD & DRUG L.J. 327, 344, https://scholarship.law.missouri.edu/facpubs/644/.

[8] *Id.*

timeframe for onshoring and friendshoring, prohibit gaming, and set effective dates that are consistent with FDA's approach under the Medicare Modernization Act ("MMA"):

- Importance of API Reshoring / Staging: I want to emphasize a key point: onshoring is not achieved without API and KSM returning to the United States. API and KSM are almost exclusively made overseas, and my overarching point today is that it is not sufficient for manufacturers in the United States to merely repackage foreign medicines. To be clear, it will take time to onshore API and KSM as this Committee has noted,[9] and Apotex supports staging. Specifically, it has been contemplated that, for the first five years after enactment, an ANDA applicant is eligible for the domestic 180-day exclusivity if the finished dosage form (FDF) is manufactured in the United States. After five years, the country of origin of the active pharmaceutical ingredient (API) would then be incorporated into the eligibility criteria for the exclusivity along with the U.S. FDF manufacturing requirement. Importantly, the Centers for Medicare & Medicaid Services (CMS) recently considered a similar approach focusing on FDF manufacturing and API country of origin as part of a proposed rulemaking on Medicare reimbursement for essential medicines.[10] Apotex is supportive of such an approach. That said, Apotex believes that because the most urgent pharmaceutical supply chain vulnerabilities to U.S national security and the public health system are our dependence on overseas API and KSMs, policies to achieve onshoring objectives, especially concerning generic medicines, must focus on incentivizing API and KSM manufacturing in the United States.

  While Apotex would not oppose an approach first focusing on FDF, ***immediate API incentives are the better policy option for addressing U.S. pharmaceutical supply chain national security and public health vulnerabilities as quickly as possible***. The U.S. by and large has very ample FDF capacity already. That fact, in our view, warrants demand signals that prioritize incentivizing the onshoring of API capacity immediately, not years down the road. Establishing the use of U.S. manufactured API turned into FDF in the US from the start as the NCE-1 exclusivity criteria achieves that goal. Congress could also consider a phased construct first focusing on APIs and FDFs made in trusted ally countries, including mutual recognition agreement (MRA) countries and countries that have a free trade agreement (FTA) with the United States, as well as requiring domestic bioequivalence studies as part of the eligibility criteria for NCE-1 exclusivity. The critical point is this—delaying API incentives delays onshoring. The United States

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[9] United States Senate Special Committee on Aging, *Protecting Seniors' Access to Essential Medications: Securing the Foreign Generic Pharmaceutical Supply Chain*, at 26 (Oct. 20, 2025), https://www.aging.senate.gov/imo/media/doc/senate_aging_american_drugs_report.pdf ("October Report").

[10] Department of Health and Human Services, *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems*, at 610 (July 7, 2026), https://public-inspection.federalregister.gov/2026-13656.pdf ("HHS Proposed Rule").

currently lacks capacity for API, and constructs must incentivize API reshoring immediately to ensure that there is not a protracted delay in bringing API back to the United States.

- Traditional NCE-1 timing remains when there is no domestic manufacturer: Apotex strongly supports legislative language providing that all ANDA applicants will still submit on the NCE-1 date, and FDA will subsequently determine whether there is a qualifying first applicant. This helps ensure that the proposed changes do not fundamentally modify NCE-1 submission dates and result in some generics submitting later in time. In other words, this language will ensure that all manufacturers are still incentivized to submit on the earliest date even if a domestic generic is not available. This will ensure that patients have the earliest access to lower-cost medicines.

- Prohibitions against gaming: Legislation should ensure that FDA cannot approve immediate technology transfers and/or secondary FDF sites that would enable gaming of the domestic incentive. In simple terms, generics should not be allowed to game the system by initially listing domestic sites and then transferring to foreign sites immediately after becoming eligible for the exclusivity. Our objectives are only achieved if there is actual domestic manufacturing.

- Effective dates consistent with MMA: These new exclusivity provisions should only apply for ANDAs for a listed drug submitted after the date of enactment where no paragraph IV certifications to that listed drug were made prior to the date of enactment. This approach helps ensure that the same exclusivity framework applies to ANDAs with paragraph IV certifications to the same listed branded drug.

These provisions will help incentivize domestic API and FDF manufacturing and restore the importance of 180-day exclusivity for NCE's. As I noted above, incentives are needed to change behavior, and 180-day exclusivity is the most powerful business incentive in our industry. Adopting this policy would not only benefit future generic production, but it would also play a critical role in incentivizing the onshoring of essential medicine APIs. Indeed, this policy could be coupled with the myriad of policies that are being considered to incentivize the purchase of essential medicines, including proposed rulemaking from CMS on Medicare reimbursement for essential medicines.[11] Such coupling will assure the API manufacturing capacity that will return to the US will be employed to manufacture APIs for not only new generic drugs, but essential generic medicines as well.

The Committee has also rightly recognized, in its October 2025 report, that there needs to be a "federal buyer's market for essential medications," including implementation via long-term direct procurement.[12] Apotex applauds this recommendation and the demand signals it sends. At the same time, direct federal procurement through Veterans Affairs

[11] *See id.*

[12] October Report at 24-27.

(VA) and the Department of Defense (DoD) represents only approximately 5% of the overall market, a far smaller piece of the pie than the Medicare and the commercial markets. In order to construct a durable long-term policy solution, ***policies must target the entirety of the market***. Because 180-day exclusivity is so foundational to every aspect of the generic market, it is the single most important lever to target.

My focus today is providing the Committee and Congress the information they need to help make onshoring a reality as quickly and most efficiently as possible for this generation and future generations. Below, I provide a more detailed overview and supporting documentation for each of these points. I look forward to working with the Committee to achieve these incredibly important objectives.

I. APOTEX IS COMMITTED TO NORTH AMERICAN MANUFACTURING OF GENERIC MEDICINES

Apotex has invested substantially in North American manufacturing of essential generic medicines. Apotex Corp., headquartered in Weston, Florida, is an affiliate of Apotex Inc., a Canadian-based global health company. In the United States alone, Apotex markets more than 130 different product families covering 12 therapeutic areas. We have 313 approved ANDAs and 78 pending at FDA. Importantly, approximately 90% of the medicines that Apotex supplies annually to the U.S. market are manufactured at our high-quality sites in Toronto, guaranteeing a safe and secure supply for generic pharmaceutical medicines. Our Brantford facility, which is one of the remaining API sites in Canada, has special expertise in APIs and currently makes over 30 different APIs.[13]

Apotex is consistently recognized by U.S. regulators, quality organizations, and customers for our high levels of operational excellence, ability to meet market demands, and help in alleviating drug shortages. Recent examples include the U.S. Pharmacopeia's (USP) Champion of Quality award for our industry-leading role in helping launch USP's Pharmaceutical Product Quality Testing Program and our 2023 receipt of the FDA Drug Shortage Assistance Award for our work to alleviate a shortage of varenicline tablets.[14] This example demonstrates the role that Canada has played and can play in alleviating critical drug shortages and the benefits an integrated North American approach to strengthen the generical pharmaceutical supply chain can bring to the United States. In the case of varenicline, Pfizer's product was recalled and there was no generic available in the United States. FDA exercised its waiver authority for Apotex's Canadian-approved product, and Apotex was able to simply drive varenicline across the border to get it to American patients and avert a shortage. ***This example underscores***

[13] According to the API Innovation Center, there are only four API facilities in the U.S. that can produce over 30 APIs and only 15 sites that can make over 10, compared to 350 outside the U.S. See Anthony Sardella, *The US Active Pharmaceutical Ingredient Infrastructure: The current state and considerations to increase US Healthcare Security*, the API Center, at 5 (Aug. 1, 2021), https://apicenter.org/wp-content/uploads/2024/07/The-US-Active-Pharmaceutical-Ingredient-Infrastructure.pdf ("Sardella Report").

[14] FDA, *Drug Shortage Assistance Award to Apotex* (Apr. 4, 2023), https://www.fda.gov/media/173979/download?attachment.

the important role geographic diversity of assets and nearshoring to North American countries can play in the effort to strengthen the U.S. drug supply. Not all products are approved at the same time in all markets, so situations can—and this case did—arise where a generic was not yet on the market in the U.S. but was in Canada, and was easily able to be brought into the U.S. to avert a shortage.

With world-class, large-volume manufacturing finished dosage and API facilities in North America, Apotex is extremely well-positioned to play a leading role in the U.S. effort to reduce dependence on and the concentration of prescription drugs from overseas suppliers. Indeed, in June of this year, Apotex became a public company after being owned for several years by a U.S. private firm, S.K. Capital, that manages several pharmaceutical facilities across the U.S. and Canada. The offering was the largest life sciences Initial Public Offering (IPO) in the history of the Toronto Stock Exchange. Apotex committed again to U.S. domestic production in April of this year, announcing a strategic partnership with New Jersey-based Halo Pharmaceuticals. This partnership provides Apotex with critical sterile injectable manufacturing capacity in the United States in Whippany, New Jersey. S.K. Capital remains Apotex's largest shareholder.

II. GENERICS MEDICINES ARE THE CRUCIAL BACKBONE OF THE HEALTHCARE SYSTEM

A thriving generics industry is an essential part of the promise to provide Americans with access to affordable medicines. Almost 90% of drug prescriptions are filled with generics—and at a much lower cost than brands.[15] Last year, the generics and biosimilars industry saved Americans $496 billion.[16] Over the last decade, that figure amounts to cumulative $3.6 trillion in total savings.[17] Generics are also critically important to the healthcare of America's senior citizens, with Medicare saving over $3,000 per beneficiary, over $160 billion, in last year alone.[18]

These savings, however, come at a cost. The entire generic industry generated less revenue last year from the sale of over 1,000 different drugs than the revenue generated from the sales of just two branded drugs—Mounjaro® and Ozempic®.[19] This economic reality is the defining feature that shapes all generic supply chain decisions.

Generic manufactures are being pinched from both sides. Generic products have thin profit margins that push generic manufacturers to reduce costs wherever possible, including in response to unfair competition from overseas manufacturers that has driven

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[15] AAM Savings Report at 9-10.

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.* at 21.

prices to unsustainable levels. At the same time, generic drug companies are under increasingly intense pricing pressure due to substantial consolidation, in both the retail and institutional channels, of three large generic buying groups that collectively control almost 80 percent of the market.[20] These buyers use their market power to demand contract terms allowing them to terminate purchase contracts if an oversees competitor is able to offer a lower price, even if just by one cent. Even worse, studies show that PBMs are pushing out generic drugs in favor of higher-priced brands which can afford to offer large rebates to the PBMs.[21]

This economic reality has been pushing generic manufacturing overseas for years. Indeed, generics rely on the cost savings provided by an overseas workforce to make the math work. Thus, even if a generic wanted to onshore its manufacturing, it would simply lose out to lower-priced competitors taking advantage of lower labor costs, lesser regulatory standards, and governmental subsidies.

As a North American based generic pharmaceutical manufacturer that has been in operation for over 50 years, Apotex has direct experience with these core sustainability issues. Due to the unsustainable economics of cephalosporins and penicillins fueled by Chinese and Indian government subsidies for their own domestic manufacturers, along with other unfair trade practices, Apotex offshores production of these antibiotics to partners abroad. This allows us to compete in North American markets and continue to make these critical medicines available to U.S. patients. Current market incentives have produced an unsustainable market that has led to shortages and market exits.

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

Had sufficient push-pull incentives been available from North American governments, Apotex would have been willing to invest in the facility and ensure the availability of North American produced antibiotics. However, the inability to compete with overseas antibiotic manufacturers made any such investment unfeasible. Apotex is currently evaluating options regarding its idle cephalosporin facility.

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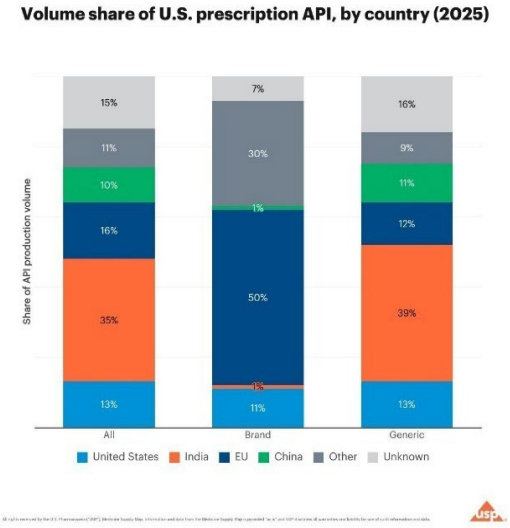
[20] Letter from David R. Gaugh, Interim President and CEO, AAM to Lina M. Khan, Chair, Federal Trade Commission, and Xavier Becerra, Secretary, U.S. Department of Health and Human Services, *re: Request for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages*, at 3 (May 30, 2024), https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Response-to-FTC-HHS-RFI-on-Drug-Shortages-5-30-2024.pdf.

[21] AAM, *Middlemen Increasingly Block Patient Access to New Generics*, at 4 (Jan. 2023), https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Middlemen-Block-Patient-Access-New-Generics-2023-1.pdf.

The significant economic pressure on the generic industry has directly led to drug shortages due to the "lack of incentives to produce less profitable drugs."[22] As an interagency task force concluded during the first Trump Administration, "[m]anufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements all of which limit potential returns" and "contribute to a 'race to the bottom' in pricing."[23] In fact, the situation has deteriorated to the point that the economic sustainability of the generics industry has been called into question, with the market price of essential drugs falling below cost levels that can be maintained. This has prompted companies to exit the U.S. market.[24] Thus, to move generic manufacturing back to America, we need to change the incentives.

III. USP DATA CONFIRMS THAT THE GENERIC SUPPLY CHAIN IS INCREASINGLY RELIANT ON FOREIGN COUNTRIES

The fundamental sustainability issues facing the generic market are borne out by data published by USP.[25] As shown below, generics have largely left the United States in a "race-to-bottom" to stay competitive—only 13% of the API for U.S. generic drugs is sourced domestically, while China accounts for 11%, India accounts for 39%, and the European Union accounts for 12%.



[22] FDA, *Drug Shortages: Root Causes and Potential Solutions*, at 6 (2019) (revised Feb. 11, 2020), https://www.fda.gov/media/131130/download?attachment.

[23] *Id.*

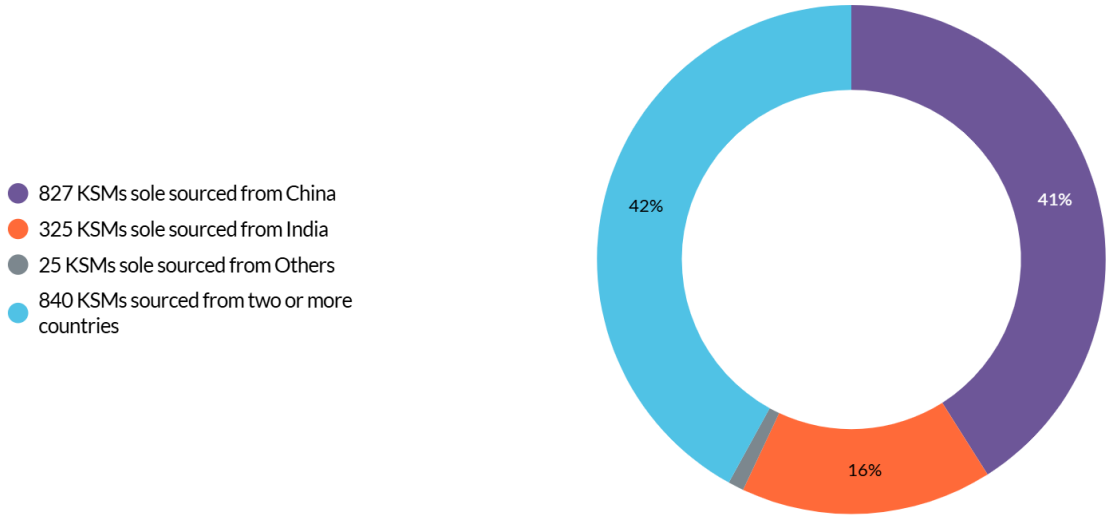
[24] AAM Savings Report at 22.

[25] USP, *India, EU supply majority of API volume for U.S. medicines, while China reaches double-digit share* (Sept. 11, 2026), https://www.usp.org/blog/india-eu-supply-majority-api-volume-us-medicines-while-china-reaches-double-digit-share

This data is consistent with findings from the API Innovation Center, which documented that "more than four out of five of the top 100 generic medicines consumed in the U.S. have no U.S. source of their API,"[26] and "[l]ess than 5% of large-scale API sites, globally, are located in the US."[27]

USP published similar data on KSMs earlier this year.[28] As shown below, China is a dominant producer of KSM used to make APIs:

Figure #1: 58% of KSMs used for U.S.-approved APIs are sole sourced from a single country.[3]



China has a particularly dominant share of KSMs for antibiotics, with USP observing that the antibiotic amoxicillin depends on four KSMs, all of which are exclusively produced in China.[29] The national security implications of this data counsel in favor of taking action to encourage generic manufacturing to return to our shores. Market-based and buy-side policies are central to achieving this objective.

Until policy changes, this situation will predictably get only worse. As I discuss in the next section, we must focus on incentives that have a meaningful impact and reward

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[26] The API Innovation Center, *Building a Resilient Domestic Drug Supply Chain: The Path to National Security*, at 2 (Mar. 25, 2025), https://apicenter.org/wp-content/uploads/2025/03/APIIC-White-Paper-2025-Building-a-Resilient-Domestic-Drug-Supply-Chain.pdf.

[27] Sardella Report at 4.

[28] USP, *USP insights on key starting materials (KSMs) for pharmaceuticals* (June 4, 2026), https://www.usp.org/blog/usp-insights-key-starting-materials-pharmaceuticals.

[29] *Id.*

manufacturers that take on the expense of making medicines in the United States. We must ensure that if products are made in the United States and North America, manufacturers will have confidence that there will be a robust market for those products.

IV. 180-DAY EXCLUSIVITY IS AN ESSENTIAL DOMESTIC MANUFACTURING LEVER

A. 180-Day Exclusivity is the Singular Incentive for Generics to Take on Increasingly Large Brand Patent Thickets.

Bringing a pharmaceutical product to market requires significant investment in research and development, clinical trials, and in the regulatory submission process itself. Many of these costs are large, fixed-cost expenditures that are recouped over decades, not years. And the success of these investments is highly uncertain.

To incentivize companies to make the significant investments required to bring a product to market, Congress has used the promise of exclusive marketing periods as a powerful reward for these efforts. For brand companies, there is a five-year period of exclusivity for NCE's. For generics, the Hatch-Waxman Act provides the 180-day exclusive period that is free from competition from subsequent generics with paragraph IV ANDAs.

While quite modest in comparison to the exclusivities offered to the brands, the value of this 180-day exclusivity period to generics cannot be overstated. For a generic manufacturer marketing a product where it is the sole first applicant, the vast majority of lifetime profits comes during that 180-day exclusivity period.[30] By the time multiple generics enter the marketplace, the generic market tends towards commodity prices, which invariably pushes generic supply chains overseas.

Before the Hatch-Waxman Act was passed in 1984, generic companies would wait until all the patents protecting a brand product had expired, delaying patient access to affordable drugs. The Hatch-Waxman Act changed everything. By providing an abbreviated approval pathway for generic drugs and offering eligibility for 180-day exclusivity to the first applicant to challenge the brand's patents, generics were incentivized for the first time to take on the brand's patents. And the savings to patients and the system from the incentive are massive—by accelerating generic competition, the 180-day incentive saves the system billions of dollars.[31]

I want to be clear: the 180-day exclusivity period is the most important incentive to generic companies, and as such, it is Congress's best tool for shaping the behavior of generic companies in developing and manufacturing their products. Thus, if it is tied to domestic

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[30] C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 948 (Jan. 2011), https://law.stanford.edu/index.php?webauth-document=publication/259458/doc/slspublic/ssrn-id1736822.pdf.

[31] AAM Fact Sheet.

manufacturing requirements, the reward of an exclusive marketing period will bring generic drug manufacturing back to America.

B. The 180-Day Exclusivity Incentive Has Been Dramatically Diminished for NCE's Under Current Law

The Hatch-Waxman Act represented a "grand bargain" between the interest of the brands and the interest of patients in gaining timely access to affordable medicines. The drug development and approval process takes significant time, which ate into the term of the patents protecting the brand's monopoly. The Hatch-Waxman Act restored that lost time, while at the same time creating an approval pathway for generic drugs. Critically, the Act also created the 180-day exclusivity period for first applicants to incentivize generic companies to invest in challenging weak patents that keep affordable drugs from patients.

Over the decades since, however, the generic side of the bargain has quietly eroded. Twenty years ago, being a sole first applicant was so valuable that generics applicants would line up outside after "literally camping out adjacent to, an FDA building for periods ranging from 1 day to more than 3 weeks."[32] To address that situation, FDA issued guidance that it would treat all ANDAs "submitted on the same day as being submitted at the same time for purposes of 180-day exclusivity."[33] This approach was subsequently folded into the statute when Congress passed the MMA.[34]

Since those changes, the number of "first applicants" on an NCE product has grown steadily year-after-year, eroding the value of being the first to file. It is now common for there to be 15 or more generics sharing first applicant status on popular drugs like Entresto®, Farxiga®, and Rexulti®—all of which have been included in Medicare's price negotiations under the Inflation Reduction Act of 2022. Indeed, Eliquis®, a blood thinner prescribed to millions of seniors, had 25 generics share "first applicant" status.

The large number of applicants with shared exclusivity for these products all but ensures a commodity market during the 180-day period, destroying the incentive the 180-day exclusivity period was intended to provide. In addition, because a court ruling invalidating the brand's patents benefits all generics equally, there is little incentive for any individual generic to litigate hard to invalidate weak pharmaceutical patents when the result of success is only a hollow victory shared by dozens of first applicants flooding the market during the exclusivity period.

This situation calls for a solution. Apotex has been an industry leader in operating as a vertically integrated company and knows first-hand the value of manufacturing its products here in North America. By tying the reward of 180-exclusivity to a domestic

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[32] FDA, Guidance for Industry: 180–Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day, at 4 (July 2003), https://www.fda.gov/media/71304/download

[33] *Id.* at 5.

[34] *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

manufacturing commitment, Congress has a unique opportunity before it to restore the value of this critical incentive and bring generic manufacturing back to America.

V. POLICY RECOMMENDATIONS: USING 180-DAY EXCLUSIVITY AS A MECHANISM FOR ONSHORING

Apotex strongly supports modifying 180-day exclusivity for NCE's to incentivize onshoring. As I mentioned above, 180-day exclusivity is the singular incentive for generics to invest the time and expense of challenging brand patents, and it drives virtually every decision that generic manufacturers make with respect to their ANDAs. That makes the incentive a perfect candidate to meaningfully drive and change behaviors. Because the generic industry operates on such thin margins, this is the exact type of incentive that Congress and this Committee need to target.

Congress should consider at least four important points to avoid unintended consequences and ensure that 180-day exclusivity appropriately serves as a demand signal to onshore generics. *First*, onshoring and reshoring are not achieved without focusing on each part of the supply chain, including API. We will not achieve our extraordinarily important goal of making generic medicines in the United States if we merely repackage foreign medicines here. As the Committee has recognized, this process unquestionably takes time. The runway to build new facilities, transfer technology, receive regulatory approvals, and receive environmental permits is substantial.

All that said, I want to reemphasize that onshoring is not achieved without API returning to the United States. We will not achieve our goal in the fastest, most efficient manner possible by phasing in API incentives after a period in which foreign APIs continue to be simply converted into FDF in the United States, as is happening today. We need to see API return as quickly as possible. That is where the vulnerability to the U.S. is far and away most acute. It is therefore better if legislation immediately focuses on and prioritizes API reshoring in addition to FDF. Approaches focused on API and FDF from trusted ally partners, including MRA and FTA countries, should be among the models considered, as should the inclusion of domestic bioequivalence studies in the eligibility criteria for NCE-1 exclusivity. Absent that focus on API, we will lose critical time in the effort to redress acute national security vulnerabilities in the U.S. generic pharmaceutical supply chain. Importantly, there is already existing FDF capacity in the United States that can be employed to convert reinvigorated U.S. API manufacturing capacity into finished dosages.

Second, standard NCE-1 submission rules should remain in effect. In other words, all ANDA applicants will still submit on the NCE-1 date, and FDA will subsequently determine whether there is a qualifying first applicant. This approach is critically important to ensure that NCE-1 submission dates, which are well-established in the law, are not inadvertently altered. From my own experience, 180-day exclusivity is complicated and has been subject to extensive litigation. In that regard, Congress should consider surgical edits, and keeping NCE-1 submission rules as they have been for many years is important.

Third, safeguards should be included to prevent gaming. We want to see generics actually onshore, not merely create the impression that they are onshoring. To achieve that objective, language should be included that prevents a tech transfer from a qualifying first applicant to a foreign site. Similarly, the legislation should ensure that a first applicant cannot use a secondary foreign site to achieve the same objective. These safeguards are critically important to prevent gaming.

Fourth, and consistent with my recommendation for surgical edits, the effective date should align with how 180-day exclusivity has been treated post-MMA. Specifically, the legislation should apply only to ANDAs submitted after the effective date for a listed drug for which no paragraph IV certifications were made before the effective date. This language helps ensure that FDA does not need to grapple with situations where some paragraph IV ANDAs were submitted pre-effective date and some post-effective date, both to the same listed brand drug. That would create complicated exclusivity questions and would invariably lead to unnecessary litigation.

We also respectfully request the Committee continue to investigate the pricing and economic dynamics faced by generic companies. Until the economics change, it will be increasingly difficult for generic companies to onshore production to the United States or North America.

Apotex strongly supports the Committee's careful and considered approach on such a critical incentive. We look forward to continuing to work with Congress on this important issue and a suite of other issues, including the Medicare payment adjustments for essential medicines that CMS is considering, to help onshore these important medicines.

VI. CONCLUSION

Apotex is committed to onshoring generic medicines, both for our generation and generations to come. Apotex sincerely appreciates this Committee's work in making that objective a reality. Thank you for your time, and I look forward to your questions.