Testimony for the Senate Special Committee on Aging

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

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Chairman Scott, Ranking Member Gillibrand, and Members of the Committee: Thank you for the opportunity to testify on the regulatory and economic conditions that will determine whether the United States rebuilds the capacity to make its own generic medicines.

The Coalition for a Prosperous America (CPA) is a bipartisan organization of manufacturers, workers, and farmers working to rebuild the U.S. industrial base. Over the past eighteen months my colleague Andrew Rechenberg has led CPA's research on pharmaceutical supply chains, including the July 2026 report *The Hollowing Out of America's Medicine Cabinet*, which this Committee invited us to present, and CPA's forthcoming cost-benefit analysis of generic drug reshoring. This testimony draws on both, on CPA's October 2025 testimony before this Committee, and on CPA's comments to the Department of Commerce, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA).

The Committee has asked the right question. FDA approval timelines, inspection expectations, and permitting burdens do delay new and expanded U.S. manufacturing, and this testimony offers specific reforms to each. But the evidence CPA has assembled points to a harder conclusion, and the Committee should hear it plainly. The generic plants America has lost over the past decade held every FDA approval and every permit they needed. They closed because the price of the medicines they made fell below the cost of making them reliably. Regulatory streamlining is necessary. On its own, it produces faster approvals for plants that cannot stay open.

This testimony first documents how far domestic capacity has fallen and what that decline looks like for two categories of medicine older Americans depend on daily. It then explains how the playing field tilted, on price and on oversight; where the time goes in the domestic approval and permitting pathway; and why the economics of reliable domestic supply favor acting now. It closes with five pillars of reform that work together:

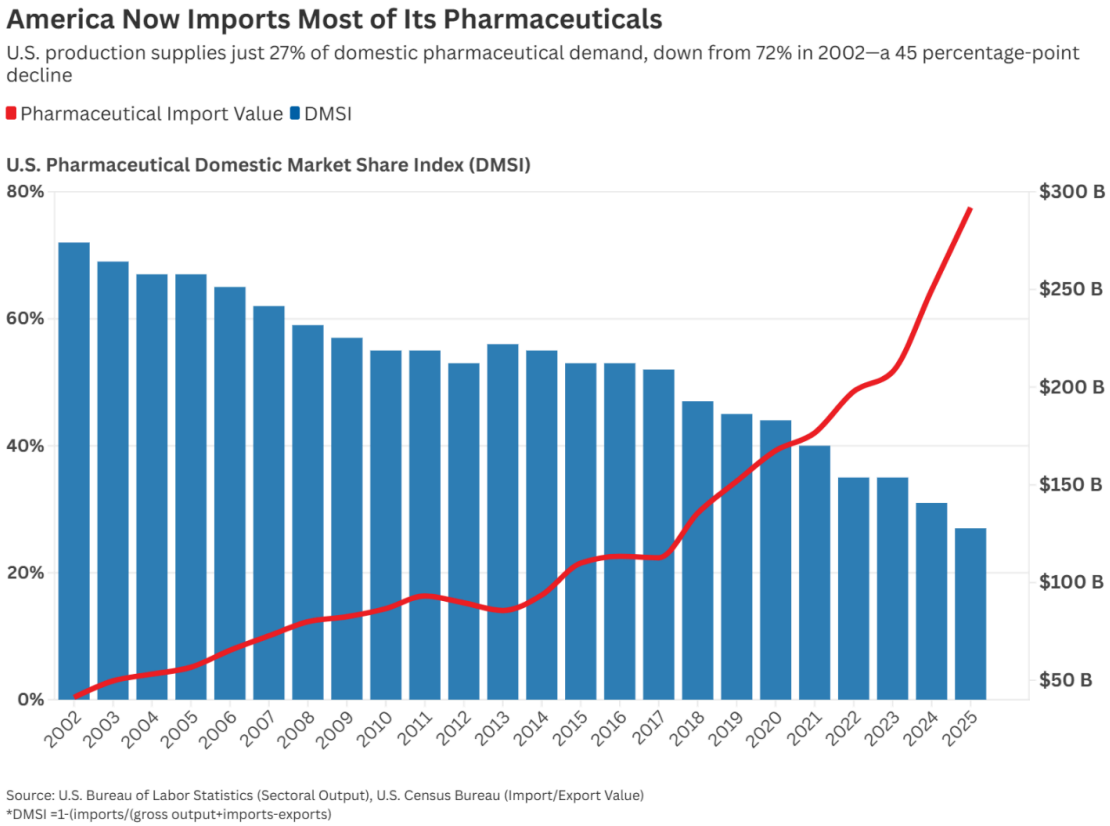
1. Rewarding production that moves home in the FDA approval process.
2. Applying one inspection and compliance standard to every plant that supplies the U.S. market.

3. Using the Generic Drug User Fee Amendments (GDUFA) reauthorization now before FDA to fund parity and clear the domestic pathway.
4. Putting a clock on cross-agency permitting for essential-medicine facilities.
5. Pairing those regulatory changes with the demand-side and trade tools that make reliable domestic production profitable before the next shortage, without raising costs for seniors.

I. America Now Imports Most of Its Medicine

The United States makes 27% of the pharmaceuticals it consumes, down from 72% in 2002. CPA's Pharmaceutical Domestic Market Share Index, computed from Bureau of Labor Statistics sectoral output and Census Bureau trade data for pharmaceutical and medicine manufacturing (NAICS 3254), fell 45 percentage points in a single generation, and the 2025 reading is the lowest on record [1] [2]. Pharmaceutical imports reached $292 billion in 2025, roughly seven times their 2002 value, and the pharmaceutical trade deficit reached about $165 billion.

Figure 1:



Source: CPA Pharmaceutical Domestic Market Share Index, computed from BLS sectoral output (NAICS 3254) and Census Bureau import and export values. DMSI = 1 − imports ÷ (gross output + imports − exports).

Nearly all of the growth in what Americans consume has been met by foreign production. Since 2002, implied U.S. pharmaceutical consumption, meaning domestic output plus imports minus exports, has risen by about $253 billion. Imports rose by almost exactly the same amount, so 99% of that growth was supplied from abroad. U.S. output did roughly double over the period, from $124 billion to $234 billion, but the entire increase went to exports, and most of that export growth was high-value biologics rather than the high-volume commodity generics that hospitals and pharmacies use every day. Pharmaceutical production actually serving the domestic market grew 2% in twenty-three years.

The picture is worse one layer upstream. Announcing a domestic generic-manufacturing pilot in October 2025, FDA reported that only 9% of active pharmaceutical ingredient (API) manufacturers are located in the United States, against 22% in China and 44% in India [3]. The United States Pharmacopeia (USP) found that China is the sole supplier of at least one key starting material (KSM) for about 700 APIs, or 37% of the APIs it analyzed, and that 44% of drugs in shortage depend on at least one KSM made in a single country, typically China or India [4] [5]. A tablet finished in India often begins as a chemical made only in China. The country has lost more than its finished-dose plants. It has lost much of the industrial base needed to make medicine at all.

II. Two Case Studies: What Dependence Looks Like for Older Americans

Liquid fever and pain medicines. Acetaminophen and ibuprofen oral suspensions are the medicines used in pediatric wards, in homes, and in long-term care settings for patients who cannot swallow tablets. For an elderly patient with dysphagia, dosage form is access. U.S. imports of these two suspensions have doubled since early 2024, from about 1,000 metric tons a month to peaks above 2,000 [2]. From January 2025 through April 2026, India supplied 82.7% of that import volume and China another 6.7%. Upstream, China supplied 99% of U.S. ibuprofen API imports and 68% of acetaminophen API imports over the same period.

Figure 2:

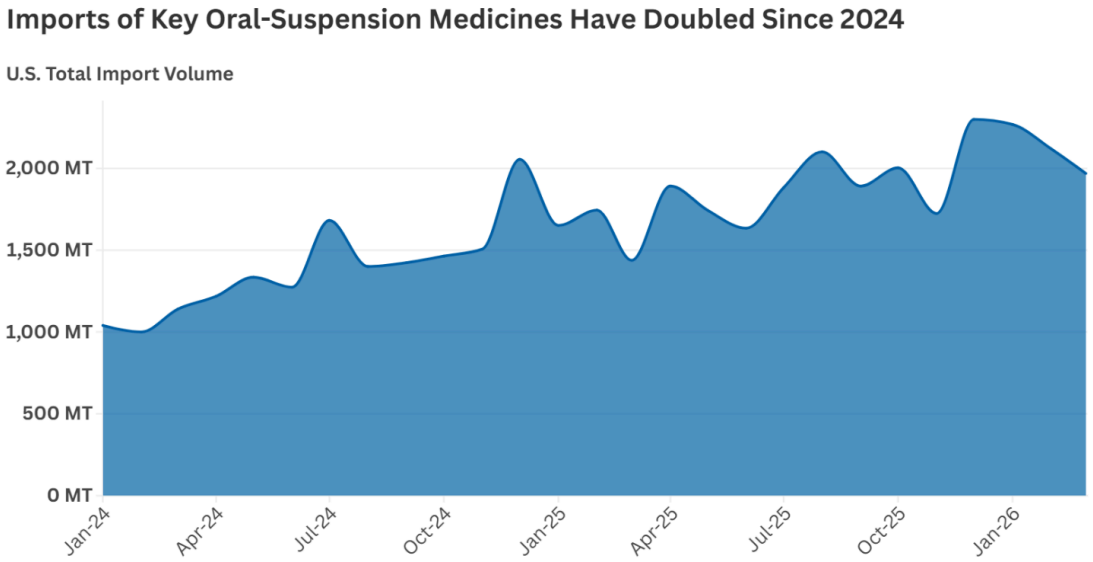
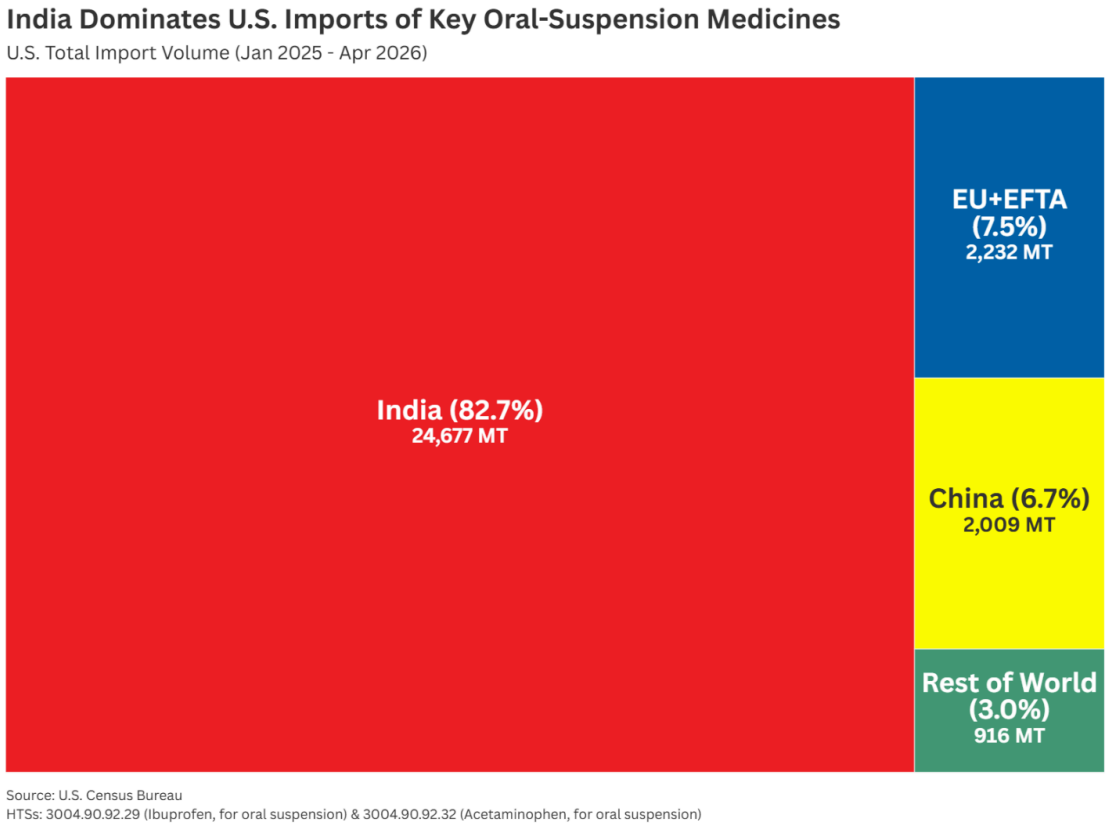


Figure 3:



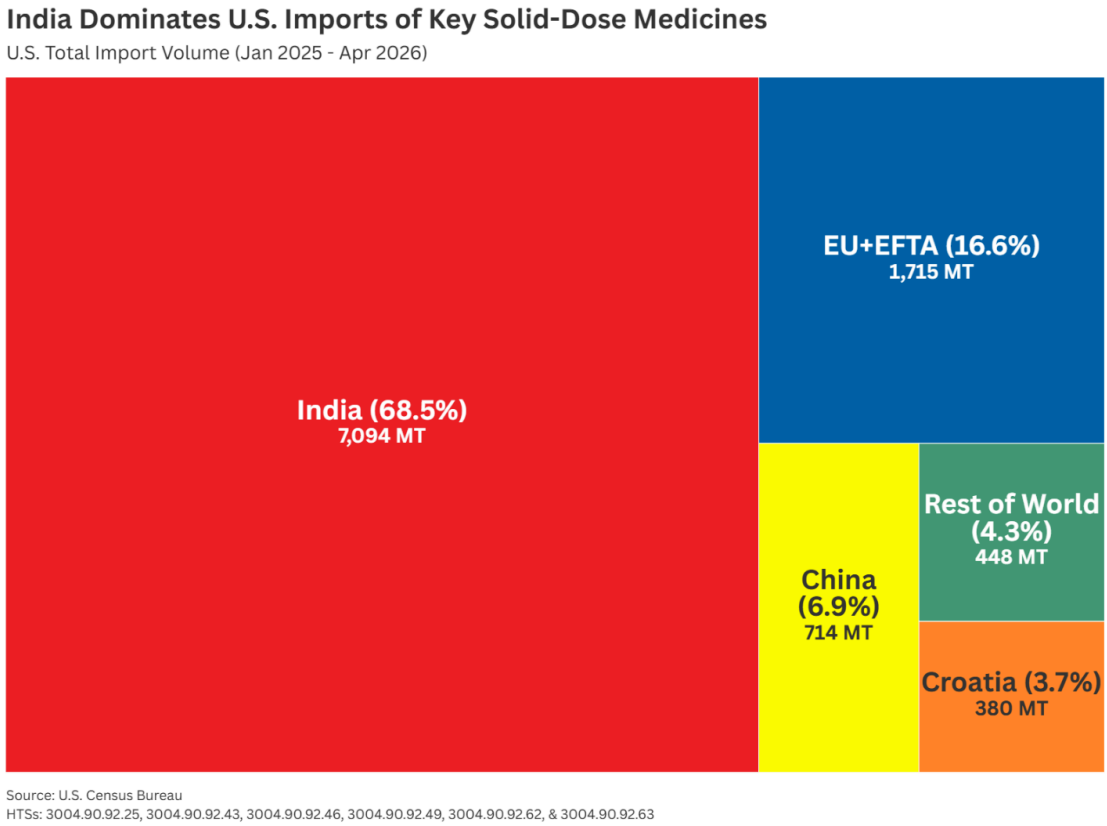
The 2022–23 fever-medicine shortage showed the cost of that structure. As RSV, influenza, and COVID converged, FDA stated that ibuprofen and acetaminophen suspension supplies had fallen short of demand [6]. Seattle Children's Hospital reported it had run out of liquid ibuprofen and "moved completely away from the liquid preparations," crushing tablets and mixing them into liquid by hand [7]. FDA temporarily allowed designated facilities to compound ibuprofen suspension in bulk for hospitals, a workaround that produced unapproved products and could not reach retail pharmacies, where the shortage was deepest. The domestic base had thinned in the years before: Teva discontinued its 100 mg/5 mL prescription ibuprofen suspension in 2023, leaving a single prescription supplier in the retail market [8].

Liquid suspensions are also the category where reshoring is most achievable, because their economics already lean toward domestic production. A suspension is mostly water and packaging, heavy and bulky to ship, temperature-sensitive, and losing shelf life every week in transit. Those freight and storage penalties cut into the offshore cost advantage before any policy is applied [9], and a U.S. liquid-manufacturing base still exists to build on.

Eleven tablets America lives on. The second case study examines eleven high-volume solid-dose generics: amlodipine and hydrochlorothiazide for blood pressure; spironolactone for heart failure; glipizide for type 2 diabetes; sotalol for cardiac arrhythmia; primidone for seizures and essential tremor; trazodone, buspirone, and imipramine for depression, anxiety, and insomnia; and methocarbamol and carisoprodol for muscle spasm. Amlodipine and hydrochlorothiazide alone account for tens of millions of prescriptions a year [10]. These are the daily maintenance drugs of the Medicare population.

The United States relies on imports for 78% of the solid oral generics it consumes [11]. Across the tariff lines covering these eleven medicines, India supplied 68.5% of U.S. import volume from January 2025 through April 2026, against 16.6% from the European Union and European Free Trade Association and 6.9% from China [2]. By dispensed volume, India accounts for roughly 61% of all solid oral generic consumption in the United States, and U.S. facilities produce only about 22%, part of which reflects controlled substances that Drug Enforcement Administration (DEA) rules require to be made domestically [12].

Figure 4:



For a senior, an interruption in these medicines is a medical event. A sotalol patient cannot simply restart after a gap; because the drug can itself trigger dangerous arrhythmias, FDA labeling requires at least three days of in-hospital cardiac monitoring when therapy is initiated or re-initiated [13]. A primidone interruption can mean breakthrough seizures [14]. A glipizide gap can destabilize blood sugar in a diabetic senior [15]. Patients on fixed incomes are the least able to chase scarce medicine across pharmacies or absorb the cost of an emergency room visit when a maintenance drug disappears.

III. How the Field Tilted: Subsidized Overcapacity and a Market That Pays for Nothing but Price

China and India built their generic industries on state support, and the United States lost its own to that support. China pursued a deliberate strategy to make itself indispensable to the global drug supply chain, subsidizing capacity in upstream chemicals and APIs and undercutting competitors until domestic producers could no longer justify staying in the market. Brookings documents Beijing's explicit strategy to expand its global pharmaceutical position through state tax breaks, subsidized loans, and infrastructure investment [16]. India's Department of Pharmaceuticals lists production-linked incentive schemes for pharmaceuticals and for critical KSMs, intermediates, and APIs, alongside a Bulk Drug Parks program offering subsidized land, utilities, and common infrastructure [17] [18]. The market effect is visible product by product: in

June 2025, global ibuprofen prices fell sharply amid oversupply, with Chinese manufacturers holding “acute overcapacity” and flooding the global market to clear inventory [19].

The U.S. purchasing system then locks that pressure into the domestic market. Generic medicines account for more than nine of every ten prescriptions, but three group purchasing organizations control roughly 90% of hospital generic contracting and three wholesaler-aligned buying alliances control about 90% of retail generic purchasing [20]. Hundreds of manufacturers compete for access to a handful of buyers, often with a dozen firms making the same product, and the contract goes to the lowest price. Over the prior five years, U.S. patients consumed more generics by volume while the total value of generic sales fell by $6.4 billion [21]. The generic trade association itself warns that this price deflation causes companies to discontinue products, close facilities, or shut down altogether [20].

The exits are on the record, plant by plant. In 2021, Viatris closed the Chestnut Ridge plant in Morgantown, West Virginia, one of the largest generic factories in the country, eliminating roughly 1,500 to 2,000 jobs and sending work overseas, including to India; union officials estimated $150 million to $200 million in lost income for north-central West Virginia [22]. Endo closed its Charlotte, North Carolina plant and its Huntsville, Alabama complex in 2016 and 2017, 875 jobs at Huntsville alone, citing “greater than expected price erosion across the generics sector” [23] [24]. Amneal shut its Hayward, California facility in 2018, about 550 jobs [25]. Teva exited its Irvine, California sterile-injectables plant in 2022, 305 workers [26]. Akorn filed for Chapter 7 in February 2023 and closed every U.S. site, in Decatur, Illinois, Somerset, New Jersey, and Amityville, New York, terminating about 400 workers without severance [27]. Sandoz closed its Wilson, North Carolina tablet plant in 2024, 213 jobs [28]. In June 2024, Jubilant Cadista closed its 1.5-billion-dose Salisbury, Maryland facility, stating that U.S. generic pricing pressure had made domestic manufacturing unprofitable; it now supplies the U.S. market from plants abroad [29]. At its 2023 investor day, Teva said it would stop chasing the lowest-margin generics altogether [30].

The result is a supply base with no slack. Of 1,838 small-molecule drugs in 2022, 43% had only one manufacturer and another 16% had two or three, so nearly 60% had three or fewer suppliers [31]. On CMS’s National Average Drug Acquisition Cost benchmark, the invoice price pharmacies actually pay, hydrochlorothiazide runs about a penny a tablet, amlodipine about a penny and a half, and buspirone about three cents [32]. Year-over-year deflation on generic oral-solid tablets is running at 13.4% [33]. At those prices there is no margin for redundancy, quality investment, or domestic production.

Imports produce shortages by way of the price they set. Subsidized overcapacity abroad and concentrated buying at home push prices below the cost of reliable production; producers exit; the products that remain are made by one or two plants; and an ordinary disruption at one of them, a contamination finding or a fire or an export restriction, becomes a shortage with no second source to absorb it. FDA’s own Drug Shortages Task Force reached that conclusion in 2019, finding that shortages are primarily the consequence of economic factors, led by a lack of incentives to produce less profitable drugs, and that many began with outright discontinuation [34]. The same economics explain why shortages last. Of 163 shortages FDA examined, only 42% ever saw a significant production increase and only 30% saw supply fully restored,

because no firm will add capacity for a product that loses money and FDA cannot compel any firm to make anything [34] [35].

The shortage data show what that structure produces. The American Society of Health-System Pharmacists counted 227 active drug shortages at the end of June 2026, the third consecutive quarterly increase; 48% of the shortages that began in 2026 involve a sole-source product, and 16% involve controlled substances [36] [37]. USP's 2026 annual report finds the average active shortage now lasts 5.3 years, up from 4.3 years in 2024 and roughly two in 2019; more than 64% of drugs currently in shortage have been unavailable for over three years and 39% for more than five [5]. Drug product discontinuations rose 60% from 2024 to 2025, to a five-year high, and 65% of discontinued oral solids were priced below $1 per unit, with the median price falling from $1.80 to $0.40 [5]. IQVIA finds 56% of drugs in shortage priced below $1 per extended unit [38]. The medicines most likely to disappear are the cheapest ones.

The savings from cheap imports vanish the moment a shortage hits. Drug shortages raise hospital error rates by 1–5%, create unsafe conditions in 60% of cases, and often force hospitals to pay 300–500% markups to obtain critical medicines [39]. Vizient's 2025 survey found shortages cost hospitals roughly 20 million staff hours and nearly $900 million a year in labor alone, more than double the 2019 figure [40]. The HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) and RAND found that a shortage raises the price of the affected generic by 14.6% and that fills fall by a median of 37.6% after a shortage begins, pushing patients toward branded alternatives or no treatment at all [41]. The country has been paying a resilience premium all along, in the most expensive form available.

IV. The Regulatory Double Standard

The playing field is tilted on the oversight side as well. Domestic drug plants can be inspected without warning at any time. Foreign plants, for most of the past two decades, have received advance notice. In fiscal year 2023, roughly 90% of FDA foreign inspections were preannounced, with notice of up to twelve weeks, and the inspected firm often supplied the translators [42]. COVID widened the gap, leaving many overseas facilities unvisited for five years or more [43]. The Government Accountability Office found in November 2024 that FDA's drug-investigator vacancy rate had risen from 9% to 16% between 2021 and 2024 and that fiscal 2023 inspections were 36% below the 2019 level [44]. The manufacturers who testified before this Committee in November 2025 described the asymmetry from their side: Oxford Pharmaceuticals said an unannounced Form 483 would close its Birmingham plant and expose its officers to prosecution, while USAntibiotics said its foreign competitors receive inspection notice "up to twelve weeks in advance" [45] [46].

Advance notice matters because it changes what inspectors find. A former FDA investigator told this Committee that unannounced inspections identify problems about 40% of the time, against 5–10% for announced visits [47]. FDA's own India pilot of unannounced inspections was three to four times more likely to produce a warning letter [48]. FDA's May 2025 announcement expanding unannounced foreign inspections acknowledged that foreign inspections find serious deficiencies more than twice as often as domestic ones even with advance notice [49]. That

expansion is a necessary correction, and FDA has published no count of unannounced foreign inspections since, so the size of the remaining gap is unknown.

The consequences reach patients. Ranbaxy, once India's largest generic maker, pleaded guilty in 2013 and paid $500 million to settle allegations that it fabricated test data and sold adulterated drugs [50]. In late 2022, FDA inspectors at Intas Pharmaceuticals, which made half of America's cisplatin, found a "cascade of failure" in quality control, including an analyst dissolving quality-control records in acid and torn testing documents hidden under a stairwell and in a truck outside the plant; the shutdown that followed forced hospitals nationwide to ration chemotherapy [51] [52]. In 2024, inspectors at a Hetero Labs facility found birds in storage areas, lizards near raw ingredients, cats around pallets, and a truck leaving uninspected after staff refused FDA access [53]. Beginning in 2018, tens of millions of blood-pressure pills were recalled after the probable carcinogen NDMA was found in valsartan ingredient made by China's Zhejiang Huahai, contamination FDA concluded may have circulated for years before detection [54]. In 2024, at Glenmark's India plant, inspectors found repeated dissolution failures in potassium chloride capsules on the facility's first inspection in more than four years; Glenmark recalled more than 100 batches, and FDA adverse-event records include at least eight U.S. death reports associated with the product [55].

Even medicines that are never recalled can quietly underperform. A peer-reviewed 2025 study matching thousands of generics found that drugs made in India were associated with 54% more serious adverse events, including hospitalizations and deaths, than the same drugs made in the United States, with the effect concentrated in mature, low-margin products where the incentive to cut corners is greatest [56]. Quality risk is part of the economic story. When buyers reward the lowest price and production moves to distant plants under weaker routine oversight, the system creates pressure to minimize cost in ways that harm patients.

The fee structure reinforces the asymmetry. Under GDUFA, a foreign facility pays a surcharge of $15,000 above the domestic facility fee, a figure unchanged since the program began in 2012 and now equal to roughly 6% of the domestic finished-dose facility fee [57]. The plants that cost the most to inspect pay a token premium for the privilege of being inspected least.

V. Why the Regulatory Fix Needs a Market Fix

A new domestic generic plant takes four to five years from decision to first commercial batch, and an API plant handling controlled substances takes longer. The manufacturers who have testified before this Committee agree on the range. Civica told the Committee it takes two to three years to bring a generic into an existing facility and more than four years from construction to first commercial sale for a new one, and that each product carries a typical FDA review of about a year, so a multi-product plant cannot break even until several reviews are complete [58]. USAntibiotics put a from-scratch rebuild of amoxicillin capacity at five years to a decade [46]. Amicus described three to five years to build a facility and another one to two years to get it inspected [59]. The Committee's own October 2025 report estimated five to ten years for new facilities and one to two years to repurpose existing capacity [60].

The time sits in identifiable places. Environmental permitting for API synthesis, which is chemical manufacturing with solvent emissions and hazardous waste, can take eight to eighteen months for the air permit alone, longer in some states, before construction begins [61]; Exiger's chief executive told this Committee that acetaminophen production "creates a waste broth that the EPA would not allow us to dispose of in the way that India or China does" [62]. Construction and qualification take two to three years. Stability testing, which requires three batches and typically six months of accelerated plus six months of long-term data at filing, cannot begin until the production line is qualified and adds six to twelve months even when everything else goes right. The abbreviated new drug application (ANDA) review goal is ten months for a standard application and eight for a priority application, with additional cycles common, and a site-transfer supplement moving an approved product to a new plant takes six months without a pre-approval inspection and ten with one [63]. For controlled substances, DEA registration and the annual quota cycle add their own months.

Each of these steps can be shortened, and Section VI proposes how. But the Committee should hold one fact alongside the timeline. Morgantown, Huntsville, Hayward, Irvine, Decatur, Wilson, and Salisbury were approved, permitted, operating plants. Oxford Pharmaceuticals in Birmingham holds FDA approval for thirteen product families, ten of which have no other U.S.-owned manufacturer, and runs at 55–60% of capacity because it sells 100 tablets for $1.50 against a Medicare reimbursement of $13.25 and loses federal bids to importers [45]. A 2022 survey of 37 U.S. generic manufacturing sites found roughly 49% excess capacity, with 57% of sites able to reach full production within a year [64]; the API Innovation Center puts the idle, FDA-approved U.S. capacity at roughly 30 billion doses [60]. Civica told the Committee, in its words, that "low prices are the principal barrier to onshoring generic drug manufacturing" [58].

The economics of paying for resilience. Domestic generic capacity pays for itself whenever the disruption losses it prevents exceed the premium paid for domestic supply. The dominant purchasing model never runs that test: buyers controlling more than 90% of generic volume score on invoice price alone and bear none of the downstream cost of a shortage. CPA has run it, and both sides can be measured.

The premium is small. Of every dollar spent at retail on generics, only about 36 cents reaches the manufacturer; the remaining 64 cents is captured by pharmacy benefit managers, wholesalers, insurers, and pharmacies [65]. Production is less than half of the manufacturer's 36 cents: a 2026 peer-reviewed study of 90 publicly traded generic manufacturers, together accounting for more than 60% of global generic sales, finds production cost equal to 45.6% of revenue at Indian firms, and finds unit production cost rises about 40% when output moves from India to the United States or Europe, and 35% when it moves from China [66]. A 40% increase on that production-cost base adds about 6.6 cents to each retail generic dollar. The 40% figure deserves precision. It applies to production cost only, roughly 16 cents of the retail dollar, so a hospital or a patient would see a far smaller change than the headline suggests. It is a cost differential rather than a tariff rate: a duty is charged on an import price that subsidies have already pushed down, and the 40% covers day-to-day production cost alone, before the capital needed to build or restart a plant. Scaled to half of every generic prescription filled in America, the premium is about $3.2 billion a year, or $0.82 per prescription, on products that already average about five cents a tablet. Because generic prices settle at roughly a fifth of brand

prices, the roughly $98 billion spent on generics each year keeps about $350 billion a year out of the system [67] [9]; the premium for making half of every generic in America is 0.9% of that value. The National Academies' commissioned economic analysis reached a compatible conclusion by another route, finding that purchasers "should be willing to pay prices that are 35 to 50 percent higher in order to ensure a reliable supply of these drugs" [68].

A single medicine shows how low the hurdle is. Generic sacubitril-valsartan, the heart-failure therapy sold as Entresto, entered at roughly a 90% discount to the brand and now costs about $37 a month at the pharmacy acquisition benchmark, against a brand price of about $458; for its roughly 700,000 U.S. patients, that $421 monthly gap is what a supply interruption puts at risk [69] [70]. Making the generic in the United States at the 40% premium costs about $57 million a year. If a persistent shortage pushed a quarter of those patients back to the brand for the 5.3 years the average shortage now lasts, payers would lose about $4.7 billion, before counting a single clinical consequence of interrupted heart-failure therapy. Domestic capacity pays for itself if it lowers the annual probability of that disruption by 1.2 percentage points, and one avoided disruption covers more than eighty years of the premium.

The exposure is large and already being paid. Hospitals spend nearly $900 million a year in labor managing scarcity [40]. Shortages raise the price of the affected generic by 14.6%, and by 27.4% within eleven months for drugs with three or fewer manufacturers; when a drug vanishes, the gray market fills the gap at markups averaging 650% [41] [71] [72]. Shortages kill: during the 2011 norepinephrine shortage, in-hospital mortality among septic-shock patients rose from 35.9% to 39.6% [73]. The price pressure that produces the fragility is measurable. ASPE examined 447 recently launched generic injectables and found roughly 70% still unprofitable three years after launch [74]; USP found generic sterile injectables in shortage priced nearly 8.5 times lower than those not in shortage, more than half of them under $5 [75]; and HHS concluded in April 2024 that generic prices are driven "to levels so low that they create insufficient incentives for redundancy or resilience-oriented manufacturing" [76]. Persistence is the median outcome: ASPE's analysis of shortages that began between 2018 and 2023 finds a median duration of 4.6 years for injectables and 4.0 years for essential medicines [77]. The risks are also correlated. India's March 2020 export restrictions fell on a list of APIs and formulations at once [78], and because roughly two-thirds of India's key APIs come from China, a single upstream decision reaches American pharmacies through every Indian finished dose simultaneously [79]. Redundant domestic capacity for one molecule hedges a plant failure; capacity across the generic base hedges the export ban.

Civica's model shows that buyers will pay for reliability when the contract is written to deliver it: its members commit roughly 50% of expected volume for a minimum of five years and hold six-month buffer inventories [80] [9]. Most contracts score price alone, and part of the resilience premium is simply paying for the reliability the market has been underpricing.

The July 21, 2026 announcement of a generic-drug tariff schedule, zero for two years from August 1, 2026 and then 100% and 200%, makes the sequencing question concrete [81]. A two-year runway is longer than the demand side needs and shorter than any plant build. If the domestic capacity the schedule is meant to summon is to exist when the duty arrives, the anchor contracts, reimbursement changes, and production incentives that make a domestic

plant bankable have to be signed now, and the regulatory pathway has to be cleared now. Regulatory reform and market reform are the same project.

VI. Policy Solutions — A Five-Pillar Strategy to Level the Playing Field

The reforms below are organized against the Committee's stated purpose: FDA approval and oversight, inspection and compliance expectations, cross-agency permitting, and the demand-side conditions that determine whether a faster approval produces a plant that stays open. Several are already before FDA in the proposed GDUFA IV commitment letter published in August 2026, on which FDA held a public meeting on September 17 and is accepting comments through October 17 [82] [83]. Congress can lock those in and go further.

Pillar 1 — FDA Approval Process: Reward Production That Moves Home

1. Make priority review for U.S.-manufactured generics permanent, and fix its eligibility. FDA's ANDA Prioritization Pilot, announced October 3, 2025, grants priority review only when bioequivalence testing, finished-dose manufacturing, and API supply are all U.S.-based [3]. That standard excludes nearly every domestic finished-dose manufacturer; Oxford Pharmaceuticals sources eleven of its thirteen APIs from Europe [45]. Congress should make the program permanent and tier it, consistent with the framework CPA proposed to CMS: U.S. finished dose with U.S. API in the first tier, U.S. finished dose with API from a country holding an FDA mutual recognition agreement (MRA) in the second, both receiving priority review, with the first tier receiving the shortest goal. The same tiering should govern the one-time ANDA fee waiver for all-U.S. applications proposed in GDUFA IV.

2. Give site-transfer supplements that move production to a U.S. facility the same priority. A company relocating an approved product home should not sit in the same queue as one relocating it abroad. Prior approval supplements that move finished-dose or API production to a U.S. site should receive the priority goal and, where FDA's risk model allows, the changes-being-effected pathway.

3. Shorten review for products added to already-approved U.S. lines and accept stability data on a rolling basis. Civica told the Committee these two changes alone could cut up to nine months from the cycle for a multi-product domestic plant [58]. Neither requires new statutory authority.

4. Enact the domestic Paragraph IV timing advantage FDA requested in its fiscal 2027 budget. FDA asked Congress to allow domestic generic manufacturers to file patent-challenge applications on the current timeline while foreign competitors wait one additional month, giving U.S. producers a structural edge in 180-day exclusivity [84]. CPA supported the proposal when it was released. No bill yet carries it.

5. Extend FDA PreCheck beyond its pilot. PreCheck's two-phase model, facility readiness review through a Type V drug master file followed by application support, is the right way to de-risk a new plant before an application is filed [85]. Its first cohort of seven includes one

generic manufacturer. It should be open to every generic finished-dose and API site being built in the United States.

Pillar 2 — Inspections and Compliance: One Standard, Applied Everywhere

6. Parity. Foreign facilities supplying the U.S. market should face unannounced inspections as the norm, at the same frequency as domestic facilities, with a statutory inspection floor and enough FDA investigators abroad to meet it. Countries or firms that refuse unannounced inspections should lose access to the U.S. market until compliance is restored.

7. Independent batch testing of high-risk imports. Critical or high-risk imported drugs should be tested in certified U.S. laboratories for identity, potency, and impurities, financed by importer fees, with a U.S.-resident accountable person on the European model. Kaiser Permanente already requires independent testing of what it buys; U.S. patients as a whole deserve the same [86].

8. Automatic consequences for serious violations. Data falsification, contamination, or obstruction of an inspection should trigger automatic import suspension, with longer bans for repeat offenders and loss of any preferential trade or procurement treatment.

9. Transparency. Pass the CLEAR LABELS Act, which cleared the Committee on Health, Education, Labor, and Pensions in July, and finalize FDA's proposed rule requiring foreign API establishments whose products reach the United States through third-country finishing to register and list [87] [88]. Purchasers and regulators cannot manage a risk they cannot see; the Department of Defense found that 22% of its essential medicines had an undeterminable source [89].

Pillar 3 — GDUFA IV: Use the Reauthorization Already Underway

10. Raise, index, and dedicate the foreign facility surcharge. FDA's proposed commitment letter would raise the foreign differential from $15,000 to $25,000 in fiscal 2028, the first change since 2012 [82]. Congress should adopt it, index it, and dedicate the added revenue to unannounced foreign inspection capacity. The plants that cost the most to inspect should pay for the inspectors.

11. Make the pre-submission inspection for domestic sites a commitment. The proposed letter would let a U.S. facility without recent inspection history request a surveillance inspection nine to twenty-four months before a planned application, removing the pre-approval inspection from the critical path [82]. This is the single largest schedule risk for a new domestic plant, and it should be a commitment rather than an option.

12. Tier the all-U.S. fee waiver. The proposed one-time ANDA fee waiver for applications naming only U.S. finished-dose and API facilities should be extended, as in Recommendation 1, to U.S. finished dose made with API from an MRA country, so that the waiver reaches the domestic manufacturers that exist today rather than only those that might exist later.

Pillar 4 — Cross-Agency Permitting: A Clock for Critical Medicines

13. Implement Executive Order 14293's permitting directive with a shot clock. The May 2025 order directed the Environmental Protection Agency to accelerate permitting for domestic pharmaceutical facilities and to designate a point of contact [90]. Congress should give that directive a statutory deadline for facilities producing essential medicines and their starting materials, with concurrent rather than sequential federal and state review. API synthesis is chemical manufacturing, and this Committee has heard from USP and Exiger that the permitting and environmental cost of chemical manufacturing is one of the reasons the starting-material base left the country [62].

14. Align DEA quotas with new domestic entrants. Sixteen percent of active shortages involve controlled substances, and the domestic solid-oral base that survives exists in part because DEA rules require it [36] [12]. DEA should provide an expedited quota path for a newly approved domestic manufacturer of a controlled substance in shortage and finalize its May 2026 proposed rule aligning quota applications with production lead times [91].

Pillar 5 — The Demand Side: Make the Faster Approval Worth Using

15. Finalize CMS's domestic-procurement designation and define "domestic" down to the ingredient. CMS's January 2026 advance notice proposed a "Secure American Medical Supplies" hospital designation with a separate Medicare payment for hospitals that buy domestically made essential medicines [92]. CPA's comments proposed a five-tier framework keyed to API origin, with U.S. finished dose made from U.S. API at the top and U.S. or MRA-country API next, so that a preference cannot be satisfied by tableting foreign ingredients in a domestic plant [93]. A proposed rule should follow.

16. Use federal purchasing as an anchor. The Department of Defense, the Department of Veterans Affairs, and the Strategic National Stockpile should sign multi-year volume contracts with domestic producers of essential medicines, close the Acetris loophole under which foreign API tableted domestically counts as American, and stop awarding contracts to repackagers and virtual manufacturers. Oxford lost a federal buspirone contract to a virtual manufacturer tied to India and China, and USAntibiotics, the last U.S. maker of amoxicillin, could not bid on a $40 million Strategic National Stockpile amoxicillin award because it was set aside for small businesses [94] [46]. Federal purchasing is a small share of the market, which is why the CMS designation matters, but it is the share the government controls directly. Those contracts should go first to existing domestic finished-dose lines, which can reach full production within a year and which, once running, pull their ingredient demand toward U.S. and trusted-partner API suppliers [64].

17. Use Section 708 of the Defense Production Act to bring the generic buyers to the table. Federal purchasing reaches only a small share of the generic market. The buyers that set the market are three retail sourcing alliances, Red Oak Sourcing (CVS Health and Cardinal Health), ClarusONE (Walmart and McKesson), and Walgreens Boots Alliance Development (Walgreens and Cencora), together with three hospital group purchasing organizations, and between them they control roughly 90% of generic purchasing [20]. None of them can shift volume to domestic or trusted-partner supply first without being undercut by the others, and they cannot lawfully coordinate that shift among themselves. Section 708 of the Defense Production

Act (DPA) exists for that problem. It authorizes a sponsoring agency to convene private companies under a voluntary agreement and approved plans of action, with a defense against antitrust liability for actions taken within the plan, under Department of Justice and Federal Trade Commission oversight [95]. FEMA used it in August 2020 to convene manufacturers and distributors under a pandemic response agreement whose plans of action covered drug products and drug substances [96]. The Department of Energy is using it now, in peacetime, to rebuild the nuclear fuel supply chain: Executive Order 14302 directed DOE to seek voluntary agreements, DOE issued implementing procedures, and it published plans of action in August 2026 [97]. HHS should issue its own Section 708 procedures, the President should make the required determination, and HHS should convene the sourcing alliances, the group purchasing organizations, and domestic manufacturers under a plan of action that commits a rising share of essential-generic purchasing to U.S. and MRA-country supply on a schedule that matches the 2028 tariff timeline, with dual sourcing, buffer inventory, and weight for FDA compliance history written into the plan. This requires no new legislation. It does require the DPA itself: the Act's non-permanent authorities, Section 708 among them, expire on September 30, 2026 unless Congress acts. The DPA Modernization Act (H.R. 7688), reported by the House Financial Services Committee by a vote of 41 to 0 in April, would extend them to 2031 [98]. Congress should reauthorize the Act this month.

18. Pass the PILLS Act. The Producing Incentives for Lifesaving Medicines Supply Act, introduced in the House by Representative Tenney and in the Senate by Senator Cotton, would provide a production tax credit for U.S.-made generics, APIs, and biosimilars, with a domestic-content bonus, and an investment credit for building or upgrading pharmaceutical facilities [99]. For solid-dose tablets, the credits offset the pennies-per-pill economics that closed the plants named above. For liquid suspensions, they accelerate a reshoring opportunity where freight and shelf life already favor U.S. production.

19. Set the generic tariff as a specific duty on high-risk imports, with trusted supply at low or zero rates, and sign the demand-side contracts now, alongside the duty. CPA supports covering generics under Section 232. The duty should be specific, assessed in cents per dose or dollars per kilogram, and it should fall on imports from high-risk countries outside FDA's mutual recognition agreements, with MRA supply entering at low or zero rates while U.S. capacity rebuilds [100]. Specific duties matter because an ad valorem tariff on a generic is charged on an import price that subsidies have already pushed down: a 100% tariff on a penny-and-a-half tablet adds a penny and a half, and it moves nothing. Oxford's chairman made the same point to this Committee [45]. The program should be administered as a tariff-rate quota, with in-quota volumes set to current demand less domestic capacity and adjusted annually as capacity grows, shortage waivers, reduced rates for firms with approved U.S. manufacturing plans, and strict origin documentation to prevent transshipment; the United States already runs this model in sugar [101]. On timing, the duty should arrive sooner rather than later. The two-year zero-tariff runway announced in July should be treated as the outside date rather than the target, because every year at zero is a year in which the most import-dependent, shortage-prone segment of the supply chain has no reason to move, and the demand-side instruments that make a domestic plant bankable should be signed now, alongside the duty, so that capacity is financed as the market is created. The tariff-rate quota is what

makes that sequencing safe: the volume the country cannot yet make enters in-quota at a low rate, so the duty can arrive first and capacity can follow without a shortage.

This package keeps costs flat for seniors at the pharmacy counter. The domestic premium is pennies a prescription, and it falls on the 36 cents of each retail generic dollar that reach the manufacturer; the 64 cents captured by intermediaries are untouched [65] [66]. Medicare Part B reimburses physician-administered drugs at average sales price plus 6%, and the Medicaid and Part D benchmarks reprice weekly, so changes in acquisition cost flow to insurers rather than to patients at the counter; Part D's annual out-of-pocket cap, introduced at $2,000 in 2025 and indexed since, applies on top [102] [103]. What reaches seniors is the shortage: the missed dose and the emergency visit that follows it. Hospital pharmacists have told this Committee they would pay 10–15% more for reliable supply [104]. The country is already paying far more than that, by surprise.

Conclusion

The United States makes 27% of the medicine it consumes. The children's fever medicine that ran out in 2022, the eleven tablets that tens of millions of seniors take every morning, and the plants from Morgantown to Salisbury that closed one price cut at a time are the same story. Subsidized foreign overcapacity pushed prices below the level at which reliable American production could survive; the purchasing system rewarded that price and nothing else; and the oversight system inspected the surviving domestic plants without warning while giving foreign plants twelve weeks' notice and five years between visits.

The regulatory reforms in this testimony can take a year or more out of the path to a new American plant, and most of them are already drafted, in FDA's own pilots and in the GDUFA reauthorization before Congress now. They should be enacted. They will matter only if the plant they speed into existence can sell its product at a price that covers reliable production. That requires a purchasing system that pays for resilience, incentives that offset the subsidies American producers compete against, and a trade tool that keeps subsidized, under-inspected supply from setting the price. Paying for resilience by design costs cents on the dollar. Paying for it during a shortage costs hospitals hundreds of millions of dollars a year and costs older Americans their medicines. Congress can choose the cheaper option, and it should choose it now.

Thank you. I look forward to your questions.

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