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Written Testimony of Kurt Orlofski

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"Leveling the Playing Field: Restoring America's Edge in Generic Drug Manufacturing"

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee:

Thank you for the opportunity to testify about an issue that is fundamental to both America's health security and its economic security: whether the United States will retain the ability to manufacture the medicines Americans rely upon every day.

My name is Kurt Orlofski, and I am the Chief Executive Officer of PAI Pharma.

PAI traces its history to 1968. For nearly six decades, our company has been manufacturing medicines in the United States. We are a leader in generic oral liquid medicines, including ready-to-dose products used extensively in hospitals, long-term care facilities and other healthcare settings. Today, following our acquisition of Nivagen Pharmaceuticals, we are also building a significant domestic sterile injectable platform from a newly constructed aseptic manufacturing facility in Sacramento, California. Lastly, through our VistaPharm label, we service addition treatment clinics across this country with products used in the treatment of opioid addiction.

Our manufacturing is American. We manufacture in South Carolina and California, and our pharmaceutical research and development activities are based in New Jersey, South Carolina, and California. We believe companies like PAI demonstrate that pharmaceuticals can still be developed and manufactured in the United States. But we also see, every day, how the economic and regulatory rules of the generic drug market make that decision increasingly difficult.

As of 2025, FDA itself reports that approximately 69% of generic drug products are manufactured outside the United States. Depending on the FDA dataset used, less than one in ten API manufacturers is located here. (https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-onshoring-manufacturing-drugs-and-biological-products-09302025).

The problem is not that generic competition has failed. In one sense, it has been extraordinarily successful. Generics save Americans enormous amounts of money.

The problem is that we have optimized the system almost exclusively for one variable: the lowest possible price today. We have not adequately valued where a medicine is manufactured, whether there is redundant domestic capacity, whether a domestic plant can remain economically viable, or whether the United States will still have the technical capability to make a critical medicine during the next geopolitical crisis, pandemic or supply disruption.

A US manufacturer pays American wages, maintains American laboratories and quality systems, supports downstream domestic suppliers, complies with American environmental and workplace standards, maintains FDA-regulated facilities and carries redundant domestic capacity. Yet when its

product enters a generic bid, the system typically treats that product as economically indistinguishable from an equivalent product manufactured thousands of miles away.

That is not a level playing field. If Americans are to be given a choice about the medicines they take, then we need to level that playing field. PAI's framework is simple: **Let Americans see it. Value it. Prioritize it. And make it worth investing in.**

I. SEE IT: Give Americans meaningful transparency about where their medicines are made

PAI strongly supports the direction of Chairman Scott and Ranking Member Gillibrand's bipartisan CLEAR LABELS Act.

The Senate-reported version of S. 3788 would require information about the original manufacturers of the finished drug product and its active pharmaceutical ingredients and permits that information to be provided. We would encourage Congress and FDA to make the ultimate consumer-facing information extraordinarily simple. An American should be able to pick up a medicine and determine, without conducting an investigation:

> *Finished dosage form: Manufactured in South Carolina, USA.*
> *Active pharmaceutical ingredient: Manufactured in [country].*

A QR code can provide deeper detail about the original manufacturer, facility and supply chain, but the basic country-of-manufacture information should not be buried.

That matters for two reasons.

First, transparency creates accountability. Today, a company headquartered or distributing a product in the United States may appear American to a customer even though the actual finished dosage form was manufactured overseas. A US commercial address is not the same thing as US manufacturing.

Second, transparency creates the possibility of choice. Consumers cannot value American manufacturing if they cannot identify it.

Labels alone will not solve the problem because pharmacy inventory, wholesaler buying decisions, PBM contracts and substitution rules determine which generic is actually dispensed. But transparency is the necessary first step. Over time, government purchasers, health plans, hospitals, pharmacies and patients should be able to incorporate manufacturing origin into their purchasing decisions.

The reported version of the CLEAR LABELS Act contemplates a five-year implementation period. PAI would respectfully encourage Congress to consider whether basic finished-dose country-of-manufacture information can be made available materially sooner, *starting in 1 year*, while more complex API and lot-level requirements are phased in.

Transparency also has to extend beyond the label. PAI supports the transparency objectives of the bipartisan Pharmaceutical Investment Oversight and Accountability Act introduced by Chairman Scott, Ranking Member Gillibrand, and Senator Warren, which would require the Federal Trade Commission and the Committee on Foreign Investment in the United States to analyze foreign control and influence over US pharmaceutical manufacturing and sensitive biomedical technologies. PAI also supports the Patients

Before Monopolies Act, led by Senators Warren and Hawley, which would prohibit common ownership of PBMs or insurers and pharmacy businesses. These proposals address different parts of the same generic-drug system: one shines a light on foreign control over the supply chain; the other addresses vertically integrated domestic structures that can shape which products are purchased, reimbursed, and dispensed. Together with CLEAR LABELS, they bring transparency to both where our generics are made and how they move through the market. (US Senate Special Committee on Aging; Office of Senator Elizabeth Warren)

II. VALUE IT: Use the dollars already in the generic supply chain to value domestic resilience

The second issue is reimbursement and purchasing economics. There is a commonly held assumption that paying a domestic manufacturer somewhat more necessarily means charging the patient more. That is not necessarily true.

The price received by a generic manufacturer is only one component of the amount ultimately paid through the pharmaceutical distribution system.

A published analysis of 2021 Medicare Part D data provides a useful example. For donepezil, gross Medicare Part D spending averaged $14.93 per prescription. The study estimated manufacturer revenue at only $4.94 per prescription. It estimated approximately $3.82 of wholesaler gross profit, $1.82 of pharmacy gross profit and $4.89 of PBM gross profit. Those are modeled gross margins, not audited net profits, and the authors appropriately disclose limitations in estimating confidential contracts. But the example demonstrates something important: there can be substantial economic space between the manufacturer's price and total prescription spending. (https://jamanetwork.com/journals/jama-health-forum/fullarticle/2810783).

We therefore should not begin the domestic manufacturing debate with the assumption that every additional dollar paid to an American manufacturer must come from a patient's pocket. PAI recommends that Congress direct HHS and CMS to develop a Domestic Generic Resilience Pass-Through.

When a qualifying US-manufactured generic is available within a defined reasonable range of an imported product, federal purchasing and reimbursement policy should permit that differential, but require that the incremental resilience payment actually reach the domestic manufacturer rather than simply increasing an intermediary's spread.

At a minimum, such a framework should ensure that choosing the qualifying domestic generic does not increase the beneficiary's generic copayment solely because of manufacturing origin, and it should require sufficient reporting to determine how much of any domestic premium actually reaches the manufacturer investing in American capacity.

A first demonstration could be easier in direct federal purchasing, namely VA, DoW and other federal programs, before applying the framework more broadly to Medicare Part D.

III. PRIORITIZE IT: Make FDA's fees and regulatory timelines reflect America's supply-chain priorities

Our third recommendation concerns FDA. FDA deserves credit for recognizing this problem and beginning to move in the right direction. In October 2025, FDA launched an ANDA prioritization pilot designed to reward US generic manufacturing. That is an important start, a pilot program is not a durable industrial policy. (https://www.fda.gov/drugs/drug-alerts-and-statements/fda-announces-new-anda-prioritization-pilot-support-us-generic-drug-manufacturing-and-testing).

Congress now has a particularly important opportunity through GDUFA IV. The current GDUFA authorization expires in September 2027, and FDA and the generic drug industry have developed proposed recommendations for the next five-year authorization covering fiscal years 2028 through 2032. Importantly, those recommendations already recognize domestic manufacturing as a policy objective. FDA has proposed increasing the foreign facility fee differential, waiving the original ANDA application fee in certain cases where both finished-dose manufacturing and API supply are located in the United States, allowing qualifying US facilities to request surveillance inspections before a planned submission, and expanding early review opportunities for certain US API sources.

PAI supports that direction. We believe Congress should use GDUFA IV to make it more meaningful, durable and actionable. The fundamental Made-in-America principles should be established in statute for the full five-year authorization period, rather than depend solely on a discretionary pilot or policy that can change administratively. FDA can then implement those principles through defined review goals, inspection commitments and prioritization procedures.

A manufacturer deciding whether to put capital into an American plant needs to know that the incentive will still exist when that equipment is installed, the process is validated and the regulatory submission reaches FDA. GDUFA IV provides an opportunity to give manufacturers something they can actually invest against: a predictable domestic-manufacturing framework extending from fiscal year 2028 through 2032.

That priority also needs a clear hierarchy. National-security needs may justify using North America more broadly in the near term, especially where a US-only supply chain cannot be created overnight. But North American resilience and American industrial policy are not the same thing. USMCA manufacturing can provide a faster security bridge, especially for API manufacturing base. Within GDUFA IV and other federal programs, however, products actually manufactured in the United States should remain in the highest-priority lane for FDA review, fee relief, federal procurement, reimbursement incentives and other policies specifically intended to rebuild American industrial capacity. Made in America should mean Made in America.

The proposed GDUFA IV package demonstrates that FDA already recognizes this principle, but the economic differential remains modest. FDA has proposed increasing the foreign facility differential from today's $15,000 to $25,000 beginning in FY2028. It has also proposed a one-time original ANDA fee waiver where an application identifies only US facilities for both finished-dose manufacturing and API supply. Those are meaningful directional steps. PAI believes Congress should consider whether the differential should be large enough to actually influence manufacturing-location decisions.

For fiscal year 2026, the ANDA application fee is $358,247, the Type II API DMF fee is $102,584, and the annual large applicant program fee is $1.918 million. A domestic finished-dose facility pays $238,943, while a foreign facility pays $253,943, only $15,000 more. A domestic API facility pays $43,549, compared with $58,549 overseas. FDA explains that the $15,000 differential is intended essentially to cover the incremental expense of conducting a foreign inspection. (Federal Register Public Inspection)

An illustrative enhancement to the GDUFA IV domestic-manufacturing framework

Fee	FY2026 current	Qualifying US proposal	Foreign-manufactured proposal
ANDA	$358,247	**$286,598**	**$716,494**
Type II API DMF	$102,584	**$82,067**	**$205,168**
FDF facility	$238,943 US / $253,943 foreign	**$191,154**	**$507,886**
API facility	$43,549 US / $58,549 foreign	**$34,839**	**$117,098**
CMO facility	$57,346 US / $72,346 foreign	**$45,877**	**$144,692**

Those numbers are illustrative; the precise differential should be determined through the reauthorization process. The policy principle is more important: qualifying US manufacturing should receive a meaningful economic advantage, while manufacturing that requires FDA to oversee facilities thousands of miles away should bear a meaningfully greater share of the program's cost.

FDA and industry have already proposed moving from a $15,000 to a $25,000 foreign facility differential. PAI believes Congress should examine whether that is sufficient to influence the location of the next manufacturing investment. A fee differential designed primarily to recover travel and inspection costs is different from a fee structure designed to advance a national objective of rebuilding domestic pharmaceutical capacity.

I would treat the applicant program fee differently. Because the program fee is assessed at the company/portfolio level, a simple US-company-versus-foreign-company distinction could easily be gamed. Instead, the program fee should be adjusted according to the percentage of an applicant's approved ANDA portfolio actually manufactured in the United States. The focus should be the factory, not the flag on the corporate headquarters.

FDA's own FY2026 fee-setting data show how geographically asymmetric the current system already is. Of 478 fee-paying finished-dose facilities, 153 are domestic and 325 are foreign. Of 707 API facilities, just 76 are domestic and 631 are foreign. FDA forecasts approximately 618 new original ANDAs in FY2026 and approximately 11,699 supplements. (Federal Register Public Inspection)

This is a very large regulatory workload and the FDA has done a fantastic job meeting its goals, despite constrained resources and budget cuts. They should be commended, but we would consider what more the FDA could do if they were better funded.

GDUFA is structured around a statutory revenue target, so simply changing relative fee rates does not automatically produce additional resources for FDA. Congress would have to expressly authorize FDA to retain the incremental collections or adjust the GDUFA revenue target. If Congress did so, using FDA's current facility population as an illustration, reducing qualifying domestic facility fees by 20% while doubling foreign facility fees could generate approximately $121 million in additional annual resources. (Federal Register Public Inspection)

Imagine what the FDA could accomplish with these additional funds. Those incremental resources could fund faster domestic manufacturing supplements, early US facility inspections, domestic API/DMF review, additional foreign inspection capacity, better supply-chain-origin data, and dedicated review teams for shortage and national-security products.

Fees are only half of the opportunity. GDUFA IV can also make regulatory time a domestic-manufacturing incentive. Congress should apply the same asymmetry to time, not merely dollars. Current GDUFA goals generally provide a 10-month standard review for original ANDAs and an 8-month priority clock where applicable. A standard PAS generally has a 6-month goal if a preapproval inspection is not required and 10 months if one is required; priority PAS review can be 4 months without an inspection and 8 months in certain cases involving an inspection. (US Food and Drug Administration)

PAI believes Congress should build on those concepts and establish a durable statutory principle that moving pharmaceutical production into the United States receives regulatory priority.

Moving finished-dose manufacturing into the United States: automatic eligibility for FDA's fastest applicable priority review.

Qualifying a US API source: automatic priority for the associated DMF and linked ANDA or PAS. (US Food and Drug Administration)

Moving manufacturing out of the United States: no special priority; where a product previously benefited from a federal domestic incentive, Congress should consider an appropriate anti-transfer period.

FDA should also distinguish between competition and redundancy

IQVIA's 2025 analysis of Orange Book and sales data found that 39% of ANDAs approved since 2013 had not launched, including 42% of injectable approvals. For the 2023 approval cohort, approximately 47% had launched by July 2025. (FDA Orange Book, July 2025; IQVIA National Sales Perspectives / IQVIA Institute, July 2025)

There are legitimate reasons why an approved ANDA may not yet launch - patent litigation, exclusivity, commercial timing and other constraints. The data should not be interpreted to mean that 39% of FDA's work will not find its way to the market, but they should cause us to ask whether the 20th application for a mature, well-supplied product deserves the same regulatory priority as the first domestic supplier, a

shortage product or a new source of a critical medicine. In FY2025 alone, FDA approved 689 ANDAs. (US Food and Drug Administration) We are asking FDA to review hundreds of original applications and more than ten thousand supplements every year. Prioritization matters.

FDA continues approving additional applications, all with foreign manufacturing sites in Asia, in already crowded categories. In March for example the FDA approved the 23rd lidocaine injection, 18th ticagrelor tablets, 17th Rocuronium injection, 13th oxcarbazepine suspension, and the 11th micafungin injection.

PAI is not suggesting that FDA refuse lawful applications merely because they are foreign. We are suggesting that Congress establish a clear priority hierarchy: first time generics, shortage drugs, critical medicines, products creating meaningful supply-chain diversity and qualifying US-manufactured medicines should come first. The fifteenth or twentieth foreign-manufactured copy of an adequately supplied commodity should come later.

That is a rational allocation of limited government resources.

The timing makes this immediately actionable. GDUFA IV is being developed now and will govern the generic drug program for fiscal years 2028 through 2032. FDA and industry have already put domestic manufacturing into the proposed package. The question for Congress is how consequential that preference should be. (US Food and Drug Administration)

PAI would encourage this Committee to recommend that Congress use the GDUFA IV reauthorization to establish a durable Made-in-America framework: meaningful fee relief for qualifying US production, a stronger foreign facility differential, automatic regulatory priority for moving finished-dose and API manufacturing into the United States, and transparent annual reporting on whether those incentives actually create domestic capacity.

Because the Senate HELP Committee has legislative jurisdiction over FDA user-fee reauthorization, we would encourage the Aging Committee to work with HELP to incorporate these principles into the final GDUFA IV legislation.

This does not require Congress to create a new regulatory program from scratch. FDA has already established the direction. Congress can use GDUFA IV to turn that direction into a predictable five-year policy that American manufacturers can make investment decisions against.

IV. INVEST IN IT: Restore an economic reward for companies willing to build and manufacture here

Finally, we need to fix the underlying investment equation. We are starting from a deep imbalance: FDA reports that approximately 69% of generic drug products are manufactured outside the United States.

COVID-19 showed that this risk is not theoretical. In March 2020, as the pandemic accelerated, the Government of India changed the export status of 13 active pharmaceutical ingredients and 13 formulations from “free” to “restricted.” (DGFT Notice) The list included commonly used medicines and ingredients such as paracetamol, metronidazole, acyclovir, erythromycin, neomycin, clindamycin and several B vitamins. (DGFT Notice) Later that month, India went further and prohibited exports of hydroxychloroquine and its formulations, subject to limited exceptions. And during India's severe COVID

wave in April 2021, the government prohibited exports of remdesivir and remdesivir API as it sought to preserve domestic supply. (DGFT Notice)

These actions were not directed specifically at the United States, while most of the initial 2020 restrictions were subsequently relaxed. This is precisely the point. When a national emergency occurs, governments will understandably put their own citizens first. At the time, members of the US Senate specifically cited India's export restrictions as evidence of the vulnerability created by America's dependence on overseas pharmaceutical production. A supply chain is not truly resilient simply because FDA has approved multiple suppliers if those suppliers ultimately depend on the same foreign geography. That experience supports building a more secure North American supply chain where necessary in the near term, but it also reinforces why the United States needs a separate, higher-priority lane for actual American manufacturing.

The economic system that produced that dependence is equally important. The current generic model can produce a paradox. A medicine can have billions of dollars of brand sales before loss of exclusivity. Twenty or twenty-five generic manufacturers may then be ready to compete. The resulting generic price can fall immediately to only a few cents on the former brand dollar. Patients and payers receive extraordinary savings. But the manufacturers responsible for supplying nearly all of the medicine may collectively capture only a tiny fraction of the economic value.

We would suggest an analysis which models a major conventional generic launch with 20–25 credible suppliers at approximately 2-5% of former brand pricing initially and potentially 1-3% at maturity. Those are commercial modeling assumptions. That economic model creates a powerful incentive to locate future production wherever costs are lowest.

Congress can change that investment equation without abandoning competition.

Tariffs can also be part of leveling the playing field and changing the investment equation for generic medicines. In July 2026, President Trump announced a proposed tariff framework specifically for imported generic pharmaceuticals. Under the proposal, imported generics would remain free of additional tariffs during a two-year transition period beginning August 1, 2026, followed by a 100% tariff beginning August 1, 2028, and a 200% tariff beginning August 1, 2029. The announced framework has not yet been implemented through formal action, but its structure sends an important investment signal: manufacturers would have time to make capital decisions, qualify US facilities and move production before a significant differential is imposed between importing a generic medicine and making it here.

That concept fits within the broader Section 232 framework already established for pharmaceuticals. In April 2026, following a Section 232 investigation, the Administration formally determined that imports of pharmaceuticals and associated APIs and key starting materials were occurring in quantities and circumstances that threatened to impair US national security. The resulting action applies tariffs to patented pharmaceuticals while providing preferential treatment for companies that make enforceable commitments to onshore production. Generic medicines are exempt from the Section 232 tariffs today, but the proclamation specifically directs the Secretary of Commerce to reassess within one year whether action should also be taken on imported generics and their ingredients. (Presidential Proclamation)

PAI believes that same principle can be applied thoughtfully to generics: use tariffs not simply as a penalty on imports, but as a predictable signal that changes the return on investing in the United States. Any generic tariff framework should include appropriate safeguards for shortage, sole-source and other medically vulnerable products and should provide sufficient transition time for companies to qualify domestic capacity. And where tariff revenues are generated, Congress could consider directing a portion, through appropriate authorization and appropriation, to the very capabilities the policy is intended to build: FDA resources to accelerate domestic transfers, modernization of US pharmaceutical plants, and CMS or federal-purchasing incentives that create sustainable demand for qualifying US-made generic medicines. The objective should be a reinforcing cycle: make importing relatively less attractive, make investing here more attractive, and use the proceeds to accelerate the transition.

The NCE-1 proposal that PAI is advancing along with a broader coalition of companies committed to making products in the United States would provide a filing advantage for qualifying domestically manufactured Paragraph IV ANDAs. Congress created the Hatch-Waxman to create a priority for generic competition and this helps to align that same reward system with today's priorities. The objective is to make the domestic manufacturers more likely to establish first-applicant status and participate in the existing 180-day exclusivity opportunity while providing a meaningful step toward national security and domestic supply chain independence. But it should be a floor for resilience, not a ceiling for domestic industrial policy.

Under the current framework, for the first five years, eligibility would require substantive US finished-dose manufacturing. Thereafter, the proposal would also require API to be sourced from the United States, Canada or Mexico. Merely putting imported tablets into an American carton would not qualify: formulation, fill-finish and primary packaging must meaningfully occur here.

If there is no qualifying domestic first applicant, the traditional Hatch-Waxman mechanism remains available. At the same time, other tools - FDA priority, fee relief, federal purchasing, CMS reimbursement, and any reinvestment of tariff receipts - should preserve a separate and more favorable lane for actual US manufacturing. If there is no qualifying domestic first applicant, the traditional Hatch-Waxman mechanism remains available. This is important because the proposal changes the sequence of competition, not its ultimate destination.

Going back to the analysis earlier, if we then model five domestic manufacturers competing during the first 180 days, followed by unrestricted global entry beginning on Day 181. Five generic companies are still competition: customers can bid, multisource, establish backup suppliers and punish poor performance. Assuming a five-company domestic market could produce generic pricing at approximately 5-15% of the former brand price, still an 85-95% reduction, before global competition drives the mature market lower.

Entresto demonstrates the opportunity

Sacubitril/valsartan, the generic of Entresto, provides a striking illustration. IQVIA MAT prior to generic competition has US sales of approximately $6 billion for the product. Our review of the Entresto approval landscape identified over 15 distinct generic ANDA holders and no clearly identified US finished-dose manufacturer in that reviewed group.

Under an immediate broad-entry scenario at a 3% generic price, our model estimates that all generic manufacturers would share approximately $50 million of manufacturer revenue during the first six months.

Under a five-company domestic window at a 10% generic price, the generic manufacturer pool would be approximately $180 million. Yet patients and payers would still realize approximately $1.6 billion in savings in those first six months compared with continued brand pricing. The difference, about $125 million, is the economic incentive. This is not a government grant, it is not an appropriation, and it is not permanent protection.

It is a temporary market return available only to manufacturers that invest in qualifying American capacity, develop the product, successfully file the ANDA, secure FDA approval, launch the medicine and actually supply American patients. On Day 181, full global competition begins.

That is precisely the type of incentive that can influence a board's decision about whether the next manufacturing line is built in South Carolina or overseas.

The incentive also must be protected against gaming. Domestic manufacturing should mean substantive manufacturing. Companies that fail to launch or supply should forfeit the benefit. A company receiving the benefit should not immediately transfer the product overseas. Our draft contains exactly that type of anti-transfer provision.

Conclusion

America does not need to choose between inexpensive generic medicines and a domestic pharmaceutical industry. But we do need to stop pretending that the current system will produce both outcomes on its own.

For decades, every economic signal has pointed in the same direction: find the lowest manufacturing cost, bid the lowest possible price, treat manufacturing location as irrelevant and approve another supplier regardless of whether the country gains additional resilience.

We should change those signals. Our framework is simple: **Let Americans see it. Value it. Prioritize it. And make it worth investing in.**

That means transparent origin and ownership, purchasing economics that recognize resilience, FDA resources that favor strategically valuable supply, and investment tools - including targeted tariffs and the NCE-1 framework - that reward real manufacturing capacity.

Where national security requires a North American bridge, we should use it. But when policy says Made in America, it should mean exactly that, and US manufacturing should remain the highest-priority lane.

PAI has been manufacturing medicines in America since 1968. We intend to keep doing so.

The question before Congress is whether the rules of the market will make companies like ours the beginning of a domestic manufacturing resurgence - or the exception to an increasingly offshore system.

Thank you for the opportunity to testify.