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PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS

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C O N T E N T S

PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS

Wednesday, September 17, 2025

U.S. SENATE
SPECIAL COMMITTEE ON AGING
Washington, DC.

The Committee met, pursuant to notice, at 3:24 p.m., Room 216, Dirksen Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

Present: Senator Scott, McCormick, Johnson, Moody, Gillibrand, Kim, and Alsobrooks.

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. Nearly everyone will be prescribed a medication at some point. Whether it be an antibiotic for an infection or a treatment for a chronic condition, people depend on access to safe and high-quality medications. This is especially true for seniors.

In 2021, a federal study found that 88.6 percent of older Americans surveyed reported having been prescribed at least one medication in the past 12 months. Ninety-one percent of prescriptions filled are for generic drugs. The problem is the United States relies disproportionately on foreign made generic drugs from communist China and India.

The U.S. currently depends on overseas manufacturers for about 75 percent of its essential, essential drug supply. Communist China is not our friend. They are the world's largest producers of the active pharmaceutical ingredients, and India relies on Communist China for approximately 80 percent of the active pharmaceutical ingredients they use.

A study from Washington University in St. Louis found that 83 percent of the top 100 generic drugs consumed by U.S. citizens have no U.S. based active source—U.S. based source of active ingredients. Not only is the U.S. over-dependent on foreign drugs, but these foreign drugs are often lower quality and more dangerous than drugs manufactured in the United States.

Earlier this year, a study showed that serious adverse events like hospitalization and death were 54 percent more likely for foreign generic drugs compared to American made drugs. Bad drug quality doesn't just mean that a drug is less effective—it can kill. In 2007, 2008, the medication Heparin had contaminated ingredients from Communist China, killing nearly 100 people.

Deaths from unsafe medications like these, contaminated Heparin, devastated families. LeRoy Hubley lost his wife of 48 years, Bonnie, and his son, Randy, just weeks apart. Bonnie and Randy died due to contaminated Heparin that they needed for their dialysis treatment. They were undergoing due to a genetic kidney disease. People who relied on their medication, and trusted that it was safe, died. This was an absolute tragedy and must never happen again.

Almost 20 years later, we are still seeing many of the same problems and quality issues that existed back then. There is still no routine testing done by the FDA and no incentive for quality. In 2023, contaminated eye drops from India killed four people and caused adverse events in at least 55 patients.

Foreign drug manufacturing plants simply aren't subject to the same level of oversight as manufacturing plants here in the United States, and Americans are—that doesn't make sense to any American. Inspections of drug manufacturing facilities in the Unites States—they are unannounced.

In Communist China and India, many inspections are pre-announced up to weeks in advance, giving manufacturers time to present false conditions or conceal non-sterile and unsafe manufacturing practices. While many quality issues present an immediate threat to the lives of seniors and their loved ones, supply chain vulnerabilities presents an existential threat to the country.

I know my remarks paint a very dark picture of the reality we face, but it gets much worse. Think about this, if Communist China or India want to shut down the supply of prescription drugs to the United States, they can do so at any moment, and currently the United State does not have a backup plan.

Let me say that again. If the Communist China or India decide to stop supplying the United States with prescription drugs, we will run out of prescription drugs very quickly and people will die. Let that sink in. Millions of Americans will not have life-saving drugs available to them. Americans will get sick. Americans will die. We have seen China place expert restrictions on rare earth elements over trade negotiations, and there is no reason they can't do that for drugs.

Additionally, during the COVID–19 pandemic, we saw India block the export of critical ingredients. Many of the disruptions were prompted by supply chain disruptions from Communist China, the birthplace of the COVID–19 pandemic. We simply cannot rely on other countries, especially those who want to destroy us like Communist China for something as vital as essential medicines.

Yet, despite these dangers, we still depend almost entirely on Communist China and India for generic medications, and their grip on the market continues to grow. As of 2021, Communist China and India accounted for 85 percent of active drug master file submissions—85 percent—applications submitted to the FDA by companies that want to supply drug ingredients to another company.

In 2000, that accounted for just 24 percent. The Administration for Strategic Preparedness and Response, the federal agency that oversees the Strategic National Stockpile, ensures the Nation has medical countermeasures ready for public health emergency, lacks

the data to understand the supply chain of the key starting materials or critical building blocks for pharmaceuticals.

Communist China has a stranglehold on antibiotics, with 90 percent of global antibiotics being of Chinese origin. While Communist China and India have dominated the market, American manufacturing has just withered away. A 2024 report from the API Innovation Center stated that in the past decade, the number of facilities located in the U.S. that produce active pharmaceutical ingredients has decreased by 61 percent.

In 2024, the U.S. manufactured 37 percent of its consumed pharmaceuticals. Just over 20 years ago, in 2002, that figure was 83 percent. Over 40 percent of generic drugs sold in the U.S. have just one FDA approved manufacturer. I am a business guy. You would never rely on one supplier.

This means in the event of a shortage, the FDA must scramble to find an alternative. In 2023, the chemotherapy drug Cisplatin went into shortage due to the FDA placing import restrictions on the manufacturer that accounted for 50 percent of the market. There was no FDA approved alternative, which forced the FDA to turn—unapproved Chinese drug company to fill in the gap. The supply chain is unacceptably vulnerable, and we can't just hope that shortages won't occur.

If we can't solve this problem, our public health and national security are in grave danger and people will die. We will soon hold another hearing to discuss the solutions to these problems, but the American people deserve to know the dangers of bad quality medications and a vulnerable supply chain.

Now, let me turn it over to the Ranking Member Gillibrand for her opening statement.

OPENING STATEMENT OF SENATOR KIRSTEN E. GILLIBRAND, RANKING MEMBER

Senator GILLIBRAND. Thank you, Chairman Scott, for calling today's hearing. I really appreciate it. Thank you to our witnesses for being here today. Combating drug shortages and supporting high quality generic drug production is one of the most important issues facing Congress today.

In 2023, I heard from countless New York constituents who struggled with access to chemotherapy treatment due to shortages of essential generic cancer drugs, including Cisplatin and Carboplatin. When you are fighting a disease as devastating as cancer, the last thing you want to worry about is whether the lifesaving drug you need is available.

Another issue that is extremely concerning is the quality of generic drugs, especially those that we import from overseas. I have heard time and time again the difficulties the FDA foreign inspectors face when they are inspecting these foreign facilities. This can include basic logistical support or a third-party translator.

When an inspector is abroad for months in a place where they may not speak the language, it can be very disheartening. Inspectors can also be put in a position where they must recommend the closure of a facility, but this can have a cascading effect of domestic generic shortages.

The FDA needs adequate funding and support from Congress to ensure that they cannot only conduct these inspections but also enforce violations to protect the health and safety of the American public. We also need to work on solutions that promote transparency and quality benchmarks in the generic drug supply chain. The pharmaceutical supply chain can be very long and opaque, where several countries and companies are manufacturing various ingredients at various levels of quality.

Purchasers need to be incentivized to purchase high-quality drugs that have proven reliability and a proven reliable supply chain. Hospitals and practitioners are spending millions of dollars a year due to drug shortages.

Ultimately, it is the health and safety of our patients and our constituents that are being put at risk. I am looking forward to working on bipartisan solutions to promote safe and reliable supply chains for generic drugs. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Ranking Member. I would like to welcome our witnesses, experts who are here to talk about why dangerous, low-quality drugs have been allowed to enter the U.S. market and just how reliant we are on foreign countries for the medications we need. First, I would like to recognize Peter Baker.

Mr. Baker is a former FDA Inspector who spent time in both India and Communist China. As an Inspector, he witnessed firsthand the unsafe manufacturing conditions and tactics used by manufacturers to deceive and even obstruct the FDA from conducting proper investigations of manufacturing facilities.

Mr. Baker, thank you for being here today and I look forward to hearing your testimony.

STATEMENT OF PETER BAKER, FORMER FDA INSPECTOR, PRESIDENT, LIVE OAK QUALITY ASSURANCE, AUSTIN, TEXAS

Mr. BAKER. Chairman Scott, Ranking Member Gillibrand, members of the Committee, thank you for the opportunity to testify today. I want to thank you for this bipartisan focus on enhancing the security of our generic pharmaceutical supply chain.

When a patient, especially those most vulnerable, such as the young and old, fill a prescription which has a 91 percent chance of being generic here in the U.S., there could be no doubt about the safety and efficacy of the medicine, or if the generic will perform as well as the brand name.

There are too many uncontrollable variables to allow this one to play any role. The FDA has a long history of protecting and promoting public health and performs extremely challenging work around the world on a daily basis to achieve that goal through site inspections, often in remote corners of the world that do not have internationally recognized regulatory bodies, which I will refer to as unregulated markets.

FDA investigators often have to deal with demanding travel conditions and can fall ill due to other unsafe conditions, such as drinking untreated water, a contaminated meal, communicable and non-communicable diseases, or fall prey to other risks often present in still developing nations.

The majority of our overseas pharmaceutical inspections are preannounced, often up to two months in advance of our arrival. In

my experience, upon arrival for the inspection, a strong smell of paint is in the air, fresh paint. The landscaping is immaculate. All garbage cans are empty.

Potential problematic operations are all shut down, some employees are sent home, and critical operations are choreographed as if performing on a stage. Those of us who performed foreign inspections refer to this as the dog and pony show, which is frustrating because this is serious business.

How do I know this to be true? Having spent seven years in three different FDA foreign offices starting in 2012, based out of our embassies strategically located around the world, we were tasked with developing inspection techniques capable of identifying if products exported to the U.S. from unregulated markets were really meeting our standards because things seemed too good to be truth. No rejected batches. No issues at all, really.

We knew the quality of products being manufactured in Ohio but really had no idea what was happening outside of our borders, especially in unregulated markets. We spent countless hours reviewing computer records, dug through piles of garbage, and showed up at times unannounced.

Booking our travel through Expedia versus the embassy travel portal to alleviate any concerns, someone would tip off the sites to our plans. What we found was terrifying. This testimony only addresses the tip of a massive iceberg. Fake laboratories pumping out hundreds of results a day that certified products as 100 percent pure when in fact the product was never tested.

For those products that did get tested, any failing result was simply ignored and replaced by a fabricated passing value. We identified filthy registered shadow facilities that would funnel their drugs through modern and clean registered sites which we refer to as the show facility.

We found fabricated manufacturing and quality records, painting a picture of a site in total compliance, when in fact substandard or fake medicines were being shipped to the U.S. by the tens of thousands a day. Following these experiences, I have no doubt that adverse events, including death happen on a daily basis here in the U.S. as a result of substandard generic products from unregulated markets.

The true culprit of these preventable adverse reactions lies in shortcuts and fraud. Shocking inspection reports continue to roll in on a monthly basis. The bad players list is no secret, and they continue to avoid any significant consequences. Meanwhile, those most vulnerable in our society taking these drugs have no idea of the games being played and certainly no idea that the game as designed today can never be won.

Personally, if I had a choice, I would never consume a drug product produced in an unregulated market, and any experienced FDA investigator will give you the same answer. When my 91-year-old grandma was alive, we would go pharmacy hopping around our rural Oregon hometown in hopes of finding a batch that was made by a reliable producer. Sometimes we succeeded and sometimes not.

I remember one time having to settle for a product manufactured by Rambaxi, who had just settled with the DOJ for $500 million

for faking countless data points used to demonstrate their products were safe. I tried to stay positive because causing her panic wasn't going to help, but inside I felt sick, and I was not the one receiving cancer treatment.

I urge this Committee to consider these four points. One, harsher penalties for companies who engage in illegal practices via the existing authority within FDA and DOJ. Two, changes to labeling so that patients can see where their medications were made and put pressure on supply chain decisionmakers to prevent them from taking a pill made from an unregulated market.

Three, independent third-party testing of every batch of every product arriving from an unrelated market. The European Union already does this, and it is a proven model. Four, resources to support the foreign pharmaceutical inspection program.

The FDA has made great progress to increase the number of unannounced inspections they are conducting, but they need additional resources to be directed to expand the number and quality of unannounced inspections as already outlined by Commissioner Makary's public statements. Thank you for your time and attention to this important matter. I welcome your questions.

The CHAIRMAN. Thank you, Mr. Baker. Next, I would like to introduce Dr. George Ball from Indiana University, where his teaching and research focus on operations, supply chains, and regulatory compliance in the drug industry.

Dr. Ball has been at the forefront of generic drug quality research, analyzing the intersection of global manufacturing, FDA oversight, and patient safety.

His work provides critical insights into how supply chain vulnerabilities translate into risk for American consumers. In a study published this past February, he and his colleagues found that generic drugs manufactured in India have higher rates of adverse events compared to those made here in the United States.

This research highlights in measurable terms what other witnesses have seen firsthand. Weaknesses in oversight of foreign manufacturing can directly affect the safety and quality of medicines reaching American patients. Dr. Ball, thank you for being here. I look forward to your testimonie.

STATEMENT OF GEORGE BALL, PH.D, ASSOCIATE PROFESSOR AND WEIMER FACULTY FELLOW, KELLEY SCHOOL OF BUSINESS, INDIANA UNIVERSITY, BLOOMINGTON, INDIANA

Dr. BALL. Thank you, Chairman Scott, Ranking Member Gillibrand, and members of the Committee for the invitation to speak with you. As Chairman Scott mentioned, I am an Operations Management Professor at the Kelly School of Business at Indiana University.

For the last 15 years, I have researched causes of product quality problems in FDA regulated industries. Prior to that, I spent a decade as a medical device manufacturing manager. Most recently, my research has examined generic drug quality and FDA policy. These topics are the focus of my detailed submitted written testimony, which I will briefly overview now.

In my view, the root cause of the generic drug quality problem is the original design of the generic drug marketplace. While the

Hatch-Waxman Act lowered health care costs via affordable generic drugs, it relies on an unrealistic assumption. That is, if an original drug is safe and of high quality, then its generic counterparts will be as well, requiring little quality verification and no transparency.

Why is this unrealistic? The answer lies in operations research regarding cost and quality, as well as sources of defects. First, quality is not free. Higher quality products normally require higher production costs. Further, quality defects originate from two primary sources, design and manufacturing. While the design of a generic drug must be equivalent to that of the original, two equivalently designed drugs can be made in vastly different ways.

One can use well-trained employees, sophisticated equipment, and mature suppliers that make premium raw materials. Another can be made using poorly trained employees, cheap equipment, and corner cutting suppliers. In a market where quality is assumed to be high, while it is unverified and opaque, the rational economic choice is to focus solely on cost. This will nearly guarantee poorly manufactured drugs.

This assertion, however, has remained predominantly theoretical because identifying where a drug is made, which allows one to study plant, firm, or country level factors that may influence drug quality is quite onerous. As mentioned, a team of colleagues and I have recently published a study referenced in my submitted testimony that begins to address this gap.

We exactly match generic drugs made in the U.S. against equivalently designed generic drugs made India. We find that generic drugs made in India, particularly older ones that have lower profit margins with greater incentives to cut costs, have significantly more serious adverse events than equivalent generics made in U.S. Two working papers that our team has under review, also referenced in my testimony, provide two policy changes that may help mitigate this problem.

Transparency is first and foremost. In an experimental study with thousands of subjects, we find that consumers and pharmacists are unconvinced by FDA messaging that generic drug quality is to be trusted regardless of where it is made. We see a strong preference for U.S. and Canada made drugs over China and India made ones when we only reveal manufacturing location.

However, when location and quality are both made transparent, quality tempers these location effects. High quality China or India made drugs are preferred over lower but moderate quality U.S. or Canada made drugs. When comparing equally high-quality drugs however, subjects continue to prefer U.S. and Canada over China and India.

Drug quality and location transparency can enable market forces to reward firms for high quality regardless of where they are made while simultaneously incentivizing high quality onshoring and near shoring of generic manufacturing. Second to this is aligning FDA's inspection strategy across the globe.

As has already been mentioned, the FDA inspects China and India plants after giving weeks or months of advance notice versus conducting them unannounced in the U.S. In another working paper that we have under review, we have examined newly available data from an FDA unannounced inspection pilot conducted in

India. We conclude that pre-announcing inspections hinders the FDA's ability to assess the true state of quality at foreign manufacturing plants.

We show that such inspection obscurity aggravates the cost only focused on harming generic drug quality. I advocate for drug quality and location transparency, as well as global FDA inspection parity. Our research indicates these two changes should help to meaningfully improve generic drug quality. Thank you.

The CHAIRMAN. Thank you, Dr. Ball. I would like to introduce Brandon Daniels. Mr. Daniels is the Chief Executive Officer of Exiger, a global leader in supply chain risk management, transparency, and compliance.

With decades of experience in regulatory compliance and technology, Mr. Daniels has led efforts to help Governments and private industry strengthen the security and integrity of critical supply chains, including those in pharmaceuticals, defense, and healthcare.

At Exiger, he has overseen the development of innovative tools that identify vulnerabilities, improve visibility, and help ensure that products and medicines reaching American consumers are safe, reliable, and free from hidden risk. Mr. Daniels, thank you for being here, and I look forward to your testimonie.

STATEMENT OF BRANDON DANIELS,
CEO, EXIGER, WASHINGTON, D.C.

Mr. DANIELS. Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify today.

For 20 years, I have worked with pharmaceutical and medical device companies supporting them through some of the most significant crisis management and litigation matters affecting their product development, research, and supply chains.

During the COVID–19 pandemic, I served on the White House's Joint Acquisition Task Force where I worked alongside federal partners to secure PPE, medical devices, and life-saving pharmaceuticals.

That experience underscored for me the fragility of our pharmaceutical supply chains and the urgent need for reform. In my role at Exiger, I am leading the development of artificial intelligence to map supply chains down to their raw material origins.

This work reveals, in precise detail, the vulnerabilities hidden in our healthcare system. The scope of this problem is enormous. America's medicine cabinet is no longer made in America.

Nearly three-quarters of the essential medicines used in the United States are sourced overseas. India now supplies about half of the generic drugs we consume, but 80 percent of the active pharmaceutical ingredients that make those drugs possible come from China.

In Fiscal Year 2024, Chinese firms supplied 77 percent of India's penicillin G and 94 percent of its 6-APA, which is the indispensable intermediate for penicillin-derived antibiotics. This concentration creates a dangerous single point of failure for drugs that every hospital, clinic, and pharmacy in this country depend on.

That means a Medicaid prescription filled in Ohio, or a Medicare prescription processed in Florida can often be traced back to a Chinese supplier. The choke points for our most basic medicines are controlled by Beijing, and we are not just dependent, we are actively financing that dependency.

In 2024, Medicaid reimbursed more than $150 million to a single generic drug company that sourced ingredients from at least six Chinese firms tied to forced labor and national security concerns. Dual eligible patients who represent just about 14 percent of Medicaid enrollment, but consume more than a third of its spending, are the most exposed to this fragile system.

Every taxpayer dollar spent on these medicines strengthens the leverage Beijing has over our health care system. The consequences for seniors and all American citizens cannot be ignored. As Chairman Scott mentioned, contaminated eye drops from India have left American seniors permanently blind.

Blood pressure and diabetes medications imported from Asia have been recalled after testing positive for carcinogenic impurities. These are not outliers. Over 30 percent of recent FDA import alerts involve Chinese producers, and another 16 percent involve Indian suppliers. These are the very countries we rely on most.

Even more troubling, our data shows that forced labor is woven into these pharmaceutical supply chains. Chinese state-owned enterprises with documented links to Uyghur forced labor in Xinjiang supply raw materials and active ingredients that ultimately find their way into drugs consumed by Americans.

This creates both an economic competitiveness barrier through labor arbitrage and a quality hazard for U.S. pharmaceutical supply chains. The weakness in our medicine cabinet is also a weakness in international security. More than 54 percent of the Department of War's pharmaceutical supply chain is classified as high or very high risk because of reliance on foreign suppliers.

Chinese State media has openly suggested that drug exports could be withheld as a weapon in conflict. In that scenario, the most basic medicines in our hospitals, our pharmacies, our military stockpiles could become tools of coercion. No adversary needs to fire a shot if they can choke off our access to antibiotics or insulin. The path forward will not be simple, but it is clear.

We must expand domestic production of critical medicines, particularly antibiotics and essential generics. We must diversify supply chains to trusted allies and ensure no federal program relies on a single country. We must enforce forced labor laws so that no American patient consumes medicine produced through coercion.

We must demand transparency at every level, using modern mapping and monitoring to stress test these supply chains before they fail.

The stakes could not be higher. Every time a senior fills a prescription, every time the service member receives treatment, every time our children and grandchildren need to fight an ear infection, there is a real chance the supply chain leads back to a potentially compromised source.

Thank you for your time this afternoon. I look forward to answering any questions you may have.

The CHAIRMAN. Thank you, Mr. Daniels. Now we are going to hear from the Ranking Member to introduce the next witness.

Senator GILLIBRAND. Thank you, Chairman Scott. I want to move to introduce our next witness, Dr. Ronald Piervincenzi. As Chief Executive Officer of U.S. Pharmacopeia, Dr. Piervincenzi is responsible for providing strategic leadership to his global staff of over 1,300 employees.

Dr. Piervincenzi has helped USP modernize and expand its operations, including in the areas of digital medicine, advanced biologics, quality manufacturing, consulting, and education. You may begin.

STATEMENT OF RONALD PIERVINCENZI, PH.D, CEO, U.S. PHARMACOPEIA, WASHINGTON, D.C.

Dr. PIERVINCENZI. Thank you, Ranking Member Gillibrand, and Chairman Scott, and members of the Committee for the opportunity to provide the testimony here today about the United States medicine supply chain that our Nation's seniors rely on.

As CEO of the United State Pharmacopeia, sometimes I have to describe who we are, and USP is an independent scientific nonprofit organization founded on the 1st of January in 1820 when 11 physicians gathered together in the old Senate chamber concerned about the safety and quality of imported medicines to the then new United States. On that day, they formed the world's first national Pharmacopeia.

Today, the 1,200 employees work with hundreds of scientific experts to set thousands of quality standards for medicines. USP also offers ingredient verification, product quality testing, and programs to advance the adoption of pharmaceutical advanced manufacturing technologies.

USP works to strengthen medicine supply chains to ensure that patients, and especially older Americans managing their chronic conditions, can access the generic medicines they need, when they need them, and very importantly, to trust in their consistent quality.

Low-cost generic drugs, which account for over 90 percent of the U.S. medicine supply, have grown quantitatively and increasingly vulnerable due to geopolitical tensions, natural disasters, pandemics, and importantly, market pressures. The globalization has expanded capacity and lowered costs, but it has also made the supply chains longer, more fragmented, and less transparent, jeopardizing both patient care and national security.

Since launching the medicine supply map in 2019 to gain insight into an opaque supply chain, USP now analyzes 94 percent of U.S. prescription drugs, providing an unprecedented visibility into key public health and national security vulnerabilities. USP's work quantitatively points to four interconnected drivers of our vulnerability. The first is a continual downward pricing pressure on generic drugs that creates an unsustainable market for these essential medicines.

The vulnerability number two, is manufacturing complexity, which is limiting capacity and causing an even greater risk. Third vulnerability is geographic concentration, exposing supply to single

points of failure wherever those might be, and finally, the fourth vulnerability are quality disruptions, which destabilize the supply.

These four factors combine to create an environment that undervalues resilience, constrains abilities to build redundancy, and discourages reinvestment in quality systems. This leaves patients, especially vulnerable seniors, at risk of delayed access or reliant on less effective secondary treatments. It is simply unacceptable when we know practical solutions exist.

No one stakeholder is to blame for the current supply—for the current state of our supply chain, but our hurdle is rather our willingness to take this first step together. Solution must uphold quality, incentivize greater stewardship of our supplied chain, and preserve the savings that generic medicines have delivered to patients and seniors.

I commend the chair and the ranking member for their holistic approach and respectfully urge the Committee to consider the following solution in three parts. Part one is to improve the supply chain visibility, identifying key vulnerabilities and updating this assessment continuously.

Tools like the medicine supply map provide the intelligence needed for proactive risk management. Understanding risk starts with increasing visibility into our current blind spots such as the vulnerable essential medicines, widely used excipients, and single-sourced key starting materials. We recommend authorizing an annual assessment that provides insights into our most significant vulnerabilities and makes recommendations for mitigation.

These insights could help guide commercial investment to shore up risky supply lines, certainly involve and inform policymaking, and direct agency attention and funding where it matters most.

Part two of the solution is to create pathways for America to innovate and scale new methods for manufacturing essential medicines. Advanced manufacturing, alternative synthesis routes, and new biology-based methods are no longer theoretical.

USP is partnering with ARPA-H today to explore wheat germ extract as a U.S. based method for producing a critical API, thymidine, an example of how the U.S. Government might leverage advanced manufacturing to reduce reliance on foreign sources for key ingredients, and part three, establish a benchmark for a stronger, more resilient medicine supply.

The most important factor underlying the fragility of the U.S. medicine supply chain is the unsustainable U.S. generics market. Pricing pressure on low-cost essential medicines drives generic drug purchases below sustainable production costs, discouraging investment in quality systems and pushing manufacturing offshore. Shifting the paradigm to reward a more resilient supply of medicines is central to promoting an environment that values reliability, reinvestment in quality systems, and a competitive domestic industrial base.

Specifically, we propose a resiliency benchmark for manufacturers of important medicines prepared with incentives for purchasers to prioritize those who need it, encouraging sustainable procurement and investment in quality systems, surge capacity, diversified supply, and greater domestic production.

To help ensure that America's seniors have consistent access to quality, the Government should leverage Medicare's significant purchasing power, along with the DOD-NVA to incentivize the resilience. Strengthening the supply is a national security imperative and critical to millions of seniors.

Together we can and must forge a more secure future for America's medicine supply. The well-being of millions depends on it, and I thank you for this opportunity.

The CHAIRMAN. Thank you, Dr. Piervincenzi. Now, we will go to questions. I will turn it over to Senator Ron Johnson.

Senator JOHNSON. Thank you, Mr. Chairman. Thank you for holding this hearing. This may be the most important hearing of this Congress, and maybe many Congresses. Now, it is not getting much attention, but it needs to.

I first became aware of our vulnerability in February 2020, my first hearing as Chairman of Homeland Security about the pandemic, and I had Scott Gottlieb, Judy Gerberding there. I had no idea that we were so dependent on advanced—or API and the precursor chemicals on China and India's.

Have we done anything about it? No. We passed a one and a quarter-trillion-dollar infrastructure bill and didn't even address it. I think the issue is how do you bring the manufacturing back to the U.S. where it can be inspected properly, right. It is not an easy task, but part of the problem is the precursors chemicals, that is refining and that needs permitting.

That is expensive to do in America, which is why we have offshored it to China, so you know, how do we do it? What I like, and this was Mr. Ball's suggestion here, and I would love to cosponsor this bill with you, just simply requiring labeling in terms of where the drug comes from. They are putting tremendous pressure on the companies to reshore these things.

It is not going to happen overnight, but, you know, Government edicts—you know, spending money to bring, you know—what you could do potentially is just not tax somebody who brings a refinery over here, but you got to be able to permit it. I mean, there is so many impediments to this.

This is a very complex issue, but we have got to start doing the basics first. But the first one is, again, understanding the problem, acknowledging we have it. Understanding how vulnerable we truly are. You know, things like Heparin. We have known about this for years and we have literally done nothing about it.

Again, I am looking for really the most practical first steps we can take. I mean, we can talk about all kinds of, you know, complex solutions but would you agree that just the labeling itself—I mean, that would be a pretty easy bill to pass. It will be interesting to see if we could.

I guess I want from all four of you, what is your number one single first step that we could take here to address this? By the way, first it starts with the information, and we need a lot more information. Again, there is all this—you have all mentioned the pricing pressure, right. You are all beating up on drug companies over pricing.

Well, the fact is, on generics, it is probably underpriced is what you are telling us. Let's just go down the list and just give me kind

of the one thing that you—you know, the first step we ought to take.

Mr. BAKER. From my perspective, I think enforcing the existing laws, as they are already written through the authority of the FDA and DOJ, would let the good players know that it is going to be a level playing field for them.

Senator JOHNSON. We have laws that are not being enforced. Why? I mean, how would you enforce them?

Mr. BAKER. It is difficult to enforce them at the moment because of the issue of drug shortages. When issues are uncovered at some of these factories, they are allowed to—they carved out the ability to keep supplying these drugs, because if they were prevented from entering the U.S., then we would have a supply chain issue, a shortage issue, so it is going to have to be weaning off of that situation, but it is going to have to start with letting everybody know that the laws are going to be enforced, and it is going to——

Senator JOHNSON. You know, one thing Congress relies on is whistleblowers. I have been trying to pull information out of Government agencies for many years now. They don't give up their secrets very well. Will there be whistleblowers that would tell us of those instances where there is a quality problem here and FDA just looked the other way? I mean, we are going to need examples of that.

Mr. BAKER. Absolutely. FDA works with whistleblowers all over the world pretty much on a daily or a weekly basis.

Senator JOHNSON. I guess I would encourage whistleblowers to come forward to this Committee or Permanent Subcommittee on Investigations. Tell us your story so we can highlight that, so we can expose it, so we actually start enforcing our laws. Mr. Ball, I already used yours, but if you got a better one.

Dr. BALL. Well, I agree with you, obviously, because it was something I talked about. It is the only marketplace where firms do not reveal their quality and consumers that purchase a product cannot assess it.

The marketplace is not allowed to work properly for generic drugs. If quality and location are transparent, the market would fix, in my view and from research we have done, quite a bit of the problem. Because market forces would then start to reward high quality manufacturers and punish low quality ones.

It is a relatively inexpensive solution because it is—somewhat the invisible hand of the market would fix this issue if the market was no longer opaque. When it is opaque, the market is broken, and we have thought long and hard about other comparable markets like this, and there are very few.

I think transparency of both quality and location is the answer.

Senator JOHNSON. I used that when I said it is about information. The consumers need information which we don't have right now. Mr. Daniels.

Mr. DANIELS. I think the biggest thing from my perspective is right now we have economic coercion on the other side that is keeping these key starting materials in particular at artificially low prices. That is not actually how much they cost to manufacture. They are significantly subsidized. They are in free economic zones.

In many cases, they are using labor that is insufficient in order to conduct these operations. There has got to be an economic disincentive, some sort of ADCVD against the KSMs that China is dumping into the market in order to create a U.S. domestic market that is available and viable, and there are today, whether it is in fermentation for critical key starting materials for antibiotics or it is for drugs like Heparin, there are continuous flow manufacturing capabilities that we could bring to the United States.

Everyone thinks it is going to take some huge delta between the current price and the future price to bring investment into a market. It is not. I mean, you remember in 2008 we had gas prices spike.

IKEA brought Swedwood, furniture manufacturing, back to Danville, North Carolina because of the small additional cost that sat on the top of every piece of furniture. They brought their entire manufacturing capability back.

Senator JOHNSON. As long as you can permit it.

Mr. DANIELS. Yes, the permitting is a big piece.

Senator JOHNSON. I suggest to all of you, help us identify those drugs or drug that we need to start with. You start with one, you know, succeed in that and then move forward. Mr. Piervincenzi, actually—I think I got that right. Close?

Dr. PIERVINCENZI. Perfectly. Thank you. I appreciate that. I would suggest a market based resiliency benchmark, which is a positive incentive. It would need to be market-based. It would absolutely require the Government to kick-start it, and this would reward the resiliency of having a secure facility with past inspections on a consistent basis.

All the things we know, and in fact, we created a draft of these types of benchmarks and just about every factor that was shared, very much including location of production, your own supply chain, and from that, even if we were to start, let's say in hospital systems for hospital use drugs as a starting point, although I am not saying it is the whole solution, and then put a hook on that where hospitals have to reward this through a better contract, a slightly better price.

These are the cheapest medicines, which means a better price is still not going to break the bank.

Senator JOHNSON. I think hospitals are still going to be opaque. I think it has got to be consumers, and if you have too many elements in that benchmark, again, it is going to difficult to pass. That is why I am kind of looking at how much just country of origin as a starting point.

Mr. Chairman, honestly, this is an incredibly important hearing. I want to work very closely with you and your witnesses and other experts on this, and we need whistleblowers.

The only way this gets passed in Congress is the American public has to understand how vulnerable we are and what risk they are at, but thank you for this hearing.

The CHAIRMAN. Thank you. Ranking Member Gillibrand.

Senator GILLIBRAND. I would like to turn it over to Senator Kim.

Senator KIM. Thank you, Chairman and Ranking Member. I agree, this is an incredibly important issue, and I hope that this is something that can spur us to work in a bipartisan way.

You know, certainly from my State of New Jersey, a lot of what we need to be thinking about in terms of what comes next when it comes to medicine, pharmaceuticals, but recognizing that we need to do a lot more when it come to the manufacturing and the supply chain side to make us more resilient.

I think resilient is the right word, because we see not just with the national security side, but you know, a lot when it comes to just the economic competitiveness of the United States and understanding where we need to be going to on a number of different fronts. I would like to just pick up where my colleague left off.

You know, Dr. Piervincenzi, I just wanted to get a little bit more of a sense of this market-based resilience benchmark I think you framed. Is there a comparable example or is there something that is being used in other industries or sectors that can help us kind of understand how this might come about and how it might be structured?

Dr. PIERVINCENZI. Thank you for that question, and yes, in fact, you don't have to leave the pharmaceutical industry. Let's take a sophisticated multinational company, generic or innovator, they do this themselves on the goods that they purchase.

Let's say you are a large innovator pharma company, and you are looking to ensure that your multi-billion-dollar product is never short because you have a huge economic incentive to do so. What you do in your own supply chain is you would never buy all your key ingredients from one place.

You will have two sources for every ingredient. In addition, you will send your team to inspect their facilities and make sure they meet your own quality standards. You will create a contract which is a long enough term that the supplier is committed to you just as you are committed to them.

This is normal. Everybody does this. This is nothing innovative. That process I just described, it works. It is why innovator drugs are not on the shortage list except for unusual demand spikes, which we know are something entirely different.

Senator KIM. Then, how do we then take that type of model though at a societal level? When we are not talking about just a company looking out for its own bottom line, and in particular, you know, what is the role of Government? What can Government do that others can't do so that we can understand how to fit this all together?

Dr. PIERVINCENZI. The key here is that the buyer, in the case I just described, is one single company with a rational reason to create a resilient supply.

The challenge we have in the U.S. is there are thousands and thousands of buyers who all wish this to be true, don't feel empowered to do so, and actually don't have the mechanism to even pay more money because they don't know what they are paying for.

Then the answer would have to be both, the creation of the benchmark, so they no longer have the excuse that they don't know how to pay for quality, and once you have that, then you have to create an incentive, or perhaps force, there to be contracts that reward people from scoring high on those benchmarks.

There are different parts of our drug supply which will be harder in some than others, but we believe that where you see the most

drug shortages today, which are in hospital administered drugs, is actually probably one of the easier places for leverage, especially because the Federal Government has its own leverage for how it purchases medicines, and you see this in quality of care, the tools that can be used. I am not saying it is extremely easy, but it is not unprecedented, even in health care.

Senator KIM. Thank you for that. Dr. Ball, I wanted to just pick up on something you said, which is about that quality assessment and being able to have that alongside the geographic. Can you give me a better sense of how that quality assessment could be done at the scale of what we are talking about here?

Dr. BALL. Absolutely. The paper I referred to assumes that the FDA's site selection model scores, which are risk adjusted scores that the FDA uses both at the drug and plant level to determine when to inspect a plant, that some form of those would be amalgamated into a five-star rating on a drug, and that a five star would be the lowest risk facility, three star would moderate risk, and that is what we used in this study. The FDA has this data. They would be very resistant, I believe from my experience in discussing this with them, to give it out and use it, but it is at least a starting point, and it is a combination of adverse events, recalls, inspection scores. Anything that has happened at the plant or the drug that is a negative experience creates a higher risk drug and that would be used to put a score on the label.

Senator KIM. I see. Mr. Baker, I just want to end with you here. You know, in your testimony, you highlighted how FDA investigators often have to deal with demanding travel schedules and conditions, can fall ill. How, you know, in many parts—and many of these inspections are taking place in locations where English may not be a primary language spoken, yet there is no requirement for independent translators. I wanted to just get a little bit more of a sense from you. What steps do you think Congress should prioritize to ensure that we are giving our FDA workforce the support that they need? Also just thinking through, are there other steps like better strengthening our collaboration with foreign regulators and other steps that we can do to try to address these needs?

Mr. BAKER. Yes, thanks for that question. I think one of the things that can be done is to increase the level of investment in the FDA investigators. A lot of disruption happened in the FDA during the COVID times where a lot of, for example, for onsite training and hands-on training was sort of moved to remote, and that isn't as effective. You know, prior to that, it would take two or three years to get qualified, so to speak, to do a foreign inspection. Whereas now, due to resource constraints, you may be tasked with doing those inspections, those challenging inspections that you just mentioned, in like two months after getting hired. You may not have the skills and the training necessary to do those effectively. It is very challenging. You will fly into an airport and then you get in it—especially if you are trying to do it unannounced. You are going to get in a car, taxi, with someone you don't know, and drive four to six hours to get to your hotel that may or may not air conditioning. It is very difficult and challenging. They need additional support to really enhance this existing program that they know works. Those unannounced inspections have about a four time

greater chance of identifying a problem that is going to cause harm to a human versus an announced. That is what the data shows. They are very effective, so investment in that area is worth the effort.

Senator KIM. Thank you, and with that, I will yield back.

The CHAIRMAN. Thank you, Senator Kim. Mr. Baker, as a former FDA Inspector, are you confident in the quality and safety of generic drugs coming from foreign countries like China and India?

Mr. BAKER. Thanks for that question. The answer is going to be no. I am not confident about the quality. I am confident in the sites that I have been to, and I have seen world-class sites everywhere in the world, manufacturing drugs, and I am confident in taking those products. But for the majority, I would say no.

The CHAIRMAN. Dr. Ball, what types of adverse events, deaths, did you find foreign medications caused in your research?

Dr. BALL. We found examples of cardiac arrests, gastrointestinal hemorrhage, delirium, cellulitis, acidosis. Those were just a random sample I took this morning of the adverse events in our study. There are millions of adverse events that get reported to the FDA's adverse event reporting system. These are just a few.

They are serious, and in this paper, we only counted those adverse events that were caused by the drug, reported by the manufacturer, mandatorily reported, and caused serious health outcomes, and there is still millions of those.

The CHAIRMAN. Do you think they might be under-reported?

Dr. BALL. I think underreporting is a problem for recalls and adverse events, and it leverages a lot of what Peter mentioned. The more FDA is present in a facility in an unannounced manner, the less likely an un-reporting will go, because you can discover unreported events in these inspections, but not if they are announced weeks or months in advance.

Those are exactly the type of things that a firm is likely to hide if they have advanced notice. If they don't, it is very hard to hide those things. The FDA inspection strategy goes hand in hand with reducing these adverse events.

The CHAIRMAN. Mr. Daniels, how much supply of drugs do we have if Communist China shuts supply off to the United States?

Mr. DANIELS. Thank you for the question, Chairman. The supply chains are interwoven, and I think that is the biggest issue because you will have specialty pharmaceuticals that are untouched for six or nine months.

Then when you start to get to the end of that supply chain and that manufacturing process, you might have severe runs on the key starting materials or the precursors that are necessary to support that drug manufacturing.

In the context of generics, and specifically critical generics like antibiotics, heart medications, insulin, you could see all supply outside of what is used in emergency rooms shut down within months if China decided to stop supply to the United States, especially if they decided to stop supply chains on a supply chain like sanction, like we have done on forced labor prevention in China.

If they stopped the sort of intermediaries from selling us the goods that are manufactured utilizing their materials, it could be a severe constraint that would look cataclysmic.

The CHAIRMAN. Dr. Piramvincenzi, USP is a global organization with labs and operations abroad. From your perspective, are foreign made drugs consistently meeting USP standards, or do you see widespread quality failures?

Dr. PIERVINCENZI. Thank you, Senator. I may also just maybe build a bit on Mr. Daniel's comment. The quantifying the if China were to cutoff supply, what would the impact be is challenging, but in the next two months or so, USP will issue a report that covers about 90 percent of our generic supply, so not all of it, but a vast majority, that will map down to the key starting material and location of origin.

It will actually be the first time ever I will be able to answer it. A rough number though, just because we have to start with something. Half our medicines come from India. Seventy or eighty percent of their starting materials come from China.

You start to do the math, it is not going to be a majority, but it is going to be a very large percentage of U.S. medicines that would become highly vulnerable. Some completely, but many highly, highly disrupted in short.

The CHAIRMAN. Do you have any feel for how much is in the supply chain that is already in the United States? I mean, I can't imagine that people that—I used to run a hospital company. I don't think we sat there and said, let's have one year supply of drugs just in case something happens. Do you have any feel for what a typical doctor's office, a group purchasing organization, or hospital would have in inventory?

Dr. PIERVINCENZI. At the very end of the supply chain is extremely little but if you were to say what is onshore in the United States at a distributor and such, of course it varies, but it is months, not years, and not weeks—it is months.

If you continue down to your starting materials in your API, it gets a little longer, and that matters because it makes it hard for us to get signals. Something might happen, the manufacturer stops producing, and everything seems fine for a while. Nine months goes by and suddenly we have a shortage. It is not really sudden, but it appears sudden at the end because it takes a while for the chain, and since we don't have good transparency, we are not watching this happen as it comes along.

Months is the answer. However, as soon as somebody knows it has been cutoff, hoarding behavior begins, and the shortage would take a matter of days in real life. In real life, you would know if a hurricane hit a plant and everyone knows there is a problem, everything would be bought up within hours.

The CHAIRMAN. Those stores are empty in hours, actually. Yes.

Dr. PIERVINCENZI. If nobody knows it happened, of course, then it would be months. But odds are it is going to leak, right.

The CHAIRMAN. All right. Let me turn it over to Ranking Member Gillibrand.

Senator GILLIBRAND. Thank you. For Mr. Piervincenzi, what are the risks of relying solely on the United States for production of drugs, and what precautions can we take against such risks?

Dr. PIERVINCENZI. Thank you, Senator. One of the four drivers of resilience was the geographic concentration. That is agnostic to location. There are different issues about quality that we are also

talking about. Some of the most acute drug shortages the U.S. has had in the last few years have been actually on the U.S. shores with an unfortunate hurricane and other things.

Natural disasters—just things can happen, and they do. It is possible to create diversification even within the United States, as long as you don't have all your plants in one place, and so, there is a nuance to this, what geographic diversity looks like. If you have two plants in North Carolina across the street from each other, I would argue that is not very resilient. If one was on the West Coast and one on the East Coast, you might be in pretty good shape.

Senator GILLIBRAND. In your testimony, you indicate the importance of aligning supply and demand forces so that American patients have more predictable, sustainable, and quality supply chain. How can the Federal Government promote a coordinated effort amongst different stakeholders to move toward a resilient supply chain?

Dr. PIERVINCENZI. The simple answer is somebody has to pay for it. I think you have heard four different versions of that same thing here, is that somebody has to be not just willing to, but able to, so a willingness says, I am willing to pay $0.13 rather than $0.10 for a pill.

Just about everyone is willing to do that. The problem today is no one has any evidence of how do I do that? If I can pay $0.13 for the same pill, I don't—it doesn't buy me more resilience, so this is where a large organization, including—very much including the U.S. Government, has that power.

To say, for now on, especially for a certain set of drugs as we know are vulnerable, we will only pay with resilience. Meaning, this is what we expect, and you will get this price. The market solution like that means if somebody doesn't meet those benchmarks, they will be less preferred, so the market can fill in. It won't force it because it is not a binary decision.

Because margins are so small, just extending—having a small, tiny bit paying just a bit more or having a slightly longer contract could make an enormous difference. I think that is the benefit of this problem, is that it can be solved with much less money than if these were expensive medicines.

Senator GILLIBRAND. Mr. Daniels, in your written testimony, you recommend the Federal Government conduct regular stress tests of the pharmaceutical supply chain to stimulate worst case scenarios and identify weak points before failure. Can you speak a bit more about how the Federal Government could address identified weak points from these stress tests?

Mr. DANIELS. Absolutely, and thank you, Ranking member Gillibrand, so two things. One, just to speak about what Dr. Piervincenzi just mentioned. There are multiple ways to reduce the cost of these drugs as we reshore them. One of them is also relying on the innovation of our allies, right.

I mean, there is a global market for pharmaceuticals, and as we start to look at that market, we do need to diversify both location, but also, we need to diversity end platforms, and so, in many cases, there are multiple areas in the supply chain where we are advising our customers, which are the Fortune 500, we are advising our cus-

tomers to find two or three suppliers downstream to purchase metals, to purchase chemicals, to purchase goods from.

They can do two things at that point. They can, one, utilize their purchasing power to actually reduce the cost of the underlying chemicals, precursors, whatever it might be, key starting materials. Two, they can give back some of that. Our customers, when they do what is called a directed or embedded spend program, they typically save between seven to twenty-two percent on landed cost on the end goods.

They can actually share back some of that to get to a resilient supply chain and to get a supplier that is willing to agree to ethical quality standards, so these programs exist today. They exist in other industries. They are not as common in pharmaceutical supply chains, but there are pharma companies in Europe that we are working with today that are engaged in these activities, and they are doing it specifically to address CSDDD.

To get to your second question, which is on these stress tests. We have been working across a number of different federal agencies, DLA, FDA, to map the 227 critical medicines within our supply chains and to understand what are the consequences of whether it is disruption, like the hurricane which knocked out our IV fluids capacity in the United States, or it is major shortages in war gaming due to conflicts with near peer adversaries, or if it is due to significant changes in availability of underlying materials. When we are doing this analysis, it is simple supply chain planning.

Companies do this all the time. Now, what we have to do is we have to work probably across a consortium with companies like Exiger and Pharmacopeia to create a complete view of the supply chain, and that complete view the supply chain doesn't stop at sort of the specialty pharma or the innovative pharma company or the generic pharma companies and their suppliers.

It has to go all the way down, and what we have to see is that reverberating impact. Because Dr. Piervincenzi said, it is true that many companies have 15 suppliers of the same product at that next year, and then they have four suppliers at the next year, and then it goes back to one.

Just no one knows it. That is what happened with ventilators during the COVID–19 pandemic. All of our solenoid valves went back to one company in Italy, and so, even though Ford and GM and everybody stood up to make more ventilators, we couldn't truly make more because there was only one company that had that solenoids valve for the commodity ventilators.

We actually have to make sure that mapping is complete, and then we have to makes sure that we are assessing all of the risks that can actually impact to that environment, whether it is geopolitical, it is natural disasters, or it is material shortages.

The CHAIRMAN. Thank you. Senator McCormick.

Senator MCCORMICK. Thank you all for being here. Mr. Baker, can you describe what level of transparency already exists for American health care consumers with regard to what country a medicine or its APIs are from, and what improvements could be made to ensure Americans have better insight and understanding on the origins of their medicines?

Mr. BAKER. Yes. At the moment the transparency in the supply chain, as far as patients know about where their medications are made, is virtually nonexistent. There could be some improvements in the labeling. It is a complicated issue, because there is many players in the supply chain as outlined already, from the key starting materials all the way to the finished drug.

We would have to take a risk-based approach, where the most critical step—like for example if it is an aseptically filled product that is intended for injection, the step in a supply chain at which that product was aseptically filled in a sterile environment would be on the label.

It is not a perfect solution, but it is the best we can do to help increase transparency and let the market fix the issues as already outlined by my colleagues.

Senator MCCORMICK. Thank you. Mr. Daniels, how can technology and AI be deployed for hospitals and others to map their supply chains? I know you touched on this at some level, and what can be done to advance any reshoring or near-shoring of drugs and APIs?

Mr. DANIELS. Thank you, Senator McCormick, for the question, so first, hospitals are mapping their supply chains. We work with multiple hospitals across the United States to map their supply chains.

They also, in large part, go back to large distributors, right, that are intermediaries between those hospitals and the actual drug manufacturers or medical device manufacturers or PPE manufacturers. The key first step is to use artificial intelligence to actually break down that bill of material of each of those pharmaceuticals and then tie those back to the literal suppliers that those pharmaceutical are coming from.s

The thing is, you can't just map the products you are buying. You should be mapping the products you are not buying, and what I mean by that is, you should be—you should understand the spectrum or the panoply of alternative suppliers that you have available to you prior to a major disaster—the customers of ours—we are endorsed by the American Hospital Association as the key risk management technology company for all U.S. hospitals.

The customers of ours that had our software deployed knew almost a month in advance that IV fluids would be subject to disruption due to Hurricane Helene, and so, that kind of visibility, of course, it can lead to the stockpiling point that we just made, but it also can save American lives, especially in operating rooms.

The second question you had was on the reshoring. I mean, first, Senator Johnson brought up this point. One of the biggest issues we have is permitting. We have a huge backlog and delays in permitting of new facilities and capabilities. The other thing is a lot of this stuff is pretty dirty to make.

Acetaminophen, just taking as an example, creates a waste broth that the EPA would not allow us to dispose of in the way that India or China does today. One of the things that we have to look at is that there are novel ways to actually manufacture these. These aren't novel ways that are not taken to scale yet through BARDA and multiple other programs that are looking for advanced research and development capabilities in emerging biotechnology.

In BARDA, we have actually taken some of the continuous flow manufacturing capabilities to scale, so first, if we can permit, we can actually make it cost effective, and then the second thing is, with AI and automation in the actual manufacturing line, we take away the single and only differentiation between us and emerging markets in manufacturing pharmaceuticals at scale, which is labor arbitrage.

Implementing AI and automation inside of the pharmaceutical manufacturing process—I mean, there are places in North Texas that are cheaper than places in Shenzhen, right. We can start building these factories and actually start, you know, competing on a global basis.

Senator MCCORMICK. Thank you. Mr. Chairman, Ranking Member, thank you for having this hearing. Great, great topic. Thank you.

The CHAIRMAN. Senator Alsobrooks.

Senator ALSOBROOKS. Thank you. Thank you so much, Chair Scott. Thank you so much, Ranking Member Gillibrand, for hosting today's hearing, and thank you so much as well to our witnesses for being here.

What we know is far too many seniors still face the cruel reality of needing medication that they can't reliably access or afford. High drug prices, unexpected shortages, and now Secretary Kennedy's policies are preventing Americans from accessing the medicine and vaccines that will keep them safe and healthy. This couldn't be a more relevant topic.

In the past few weeks, I have heard from my constituents, so many seniors across our state who are eligible for the latest COVID vaccine, and they are now being turned away because of the confusion caused by Secretary Kennedy's new guidelines, and others are being told that their local pharmacy is struggling to stock the vaccine because of a lag between FDA approval and the forthcoming recommendations from the Advisory Committee on Immunization Practices.

When it comes to vaccines, we know that so much doubt is being cast on life-saving vaccines, as well as dismantling our public health infrastructure, and that is why this conversation is so critical. Seniors deserve not just reliable medications, but a health system that they can trust to put science and safety above politics. My first question is for Dr. Piervincenzi.

I would like to ask you, when we see how fragile our drug supply chains can be when it comes to medicines that seniors rely on, and vaccines we know are no different, this is a time, as I have mentioned, when Secretary Kennedy, I believe, is really destabilizing public trust in vaccines.

Older Americans can't afford disruptions to flu, RSV, or COVID. I would like to know, how has the confusion regarding vaccine approvals and recommendations this year made seniors across the country less safe?

Dr. PIERVINCENZI. Thank you, Senator. An interesting fact on the vaccines, as compared to many of the low-cost generics, there are quite a few manufactured in the United States.

If you consider United States, Europe, Canada, there is a disproportionately high quantity, so there is the ability for FDA to do

more robust inspections, including surprise for majority of vaccine sites, and so, the public should have more confidence, if anything, that they are able to rely on the quality of the vaccines. As a complex biologic, there are linkages to the complex generics that are the ones showing up on the shortage lists the most.

Because they are the kind of medicines used in hospitals, just for that reason alone, they are impacting two groups the most—the most senior, especially in oncology, and the youngest, the pediatric population. Also tending to be oncology but not only, and these two populations have been most affected. There is an extra layer to this problem is that these are the medicines that are least substitutable—it is an art form to try to treat these cancers.

We haven't cured cancer, so the best we can do is slow it down in many cases. But a small change from one chemotherapy to another and the progression advances, it is the person's life that is at stake, so the vulnerability isn't just about the medicine, but about the patient and essentially what the next best alternative is.

From a quality standpoint, items like vaccines are very different because they are given, of course, to a healthy patient, so you are measuring it in two very different ways. However, a poor quality vaccine, you are only going to test that perhaps 30 or 40 years later when you are exposed to a disease.

You think about when you need to rely on quality, I can't think of a medicine more important than vaccines. Thank you.

Senator ALSOBROOKS. Thank you. Now, I have one other question regarding—or two actually. The next question is regarding transparency, and what we know is for seniors in particular, and this is for any witness, it is not just about how the drug or where the drug is manufactured, but it is whether or not they can trust that what is in their pill bottle is safe, effective, and available when they need it.

Too often our system reacts after a crisis, instead of putting preventive measures in place, leaving seniors and their caregivers to find out too late that their medication is suddenly unavailable.

How should we be thinking about transparency, not just as a tool for regulators and industry, but as a preventive measure that empowers patients, especially seniors, to make informed choices about their medications and avoid being blindsided by shortages? That is for any witness.

Dr. PIERVINCENZI. I will be brief to allow others time as well. I would emphasize pharmacy, if I might, so there is a big gap to the patient in knowledge and understanding, but we have an army of hundreds of thousands of health care practitioners called pharmacists out across our country who are unusually close to patients, have access on essentially a prescription by prescription basis.

That is a huge positive. There is an opportunity to have them play a more active role when it comes to supply chain and quality. It is not typically a topic that they touch. I think if we want to be able to help empower patients, we are going to have to solve this through partnership with pharmacy and pharmacy organizations that I know are very open and willing to have this conversation. Thank you.

Senator ALSOBROOKS. Thank you.

Dr. BALL. Thank you for the question on transparency, so this is something I have spent a lot of time working on, and when our paper that I talked about in my introduction got published, our author team started getting random emails from the public, scared emails about how can I find out where my drug is made?

We know know how to figure this out, so this is something that we were able to do in this study we published, but it is very difficult, and this is why we advocate for forcing firms to put the country, the location on the label so that it is transparent for everyone. We have developed a website that we are hoping to launch where you can type in a national drug code number and a flag will pop up to tell the consumer this is where it is made.

Even developing that website by this author team that we worked on this paper has been very hard for us because it is a difficult step to go from a national code, which is on every drug label, to a country manufacturer, which is very hard to find out.

Senator ALSOBROOKS. Thank you.

The CHAIRMAN. Thank you, Senator Alsobrooks. Mr. Baker, in your testimony, you mentioned that Indian generic drug manufacturers using fake labs to pump out fake results to show a product was never tested. Can you talk us through what is supposed to be happening, and what you found and how you found it?

Mr. BAKER. Thanks for the question. Yes, what is supposed to be happening is that the FDA publishes manufacturing standards and the Code of Federal Regulations that they are supposed to follow says when you test something, for example, you are supposed report all the results that you generate.

You can't just pick one or two that you like and then use that as the data to release the product. That is what is supposed to happen. What we found when we started the unannounced inspection pilot back in 2012 and 2013 is that those standards aren't being always followed. Some players are following those standards, but some aren't.

It is difficult because the ones that want to follow the rules oftentimes won't be able to win a contract to ship those products to the U.S. because they can't compete with the folks that aren't actually testing it. Because as already mentioned, it does cost a few more cents to do it right, but not a lot. That makes a difference when the margins are so small.

The CHAIRMAN. Mr. Baker, in the book, A Bottle of Lies, it talks about how foreign companies plan guided tours, but you rejected that, instead wanting to go directly to the quality control labs. Can you talk about your experiences with foreign companies? Why did they start with the tour?

Why did you decide to change things up and go directly to quality control instead? How has that changed the inspection process? Were you the only one doing that? Do other inspectors do similar things?

Mr. BAKER. I remember the moment that we decided to focus on the unannounced inspection pilot, and, you know, I had been trained to do inspections here in the U.S., and we did those before I got deployed into New Delhi.

Fraud happens here, too, but it is much more limited, like one person or a small group. I remember that moment being over there,

and I was with a co-inspector, and I just remember like we looked at each other and we thought, actually, this is—everybody is involved in this. It is not just a single person or a small group. It comes from the top down, and it was kind of like an aha moment.

It is like, have we got to do something about this. We went back and worked with folks at the embassy to develop ways where we could gain further insight into what is actually happening, and that involved showing up unannounced, which hadn't been done prior to that.

We would arrive unannounced, and we would skip the conference room presentation and go straight to the lab, and what we found, like for example, I can think of one that really just sticks out, one of the larger aseptically filling sites in the entire world. I mean, some of these are the size of a small town, and instead of going to the conference room, we went straight to the microbiology laboratory where they do the sterility testing. I mean this is a life or death test.

We walked in and there was only one microbiologist on staff. That was unusual, right. We walked into the chambers where they are supposed to be testing all these products, and they were all there, but they were all unlabeled, and so, we are like, well, where is the sample number on all these samples that you are supposed to be testing?

All the paperwork was completed, you know, no growth, no growth, it is sterile, it is sterile, but in reality, none of the products were getting tested, and once we sort of caught on that this was happening, that program expanded and continues to today, and again, like I mentioned, when those inspections are performed, they result in an ability to find those problems that are causing these adverse events.

About 40 percent of the time we find issues. Whereas on an announced inspection, where we show up and the dog and pony show continues, that is about a five to ten percent chance of finding those problems, because it is so much more difficult.

We don't do announced inspections in the U.S. Why would you do that? You show up unannounced and you want to see what is the real quality of the product. You know, this is shown that maybe the playing field isn't so level.

The CHAIRMAN. You mentioned that the bad players list is no secret, and these bad companies continue to avoid any significant consequences. That is telling me that the FDA knows which are the problem companies, but they aren't being inspected frequently enough or are still being allowed to import drugs. Does the FDA have a list of bad companies? What consequences should these companies be facing?

Mr. BAKER. Yes, that list exists. Yes, I mean, I could just look into the data base and see if which—if I was going to fill a prescription, which provider I would like to choose, and I will do that pharmacy hopping to find it, and—sorry, what was the second part of your question?

The CHAIRMAN. Well, what consequences should they—?

Mr. BAKER. Oh, yes. The consequences should be, if you are caught breaking the law, you know, as outlined in the regulations,

you should be prevented from shipping products to the United States.

The CHAIRMAN. They have got a list——

Mr. BAKER. Yes.

The CHAIRMAN. There is no consequences.

Mr. BAKER. Very little consequences. When the FDA takes action, what they will do is they will just shift those products to another facility in their network, and so, it is this cat and mouse game, right.

Then this facility gets shut down, so now they are shipping out of this one. Then FDA goes over here, but by this time—by that time, this one is already back in the market, you know, because they will go back two years later.

It will sometimes be an announced inspection and the game resets. It is just I go here, I go here, and so, you know, just enforcing the law and saying, if you break the laws, you are not going to be allowed to participate, could go a long way.

The CHAIRMAN. Then we put that in our bodies.

Mr. BAKER. That is correct, yes.

The CHAIRMAN. Ranking Member.

Senator GILLIBRAND. Very depressing. Dr. Ball, you have studied the impact of five-star quality ratings and country of origin labeling on consumer choice. As you know, not everybody has the skill set that Mr. Baker described of being able to know which vendor is actually safe.

Patients don't have much choice in choosing which medicines their pharmacies or hospitals or nursing homes choose to stock, and they arguably don't have the level of sophistication they would need to be able to choose anyway. In hospitals and some nursing homes, patients may not have access to containers where the five-star quality rating or country of origin labels would be placed.

How can a five-star quality rating system and country of origin label promote the use of high-quality drugs when patients often don't have much choice? How can this proposal incentivize hospitals and other purchasers to purchase high-quality drugs when institutions often face pressures to keep costs low?

Third, how would you recommend that the FDA conduct inspections and update their five-star quality ratings?

Dr. BALL. Thank you Senator for the great questions. Our solution that we have tested in our paper is a first step. The first step is—and I have had my parents and elderly family members ask me, how do I know where this drug is made and if it is safe. If you arm the person at the pharmacy desk or the patient to look at a bottle and say, now, why is this a three-star drug?

That question in and of itself could make a big difference because groups like the AARP could all of a sudden have a voice to say, why are we selling three-star or two-star drugs to our constituents? You are correct that it wouldn't fix everything overnight. That hospitals, when they buy it in group packaging, may not have the stars on them until the solution get properly fixed there. That group purchasing organizations may be less sensitive.

The notion is that if it becomes transparent for every level of the supply chain, the manufacturers are no longer able to hide, and they have to somehow figure out a way to compete on quality.

It wouldn't fix the problem overnight, but it would also allow group purchasing organizations who change suppliers based on pennies, which is often the case that we hear in our research, to look at this and say, yes, we may save a penny, but this is going from a three star drug to a two star drug.

That has consequences for the people that are in the insurance program that they serve, or the elderly person that picks it up at CVS and asks their pharmacist, why are you giving me a two-star drug? That conversation is the starting point to put pressure on firms. It is not perfect, but it is the beginning, and it is much better than what we have now.

Senator GILLIBRAND. Thank you. Mr. Baker, off of Dr. Ball's answers, how should country of origin labeling be implemented to take into account the origins of a generic drug's components versus the manufacturing site of the generic in its final form?

Mr. BAKER. Yes, I have been thinking a lot about that because over the years, having seen the sites and thinking about transparency, that this would eventually come based on what we were uncovering.

There is no real perfect solution, but there are some—for each different type of drug, if you are talking about a solid oral product or an injectable product, there are—at least one step that is very critical to quality, for the purity and in some cases, sterility.

Putting that on the label would force companies to take that step seriously, and also possibly diversify supply chain for those critical steps to have those in areas that are reliable, and so, for example, an aseptically filled product, where is that bottle being filled? Because that is, again—there are other players, but that one is the most critical.

Senator GILLIBRAND. Dr. Piervincenzi, your written testimony indicated the United States relies heavily on Indian and China, and I think the chairman's questions about those two countries have been very insightful.

The majority of these KSMs are produced in China. You also highlighted how one KSM, thymidine, is produced only in China. Can you speak to why the United State is currently unable to produce certain key starting materials, beyond the environmental impacts of the manufacturing process?

Dr. PIERVINCENZI. Yes, so thank you, Senator. The key starting material is a fancy term, I think Senator Scott you sort of said this earlier, that is only relevant to its use in a pharmaceutical arena.

What the rest of the world will call them is chemicals. They are chemicals. The chemical industry left the U.S., for the most part, a long time ago, before pharma. In fact, that is how pharma started in the U.S. It followed the chemical industry in New Jersey—it became pharma.

There is no mystery as to why it left the U.S.—for environmental reasons and just cost and all the reasons we know. There is something unique about medicines is that they are very light users of very expensive chemicals. What I mean is—and many of the chemicals used in drugs are used for lots of other industrial and other purposes, but in much, much larger quantities.

That the chemical company—so they are very rarely to have a key starting material company, because most of them are chemical

companies who sell some key starting materials. They therefore are a small portion of their business.

This further complicates the supply chain, because later on—we are talking about medicines all the way along, API, finished dose, regulated by FDA, but these chemical companies, they are not even in the medical business, so the incentive or to think about how do we secure our key starting materials, it is not only in the area of greatest risk.

It is what we least have in the U.S., or even among U.S.'s allies. It is also the hardest of the three pieces to solve, and we think we have to look at the KSM model, your chemicals, and think, well, how do we start to source it? Where else in the world—I think we need to be more flexible about the world and think about it.

We may consider more onshoring on API, but we have to be pretty flexible on the key starting materials, but the current model is unsustainable, but we will have some real numbers in a couple of months. I think it is about even less than two months where we can start to look at them as tangible.

Senator Scott, to your point earlier, we have to be able to have some data. Otherwise, it is very hard to get action going, and hopefully, this will be the first time we have data on specifically what key starting materials, where, and then we have the very important next conversation, is how else can we make them.

Maybe just to wrap up there, but there are some cases we can make them a different way that doesn't follow the chemical industry but uses biotech processes, and that we could do in the U.S.

Senator GILLIBRAND. That is good. Thank you, Mr. Chairman. Great hearing.

The CHAIRMAN. Mr. Baker, you highlighted the story of your grandmother. What was your experience pharmacy shopping? How many pharmacies did you visit? Did you find that they had the same drug from the same company? Was there diversity in manufacturers?

Mr. BAKER. Yes, I come from a pretty small town in Oregon called Lebanon, and there is about three pharmacies in the area, and so, we went to all three, and each one actually had the same product by the same manufacturer, so we reluctantly made that choice, and I felt bad because already then—at the first pharmacy, I had already sort of hinted that this was not going to go well, and so, you know, it is an experience that is going to stay with me for the rest of my life because it shouldn't be like that. I think we can do better.

The CHAIRMAN. How would you feel buying a drug from a company that just settled with the DOJ for faking lab data?

Mr. BAKER. Yes, it was a tough decision, and again, as I mentioned, trying to stay positive is the one thing because you don't want to cause unnecessary panic in someone, and, you know, a lot of people ask me before they will take it. They will give me a call or send me an email, like, hey, what do you think about this one?

I will give them advice, and to be honest, over the years, sometimes I have to fake that advice because I know there is no alternative, and I will have to just send a positive email when in fact inside I know that that is not the truth.

The CHAIRMAN. How do you do it when you buy drugs for yourself?

Mr. BAKER. For myself, I would do the same thing. I live now in Austin, so I have more choices there and try to do my best to shop around or even consider like an online pharmacy if I can call them and find out where—you know, what manufacturer they are going to use to fill that prescription.

The CHAIRMAN. Do you believe Americans are dying because of poor oversight done at foreign generic drug manufacturing facilities?

Mr. BAKER. Not poor oversight, but poor enforcement, but again, it is complicated to enforce because of the drug shortage issue. Again, it is not one person or one organization's fault. It is just—it is the system.

The CHAIRMAN. Why did the FDA set up this foreign surveillance system the way they did?

Mr. BAKER. It was a collaboration with embassy, and FDA, and folks at HHS to sort of evaluate—to tell the story. You know, what we were finding in our initial times when those foreign—you mentioned Heparin earlier.

That was the reason, one of the reasons, but I think the main one why the foreign offices were established in strategic locations around the world was to be that sort of rapid response and gain further insight into what was happening with our supply chain. I think, you know, 15 years later, the picture is pretty clear.

The CHAIRMAN. Dr. Ball, so what causes—if they are all FDA approved, what are some of the things that causes one to be different than the other one?

Dr. BALL. I think the notion that if it has the same active pharmaceutical ingredient dosage form and route of administration, which is kind of what a generic equates to an original, if you match those, the drug will work. That discounts all of the manufacturing influence on quality.

These are subtle changes, and my intuition is that they are often not on purpose. If I was in a market where I was only competing on cost, I would find the very cheapest place to make my product, the cheapest labor, the cheapest equipment, the cheapest suppliers. It is the rational thing to do.

When Peter says it is the system, it truly is, because I believe these manufacturers are acting very rationally. If you cannot judge quality and it is opaque, cost is the only thing that matters, that will inevitably reduce quality. It actually must. It is like a scientific fact.

If you cut the corner in every part of making a product, if quality doesn't suffer, something is wrong. You haven't cut corners enough, so quality will suffer eventually. It is in every aspect of the supply chain.

The CHAIRMAN. Mr. Baker, when you did a foreign site inspection, did the FDA or the foreign facility pay for your translator? Is that a problem either way?

Mr. BAKER. Yes, so in my experience, most of the translation is provided by the sales department within that company, who oftentimes has the best English because of their job. They don't know

much about manufacturing, but they know they are supposed to tell the story well. That is oftentimes what I experienced.

Luckily for me, I had studied Mandarin for about 15 years prior to going to China, so I could sort of overcome those challenges, but yes, that is the norm. Not always. Sometimes they will provide an independent translator, but it is voluntary.

The CHAIRMAN. Mr. Baker, when you went to China, did they let you just go anywhere you want?

Mr. BAKER. Yes.

The CHAIRMAN. You could go, but the Government would let you go anywhere, and you could walk in any facility—and you can walk around any facility you wanted?

Mr. BAKER. Oh, yes. Yes, we had a very good working relationship with what they would call CFDA at that time, and they would shadow us on a lot of our inspections to learn our techniques.

The CHAIRMAN. Why would they shadow you?

Mr. BAKER. To learn how we uncovered the issues that we were finding using forensic computer inspection techniques, things like that.

The CHAIRMAN. What would be—what would—give me an example of a facility that you were most disappointed.

Mr. BAKER. Most disappointed, I think, are the ones where—there is multiple, but you would show up at the show—I mentioned this in the five-minute testimony where you would up at show facility. This is the clean one. We knew, like showing up, you knew that there is no way they are making the amount of products that I can see on the customs import list, right.

There is just no way, and so, what you will do is you will try to find—you will show up midnight and just watch operations, you know, from the outside and try to out what is going on, and then you will eventually uncover like a shadow facility. It could be like next door, or it can be somewhere else you will watch trucks come in, right.

When you find that shadow facility, that is I think one of the most concerning things because those are totally off the radar. I mentioned the problems with announced inspections, but just exponentially worse when you don't do any inspections there, and so, that is the—and I think when we were there we probably figured that 10 percent of the API getting exported to the U.S. was from shadow facilities.

I have no data to support that. That was just a rough number that we sort of came up with, and compounding pharmacies are really suffering as a result of this because they are importing products, and they really don't have any ability to determine where they are coming from.

The CHAIRMAN. How long could the facility that was doing the wrong thing stay in business before they are shut down?

Mr. BAKER. A long time, especially if they had any drug that was on the shortage list, and so, you could prevent some of their products from reaching the U.S., but they would continue to ship a couple that we called them carve-outs, right, because we just couldn't prevent the supply, and then they will ask for a re-inspection in about one to two years.

It will—FDA will go back, and oftentimes that will be announced because it is resource intensive to do unannounced all the time, and then that would be a choreographed inspection and the clock resets. They can hang on for years because we are addicted to these sites.

The CHAIRMAN. Dr. Ball, you reviewed adverse event data that the FDA had cross-referenced to drugs made in India, right?

Dr. BALL. Correct.

The CHAIRMAN. Okay. Where does the adverse event data come from? What did you consider to be an adverse event? What conditions were eliminated as an adverse event?

Dr. BALL. An adverse event—we used FDA's FAERS data base, and they make the determination. The manufacturer must report an event that occurs, that they hear about, where a consumer was injured, hospitalized, or died because of a drug, and then through the FDA's analysis of these adverse events, there are flags that are put on to the adverse event. Things like a drug characterization field.

That field means that the drug is the likely cause of the event, and a de-challenged field. The de-challenged field means that if the patient was taken off the drug, the problem that is discovered went away.

We tested just the de-challenged drugs, which was very convincing for us as an author team, we are really onto something here because our effects still hold on the de-challenged drugs on those that cause death, hospitalization, or injury. To answer your very first question, the firm must report it when they hear about it. It is mandatory.

The CHAIRMAN. The firm, who is that?

Dr. BALL. The manufacturer. The manufacturer hears about adverse events from patients, from physicians, from lawyers.

The CHAIRMAN. There is no obligation that a patient says it?

Dr. BALL. Correct.

The CHAIRMAN. There is no obligation to the hospital, and there is no obligations that a doctor?

Dr. BALL. Correct. In the order you just gave though, the nurses and physicians are much more attuned to how the system works than patients, and so, from our experience, like physicians and hospitals know that this FAERS data base is there and that they need to report what they have found, but there is no obligation.

There is a selection bias there. It must be under-reported. It has to be because it is not forced, but this does come back to the FDA's enforcement authority because these reports come into firms, and these firms maintain complaint data bases.

When you can access those complaint data bases on an unannounced inspection, you are going to get a real honest look into how the quality of the firm is operating, versus if you give them even a week's notice, the look may not be the same.

The CHAIRMAN. How many—what is the total list of adverse reactions? Do you have a list of how many?

Dr. BALL. I can get that to you. It is incredibly long.

The CHAIRMAN. A half a million?

Dr. BALL. I know it is in the thousands. It is a very long list.

The CHAIRMAN. Why do you think it is different in the United States if it is manufactured in the United States versus India or China?

Dr. BALL. This is speculation somewhat because in the study we were not able to get at that core mechanism.

Theoretically it makes a lot of logical sense that when you source a product in the lowest cost place where you are furthest from the regulator, the temptation to cut corners that will affect quality just goes up and up, and then to accentuate that temptation, if quality is assumed to be high, as soon as you get FDA approval, you have that stamp of approval, you no longer have to worry about quality.

The difference I think lies in the fact that in the United States, you are much closer to the FDA, their authority is much more felt, and the costs of the suppliers and the raw materials, they are more, and as soon you get that far away, the FDA's authority is more distant and the cost of everything is lower, and that lower cost will come through in lower quality.

The CHAIRMAN. You don't have oversight.

Dr. BALL. The oversight is much more distant. It is much more distant. I don't envy the FDA. It is much harder to enforce their standards there.

The CHAIRMAN. If I understand correctly, according to your study, generic drugs manufactured in India have a 54 percent higher chance of an adverse event, which hospitalization, disability, and death compared, to similar drug made in the U.S., right?

Dr. BALL. It is more precise to say that the predicted number of serious adverse events for older generic drugs made in India (those generics that have been on the market for eight years or more) is more than 54 percent higher than the number of serious adverse events for equivalent, older generic drugs made in the U.S.

The CHAIRMAN. Let's say you are going to buy two of anything. Let's say, you are going to buy two cars. If you knew if you bought one of them, you bought like one car, you had a 54 percent chance of something bad happening to you, so, what would you do?

Dr. BALL. Well, because cars have quality ratings, like J.D. Powers, I would buy the higher quality rated car, but that can't be done in drugs, but if I knew the difference, then I would spend the money to buy the higher quality product.

The CHAIRMAN. You think the National Highway Traffic Safety Administration would let a car that was 54 percent more dangerous on the road?

Dr. BALL. See, and the regulator—NHTSA doesn't have to worry too much about that because car quality is accessible to the consumer before they buy it, and that is the difference between that and the pharmaceutical industry.

It is inaccessible before you buy it and oftentimes even after you buy. This adverse event increase is hidden in millions of adverse events. That is what makes studies like this so difficult. There is so many data points that it is easy for these types of increases to hide.

The CHAIRMAN. What was the FDA's reaction to your study?

Dr. BALL. While I have worked with the FDA before, since we published that paper, I have not had a lot of interaction with the

FDA, and in the last several months, some of my contacts have left, and so, I don't honestly know what the FDA's reaction is.

The CHAIRMAN. Did your studies show a difference in quality between generic drugs made in developed nations like Canada or the EU compared to India?

Dr. BALL. There is an overall difference between emerging economies and advanced economies, but when we took that difference and we broke it out by country, the only country that showed a difference was India to U.S.

No, there wasn't a difference between U.S and Canada. However, the volume of drugs in our study was overwhelmingly advanced economy drugs were U.S., and overwhelmingly emerging economy drugs are India.

The volume helped make the difference findable, but it was something that we didn't see when we compared like us to Canada for instance.

The CHAIRMAN. What was the landscape of generic drugs that you looked at? Did you limit it to sterile injectables, or did you try to look at everything?

Dr. BALL. We looked at everything that we could get label data on.

The CHAIRMAN. Statins, antibodies—antibiotics, and blood pressure medicine?

Dr. BALL. All of those. Everything that had a label on the data base we used, we measured it.

The CHAIRMAN. Why do you think the FDA doesn't put in, require, you know, country of origin of ingredients and country of origins of manufacturing? Why don't they do it?

Dr. BALL. This is speculation, of course, but I believe that there is a few reasons. I have heard that through some of our discussions with them that if they were to put quality or country labeling, it could cause some unexpected market reactions. It could cause shortages, for instance, because if you look at a drug and there is——

The CHAIRMAN. People might buy American first?

Dr. BALL. If the supply isn't there, then all of a sudden we have overnight shortages because we have made the market transparent. That is one of the concerns I have heard. The other is that I believe, and this is speculation, that the FDA doesn't think they have the authority to force the manufacturer to put the country on there.

They believe that is company confidential information, and then the quality rating is something that we have taken from data that they possess, and we have come up with a measure that we believe they could translate it to, but it is not something that is immediately available right now.

The CHAIRMAN. Mr. Daniels, I think you said that challenge supplies about 90 percent of antibiotic APIs consumed in the U.S. Can you talk about how you figured this out?

Mr. DANIELS. Yes. What we found was that 90 percent of the antibiotic APIs used by India, and India being the vast majority of the generic antibiotics that we were getting, were manufactured in China, and the way that we mapped this, we took every single,

critical medicine that we had in our study. We built a bill of materials for each of them.

Every single component of that pharmaceutical, of that drug, and what we did was we, once we had that bill of material, we identified each supplier, each supplier that was connected to every single one of those components. Once we identified the supplier, we knew how much of the active ingredient was in every dose, and we could see the doses that were being consumed in the United States.

We mapped that up to supplier capacity, supplier volumes coming into those companies, which we have proprietary data and customs, trade, shipping, invoicing data that informs us as to what is happening between those two companies, and we can see where the next company was sourcing their key starting materials, excipients, whatever it might have been, at that next level.

We just kept tracing down the line to the facility, so we knew which facility was actually producing which chemical compounds. Once we got down to that facility, we cross-referenced the data that we had pulled through with their certification levels, their employee information, their square footage to ensure that that capacity was visible and to identify things like shadow facilities, which there certainly is a significant volume of that kind of product coming through.

Then we rolled that all the way back up to the supply chain and identified that essentially these manufacturers in India were using this significant cost differential between the locally made goods and what was being made in China and were utilizing that to accelerate and to expand margins and the goods being sent to the United States.

The CHAIRMAN. Are there other drugs that you are aware of that we have such acute dependency on, on Communist China or another adversarial country?

Mr. DANIELS. Yes, about 50 percent of our critical medicines are in that category.

The CHAIRMAN. Do you think this is a national security risk?

Mr. DANIELS. It 100 percent is.

The CHAIRMAN. I am a grandfather. Kids usually get ear infections and strep throat, so if China were to drop liability and limit antibiotic-related APIs from being exported, would it impact us?

Mr. DANIELS. Yes. You would see at least 50 percent of the antibiotics that your kids have access to evaporate. In fact, the next time one of your grandchildren gets a strep throat or an ear infection, I encourage you to look at it. I bet you dollars to doughnuts, it is made by Aurobindo, which is an Indian manufacturer using Chinese KSMs and APIs.

The CHAIRMAN. Do you think this could create a public health emergency?

Mr. DANIELS. It almost did during COVID. I experienced it. I was working with Ellen Lord, Honorable Ellen Lord and Jen Santos and Stacey Cummings, and when they said they were going to drown us in a sea of COVID—I mean, those calls really did happen.

The CHAIRMAN. How long do you think—if they shut it off tomorrow, how long you think our supply is for?

Mr. DANIELS. I mean, it is months. As Dr. Piervincenzi said, it is months. It is month with severe constraints. I mean you would probably be treating—you know, you would be treating people in sepsis. Kids would have to weather through, and that could be very dangerous.

The CHAIRMAN. Are there any sole source drugs, which, you know, there was only one supplier?

Mr. DANIELS. There are.

The CHAIRMAN. They are relying on Communist China or India?

Mr. DANIELS. There are—I don't have the names off the top of my head, but I remember looking in the study, there were significant volumes.

The CHAIRMAN. Let me make sure I got this right, 95 percent of ibuprofen is imported from China?

Mr. DANIELS. Ninety-five percent of ibuprofen, so there is a key starting material that is—that 95 percent of it I believe is pulled from China, is sourced from China, and that ingredient then goes into ibuprofen.

There are other ways in which to source that same material. The same goes for acetaminophen. There are other ways to source that material, but they are not cost advantageous and so therefore are not used.

The CHAIRMAN. Ninety-one percent of hydrocortisone is imported from China. Does that sound right?

Mr. DANIELS. That sounds right.

The CHAIRMAN. Ingredients. Half of U.S. Penicillin and Heparin are imported from China?

Mr. DANIELS. Yes.

The CHAIRMAN. The Federal Government knows this and has done absolutely nothing about it.

Mr. DANIELS. At the moment, after COVID, there was a huge fervor. It died. We started studying the problem and stopped executing against the reshoring and strategic activities, and, you know, I am hopeful that HHS, particularly the FDA picks this up, but as of right now, we are not actively policing these supply chains.

The CHAIRMAN. Are you familiar with the Uyghur Forced Labor Prevention Act?

Mr. DANIELS. I am, Chairman, yes.

The CHAIRMAN. Do you think that is being complied with?

Mr. DANIELS. I do not believe we are conducting significant or thorough investigations in this pharmaceutical space, and at the beginning of the year, there was a significant drop in detentions that would indicate a lower volume of enforcement. Those have since rebounded, Chairman Scott. I think we could significantly stiffen and significantly strengthen our policing of that law.

The CHAIRMAN. Have you tracked the Department of Defense's reliance on China for drugs?

Mr. DANIELS. I have, yes.

The CHAIRMAN. Do we have our own source, so our military is never dependent on China?

Mr. DANIELS. We do not.

The CHAIRMAN. Why wouldn't we?

Mr. DANIELS. We, in many areas, are reliant on—it is kind of like we have in critical minerals and in magnets, Chairman Scott, where the commercial markets have so deeply been usurped by China that we don't have the investment capital coming in to offset it.

Just like we are doing in MP materials and neodymium, iron, boron magnets and things like that for our weapons systems, we have to make those same kind of investments in our pharmaceutical supply chains.

The CHAIRMAN. If China invades Taiwan or continues to attack the sovereignty of the Philippines and we go to their defense, do you think they will keep shipping us drugs?

Mr. DANIELS. I think Chairman Scott, it would be a key tactic to stop doing this.

The CHAIRMAN. Do you think it would be safe for our military to continue taking Chinese drugs?

Mr. DANIELS. No, sir.

The CHAIRMAN. Can you explain the role that Chinese Communist Party and the People's Liberation Army links play into the generic drug supply chain, and how federal programs like Medicare and Medicaid are paying for it?

Mr. DANIELS. Yes, Chairman Scott. The PLA is infused into the Chinese economy. It is called the military-civil fusion, and in many cases, and as we have pointed out in the Bitter Pill Report, several of the organizations that are producing these active pharmaceutical ingredients or KSMs are actually sponsored and funded by PLA-funded entities are directly by the PLA.

Those situations create a significant amount of command and control, what we call foreign ownership control and influence risk, in those companies, and make them essentially beholden to not only the CCP, but the PLA.

The CHAIRMAN. Would you say that the U.S. health care system is entirely beholden to the Communist Party of China?

Mr. DANIELS. At the moment, yes, sir.

The CHAIRMAN. Dr. Piervincenzi, how many sole-sourced APIs come from Communist China?

Dr. PIERVINCENZI. Thank you, Senator. We are aware of 11 that are directly coming from China, but that is not the real answer. The real answer is the APIs are coming from China to India, and we know that is where 95 percent of our challenges. I think antibiotics are a unique case, and it is real, and it was strategic.

It was a choice in China many years ago, in fact, 15 years ago to have that as a strategic asset, and it was successful, while the world wasn't really paying attention, but that is a bit of an outlier. I think the vast majority of reliance on China is coming back to the starting materials, the chemicals, in some cases the excipients as well—less often, but in some case.

The CHAIRMAN. How many generic drugs use key starting materials from China?

Dr. PIERVINCENZI. We are going to have a real answer for that, but it is going to be somewhere in the range of 20 to 40 percent would be my guess, but give me about two more months and we will have a better answer for you.

The CHAIRMAN. How about brand name drugs? Do they use APIs from India or China?

Dr. PIERVINCENZI. Rarely, and it just goes to the different incentives. It is not that they couldn't. It is just that it is not necessary. The incentive is high value product. We need to have a very reliable supply chain.

Their finished dose is rarely in those countries. They don't want to have a big, complicated supply chain halfway around the world, so they try to simplify, and so, therefore, you see the APIs manufactured mostly in U.S., Europe, Canada. If you think of those, that is going to be your majority. A bit more in Europe than the U.S. in this case.

The CHAIRMAN. What sort of random testing of generics drugs happen in our marketplace?

Dr. PIERVINCENZI. The U.S. market is a bit unique in the world today. There is a risk-based approach at FDA, which is taking into account known issues and that drives testing, and FDA has its own labs and of course can outsource testing as well.

There is very little random testing, and currently today there really is no private sector solution to do so. This is relatively common practice in most markets including in Europe, but in middle-income countries as well. It is generally called post-market surveillance, which is a fancy way to say you buy something from the pharmacy and you test it.

The CHAIRMAN. Does USP track how many drugs Americans are taking that rely on Chinese APIs?

Dr. PIERVINCENZI. Yes.

The CHAIRMAN. Does that present a risk to our supply chain?

Dr. PIERVINCENZI. If you believe that China supplying our drugs is a risk, then the answer would be yes.

The CHAIRMAN. How many of you would buy a generic drug made in India or China if you knew there was American-made drug available?

Dr. PIERVINCENZI. Senator, if I have an offer, I would if I had the assurance on the front end of the system. The system as we described is tilted today and that is the issue, and that it is an important nuance to me because that is where the solution lies, is that un-tilting and I think that is a consistency that you hear from us.

The CHAIRMAN. I think, if you listen today, based on the testimony, Americans, we have hospitalizations, we have illness and death because of adverse effects from some foreign-made generic drugs.

Does anybody disagree with that? Bad drug quality doesn't just mean drugs are less effective, which it could be, right? Also make you sick or could kill you, so every American senior—see if you agree with this, every American Senior needs to look into their medicine cabinet and ask this question, am I confident that the generic drugs I am taking are truly safe?

Do you believe today they could say that? Do they have any ability to say that? Do any of you think they have any ability to that today that if they look in their medicine cabinet, or they go to their pharmacy, they can say it is safe? I talked about LeRoy Hubley, lost his wife at 48 years, Bonnie and his son, Randy, just weeks

apart due to contaminated Heparin that they needed for their dialysis treatment. It is horrible.

This should never happen in this country. If Americans don't know where the generic drugs are taken or made, if there is no measurement system, there is nowhere they can feel confident, they can feel safe. It is clear that we have a big problem.

I am from Florida. I was the Governor. We have hurricanes. At least in hurricanes, in contrast to some other things, at least you can get out of the way, or you should. I always tell people that you can rebuild a house, but you can't rebuild your life, and you tell people to get prepared.

It seems like we are number one, even if we didn't have the concern about the way that Communist China acts, we say to ourselves, it is crazy that we are not focused on quality and focused on supply.

On top of that, we know that we have Communist China that is threatening Taiwan and threatening the Philippines, and why in God's great Earth would we ever allow our country to be dependent, whether you are talking about anybody that takes a generic drug, including our seniors, or why would we ever, ever put our military in that position? It just doesn't make any sense.

I think the bottom line is we have no choice, but we have to make significant changes. I hope the new head of the FDA will take this seriously and hope we will see change. I think we are going to see change is if the American public demands it.

My experience as Governor of Florida, my experience in this job is that if people demand it, then it is going to happen. People continue to be complacent, it is not going to happen. I would like to thank everyone for being here today and participating. I look forward to continuing to work with members across the aisle.

If any Senators have additional questions for the witnesses or statements to be added, the hearing will be open until next Wednesday at 5:00 p.m. Anything else anybody wants to add? [No response.]

The CHAIRMAN. Thanks, everybody. Thanks for being here.

[Whereupon, at 05:23 p.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

U.S. Senate Special Committee on Aging

"Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"

September 17, 2025

Prepared Witness Statements

Peter Baker

Chairman Scott, ranking member Gillibrand, members of the committee, thank you for the opportunity to testify today. My name is Peter Baker and I am a former FDA Drug Investigator – who specialized in drug manufacturing inspections overseas. I want to thank you for this bipartisan focus on enhancing the securing of our generic pharmaceutical supply chain.

Trust is one of the most, if not the most important ingredient for a healthy public health system in any country. When a patient, especially those most vulnerable (such as the young and old) fill a prescription, which has a 91% chance of be generic here in the United States, there can be no doubt about the safety and efficacy of the medicine, or if the generic will perform as well as the brand-name. There are too many uncontrollable variables to allow this one to play any role.

The role of ensuring a safe and effective drug supply is the responsibility of many players, but most of the burden falls on the FDA. The FDA has a long history of protecting and promoting public health, and performs extremely challenging and hard work around the world on a daily basis to achieve that goal through site inspections, often in remote corners of the world that do not have internationally recognized regulatory bodies. I will refer to these areas of the world without a recognized regulatory system as unregulated markets. As a result, our FDA investigators may be the only external insight into the quality of critical medicines bound for the United States (including thousands of different critical sterile injectable drugs). The ability of these investigators to identify poor manufacturing practices and prevent these medicines from reaching a patient is literally a life or death situation. However, these investigators face incredible challenges when trying to fulfil their job of determining if a site is producing, or capable of producing, a product that meets the standards outlined in our laws, regulations and guidance.

To start, FDA Investigators often have to deal with demanding travel conditions and can fall ill due to other unsafe conditions, such as drinking untreated water, a contaminated meal, communicable and non-communicable diseases, or fall prey to other risks often present in still-developing nations.

For example, a good number of sites operate in countries where English is not the primary language. The site provides a translator, typically an employee from the sales department, to facilitate interviews with site staff (there is no independent

translator required). In my experience the information is often not complete and is biased to provide the information the investigator "wants to hear". It is difficult if not impossible to gain insight into how our drugs are being manufactured when employees performing the critical work cannot be interviewed in an unbiased way. Documents cannot be reviewed if not in English, and confusion over the truthfulness of critical questions related to quality causes significant disruption to completing the mission.

The majority of our overseas pharmaceutical inspections are pre-announced, often up to 2 months in advance of our arrival. In my experience, upon arrival for the inspection – a strong smell of fresh paint is in the air, the landscaping is immaculate, all garbage bins are empty, any potential problematic operations are shut down, some employees are sent home, and critical operations are choreographed as if performing on a stage. Those of us who performed foreign inspections refer to this as the "dog and pony show" – which is frustrating because this is serious business.

How do I know this to be true? Having spent 7 years in three different FDA foreign offices starting in 2012 – based out of our embassies strategically located around the world, we were tasked with developing inspection techniques capable of identifying if products exported to the United States from unregulated markets were really meeting our standards: things seemed too good to be true. No rejected batches, no issues at all? Really? In the United States we rely on the company itself to certify the quality of imported products, unlike our colleagues in the European Union who require independent third party testing of each batch of imported drugs – so we needed a way of gaining deeper insight. Our foreign office leadership and ORA worked with us to introduce new ways of inspecting, as the current inspection program at that time was largely based on trust and good faith commitments, which is completely different than how sites in the US are inspected and regulated. We knew the quality of products being manufactured in Ohio, but had really no idea what was happening outside of our borders, especially in unregulated markets. We worked on developing forensic computer inspection techniques, dug through piles of garbage, and showed up at times unannounced – booking our travel on Expedia vs. the embassy travel portal to alleviate any concerns someone would tip off the sites to our plans.

What we found was terrifying. This testimony only addresses the tip of a massive iceberg.

- Fake laboratories pumping out hundreds of results a day that certified products as 100% pure, when in fact the product was never tested.
- For those products that did get tested, any failing result was simply ignored and replaced by a fabricated passing value.
- We identified filthy unregistered "shadow" facilities that would funnel their drugs through modern and clean registered sites, which we refer to as the "show" facility.
- We found fabricated manufacturing and quality records – painting a picture of a site in total compliance, when in fact substandard or fake medicines were being shipped to the United States by the tens of thousands a day.

Following these experiences, I have no doubt that adverse events, including death, happen on a daily basis here in the United States as a result of substandard generic products from unregulated markets. The true culprit of these preventable adverse reactions lies in shortcuts and fraud.

The big tragedy in this story is that the uncovering of this large-scale fraud was too late. In the age of rapid offshoring, starting around ~2005, the agency approved thousands of generic products from sites based in unregulated markets using a process of pre-announced choreographed inspections using biased translation, and an inspection and enforcement model based on trust and good faith. These bad actors grew to be monsters. The inspection force was under resourced, so an approval of 20 or more different drugs would be made as long as the investigator looked at one and found it to be acceptable. We were fooled by low costs and false promises.

Continuing today, any consequences faced by these bad actors are negligible. When the FDA does choose to take action, they issue a "warning letter" to the site instructing them to clean up their act, and the site quickly shifts production to their other sites, evading any financial disruptions. We call this the "cat and mouse game". Prosecutions and injunctions are exceedingly rare. Sometimes the agency issues an "import alert" banning products entry into the United States – except any product that may cause a hint of a shortage concern – these are exempted from the

ban, and these patients must face the consequences of consuming what we know to be substandard medicines. Do they even know they are consuming a product proven by an FDA investigator to be unsafe? The answer is likely no.

Personally, if I had a choice, I would never consume a drug produced in an unregulated market, and any experienced FDA investigator will give you the same answer. The problem is I and all Americans do not have a choice, as decisions are made by middle-persons such as Pharmacy Benefit Managers who purchase generic products based on the lowest costs – I have seen the consequences of producing the cheapest substandard products to win the contract.

When my 91 year old grandmother was alive, we would go pharmacy hopping around our rural Oregon hometown in the hopes of finding a batch that was made by a reliable producer. Sometimes we succeeded, and sometimes not. I remember one time having to settle for a product manufactured by Ranbaxy, who had just settled with the DOJ for $500 million for faking countless data points used to demonstrate their products were safe. In my mind I imagined they were allowed to sell the product in the US because they had monopolized the market with rock bottom prices and false promises to the FDA. I tried to stay positive because causing her to panic wasn't going to help, but inside I felt sick – and I was not the one receiving cancer treatment.

So what about today? One might think a decade after this large-scale fraud was identified and documented in hundreds of FDA inspection reports, we would have figured this out. But I'm afraid I have bad news. Once a site is caught (often because of an unannounced visit), FDA may conduct a re-inspection in 1-2 years (which may or may not be unannounced), and the choreographed pageantry of the inspection will commence, likely resulting in a green light once again – and the game resets. Many of these bad actors have received multiple bad inspection results over the years – going in and out of good "compliance" status with FDA. Each year they improve their ability to play the game and hide illegal practices, meanwhile the FDA struggles to keep up.

There are world-class manufacturing sites all around the world, including in unregulated markets, but they struggle to survive, and are unlikely to win contracts with our middle-people in the United States, as it costs money (but not much more

money) to train people and generate reliable data – basically to make a medicine that is safe and effective.

Shocking inspection reports continue to roll in on a monthly basis – and the bad players in industry, we all know who they are, continue to avoid any significant consequences – meanwhile those most vulnerable in our society who may need medication to aid with healing have no idea of the games being played, and certainly no idea that the game, as designed today, can never be won.

I urge this committee to consider these four points:

1. harsher penalties for companies who engage in illegal practices via the existing authority within the FDA and DOJ
2. changes to labeling so that patients can see where their medications were made and put pressure on any middle-person who provides them with a pill made in an unregulated market.
3. independent third party testing of every batch of every product arriving from an unregulated market
4. improving the FDA Investigator toolbox, such as independent translation and logistical and training support to show up to more sites unannounced. Showing up to a site in some of the most remote places on earth is not easy and it is not feasible or practical to conduct all foreign inspections unannounced. A risk-based approach is the most realistic solution. The FDA has made great progress to increase the number of unannounced inspections they are conducting, but they need additional resources to be directed to expand on unannounced inspections, as already outlined in Commissioner Makary's public communications.

Thank you for your time and attention to this important matter. I welcome your questions.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

PREPARED WITNESS STATEMENTS

Dr. George Ball

Thank you, Chairman Scott, Ranking Member Gillibrand, and Distinguished Members of the Committee, for the invitation to speak with you today.

I am an Operations Management Professor at the Kelley School of Business at Indiana University. For the last 15 years, my research has explored causes of product quality problems in regulated industries, with a particular focus on FDA-regulated firms that manufacture medical products such as pharmaceuticals and medical devices. In conjunction with this research program, a team of colleagues and I have also had the opportunity to work with the FDA on a federal grant and a federal contract, both of which were focused on drug quality risks. Prior to academia, I spent 11 years as a manufacturing manager and director in two medical product firms regulated by the FDA. Most recently, my research has concentrated on the areas of the pharmaceutical industry, generic drug quality, and FDA drug quality policy. These topics will be the focus of my testimony today, which will cover three dimensions of the drug industry: 1) Generic drug marketplace design, 2) Negative consequences of this design, and 3) Recommendations to mitigate these negative consequences.

Generic drug marketplace design

It is almost assured that everyone here has taken at least one generic drug in their lifetime. In fact, many Americans do so every day, and as we age, our propensity to depend upon generic drugs is only likely to increase. Thus, my research colleagues and I realize the need to rigorously explore drug quality problems, particularly generic drug quality problems, and propose solutions for these problems. We have dedicated years of research towards these endeavors.

In my view, the underlying root cause of the generic drug supply chain and quality problems we face today lies in the original design of the generic drug marketplace. While I acknowledge that the Hatch-Waxman Act of 1984 has served to dramatically lower healthcare costs by providing access to cheaper drugs, it nonetheless relies on an unrealistic assumption. That is, once an original drug is authorized to be sold by generic drug manufacturers, the quality of those FDA-approved generic drugs can be trusted and therefore requires little to no post-approval drug quality verification.

Why is this a flawed assumption? Operations management research helps to answer this question[1], and the answer hinges on the relationship between cost and quality, as well as the distinction between design- and manufacturing-related quality defects. First, we need to acknowledge that quality is not free. Quality comes at a cost; such that higher quality products demand higher product costs. Second, quality defects originate from two primary sources: design and manufacturing.

The design of a generic drug must be equivalent to the design of the originally approved drug. However, the quality outcomes of the originally approved drug may not necessarily translate directly to the quality outcomes of its generic counterparts. This is because two equivalently designed drugs can be manufactured in completely different ways. One firm can use well-trained employees, sophisticated equipment, mature suppliers, and premium raw materials. Another firm can manufacture an equivalently designed drug while using poorly trained employees, cheap and out-of-calibration equipment, and corner-cutting suppliers that make questionably adequate raw materials.[2]

The temptation to be the latter firm that cuts corners as opposed to the former firm that establishes and meets high standards is exacerbated by the unfortunate fact that generic drug quality is taken for granted, and has been for decades, and virtually no one in the supply chain can distinguish between a high- and low-quality generic drug.[3]

Thus, with quality assumed to be sufficiently high once a drug moves to generic status, cost becomes king, and the race to the bottom in costs ensues. Generic drug manufacturing firms are incentivized by this flawed marketplace design to chase after the cheapest employees, equipment, suppliers, raw materials, and manufacturing locations. This race to the bottom is economically rational because quality is not only assumed to be sufficiently high but is also essentially unverifiable. This situation will almost inevitably lead to poor quality generic drugs.

Negative consequences of this market design

Until recently however, the assertion presented above that this market design should lead to poor quality generic drugs has remained theoretical in nature. Identifying actual generic drug quality problems in large-scale rigorous scientific research has remained elusive. I will first explain why it has gone unstudied and then describe how my co-authors and I overcame these challenges.

To examine generic drug quality, one must be able to determine with a high level of confidence where a drug is manufactured. Without this knowledge, it is nearly impossible to explore country-level, firm-level, or plant-level factors that may explain why a drug is of low quality. Further, the

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[1] Ball, G. P., Shah, R., & Wowak, K. D. (2018). Product competition, managerial discretion, and manufacturing recalls in the US pharmaceutical industry. *Journal of Operations Management*, *58*, 59-72.
[2] Noh, I. J., Gray, J., Ball, G., Wright, Z., & Park, H. (2025). Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events. *Production and Operations Management*, *34*(9), 2601-2617.
[3] Anand, G., Ball, G. P., Gray, J. V., & Mukherjee, U. K. (2025). Operations Management in the Pharmaceutical Industry. *Journal of Operations Management*, *71*(3), 302-313.

notion of low quality must be measured. Neither measuring quality nor determining where a drug is manufactured is easy to do, even for well-trained researchers.

One of our recently published papers, titled *"Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events"*[4] examines serious drug adverse events and the country of manufacture for comparable generic drugs. To conduct this study, we leveraged the Structured Product Labeling database[5], which provides access to most FDA-approved drug labels. We cleaned and parsed these onerous drug labels to develop a large dataset of drugs approved by the FDA and sold in the U.S., including their respective manufacturing plant identifiers. The FDA distinguishes between plants using an FDA Establishment Identifier (FEI). With these manufacturing plant FEIs assigned for each drug, we were able to link these manufacturing plants to serious drug adverse events using FDA approval numbers and the FDA's adverse event database.[6]

A unique characteristic of this study is our exact matching method. We exactly match generic drugs based on their Active Pharmaceutical Ingredient (API), Dosage Form (DF), and Route of Administration (RA). If two generic drugs share the same API, DF, and RA, then they are designed equivalently.[7] As mentioned earlier, design and manufacturing are the two fundamental reasons for a product quality defect that can impact drug safety. Thus, if two drugs that share equivalent designs experience significantly different quality outcomes, drug manufacturing is the most reasonable explanation for these different quality outcomes.

Another significant challenge of this study was measuring product quality. We use the FDA's adverse events database to develop our quality measure for a few reasons. First, unlike drug recalls, which have some level of firm discretion embedded in them, adverse events are initiated by those outside the firm. Granted, there are many disclaimers made on the FDA's adverse event database website. The data are not perfect, but if the imperfections were randomly assigned, which they should be in a case like this, we would fail to identify such a statistically strong negative quality effect of manufacturing a generic drug in India when comparing it to an equivalently designed generic drug (same API, DF and RA) manufactured in the U.S.

Our primary finding is that where a generic drug is made matters in a meaningful way for the health and safety of the U.S. consumer. We find that generic drugs made in India, particularly older generic drugs that consequently have lower profit margins and greater incentives to cut costs, have significantly more (greater than 50% more) serious adverse events than equivalent generic drugs made in the U.S. We conclude that the lack of transparency for drug quality and the assumption that all generic drugs are equivalently safe and effective incentivizes firms to chase the lowest cost manufacturing countries, especially as generic drugs become more mature, and their prices drop.

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[4] Noh, I. J., Gray, J., Ball, G., Wright, Z., & Park, H. (2025). Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events. *Production and Operations Management*, *34*(9), 2601-2617.
[5] https://dailymed.nlm.nih.gov/dailymed/fda-drug-guidance.cfm
[6] https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard
[7] https://www.fda.gov/drugs/generic-drugs/generic-drug-facts

Recommendations to mitigate these negative consequences

The final aspect of this testimony delves into possible solutions for this generic drug health and safety concern: 1) transparency in generic drug manufacturing location and quality and 2) equivalency in FDA drug manufacturing oversight across the globe.

The key assumption of the Hatch-Watchman Act of 1984 that all generic drugs should be safe and effective as long as they are patterned after a safe and effective originally approved drug would be less problematic if the quality of a generic drug was transparent. The need for transparency cuts across the full set of generic drug stakeholders: physicians who prescribe drugs, insurers who subsidize their costs, group purchasing organizations that negotiate large volume drug price contracts, pharmacists who fulfill drug prescriptions, and finally consumers who trust this vast ecosystem and consequently take and depend upon these generic drugs. None of these stakeholders have a meaningful grasp of the varying levels of generic drug quality, but if they did, I believe that the market would identify and rectify much of the quality concerns discussed thus far.

We can start at the consumer level to envision how this transparency would impact quality. The consumer who picks up their prescription at a pharmacy has no ability in today's market to discern between a high- or low-quality generic drug. However, if their drug label included a five-star quality rating system, and the drug they were picking up was indicated as a two-star quality drug, this drug quality transparency would arm this consumer with information that enables action. Such action can be taken by the individual, such as asking their pharmacist for a higher quality option, thereby eroding sales of the lower quality drug, or by collectives, such as the American Association of Retired Persons (AARP), that could pressure buyers to provide the higher quality option for older Americans. This pressure would not only create safer alternatives in the short-term but also incentivize lower quality manufacturers to improve their quality or exit the market in the long-term. Quality transparency can move the generic drug industry from a cost-only competitive marketplace to one that competes on both cost and quality.

The importance of drug quality transparency was emphasized in the first two recommendations of a congressionally mandated National Academy of Sciences Engineering and Medicine (NASEM) Committee report published in 2022. I was fortunate to serve on the committee and helped author the report recommendations.[8] In the Security of America's Medical Product Supply Chain ad hoc committee final report, titled *Building Resilience into the nation's medical product supply chains*, Recommendations 1A and 1B call for the FDA to require both quality and country of manufacture transparency on all drug labels. A recent study that I have been working on with a team of co-authors examines the market impact of just such a policy change.

[8] National Academies of Sciences, Engineering, and Medicine. (2022). *Building resilience into the nation's medical product supply chains.* https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain

In a working paper titled *"Generic Drug Transparency: Testing a Regulatory Policy Proposal"* [9], co-authors and I test Recommendations 1A and 1B from the NASEM report. Our findings are illuminating in many respects.

Using thousands of experimental subjects, we examine how consumers and pharmacists respond to country of manufacture transparency alone and follow that with the additional influence of drug quality transparency. We examine four countries in this study: U.S., Canada, China, and India. The experimental screen that subjects view is seen in Figure 1 below:

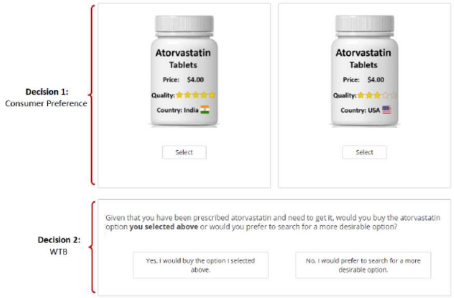

Figure 1 Screenshot with an Example of the CBC Task for Consumers.

We find that when only the country of manufacture is made transparent, drugs made in the U.S. are strongly preferred to those made in China and India and slightly preferred to those made in Canada. An important initial conclusion here is that consumers and pharmacists do not appear to be convinced that all generic drugs, regardless of where they are manufactured, are safe and effective, despite consistent FDA messaging on this point for years.[10] In other words, FDA messaging on generic drug equivalency, regardless of where the drug is made, does not seem to be resonating with consumers or pharmacists.

We note that because a plant cannot make a drug until the FDA approves the plant for manufacturing, the FDA possesses drug manufacturing location approval data, although the FDA does not make this known to the public. They consider drug manufacturing location to be company confidential information, which is why we had to go to great lengths in our earlier referenced study to find drug manufacturing plant locations. But it is important to reiterate that the FDA not only has the data on where all drugs are permitted to be manufactured, but from our understanding, we

[9] Villa, Sebastián and Urrea, Gloria and Ball, George and Gray, John and Ganio, Michael, Generic Drug Transparency: Testing a Regulatory Policy Proposal (June 02, 2025). Available at SSRN: https://ssrn.com/abstract=4639108
[10] https://www.fda.gov/drugs/generic-drugs/overview-basics

believe that they could require manufacturers to place country of manufacture on the drug label,[11] which is what the NASEM report recommended the FDA do.

We then move to examining drug quality transparency. Similar to manufacturing location data, the FDA also possesses drug- and facility-level quality risk scores (such as the site-selection model quality risk scores) that could be used to generate straight-forward quality ratings to be placed on drug labels.[12] Our experiment assumes that such quality data are amalgamated into a five-star, drug-level quality rating, and that these scores are made available on drug labels, as the NASEM report recommended.

We find that when drug quality is made transparent, as well as the country of manufacture, consumers and pharmacists consider drug quality significantly more important than manufacturing location. To demonstrate, we find that a five-star China or Indian made drug is significantly preferred over a three-star U.S. or Canadian made drug. However, when comparing equivalent drugs that all have the highest quality five-star rating on their label, consumers and pharmacists continue to prefer U.S. or Canadian made drugs over Chinese or Indian made drugs. These conclusions, for consumers and pharmacists, are depicted in Figures 2 and 3 below, which are also available in the working paper online.[13]

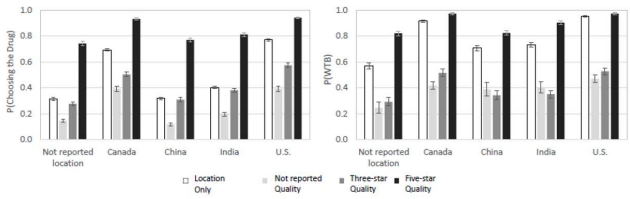

Figure 2 Margins plots including interactions with manufacturing location for Drug Preference (left) and WTB (right) for Consumers.

[11] https://www.fda.gov/drugs/fdas-labeling-resources-human-prescription-drugs/generic-drugs-specific-labeling-resources
[12] https://www.fda.gov/about-fda/cder-offices-and-divisions/office-pharmaceutical-quality#reports and https://www.fda.gov/media/116004/download#:~:text=The%20SSM%20considers%20risk%20related,a%20drug%20intended%20for%20humans
[13] Villa, Sebastián and Urrea, Gloria and Ball, George and Gray, John and Ganio, Michael, Generic Drug Transparency: Testing a Regulatory Policy Proposal (June 02, 2025). Available at SSRN: https://ssrn.com/abstract=4639108

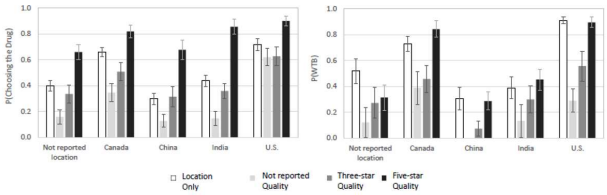

Figure 3 Margins plots including interactions with manufacturing location for Drug Preference (left) and WTB (right) for Pharmacists.

While this study is not yet through peer review, it presents hope for a generic drug policy change that could make a meaningful and relatively immediate impact on generic drug quality. As we conclude in our study, making both the country of manufacture and drug quality transparent is likely to incentivize drug manufacturers to slow the race to the bottom on drug manufacturing costs, improve the quality of drug manufacturing, while simultaneously encouraging on-shoring or near-shoring of drug manufacturing. The key to fixing this market hinges, in my view, on drug manufacturing transparency. Transparency would unleash the requisite market forces needed to drive up drug quality.

A second recommendation we have studied relates to FDA inspection policy.[14] In particular, the FDA has traditionally inspected U.S. drug manufacturing plants with little or no advance notice, while providing foreign drug plants in India and China, for example, with weeks or months advance notice. While the reasons for this advance notice relate, in part, to visa and travel planning requirements, the quality ramifications of such disparate oversight regimes, even when they have reasonably good explanations, cannot be ignored. As exposed in Katherine Eban's best-selling book, *Bottle of Lies*[15], when plants are given significant advance notice, they can obscure their true state of quality. Katherine Eban demonstrated this in numerous, powerful anecdotes. However, to examine policy changes, we need to move beyond anecdotes into large-scale empirical evidence. This is what the research team that I am a part of is currently working on.

In our working paper, titled *"Preannounced Regulatory Inspections: FDA Oversight and Drug Quality Risk"*[16], we examine the impact of giving plant managers advance notice before an FDA inspection. We leverage previously unexamined FDA data tied to an FDA unannounced inspection pilot conducted in the last few years in India. We find stark differences in inspection outcomes

[14] Noh, I. J., Gray, J., Ball, G., Wright, Z., & Park, H. (2025). Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events. *Production and Operations Management*, *34*(9), 2601-2617.
[15] https://www.harpercollins.com/products/bottle-of-lies-katherine-eban?variant=32206330134562
[16] Wright, Zachary and Gray, John and Ball, George and Noh, In Joon, Preannounced Regulatory Inspections: FDA Oversight and Drug Quality Risk (May 07, 2025). Available at SSRN: https://ssrn.com/abstract=5252874

within the same plant, contingent upon the announcement status. When we compare the inspection results of Indian plants that were given significant advanced notice of an FDA inspection prior to the pilot against the same Indian plants that were part of the pilot that were inspected unannounced, we find a nearly 250% increase in the odds of a plant receiving the FDA's worst inspection outcome, an Official Action Indicated (OAI). This is a concerning increase, which indicates to us that preannouncing inspections hinders the FDA's ability to assess the true state of operations at Indian drug manufacturing plants.

We take the analysis a step further and examine how these different inspection regimes may impact drug quality. Similar to the generic drug adverse event study described earlier, we find that plants that receive preannounced inspections in India have significantly more serious adverse events than similarly matched plants that receive unannounced inspections in the U.S.

Because the FDA is the gatekeeper of drug quality in the U.S., and because consumers and all other generic drug stakeholders are unable to ascertain drug quality themselves, conducting unannounced inspections in India and other countries is another policy change that should have a meaningful impact on the generic drug quality problems discussed in this testimony.[17]

Summary

The generic drug industry market design assumes that generic drugs will be safe and effective if the originally approved drug was safe and effective. As generic drug quality is opaque, this assumption must be trusted by physicians, pharmacists, insurers, group purchasing organizations, and consumers. The rational economic strategy for generic drug manufacturers, in a scenario in which quality is assumed high and unverifiable, is a race to the bottom on costs. Such a race will predictably lead to poor quality generic drug manufacturing.

My research has focused on two potential policy changes to significantly mitigate this problem. Drug manufacturing transparency is first and most important. I recommend that it be required for drug manufacturers to include both the country of manufacture and a quality rating on drug labels. Second to this is aligning FDA's inspection strategy across the globe. I recommend that the FDA inspects all plants using unannounced inspections regardless of the location of the inspected facility. These two changes should have a meaningful and relatively rapid effect on generic drug quality.

In closing, it is important to acknowledge my colleagues. The findings and recommendations I have discussed hinge upon published and in-progress research that I have been fortunate to conduct in collaboration with a superb team of scholars, many of whom are cited in the papers referenced in this testimony. I am sincerely grateful for their significant contributions.

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[17] The two solutions I put forward; drug transparency and FDA inspection equivalency, are clearly not the only solutions. For instance, I am aware of other potential policy changes such as drug testing, that could help address generic drug quality concerns. Solutions such as drug testing are beyond my area of expertise. The solutions put forward in this testimony leverage quality data that are already available (e.g., FDA quality data such as site-selection model risk scores) as well as market forces via drug transparency, to make a relatively expedient and cost-effective impact on generic drug quality problems.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

PREPARED WITNESS STATEMENTS

Brandon Daniels

Chairman, Ranking Member, and distinguished Members of the Committee, thank you for the opportunity to testify on this urgent issue. My name is Brandon Daniels, and I am the Chief Executive Officer of Exiger. Exiger develops and deploys advanced data analytics and artificial intelligence (AI) to illuminate risks hidden deep in global supply chains. We work with federal agencies, organizations across the defense industrial base, and Fortune 500 companies to identify vulnerabilities in their supply chains before they become crises. Today, I am here to share with you what our technology reveals about our nation's overreliance on foreign pharmaceutical production and the risks that poses for our seniors, for our healthcare system, and for our national security.

Exiger's Technology Applied to Healthcare Supply Chains

Exiger's technology has been deployed across the healthcare sector, from automating vendor risk assessments and monitoring for large healthcare providers to pharmaceutical supply chain mapping for federal agencies and enabling product developers to comply with regulators' cybersecurity requirements. Exiger is also a Preferred Cybersecurity & Risk Provider of the American Hospital Association, which represents nearly 5,000 hospitals, healthcare systems, networks and providers across the country. The AHA Preferred Cybersecurity Provider (APCP) program helps hospitals and health systems prepare, prevent and respond to today's pressing cyber threats by connecting members with highly trusted, vetted and accomplished cybersecurity service providers.

Exiger's drug mapping technology generates detailed pharmaceutical 'Bills of Materials' for individual medicines. Using this technology, our company has mapped all 227 essential medicines, detailing attributes and potential sources of supply, mapping hierarchies of finished drugs with their constituent ingredients. Drug by drug, we have uncovered numerous unique formulations of ingredients, technical characteristics and countries of origin. Our technology automatically maps drug ingredients, active pharmaceutical ingredients, excipients and chemical precursors.

Exiger also recently published a breakthrough report, *A Bitter Pill: America's Dangerous Dependence on China-Made Pharmaceuticals,* which examined 2,309 companies to surface risks

associated with the supply chains of manufacturers of active pharmaceutical ingredients (APIs) in injectable antibiotic, diabetes, and heart disease therapeutics.

America's Dangerous Dependence

Our analysis reveals that the nation's most essential healthcare programs have become structurally dependent on foreign supply chains. Nearly three-quarters of essential medicines in this country are sourced overseas, with China and India dominating global production of active pharmaceutical ingredients. For example, India supplies about half of all generic drugs used in the U.S., yet it depends on China for 80% of those generic APIs. That means that a Medicaid prescription filled at a pharmacy in Ohio or a Medicare prescription processed in Florida can often be traced back to a Chinese supplier.

This dependency is particularly acute in antibiotics and other common generics. China alone produces almost 90% of the world's antibiotic key ingredients. These are not luxury items; they are everyday medicines relied upon by seniors and low-income patients with chronic conditions. In effect, China holds the choke points for the very therapies that Medicare and Medicaid must reliably and affordably deliver to tens of millions of Americans.

The financial flows behind these supply chains are equally troubling and in many cases mean that taxpayer dollars, through Medicaid and Medicare, are underwriting foreign firms that depend on Chinese suppliers — and in some cases, companies directly owned by the People's Republic of China (PRC) government or connected to the Chinese Communist Party's (CCP) forced labor programs.

One of Medicaid's largest generic drug suppliers, for example, which was reimbursed for more than 11 million prescriptions in 2024, sources its ingredients from at least half a dozen Chinese firms implicated in labor abuses and national security concerns. That year, Medicaid reimbursements to this single firm totaled more than $150 million, even as its upstream supply chain reinforced China's dominance. When we consider that dual-eligible patients, who account for just 14% of Medicaid enrollment, consume more than one-third of the program's spending, the picture is stark: America's most vulnerable populations are the most exposed to foreign disruption.

From a strategic standpoint, we're at risk of actively financing foreign dependency. Every dollar reimbursed by Medicaid or Medicare to a generic drug provider sourcing from China strengthens Beijing's leverage over our medicine cabinet. This is not only a public health vulnerability but also a geopolitical liability. It creates the possibility that, in a moment of geopolitical crisis, access to basic medicines could be restricted, prices manipulated, or quality standards further

eroded in ways that directly threaten the health and safety of millions of Americans, especially seniors that rely on these programs.

Unless Congress and the administration act on this crisis, billions of American taxpayer dollars spent on Medicare and Medicaid will continue to flow to Chinese and Chinese-funded companies implicated in forced labor and state control. This represents an ethical failure and a national security risk.

The strategic imperative for Congress is clear. We must reorient these vital programs to support supply chain diversification, transparency, and domestic resilience. If we fail to do so, the very mechanisms designed to protect our seniors will remain instruments of dependency that threaten their health and our collective national security.

Quality and Human Rights Concerns

Exiger's technology reveals that the sector's supply chain vulnerabilities are compounded by widespread lapses in manufacturing quality and ethical standards abroad. In recent years, American patients have been directly harmed by contaminated and counterfeit medicines originating overseas. Contaminated eye drops produced in India caused permanent vision loss for seniors in the U.S. Blood pressure medications and diabetes treatments imported from Asia were recalled after being found to contain carcinogenic impurities. These are not isolated incidents but part of a broader pattern of falsified inspection records, substandard facilities, and regulatory failures that put millions of Americans at risk. The risks are amplified by the fact that more than 30% of new Food and Drug Administration (FDA) import alerts target Chinese producers, and another 16% involve Indian manufacturers, meaning the very countries on which we depend most are also the most frequently flagged for safety violations.

Even more troubling, our data show that forced labor is woven into these pharmaceutical supply chains. Chinese state-owned enterprises with documented links to Uyghur forced labor in Xinjiang supply raw materials and active ingredients that ultimately find their way into drugs consumed by Americans. For example, Chinese state-owned companies such as Sinopharm and Zhejiang Shindai Chemicals have been flagged for their use of forced labor, yet their products continue to move through intermediaries and reach the U.S. market. Medicaid's largest generic drug supplier alone has sourced from at least six Chinese firms with such ties, meaning that taxpayer dollars are financing medicines tainted not only by safety risks but by the CCP's human rights abuses.

The problem extends beyond pharmaceuticals into the supplements and vitamins heavily consumed by seniors. Consider GNC. This is a company ultimately owned by a Chinese state-owned pharmaceutical conglomerate. The company operates more than 80 stores on U.S.

military bases and hundreds more across the country, putting Chinese-controlled retail supplements directly into sensitive communities. As our research has documented, GNC's supply chains rely overwhelmingly on Chinese imports, leaving even basic vitamins and supplements susceptible to foreign control. Perhaps most concerning, GNC's contract manufacturer admitted to defrauding U.S. customs by misclassifying shipments of vitamins and supplements in order to avoid tariffs. And, still, the company continues to import tens of thousands of tons of raw materials from China into the American market.

Taken together, these findings illustrate that seniors in this country may be taking medications and supplements produced not only in unsafe and unsanitary conditions but also in direct violation of U.S. law and our core values. These overlapping factors create instability for our seniors, and the programs, products and supply chains they depend on. If we cannot guarantee the integrity of the drugs and health products our citizens consume, then the health of millions—and the trust they place in programs like Medicare and Medicaid—can be leveraged by adversaries for coercion.

National Security Risks

Our adversaries know that America's medicine cabinet is filled by foreign producers. Chinese state media has, in fact, suggested on occasion that drug exports could be withheld as a weapon in conflict. That possibility alone should set off alarm bells. If foreign governments can manipulate access to insulin, antibiotics, or blood thinners, they hold leverage over not just the health of our seniors but also the readiness of our military and the stability of our economy.

As Chairman Rick Scott has rightfully flagged, 54% of the Department of Defense's (DoD) pharmaceutical supply chain is classified as "high" or "very high" risk, given heavy reliance on non-compliant foreign suppliers in China and India. This vulnerability transforms routine medications into strategic leverage. Should supply access be manipulated or constrained, the impact would be felt not just by civilians but also across our armed forces.

The urgency of action cannot be overstated. When America cannot guarantee the integrity, stability, and availability of medications—especially for our seniors and military—our entire system becomes vulnerable to coercion, disruption, or sabotage. Ensuring pharmaceutical security is essential to preserving both the health of our citizens and the strength of our nation. It's time for Congress to act.

The Path Forward

The good news is that these risks are not insurmountable. Our data and technology point to clear pathways to resilience if we act with urgency and purpose. The challenges are complex, but the solutions are within reach.

- Invest in Domestic Capacity: The U.S. must expand its ability to produce critical medicines at home, particularly antibiotics and emergency drugs for which we currently have no reliable domestic suppliers. This requires targeted incentives for manufacturers, the use of the Defense Production Act where appropriate, and long-term procurement commitments that give industry the confidence to invest.
- Diversify and Secure Supply Chains: We must reduce our overreliance on China and India by building trusted supplier networks in allied nations and requiring redundancy in all federal procurement contracts. No federal program—Medicare, Medicaid, the Department of Veterans Affairs, or the Strategic National Stockpile—should ever depend on a single country for its supply of essential drugs.
- Prioritize Transparency Through Technology: AI-powered technologies offer enhanced capabilities that allow regulators and private companies alike to achieve new levels of transparency into supply chains. Congress must demand transparency and traceability in pharmaceutical supply chains down to the raw material level.
- Strategic Stockpiles and Stress Testing: Congress should empower the Department of Health and Human Services to expand and modernize the Strategic National Stockpile of essential medicines, vaccines, and medical devices. In addition, the federal government should conduct regular "stress tests" of the pharmaceutical supply chain to simulate worst-case scenarios like a sudden Chinese export ban or an Indian manufacturing shutdown, so we can identify weak points before they fail.
- Harness the Power of Group Purchasing Organizations (GPOs): Congress should incentivize the use of GPOs as a tool to accelerate the reshoring of critical medicines. By aggregating demand across hospitals, health systems, and federal programs, GPOs can offer manufacturers the long-term, large-scale purchase commitments needed to justify investment in U.S. and allied production capacity. This collective purchasing power reduces cost volatility, creates predictable revenue streams, and makes it financially viable to rebuild secure, domestic supply chains. Used strategically, GPOs can transform fragmented demand into a national lever for resilience.
- Eliminate Forced Labor: Enforcement of the Uyghur Forced Labor Prevention Act must extend to pharmaceuticals, ensuring no American patient consumes medicine tainted by coercion or human rights abuses. This requires third-party audits of high-risk suppliers and the addition of known offenders to federal import restriction lists.
- Strengthen FDA Oversight and Modernize Inspections: Regulators need the resources and authority to close the gap in foreign facility inspections. That means hiring more FDA inspectors, investing in real-time monitoring technologies, and requiring overseas

producers to share digital quality data. Import alerts must be enforced swiftly and remain in place until corrective actions are independently verified.

- Leverage Advanced Research Pathways: The Biomedical Advanced Research and Development Authority has demonstrated the power of advanced research investments in biodefense and medical countermeasures. By extending its remit to include critical generics and antibiotics, we can accelerate the development and domestic production of therapies that safeguard both civilian health and military readiness.
- Pass the MAPS Act: The MAPS Act mandates full supply chain mapping for essential drugs—from raw ingredient to distribution—while requiring the DoD to report on U.S. reliance on critical components sourced from adversaries like the PRC.
- Reintroduce the BIOSECURE Act: Congress has already begun to confront these risks through bipartisan measures such as the BIOSECURE Act, which would restrict federal contracts with biotechnology companies that pose national security threats. Expanding this framework to cover pharmaceutical supply chains would help ensure that taxpayer dollars are not reinforcing adversarial control over our medicine cabinet.

Conclusion

The stakes here could not be higher. Seniors who rely on Medicaid and Medicare for affordable medications are already experiencing shortages, price spikes, and safety risks that can be tied to our dependence on foreign manufacturers. If we do not act now, these vulnerabilities will only deepen, and one day could be weaponized against us.

Our data paints a picture of the problem. But data alone is not enough. What is needed is decisive action to rebuild secure, transparent, and ethical supply chains, to reduce dependence on adversaries, and to protect the health of America's seniors. Exiger is proud to support this mission, and I look forward to working with you to ensure that the medicines in every American household are safe, reliable, and free from the grip of foreign adversaries.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

PREPARED WITNESS STATEMENTS

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The United States Pharmacopeia (USP) is pleased to submit the following statement for the record on the hearing "Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans."

USP is a private, scientific, global non-profit organization founded in 1820 when eleven physicians took action to protect patients from poor-quality medicines. Convening in the old U.S. Senate Chamber, they published a national, uniform set of guidelines for medicines called the U.S. Pharmacopeia. Today, USP employs 1,300 staff, most of whom are scientists, and works with nearly 800 scientific experts with industry, government, nonprofit, academia, and research experience who volunteer their time to establish quality standards for medicines. In addition, USP offers a range of programs to help ensure the supply of quality medicines for Americans. One such offering, the USP Medicine Supply Map, tracks the upstream supply chain of medicines and their ingredients. USP also offers verification programs to confirm the quality of ingredients in medicines and initiatives to help accelerate adoption of advanced pharmaceutical manufacturing technologies, which can support domestic manufacturing.

These programs are a core pillar of USP's work to help strengthen the global supply chain so that the medicines, dietary supplements, and foods that Americans rely on for their health are available when needed and meet quality standards as expected and required. In addition to the scientific experts on USP standard-setting committees, USP is governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention.[1] Working with this broad base of knowledge from across science and health care, USP creates standards for the quality and safety for medicines.

Safe and effective medicines, consistently manufactured according to established public quality standards, are essential to preventing disease, treating illness, and saving lives. USP's standards and resources support innovation and access, providing shared, foundational platforms for industry to help accelerate the development of new technological solutions for the American marketplace. USP has over 6,000 standards for active pharmaceutical ingredients, drug products, and inactive ingredients used throughout the supply chain. USP creates these standards through an open, transparent process, offering the ability to update standards to adapt to new industry practices and keep up with evolving science and technology. USP also works closely with the U.S. Food and Drug Administration (FDA) and other government agencies to help ensure the quality and safety of products for Americans.

In addition to setting trusted standards, USP advances public-private partnerships that address systemic supply chain vulnerabilities, helping to safeguard access to quality medicines and strengthen national health security. This includes work with the Department of Defense (DoD), the Advanced Research Projects Agency for Health (ARPA-H), the Administration for Strategic

[1] USP's governing bodies, in addition to the Council of the Convention, include its Board of Trustees and Council of Experts.

Preparedness and Response (ASPR), the Biomedical Advanced Research and Development Authority (BARDA), and the FDA.

Key insights to strengthen supply chain resilience and security

Understanding factors that drive medicine supply chain vulnerabilities

More than 60% of all American adults, including nearly 90% of seniors, fill at least one prescription each year, the vast majority of which are generic medicines.[2] A robust supply of generic quality medicines is an essential component of our healthcare system. Unfortunately, supply chain disruptions and drug shortages persistently and substantially affect the care of American patients.[3,4]

USP's Medicine Supply Map[5] was created beginning in 2019 to provide unique, end-to-end data and mapping of the entire medicine supply chain. USP's analysis reveals four key factors that overwhelmingly drive vulnerability in the U.S. medicine supply:

1. **Low Prices**: Drug products with low prices, commonly older generics, have a higher risk of drug shortage.

2. **Geographic Concentration:** Drugs in which the active pharmaceutical ingredient (API) and/or the finished dose are made in a single or a few locations are more susceptible to shortages, the most extreme example being where the full supply of a particular medicine for the U.S. market is produced in only one facility.

3. **Quality Concerns:** Quality-related issues that surface in regulatory agency inspection outcomes and manufacturer recalls can also inform drug shortage risk but must be used along with other information to be actionable.

4. **Manufacturing Complexity:** Drugs with higher manufacturing complexity, such as sterile injectables, are more vulnerable to shortage. Manufacturing complexity can also be seen in certain therapeutic classes–e.g., certain antibiotics needing dedicated facilities–and in certain active ingredients that require complex chemical synthesis.

Critically, these four factors are interrelated and in combination can impact supplier decisions about whether to continue manufacturing a given drug product or to exit the market altogether. For example, manufacturing complexities increase the cost of manufacturing a medicine and can yield an unsustainable margin, especially when combined with low prices of certain drug products.

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[2] U.S. Centers for Disease Control and Prevention, National Center for Health Statistics. FastStats - Therapeutic Drug Use.
[3] U.S. Pharmacopeia. USP Annual Drug Shortages Report: Longstanding drug shortages persist in 2024. 2025.
[4] U.S. Pharmacopeia. USP Annual Drug Shortages Report: Economic factors underpin 2023 shortages. 2024.
[5] U.S. Pharmacopeia. USP Medicine Supply Map. www.usp.org/medicinesupplymap. 2025.

Generic manufacturers stay competitive largely by reducing costs, which often means concentrating production in large facilities in lower cost jurisdictions. These market conditions often discourage investment in redundancies and quality management systems.[6]

This dynamic is particularly pronounced in the procurement of the most essential generic medicines, where prices can often fall below the cost of manufacturing. In this market, reliable manufacturers, particularly those operating in the United States, face considerable headwinds. Suppliers navigating these challenges are increasingly reassessing the viability of producing low-cost, high-demand medicines in the United States. They often contemplate whether to move operations outside the United States or exit the market for a particular product altogether.

These factors combine to reveal the extent of the U.S. medicine supply chain's vulnerabilities to supply and demand fluctuation, geopolitical matters, global pandemics, natural disasters, and trade disruptions. This can have lasting impact on patients, our health systems, and national security.

Now is the time to build a more resilient and reliable medicine supply chain. In doing so, we will enhance our national security, improve our ability to respond to medical and public health crises, and most importantly, ensure that patients have access to the quality medicines that are essential for both critical and routine patient care.

End-to-end medicine supply chain mapping and analytics are essential for building resilience

Effectively strengthening the medicine supply chain begins with our ability to understand it. The global medicine supply chain is a complex marketplace of manufacturers, suppliers, and distributors from many countries. While the globalization of the medicine supply chain has helped increase access to quality medicines at a lower cost, supply chains have grown longer, more complex and fragmented, leading to a lack of visibility and an increase in the risk to resilience. Historically, there has been little insight available into the upstream supply chain for medicines, including for key starting materials (KSMs), APIs, and finished dosage forms (FDFs).

Figure 1 is a simplified schematic depicting some of the complexity involved in the drug supply chain that begins with the KSMs needed to manufacture APIs, which in turn are necessary, along with excipients and other materials, to manufacture a finished drug product.

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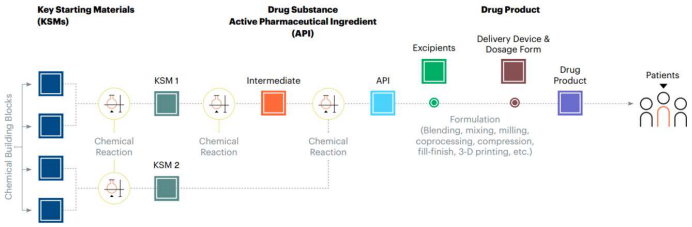
[6] Hernandez I, Sullivan SD, Hansen RN, Fendrick AM. Cheaper is not always better: Drug shortages in the United States and a value-based solution to alleviate them. J Manag Care Spec Pharm. 2024 Jul;30(7):719-727.https://pmc.ncbi.nlm.nih.gov/articles/PMC11217858/.

Figure 1: Simplified pharmaceutical manufacturing supply chain schematic.[7]



USP's Medicine Supply Map[8] – a data intelligence platform that maps where 94% of U.S. prescription pharmaceutical drug products and their ingredients are made, and identifies, characterizes, and predicts supply chain risk – can analyze and quantify factors linked to supply chain disruptions for drug ingredients and finished drug products. Using the Medicine Supply Map, USP analyzed the location of API manufacturing facilities as well as the manufacturing volume of APIs and FDFs to better understand the geographic concentration of production for U.S. prescription medicines. These insights include actionable information for APIs and FDFs; however, blind spots still exist in the Medicine Supply Map for the excipients[9][10] and KSMs necessary for many medicines. USP welcomes partnerships to fill this remaining gap.

To more fully understand the risks affecting the U.S. medicine supply and to anticipate the impacts of policy actions and market forces, decision-makers need end-to-end supply chain data and mapping of entire supply chains for medicines.

Location of API manufacturing facilities

To understand the existing concentration of manufacturing for API, USP analyzed API Drug Master Files (DMFs). API DMFs identify existing geographic locations that are manufacturing

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[7] U.S. Pharmacopeia. USP Annual Drug Shortage Report: Economic factors underpin 2023 shortages. 2024. The schematic does not provide a complete picture of the supply chain; it does not include, for example, purchasers, distributors, or healthcare providers.

[8] U.S. Pharmacopeia. USP Medicine Supply Map. www.usp.org/medicinesupplymap. 2025.

[9] Despite being called "inactive" ingredients, excipients play a critical role in drug development, delivery, effectiveness, and stability. Excipients comprise up to 90 percent of a medicine's volume and serve important functions, including as binders, disintegrants, coatings, preservatives, colors and flavorings. Excipients are sourced from suppliers around the world and are used for more than just the manufacture of medicines. The reliance of the pharmaceutical industry on the global excipients supply chain presents challenges for supply chain resiliency as well as quality and regulatory oversight. As such, breakdowns of critical excipient supply chains can have significant downstream effects including drug recalls and patient health impacts. For example, magnesium stearate is included in 32,060 drug products according to NIH DailyMed, including those to treat high cholesterol, high blood pressure, diabetes, and bacterial infections.

[10] U.S. Pharmacopeia. USP Global Policy Position: Excipients: A Blind Spot in Ensuring Medicine Quality and Supply Chain Resilience. 2024.

APIs and can suggest other locations that may be likely to have additional capacity.[11] Not all drug products utilize APIs referencing DMFs, but the geographic analysis of DMFs can provide an overall perspective on where API manufacturing capacity might be trending.

Based on these data, India maintains the greatest API manufacturing capacity with roughly 50% of API DMF filings in 2023.[12] Additionally, China's API manufacturing capacity has shown a striking rise in recent years. Between 2021 and 2023, the number of DMF filings in China increased 63%, amounting to almost one-third of all filings, while India's share of new API DMF filings decreased in 2023. The European Union (EU) saw a sizeable decrease in total active API DMF share in 2023, which was likely due to an overall increase in manufacturing activities outside the EU, rather than a decrease in its own API DMF filings. Meanwhile, the United States remained at only 4% of API DMFs in 2023, which is unchanged from 2021.

Manufacturing volume of API

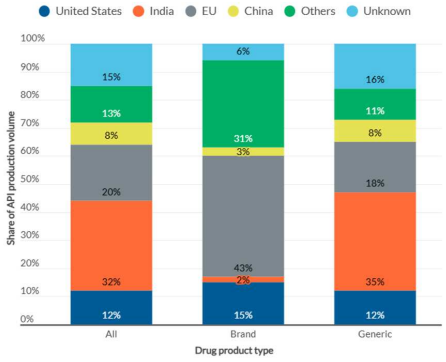
Although API DMF analysis can clarify where manufacturing facilities are based, two facilities could be producing different volumes of medicines. The USP Medicine Supply Map also determines the production volume of APIs from different geographic locations to provide a picture of where current production comes from (Figure 2).

A 2024 analysis shows:

- Half of the prescription medicines API in the United States comes from India and the EU.
- Generic drugs, which make up 90% of U.S. prescription volume, primarily come from India.
- 43% of branded pharmaceutical API comes from the EU.
- The United States accounts for 12% of total API volume analyzed.[13]
- China contributes 8% of the total volume of API analyzed.
- There is evidence of significant dependence on China for KSMs, the building blocks of API, but further work is necessary to fully understand the supply chain of KSMs.

[11] The proportion of DMFs in a particular location should not be interpreted as the proportion of APIs being sourced from that region. Aggregated DMF information is reflective of manufacturer site locations only, and this analysis does not contain information about the quantity produced or geographic distributions of APIs themselves.
[12] U.S. Pharmacopeia. USP Quality Matters Blog: Global manufacturing capacity for active pharmaceutical ingredients remains concentrated, 2024.
[13] The analysis excluded IV fluids, such as saline. If those had been included, the U.S. contribution would have been significantly higher.

Figure 2: API manufacturing landscape (excluding IV fluids) in 2024.[14]



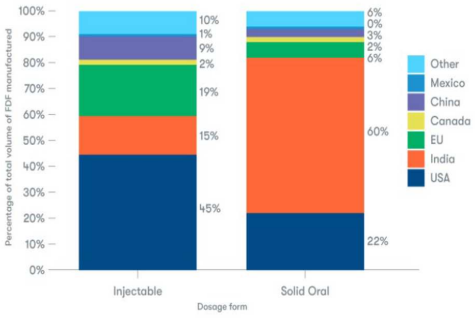
Manufacturing volume of FDF

Using USP's Medicine Supply Map, analysis of the geographic concentration of U.S. prescription pharmaceutical finished dose forms was performed (Figure 3).

- The United States is the largest manufacturer of injectables with 45% of production volume, followed by the EU with 19% of production volume.
- For solid oral dosage forms, India has 60% of production volume, followed by the United States with 22% of production volume. Market shares have remained relatively unchanged over 2022 and 2024.

[14] U.S. Pharmacopeia. USP Quality Matters Blog: Over half of the active pharmaceutical ingredients (API) for prescription medicines in the U.S. come from India and the European Union. 2025.

Figure 3: Manufacturing footprint of prescription pharmaceutical FDF in 2024.[15]



Risk assessment analysis

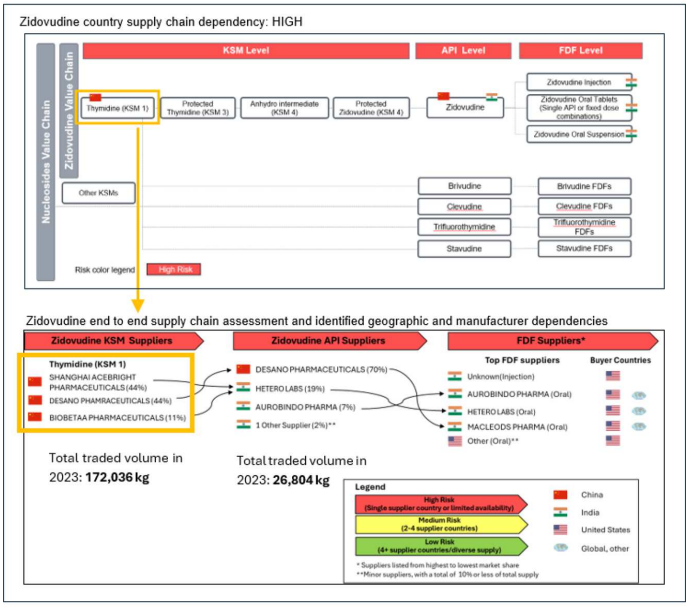
The lack of comprehensive pharmaceutical supply chain data available necessitates manual evaluation and analysis. USP is deploying scientific experts to better understand critical blind spots that remain in the knowledge of medicine supply chains and inform strategic decisions and the development of solutions. This analysis includes:

- an evaluation of the KSM and API manufacturing pathways to identify manufacturing challenges and production bottlenecks;
- a geographic and technoeconomic risk analysis to assess regional vulnerabilities, economic feasibility, and supply dependencies, enabling a structured evaluation of risk potential;
- resulting risk information that is specific to drugs or drug classes

For example, using zidovudine (a nucleoside-based antiviral medicine), analysis found a critical dependency on one KSM (thymidine) produced only in China (despite multiple API manufacturers downstream), which indicates a high vulnerability risk not just for zidovudine, but for several nucleoside-based antiviral medicines (Figure 4).

[15] U.S. Pharmacopeia. USP Quality Matters Blog: India and the United States manufacture most finished medicines for the U.S. market. 2025.

Figure 4. Zidovudine (and other nucleoside-based antiviral) supply chain components and geographic vulnerability risk analysis.



While the data presented above provides important insights into the U.S. medicine supply chain, no government agency nor any industry entity currently has a complete view of the upstream pharmaceutical supply chain (including FDFs, APIs, and KSMs). This lack of insight contributes to a limited understanding of the risks affecting the U.S medicine supply.

For example, while U.S. dependence on China for KSMs is widely acknowledged, additional work remains to fully understand this crucial but opaque part of the supply chain. **USP is currently mapping the KSMs for over 90% of the medicines tracked by our Medicine Supply Map. We expect to have this analysis completed this fall.**

Unsurprisingly, our early data shows that the United States is heavily reliant on two countries (India and China) for KSMs. Our analysis of the supply chain for the nation's most essential medicines shows a common pattern whereby 1) the majority of KSMs are produced in China, 2) provided to manufacturers in India to produce API, and 3) ultimately sold or exported for conversion to FDF in another location.

Efforts must continue to understand supply chain risk via initiatives like the Medicine Supply Map data and analytics coupled with extensive expertise in unraveling complicated supply chain maps to provide risk assessment and intelligence. Only through a comprehensive, end-to-end understanding of the pharmaceutical supply chain can we truly unlock the targeted, cost-effective interventions to strengthen the medicine supply chain. This approach should cover all U.S. medicines, starting with the most critical products, and expand analysis beyond individual APIs to include related chemical and therapeutic classes. Doing so provides a holistic understanding of supply chain dependencies.

Data- and evidence-informed policy reforms and investments can make the U.S. medicine supply chain stronger and more reliable

Building a more resilient, reliable, and secure medicine supply chain requires manufacturing medicines in more places and in new ways—and rewarding such efforts through a deliberate incorporation of quality, resilience, and reliability, in addition to price, in contracting, purchasing, and inventory decisions. USP encourages the Committee to consider a multi-faceted approach to ensure that patients, including our nation's seniors, have access to the quality medicines they need:

1. Continuously identify the nation's most vulnerable medicines.
2. Identify alternative routes of synthesis for KSMs of the most vulnerable medicines that are or could be made in the United States or other ally countries with advanced pharmaceutical manufacturing technologies for more efficient production.
3. Establish a resiliency benchmark for the purchase of medicines, enabling private and public sector purchasers to value investments in resiliency, reliability, and quality.

Identification of medicines with a vulnerable supply chain will help target interventions

USP recently published the USP Vulnerable Medicines List (VML)[16] – a list of medicines derived from an assessment of their essentiality, demand, and supply chain vulnerabilities – that can be used to identify medicines at risk of supply chain disruption.[17,18]

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[16] United States Pharmacopeia. 2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply. 2025.
[17] United States Pharmacopeia. USP Global Public Policy Position: Identifying and addressing vulnerabilities in the upstream medicines supply chain to build resilience and reduce drug shortages. 2023.
[18] USP's approach borrows from the framework proposed in the article: Wosinska, M., Mattingly, T., & Conti, R. A Framework for Prioritizing Pharmaceutical Supply Chain Interventions. 2023.

Leveraging Medicine Supply Map and additional data, USP conducted an analysis to identify 100 vulnerable medicines – 49 used to manage chronic conditions and 51 for acute care – to inform dialogue related to bolstering medicine supply chain resilience.[19] This data-driven approach accounts for the level of use by the U.S. population, public and population health necessity, the vulnerability of the medicine to supply chain disruptions, and the availability of alternative therapies. The resulting list includes a wide range of therapeutic classes of medicines as well as a variety of product types.

USP encourages the Committee to explore legislative means for carrying out an annual cadence for assessing vulnerabilities. This could be accomplished by:

1. Establishing a thorough, science-based mapping of the pharmaceutical supply chain, for essential medicines, from KSM to API to FDF.
2. Identifying vulnerabilities to the U.S. pharmaceutical supply chain, especially with respect to the nation's reliance on foreign and adversarial sources.
3. Requiring a yearly update to the VML and an accompanying report to Congress that provides actionable recommendations to Congress and the Administration to strengthen domestic resilience and mitigate national security risks.

Updating and sharing this critical information annually would help the U.S. government prioritize the most critical products, target investments, and inform initiatives to bolster the U.S. pharmaceutical supply chain and national security interests.

Innovative and scalable solutions can support greater domestic production of pharmaceutical ingredients

Enabling economically viable domestic production of prioritized APIs and KSMs is an important element of a comprehensive effort to enhance medicine supply chain resilience and support national security. Achieving this effort requires a re-imagining of the traditional chemistry processes used along the supply chains of necessary materials due to the structural, chronic challenges associated with chemical pharmaceutical manufacturing, especially for the generic medicine supply chain.[20] The use of advanced manufacturing technologies—alternate synthesis pathways, continuous flow manufacturing, and advanced chemical processes—provides a strategic solution to address vulnerabilities, enhance domestic competitiveness, and safeguard public health and national security.

Scalable solutions, beyond mapping key ingredients, to support onshoring and local production of essential drug candidates, APIs, and KSMs—and bolster rapid response capabilities within the U.S. medicine supply chain—include:

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[19] United States Pharmacopeia. 2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply. 2025.

[20] Many of the structural and chronic challenges with chemical manufacturing, especially chemical pharmaceutical manufacturing, have been due to low efficiency – among the major chemical industry sectors (oil refining, bulk chemicals, fine chemicals, and pharmaceuticals) pharmaceutical manufacturing generates the least product output, with about 1 kilogram of API obtained on average from a total of 25 to 100 kilograms of raw materials input (Fortunak, 2009 doi: 10.4155/fmc.09.60). Other complexities are associated with the hazardous conditions to produce chemical products at scale. Due to these complexities, over the past few decades, the manufacturing of upstream ingredients and bulk APIs has been outsourced to lower cost and less regulated countries rather than tackling and solving the challenges.

- **Better leveraging advanced manufacturing technologies (AMTs)** – AMTs, including continuous manufacturing and flow chemistry process intensification and controls can support more efficient production of generic medicines in the United States.
- **Harnessing alternate routes of synthesis/processes** – Design economically viable alternate synthesis pathways (a form of AMT) for necessary generic KSMs and APIs so there is capability to make them in the United States or allied countries. This work requires analysis and the development of new processes to make a medicine using ingredients that are available in the United States or multiple geographies.

Building on the above example of zidovudine, USP recommends leveraging AMTs to overcome manufacturing challenges for the API and reduce reliance on a single country.

This can be accomplished by:

- Identifying an efficient pathway to synthesize KSMs like thymidine locally from widely available chemicals and then working to optimize the API manufacturing process by using flow chemistry.
- Utilizing additional AMTs to produce the medicine more efficiently—and locally—while using the domestically produced KSM and API.

USP chemists have identified an alternate pathway to synthesize thymidine and work to optimize this new process using the AMT flow chemistry is also underway.

Through a new Advanced Technologies Lab, USP is supporting the development and application of AMTs, such as those for thymidine and its APIs, to foster more efficient and expanded production of quality medicines. USP will accelerate its work with industry and regulators to advance the application of new technologies and alternate manufacturing processes including developing alternate routes of synthesis for pharmaceutical KSMs and APIs and using AMTs such as pharmaceutical continuous manufacturing. These alternate manufacturing processes will help to mitigate identified supply chain risks, and this work can help bring quality-assured products to market more efficiently, strengthen domestic manufacturing capabilities, and build national security.

Another recent example of work to re-imagine the supply chain of pharmaceutical ingredients is the ARPA-H funded Wheat-based High-efficiency Enzyme and API Technology (WHEAT) project. A consortium of partners including USP aim to establish a new way to make APIs by leveraging cell-free protein synthesis with the aid of wheat germ extract (WGE), a key raw material derived from abundantly available agricultural wheat. This project uses WGE, in conjunction with other advanced biotechnologies to circumvent challenges associated with traditional chemical manufacturing, such as low throughput and long, multi-step complex chemical synthesis. If successful, the team will demonstrate a paradigm shift in domestic API manufacturing.[21]

[21] U.S. Pharmacopeia. USP and Ginkgo Bioworks announce ARPA-H project to support production of essential medicines using innovative cell-free expression systems. 2025.

An initiative to incentivize investment in drug supply chain resilience, reliability, and quality

In addition to the technical considerations discussed above, efforts to create a predictable, sustainable, and quality supply chain that can reliably provide critical drugs to patients must include a comprehensive assessment of the underlying market factors that influence investments in infrastructure and resilience. Economic factors play a considerable role in leading to medicine supply chain vulnerabilities and subsequent shortages of medicines.[22] Generic medicines account for nearly 90% of the medicines relied on by Americans and less than 15% of the U.S. expenditure on medicines.[23] Yet current generic drug payment policies and practices encourage purchasers to choose manufacturers largely based on lowest price.

This dynamic can weaken initiatives to strengthen supply chain resilience by limiting the ability of manufacturers to invest in new, alternate manufacturing processes, domestic production, manufacturing updates and necessary facility maintenance, quality assurance and management, or to build redundancy into supply chains.

The current purchasing and payment systems, however, lack a coordinated and collaborative means to evaluate resilience and reliability and therefore minimize and mitigate risks that affect the U.S. supply of medicines. There is a need for deliberate incorporation of quality, resilience, and reliability, in addition to price, in contracting, purchasing, and inventory decisions.

A fundamental shift in the market is needed to align supply and demand forces to create a more predictable, sustainable, and quality supply chain that can reliably provide medicines to American patients. USP encourages the Committee to consider the development of a Drug Supply Chain Resilience Initiative (DSCRI),[24] which would aim to:

- **Foster stability in the drug supply chain by providing criteria to value the resilience and reliability of manufacturers.**
- **Promote sustainable prices for generic medicines.**
- **Incentivize changes in purchasing practices with the goal of better meeting patients' needs through a reliable, safe, and resilient medicine supply chain.**

A DSCRI must include two distinct elements:

- A data-driven system to differentiate suppliers based on reliability and resilience, such as the development of an assessment or benchmark to enable purchasers to identify resilient manufacturers.
- Establishment of meaningful value-based payment and contracting reforms to incentivize supply chain resilience and reliability.

A manufacturer benchmark metric should function as a tool for decision making and consist of resilience measures, reliability measures, quality measures, as well as the base vulnerability of a drug product, which includes understanding the concentration of domestic and non-domestic manufacturing locations. Key benchmark attributes could include:

- A menu of well-established measures that are predictive of reliability and quality

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[22] U.S. Pharmacopeia. USP Annual Drug Shortages Report: Economic Factors underpin 2023 shortages. 2024.
[23] Association for Accessible Medicines. 2025 U.S. Generic & Biosimilar Medicines Savings Report. 2025.
[24] U.S. Pharmacopeia. A drug supply chain resilience initiative will better support patients. 2025.

- The ability of manufacturers to choose measures and combine values to reach the resilience benchmark
- A resilience determination per molecule, per manufacturer
- Experts to advise on benchmark metrics, criteria, and DSCRI details
- Data from the USP Medicine Supply Map Vulnerability Assessment and the USP Vulnerable Medicines List

Several measures are currently known and available that could be utilized, including those from the USP Medicine Supply Map; publicly available metrics from the FDA; manufacturer measures of product production, inventory, and delivery; and reputable product level quality testing data, among others.

Without significant market and policy interventions, current medicine supply chain vulnerabilities and drug shortage trends will likely continue or worsen. A solution to bolster resiliency can be facilitated by measuring and valuing reliability and quality using a comprehensive framework like the DSCRI.

Conclusion

The USP appreciates the Committee for holding this hearing and the bipartisan, careful consideration of approaches to forge a more resilient, adaptable, and secure future for America's medicine supply. The well-being of millions of people and our nation's security depends on it. We look forward to working with the Committee and Congress, industry, and our scientific community to make this vision a reality.

Questions for the Record

U.S. Senate Special Committee on Aging

"Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"

September 17, 2025

Questions for the Record

Peter Baker

Senator Elizabeth Warren

Question:

How would the U.S. population benefit from increased domestic manufacturing of pharmaceuticals?

Response:

The US population would benefit due to an increased supply of high-quality reliable medicines that work without side-effects that come with consuming substandard products. Currently, due to supply chain complexity and the inability of FDA to effectively regulate overseas manufacturing sites in unregulated markets (primarily India/China), the quality of our generic drug supply is known to be substandard. FDA has no legal jurisdiction in these markets, therefore punishment for distributing substandard generics is not possible. The list of manufacturing sites who regularly engage in fraud, identified during historical and current FDA Inspections, is no secret. These sites must be eliminated from the US supply chain without compromise.

The substandard state of generic drug quality in the US is demonstrated by continued FDA inspection reports outlining repeated fraud, as well results from the Dept of Defense generic drug import testing program. The US population should not be forced to consume these products due to government inaction on a known problem.

Question:

What are the dangers of overreliance upon a single supplier for pharmaceutical products?

Response:

The dangers of overreliance are that drug shortages will arise when poor manufacturing conditions are identified during unannounced FDA inspection, and sites are forced to shut down as they can no longer ethically release product for human consumption. Traditionally, these sites

have been experts at hiding manufacturing problems as they were given several months notice prior to the FDA visit. With the planned increase in FDA unannounced inspections in India/China, this problem is likely to increase rapidly as the true state of quality in these sites can be finally unveiled.

Another scenario is that the FDA may make a compromise, and allow the site to continue to ship substandard generics known to cause side effects because there is no other option. Either scenario is a bad outcome for public health.

Question:

How would the U.S. population benefit from government-owned, contractor-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

Response:

Unfortunately, I am not qualified to answer this question. My expertise is limited to the site inspections of foreign facilities and relevant FDA procedures and processes for generic drug regulation.

Question:

Which essential medicines should the U.S. prioritize securing safe, reliable access to?

Response:

Unfortunately, I am not qualified to answer this question. My expertise is limited to the site inspections of foreign facilities and relevant FDA procedures and processes for generic drug regulation.

Question:

What additional authorities could FDA draw upon to accelerate the onshoring of pharmaceutical manufacturing?

Response:

FDA could draw on existing laws and regulations to prohibit the entry of generic drugs from foreign sites not meeting our regulation/law. FDA has an excellent and world-leading foreign inspection program that regularly uncovers failure to meet the GMP regulation outlined in 21 CFR Parts 210/21. These devastating foreign inspection reports regularly demonstrate manufacturing deficiencies that cause the product to be "adulterated" under the law and not fit for human consumption.

However, the Agency has been traditionally lax to enforce the law due to a number of factors, but primarily a seemingly tunnel-like vision to lower generic drug prices to the absolute rock-

bottom, despite repeated and continuous warnings from FDA's Office of International Programs and FDA Field Investigators. FDA's Foreign Offices were established following the Heparin scandal of 2008, however, their messaging has been largely ignored: that the problem of substandard imported medicines continues and alternative supply chains (e.g. regulated markets) must be prioritized.

Question:

As part of broader layoffs at the Food and Drug Administration (FDA), "nearly 70 people who helped arrange travel, budgets, translators and contingency plans" for foreign drug inspections were fired, straining the agency's inspection capabilities. Would you advise the FDA to reverse these cuts?

Response:

Yes.

Question:

What effect would such reductions have on FDA's ability to conduct thorough inspections?

Response:

In my experience as a drug investigator, the various support departments responsible for field investigations have always been strained due to lack of personnel. These support departments were already operating as lean as possible. It is unclear how thorough inspections can be completed with even fewer staff members. Travel visas will be delayed, contingency/alternative travel and inspection plans will not be prepared, and the efficiency of the entire inspection program will suffer. The number of days dedicated to each inspection will likely need to be reduced to meet yearly inspection numbers due to inefficiencies in logistics and planning.

This may appear as a cost-saving measure for someone who has no idea how the foreign inspection program operates and has not traveled regularly to remote corners of the world for weeks/months at a time, but these cuts will actually cause an increase in cost and decrease in public health outcomes via decrease in logistics efficiency.

Question:

What effect would such reductions have on Americans' health?

Response:

As mentioned above, the reductions will likely impact public health by reducing the number of days dedicated to each inspection as a result of logistical problems that arise from poor planning and lack of contingency plans, and less comprehensive inspections of high-risk foreign manufacturing sites.

Senator Raphael Warnock

Question:

In the aftermath of Hurricane Helene, when Baxter International's North Carolina facility went offline and caused a nationwide intravenous (IV) fluid shortage, the Food and Drug Administration's (FDA) ability to conduct real-time inspections and ensure safe importation became critical. On October 10, 2024, I sent a letter to the Secretary of Health and Human Services and the Commissioner of Food and Drugs to ensure certain measures were put in place to respond to this crisis and prevent future shortages.

What additional authorities, resources, or emergency flexibilities would you recommend Congress provide FDA so that supply disruptions do not immediately endanger older adults?

Response:

Unfortunately, I am not qualified to answer this question. My expertise is limited to the site inspections of foreign facilities and relevant FDA procedures and processes for generic drug regulation. My understanding of FDA's management of drug shortages and emergency flexibilities is limited.

U.S. Senate Special Committee on Aging

"Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"

September 17, 2025

Questions for the Record

Dr. George Ball

Senator Elizabeth Warren

Question:

According to your research on the pharmaceutical industry and the quality of the U.S. generic drug supply, which components of the pharmaceutical supply chain need the greatest scrutiny or investment to increase the supply of safe and effective pharmaceuticals?

Response:

My research has not delved deeper than the Finished Dosage Form (FDF) component of the supply chain. The India vs. U.S. generic drug published paper that was a focus of my testimony only examined the FDF plants. This is predominantly due to the even greater levels of opaqueness associated with the Active Pharmaceutical Ingredient (API) or Key Starting Materials (KSM) components of the supply chain. So, while I speculate that both the API and the KSM aspects of the supply chain have serious quality challenges as well, maybe more because they are even more opaque, it is just speculation, because I have not studied that. I have only studied the FDF plants.

Question:

According to your research, what are the most significant barriers preventing the United States from onshoring more pharmaceutical manufacturing?

Response:

My research has not examined barriers preventing U.S. onshoring. I would speculate, based on my understanding of the marketplace, that the profit margins for generic drugs are too low for U.S. companies to successfully compete with Indian or Chinese counterparts. Those two countries have a cost advantage that I believe the U.S. could not compete with. This is due, in my opinion, to the lack of transparency in the market. If drugs firms could compete on more than

just cost, but also on quality and location, the market may pay more for higher quality domestic drugs, and the U.S. may then be more competitive, and the cost barrier to onshoring may lessen.

Question:

How would you suggest Congress address these barriers?

Response:

Following my answer above, a way Congress could help address the U.S. cost disadvantage is to help drug firms compete on more than just cost, but also on quality, as well as on country of manufacture. If drug firms were required, by law through Congress, to put the country of manufacture on the label, as well an objective measure of drug quality, then U.S. firms could compete on quality and location, as well as on cost. This would help alleviate some of the cost disadvantage that U.S. firms have.

Question:

How would the U.S. population benefit from increased domestic manufacturing of pharmaceuticals?

Response:

This is speculation, but I believe they could benefit by having higher quality drugs. This higher quality may come from more rigorous FDA oversight of domestic manufacturing plants, as compared to foreign drug plants. They may also benefit by having fewer shortages. I hold this opinion because with more rigorous FDA oversight, and the resultant higher quality, shortages should in theory, decrease.

Question:

What are the dangers of overreliance upon a single supplier for pharmaceutical products?

Response:

There are significant risks in relying on a single supplier for any manufactured product. If that supplier were to have a quality problem, or a natural disaster, or any other sort of major disruption, product supply could be significantly constrained. It is always risky to rely on just one supplier for any product, but especially for life-sustaining products such as drugs.

Question:

How would the U.S. population benefit from government-owned, contractor-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

Response:

I have not done research on this idea, so my views are pure speculation. On the one hand, government ownership may alleviate some of the supply chain problems that exist in the drug industry, such as excessively high prices or distant manufacturing locations that are hard to regulate. On the other hand, government-owned organizations may struggle to deliver a high-quality product unless they face real competitive pressures that are felt in a normal marketplace. However, my comment here is just my opinion, as I have not done research in this area.

Question:

How would the U.S. population benefit from government-owned, government-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

Response:

My response above to the contractor-operated question is similar to the answer for this question. The only caveat I would make is that any of the negatives associated with a government-owned, contractor-operated firm would likely be exacerbated by shifting the operations to the government as well. However, this is speculation as I have not done research in this area.

Question:

Which essential medicines should the U.S. prioritize securing safe, reliable access to?

Response:

This question is beyond my area of expertise. I do not believe I should even speculate on this response.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

QUESTIONS FOR THE RECORD

Brandon Daniels

Senator Elizabeth Warren

Questions:

How would requiring drug manufacturers to disclose the source of active pharmaceutical ingredients (APIs) and key starting materials (KSMs) used to make drugs consumed in the U.S. increase the supply of safe and effective drugs for U.S. consumers?

During the hearing, you explained that supply chain mapping can help to anticipate supply chain disruptions and critical drug shortages. Would requiring pharmaceutical manufacturers to report API and KSM sources to the federal government improve supply chain mapping?

Would a federal database with this information help avoid supply chain disruptions and critical drug shortages?

Based on your experience at Exiger, which components of the pharmaceutical supply chain need the greatest scrutiny or investment to increase the supply of safe and effective pharmaceuticals?

a.What are the most significant barriers preventing the United States from onshoring more pharmaceutical manufacturing that Congress should prioritize addressing?

b.How would you suggest Congress address these barriers?

In your testimony, you highlighted that there are national security risks to the Department of Defense (DoD) being overreliant on foreign pharmaceutical manufacturing. How do these risks undermine military readiness?

How do U.S. national security risks increase with higher rates of unsafe, foreign pharmaceutical manufacturing?

Which essential medicines should DoD prioritize securing safe, reliable access to for service members?

As you noted in your testimony, DoD revealed that "54% of the DoD pharmaceutical supply chain is considered either high or very high risk, with dependency on non-[TAA] compliant suppliers, sourcing from China, or unknown." What would be the impact on the military readiness if DoD lost access to 54% of the supply chain?

Can you provide examples of how DoD has been adversely impacted by pharmaceutical supply chain disruptions?

Can you provide examples of how DoD has been adversely impacted by drug shortages?

Can you provide examples of how DoD has been adversely impacted by unsafe pharmaceuticals?

How do DoD pharmaceutical supply chain challenges, drug shortages, or access to unsafe pharmaceuticals result in direct additional health care expenditure?

What types of indirect costs result from higher rates of illness if DoD experiences pharmaceutical supply chain challenges, drug shortages, or access to unsafe pharmaceuticals?

What other costs to DoD occur as a result of supply chain challenges, drug shortages, or access to unsafe pharmaceuticals?

How would DoD benefit from domestic manufacturing of pharmaceuticals?

What are the dangers of DoD being overreliant upon a single supplier for pharmaceutical products?

How would DoD benefit from government-owned, contractor-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

How would DoD benefit from government-owned, government-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

How would the civilian population benefit from government-owned, contractor-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

How would the civilian population benefit from government-owned, government-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

What are the dangers of DoD being forced to purchase drugs or medical countermeasures considered less secure under the Defense Logistic Agency hierarchy of drug security due to shortages or supply chain challenges? Please provide examples of when this has occurred.

What are the dangers of DoD being forced to adjust dosages or dispensing of drugs and medical countermeasures due to shortages or supply chain challenges? Please provide examples of when this has occurred.

What are the dangers of DoD being forced to pay a higher cost for pharmaceuticals and medical countermeasures due to shortages or supply chain challenges? Please provide examples of when this has occurred.

What are the dangers of DoD being forced to use different, less-optimal medication due to shortages or supply chain challenges? Please provide examples of when this has occurred.

What challenges could DoD face in finding enough adequate and cost-efficient suppliers for pharmaceuticals and medical countermeasures in instances where DoD represents all or nearly all of the U.S. commercial marketplace for that drug or medical countermeasure?

Response:

Responses were not available at the time of printing. Please contact the Committee if there are questions.

Senator Raphael Warnock

Questions:

In your testimony, you emphasized the role of advanced data analytics in identifying vulnerabilities before crises occur as well as the importance of ″stress testing″ the pharmaceutical supply chain.

Looking back at Hurricane Helene, could predictive modeling have flagged Baxter's IV fluid facility as a single point of failure for the U.S. health system, and how can Congress better leverage supply chain mapping to prevent similar crises?

What would a meaningful stress test look like in practice, particularly for scenarios such as a natural disaster or international trade disruption, including a Chinese export ban?

In Georgia, we have both a rapidly aging population and one of the nation's largest Veteran populations. Veterans represent a uniquely vulnerable population in the U.S. drug supply chain-not only because they are aging, but also because they often need a greater number of medicines to manage service-connected injuries, Post-Traumatic Stress Disorder (PTSD), and other chronic conditions. When shortages occur, as we saw after Hurricane Helene with IV fluids, Department of Veterans Affairs facilities could be forced to ration care.

How should Congress ensure that resilience planning and procurement contracts specifically account for the higher medication needs of Veterans, especially aging Veterans, so that this population is never left behind in a crisis?

Transparency into where and how medicines are made is critical for both patient safety and supply chain security.

How would requiring country of origin or manufacturing facility information on labels improve the security of our drug supply chain, particularly for seniors in states like Georgia?

What steps should Congress take to enforce existing reporting requirements and ensure greater transparency overall?

Response:

Responses were not available at the time of printing. Please contact the Committee if there are questions.

U.S. Senate Special Committee on Aging

"Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"

September 17, 2025

Questions for the Record

Dr. Ronald Piervincenzi

Senator Elizabeth Warren

Question:

How would requiring drug manufacturers to disclose the source of APIs and KSMs used to make drugs consumed in the U.S. increase the supply of safe and effective drugs for U.S. consumers?

Response:

Understanding our vulnerabilities starts with increasing visibility across the supply chain, from excipients and Key Starting Materials to Active Pharmaceutical Ingredients and Finished Dose. Armed with these insights, the U.S. government could take more precise steps to shore up risky supply lines or direct funding to take mitigating steps where geographic concentration represents significant vulnerability. Additionally, greater visibility could help guide commercial investments to diversify supply lines.

USP recommends authorizing an annual assessment and report, by an independent party, to identify our most vulnerable medicines, such as those sole-sourced from adversarial nations. The annual report would be delivered to Congress with recommendations on how best to mitigate the most significant risks.

Once identified, USP recommends that the most vulnerable medicines be evaluated for risk mitigation, including whether their APIs or KSMs could be produced through alternative routes of synthesis and/or whether advanced manufacturing technologies could aid in reducing risk of overreliance.

The enduring cycle of shortages, however, is certain to continue if a more comprehensive approach is not taken. Long-term sustainability requires that we reexamine the way we pay for our most essential medicines. We must endeavor to shift the paradigm to reward more resilient purchasing of essential medicines in order to promote an environment that values reliability, reinvestment in quality systems, and a competitive domestic industrial base.

To drive meaningful change, payment policies—such as those under Medicare—could incentivize purchasers to prioritize resilient sourcing. Emphasizing resilient purchasing would signal greater demand predictability to generic manufacturers, who would, in turn, be motivated to demonstrate reliability.

The resulting shift in market forces would promote greater predictability for reliable suppliers, and, ultimately, create an environment that rewards investment in quality systems, surge capacity, diversified supply, and other recognized resilient practices.

Question:

In your testimony, you discuss how supply chain mapping is important for identifying supply chain vulnerabilities and building resiliency. Would requiring pharmaceutical manufacturers to report API and KSM sources to the federal government improve supply chain mapping?

Would a federal database with this information help avoid supply chain disruptions and critical drug shortages?

Response:

The U.S. Food and Drug Administration (FDA) plays a critical role in mitigating drug shortages through its Drug Shortage Staff (DSS) within the Center for Drug Evaluation and Research (CDER). The DSS draws on a range of information—including mandatory manufacturer notifications of supply disruptions, real-time reports from healthcare providers, and data from industry portals—to identify and address potential shortages early. In the event of a shortage or impending event, industry and FDA typically work together in earnest to mitigate the disruption.

Pharmaceutical manufacturers are required to disclose their API (Active Pharmaceutical Ingredient) suppliers to the FDA. The CARES Act expanded reporting requirements related to API sourcing, which have improved FDA's monitoring capabilities. Manufacturer API sources are required to comply with current Good Manufacturing Practices (cGMP) and provide supporting documentation.

Identifying and addressing vulnerabilities in the upstream medicines supply chain – which includes end-to-end supply chain data – is essential to more fully understand the risks affecting the U.S. medicine supply chain. Requiring the agency to examine additional data, on its own, however, may not yield significantly different insights. Data needs to be integrated in a way that can generate actionable insights to effectively target responses that would create more resilience and potentially avoid drug shortages. Information platforms that provide actionable data-based insights into medicines supply chain vulnerabilities exist. USP suggests allowing an independent third party to conduct assessments and report findings, as a cost-effective approach.

USP recently revealed a unique level of visibility into Key Starting Materials (KSMs)—a long-obscured segment of the supply chain. This information provides critical insights that government systems may not be equipped to capture or analyze in depth. This data matters because the U.S. medicine supply remains highly vulnerable to disruption, particularly due to

raw materials that are sole sourced from a single country, posing a clear and present threat to public health and national security.

Question:

As mentioned in the previous response, USP recommends authorizing an annual assessment and report, by an independent party, to identify our most vulnerable medicines, such as those sole-sourced from adversarial nations. The annual report would be delivered to Congress with recommendations on how best to mitigate the most significant risks.

Based on your experience at United States Pharmacopeia, which components of the pharmaceutical supply chain need the greatest scrutiny or investment to increase the supply of safe and effective pharmaceuticals?

Response:

Identifying vulnerabilities in the upstream pharmaceutical supply chain is essential for ensuring patients have access to the critical and routine medical care they need. The USP Medicine Supply Map shows four risk categories correlate most directly to supply vulnerability and drug shortages: low price, geographic concentration of production location, quality issues, and manufacturing complexity. These risk factors, often interrelated, can worsen economic strain for manufacturers of low-margin drug products.

Question:

What are the most significant barriers preventing the United States from onshoring more pharmaceutical manufacturing?

Response:

Current generic drug payment policies and practices encourage purchasers to choose manufacturers largely based on lowest price, which creates adverse incentives for manufacturers to keep costs down even at the expense of needed investments in supply chain resilience, reliability, and innovation. Geographically concentrated production, especially offshore, often occurs when manufacturers respond to unsustainable price pressures by locating in lower-cost jurisdictions. Manufacturers of low-cost generic medicines may also lack sufficient margins to invest in newer technologies that could help them operate profitably in the United States.

Question:

How would you suggest Congress address these barriers?

Response:

Congress should lead the federal government to enact policies that align supply and demand forces to create a more predictable, sustainable, and quality supply chain that can reliably

provide medicines to patients. Such policies would reward quality, resilience, and reliability, in addition to price, in value-based contracting, purchasing, and inventory decisions. Incentives for quality and resilience should be made based on a transparent, public benchmarking process. Benchmarking should include resilience measures, reliability measures, quality measures, as well as the base vulnerability of a drug product, which includes understanding the concentration of domestic and non-domestic manufacturing locations.

Question:

How would the U.S. population benefit from increased domestic manufacturing of pharmaceuticals?

Response:

Longer, more fragmented, and less visible supply chains put patients at risk of losing access to the medicines they need. Drug shortages continue to be a persistent problem in the United States, touching the lives of millions of Americans and substantially affecting the care of patients. For example, a recent ACS-CAN study found that 1 in every 10 cancer patients face shortage-related impacts to care – many of whom have struggled to find substitute medications (68%) or faced treatment delays (45%).

Promoting geographic diversification of the manufacturing base for U.S. medicines can help reduce supply chain vulnerabilities. USP urges that policy reforms to promote geographic diversification of pharmaceutical manufacturing should include but go beyond onshoring and reshoring initiatives, as geographic concentration—even within the United States— can serve as a significant risk factor for drug shortages.

Question:

What are the dangers of overreliance upon a single supplier for pharmaceutical products?

Response:

USP's Medicine Supply Map data show that geographic concentration anywhere—including within the United States—increases the risk of drug shortages. Drugs in which the active pharmaceutical ingredient (API) and/ or finished dose are made in a single or few locations are at a higher risk of shortages. The risk of drug shortages is particularly acute when a single facility is responsible for producing the entire U.S. market supply for a particular drug.

Geographic concentration of the medicines supply chain is generally an outcome of specialization and pricing pressure and can result in drug shortages when a variety of issues occur, including natural disasters (e.g., earthquakes, hurricanes), trade wars, domestic or geopolitical strife, or global public health emergencies, such as the COVID-19 pandemic.

While the globalization of the supply chain has generally facilitated access to medicines at a lower cost, it has increased the risk of unreliable supply following sudden or unexpected shocks in specific locations.

Question:

How would the U.S. population benefit from government-owned, contractor-operated pharmaceutical manufacturing facilities? Please provide relevant examples.

Response:

The market for lower-cost essential medicines, particularly generic injectable drugs, does not suffer from an absence of competition. Rather, there is a lack of demand-predictability in the purchase of essential medicines that is most destabilizing to the supply, as it discourages investments in redundancies and other resilient measures and deters long term commitments to upgrade quality system. Given the significant capital investments necessary to build, maintain, and upgrade these facilities, government-owned facilities may not prove cost-effective. More importantly, it is unlikely to tackle the underlying root causes of the problem.

The U.S. government could, however, use its considerable leverage as a payor to demand that greater emphasis be placed on reliability, resilience, and quality – in the purchasing of essential medicines. Aligning incentives in this market would immediately encourage greater stewardship of our medicine supply chain. This could be accomplished broadly through Medicare payment policy or wherever the U.S. government is the primary payor, ie., Department of Defense, Department of Veterans Affairs.

USP proposes that Congress take a two-pronged approach:

- ✓ **Establish Resilience Benchmark:** Establish a Resilience Benchmark for manufacturers of essential medicines to demonstrate reliability per molecule.
    - Manufacturers, motivated to demonstrate resilience, would be measured against a Resilience Benchmark, comprised of industry-recognized practices proven to promote reliability and quality, including:
        - Surge Capacity for Finished Dose and API
        - Geographic Diversity of Suppliers

- ✓ **Payers Promote Resilient Procurement:** USP proposes that incentives be created to encourage purchasers to prioritize sustainable procurement practices.
    - As the primary payer of low-cost essential medicines, in the inpatient setting, Medicare Part A could require or incentivize more resilient-focused purchasing of essential medicines.
    - Likewise, Medicare plays a key role in the delivery of care in outpatient settings as well. Incentives could be created in Medicare Part B to ensure greater stewardship of this critical supply chain.

Combined, these elements align to promote greater stewardship of the supply chain and incentivize manufacturers and purchasers, alike, to value investments in updating quality systems, building surge capacity, and diversifying upstream suppliers.

Question:

Which essential medicines should the U.S. prioritize securing safe, reliable access to?

Response:

USP's Vulnerable Medicines List (VML)[1] offers insight on a list of medicines derived from an assessment of their essentiality, demand, and supply chain vulnerabilities – that can be used to identify medicines at risk of supply chain disruption.[2,3]

Leveraging Medicine Supply Map and additional data, USP conducted an analysis to identify 100 vulnerable medicines – 49 used to manage chronic conditions and 51 for acute care – to inform dialogue related to bolstering medicine supply chain resilience.[4] This data-driven approach accounts for the level of use by the U.S. population, public and population health necessity, the vulnerability of the medicine to supply chain disruptions, and the availability of alternative therapies. The resulting list includes a wide range of therapeutic classes of medicines as well as a variety of product types. This list can be useful to identify medicines to prioritize for mitigation efforts.

Furthermore, USP encourages the Committee to explore legislative means for carrying out an annual cadence for assessing vulnerabilities. This could be accomplished by:

1. Establishing a thorough, science-based mapping of the pharmaceutical supply chain, for essential medicines, from KSM to API to FDF.
2. Identifying vulnerabilities to the U.S. pharmaceutical supply chain, especially with respect to the nation's reliance on foreign and adversarial sources.
3. Requiring a yearly update to the VML and an accompanying report to Congress that provides actionable recommendations to Congress and the Administration to strengthen domestic resilience and mitigate national security risks.

Updating and sharing this critical information annually would help the U.S. government prioritize the most critical products, target investments, and inform initiatives to bolster the U.S. pharmaceutical supply chain and national security interests**.**

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[1] United States Pharmacopeia. 2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply. 2025.
[2] United States Pharmacopeia. USP Global Public Policy Position: Identifying and addressing vulnerabilities in the upstream medicines supply chain to build resilience and reduce drug shortages. 2023.
[3] USP's approach borrows from the framework proposed in the article: Wosinska, M., Mattingly, T., & Conti, R. A Framework for Prioritizing Pharmaceutical Supply Chain Interventions. 2023.
[4] United States Pharmacopeia. 2024-2025 Vulnerable Medicines List for the United States: A data-based approach to identify risks and enable interventions to increase reliability of supply. 2025.

Senator Raphael Warnock

Question:

In Georgia, we have both a rapidly aging population and one of the nation's largest Veteran populations. Veterans represent a uniquely vulnerable population in the U.S. drug supply chain—not only because they are aging, but also because they often need a greater number of medicines to manage service-connected injuries, Post-Traumatic Stress Disorder (PTSD), and other chronic conditions. When shortages occur, as we saw after Hurricane Helene with IV fluids, Department of Veterans Affairs facilities could be forced to ration care.

How should Congress ensure that resilience planning and procurement contracts specifically account for the higher medication needs of Veterans, especially aging Veterans, so that this population is never left behind in a crisis?

Response:

Veterans deserve access to the medications they need when they need them. The U.S., however, continues rely on a supply chain that is fragmented, complex, and opaque. The resulting environment produces persistent cycles of critical shortages. Natural disasters and supply chain disruptions exacerbate these challenges and threaten access to vital medications for millions of Americans, including some of our most vulnerable seniors and veterans.

This environment is certain to continue if a more comprehensive approach is not taken. A secure supply of our most essential medicines requires that we reexamine the way we pay for them. We must endeavor to shift the paradigm to reward more resilient purchasing of essential medicines to promote an environment that values reliability, reinvestment in quality systems, and a competitive domestic industrial base.

To drive meaningful change, the U.S. government could use its considerable leverage as a payor to demand that greater emphasis be placed on reliability, resilience, and quality – in the purchasing of essential medicines. Aligning incentives in this market would immediately encourage greater stewardship of our medicine supply chain. This could be accomplished broadly through Medicare payment policy or wherever the U.S. government is the primary payor, such as the Department of Veterans Affairs.

The resulting shift in market forces would promote greater predictability for reliable suppliers, and, ultimately, create an environment that rewards investment in quality systems, surge capacity, diversified supply, and other recognized resilient practices.

USP proposes that Congress take a two-pronged approach:

- ✓ **Establish Resilience Benchmark:** Establish a Resilience Benchmark for manufacturers of essential medicines to demonstrate reliability per molecule.
    - Manufacturers, motivated to demonstrate resilience, would be measured against a Resilience Benchmark, comprised of industry-recognized practices proven to promote reliability and quality, including:
        - Surge Capacity for Finished Dose and API
        - Geographic Diversity of Suppliers

- ✓ **Payers Promote Resilient Procurement:** USP proposes that incentives be created to encourage purchasers to prioritize sustainable procurement practices.
    - As the primary payer of low-cost essential medicines, in the inpatient setting, Medicare Part A could require or incentivize more resilient-focused purchasing of essential medicines.
    - Likewise, the DVA could require or incentivize resilient purchasing of essential medicines for veterans.

Combined, these elements align to promote greater stewardship of the supply chain and incentivize manufacturers and purchasers, alike, to value investments in updating quality systems, building surge capacity, and diversifying upstream suppliers.

Question:

U.S. Pharmacopeia's Vulnerable Medicines List has identified drugs with the highest risk of shortage. To what extent do those high-risk medicines rely on ingredients or raw materials sourced from China, and what steps should Congress take to reduce that risk?

In Georgia, where we have both a rapidly aging population and one of the nation's largest Veteran populations, what medicines on that list should we be most concerned about losing access to during a natural disaster or international trade disruption, including a Chinese export ban?

Response:

Identifying and addressing vulnerabilities in the upstream medicines supply chain is critical to build resilience and reduce drug shortages. USP's Medicine Supply Chain recently completed new analysis that provided unprecedented visibility of the long-obscured key starting materials needed to produce our medicines.

The general takeaway is clear - America's medicine supply is highly dependent on China and India for many critical starting materials. A shock to any one of these major source countries could have devastating effects on the US pharmaceutical supply chain. These vulnerabilities signify a clear and present threat to the nation's public health and national security.

USP welcomes the opportunity to share additional insights from its recent analysis on the sourcing of key starting materials for the nation's medicine supply chain.

Question:

What can Congress do to address this issue?

Response:

Building a more resilient, secure medicine supply chain requires manufacturing medicines in more places and in new ways. Rewarding quality, resilience, and reliability, encourages purchasers to prioritize these values in inventory decision-making. Addressing vulnerabilities, in the short term, requires a practical stepwise approach.

1. **Improve Supply Chain Visibility, Identify Key Vulnerabilities, and Assess Continuously**
    a. Establish an annual vulnerability assessment and report to Congress that includes independent recommendations for prioritizing and mitigating the greatest public health and national security risks to our medicine supply chain.

2. **Innovate and Scale Alternative Methods for Producing Essential Medicines, APIs and KSMs.**
    a. Identify and use alternate routes of synthesis for our most vulnerable medicines, such as those sole sourced from non-ally nations.
    b. Incentivize advanced manufacturing technologies where it may improve domestic competitiveness.
    c. Invest in scalable projects that leverage alternate pathways to reduce reliance and increase resilience.

3. **Establish a Benchmark for a Stronger, More Resilient Medicine Supply:**
    a. To strengthen the supply of essential medicines, we must reward resilience.
    We propose a resiliency benchmark for manufacturers of critical drugs, paired with incentives for purchasers to prioritize those who meet it. This will drive investment in quality systems, surge capacity, and diversified supply- supporting a more reliable and competitive domestic base.
    b. To help ensure that Americans have consistent access to quality medicines, the federal government should leverage Medicare's significant purchasing power along with the DoD and VA to incentivize resilience.

Question:

Transparency into where and how medicines are made is critical for both patient safety and supply chain security.

How would requiring country of origin or manufacturing facility information on labels improve the security of our drug supply chain, particularly for seniors in states like Georgia?

Response:

Lower-cost generic medicines make up approximately 90% of the volume and just 10% of the overall cost that our nation spends on drugs. Many of our most vulnerable medicines are generic sterile injectable drugs. These are typically administered in the inpatient setting where patients are not selecting among a range of therapies options. For this reason, country of origin labeling would have little impact on the decisions of consumers.

Purchasers in this scenario are unlikely to consider a drug's country of origin when procuring these medicines. The current environment rewards the lowest bidder, which can naturally come at the expense of a manufacturer who invests in redundancies and other resilient practices. To this end, we must reexamine the way we pay for lower cost generic drugs and shift the paradigm to reward more resilient purchasing of essential medicines. This in turn would promote an environment that more appropriately values reliability, reinvestment in quality systems, and a competitive domestic industrial base.

See Answer #2 for more details on 1) Establishing a Resilience Benchmark and 2) Creating incentives to encourage greater stewardship of our medicine supply chain by purchasers and manufacturers alike.

Question:

What steps should Congress take to enforce existing reporting requirements and ensure greater transparency overall?

Response:

The U.S. Food and Drug Administration (FDA) plays a critical role in mitigating drug shortages through its Drug Shortage Staff (DSS) within the Center for Drug Evaluation and Research (CDER). The DSS draws on a range of information—including mandatory manufacturer notifications of supply disruptions, real-time reports from healthcare providers, and data from industry portals—to identify and address potential shortages early. In the event of a shortage or impending event, industry and FDA typically work together in earnest to mitigate the disruption.

Pharmaceutical manufacturers are required to disclose their API (Active Pharmaceutical Ingredient) suppliers to the FDA. The CARES Act expanded reporting requirements related to API sourcing, which have improved FDA's monitoring capabilities. Manufacturer API sources are required to comply with current Good Manufacturing Practices (cGMP) and provide supporting documentation.

Identifying and addressing vulnerabilities in the upstream medicines supply chain – which includes end-to-end supply chain data – is essential to more fully understand the risks affecting the U.S. medicine supply chain. Requiring the agency to examine additional data, on its own,

however, may not yield significantly different insights. Data needs to be integrated in a way that can generate actionable insights to effectively target responses that would create more resilience and potentially avoid drug shortages. Information platforms that provide actionable data-based insights into medicines supply chain vulnerabilities exist. USP suggests allowing an independent third party to conduct assessments and report findings, as a cost-effective approach.

USP recently revealed a unique level of visibility into Key Starting Materials (KSMs)—a long-obscured segment of the supply chain. This information provides critical insights that government systems may not be equipped to capture or analyze in depth. This data matters because the U.S. medicine supply remains highly vulnerable, particularly where raw materials sole-sourced from a single country, pose a clear and present threat to public health and national security.

USP recommends authorizing an annual assessment and report, by an independent party, to identify our most vulnerable medicines, such as those sole-sourced from adversarial nations. The annual report would be delivered to Congress with recommendations on how best to mitigate the most significant risks.

Statements for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

AARP Statement

AARP appreciates the opportunity to submit this statement for the record and commends the committee for holding today's important hearing, *Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans*. We applaud your bipartisan efforts to examine the vulnerabilities in the U.S. drug supply chain, and the serious consequences drug shortages pose for older Americans. AARP has long maintained that every person should have reliable access to high-quality, affordable prescription drugs to support their health and well-being. The federal government can play a vital role in proactively identifying risks and addressing weaknesses in the supply chain before they result in harmful shortages.

Reduced access to needed medications, whether due to natural disasters, manufacturing disruptions, or supply chain breakdowns, can delay or deny needed care or force providers to rely on less effective alternatives. These disruptions are especially concerning for older adults, who use more prescription drugs than any other age group and are the largest age group filling monthly prescriptions prior to a drug going into shortage. For those managing health conditions, a stable and secure supply of medications is not just important, it is often life-sustaining.

AARP recognizes that the causes of drug shortages are complex and multifaceted. We view this hearing as an important step toward identifying and implementing broader, long-term solutions. We also support the Administration's August 13, 2025, Executive Order to identify and create a strategic reserve of active pharmaceutical ingredients (APIs) essential to national health and security, with a focus on domestic sourcing. Having an API stockpile will help ensure domestic manufacturers and compounders retain access to needed ingredients in the event of a drug shortage or supply chain disruption. However, it would be helpful to preemptively identify entities that can be called upon to create finished products. Similarly, it would be helpful to identify any federal regulatory updates that may be needed to successfully utilize the stockpiled APIs while also ensuring that any resulting products are safe and high-quality. We also urge policymakers to work closely with stakeholders as they prioritize APIs for inclusion in the repository. For example, the process used to create the list of 86 essential drugs mentioned in the Executive Order involved a detailed analysis and stakeholder input. AARP believes that a similar process is needed for this effort as well to make sure that provider and patient perspectives are well-represented.

AARP appreciates the bipartisan work of the Senate Finance Committee to stabilize the supply of essential generic medicines, including exploring proposals to encourage purchasing of generic medicines from manufacturers that invest in shortage mitigation and strong quality management practices. We support the Mapping America's Pharmaceutical Supply (MAPS) Act, which would bring much-needed transparency by requiring the Department of Health and Human Services to coordinate with federal agencies and the private sector to map the full supply chain for selected essential medicines. A comprehensive, end-to-end understanding of the pharmaceutical supply chain will play a critical role in successful efforts to detect and prevent supply disruptions and help ensure patients maintain access to the medications they rely on.

Finally, as the committee continues its work on prescription drug policy, AARP urges you to maintain momentum on lowering drug prices. Millions of older adults are already seeing savings from the new Medicare Part D out-of-pocket spending cap that took effect this year. In just a few months, Americans will start to see savings at the pharmacy thanks to Medicare's negotiations

with drug companies to bring down prices. This will help millions of seniors better afford their medications while also saving billions of dollars for taxpayers and Medicare. These reforms are making a real difference in people's lives. We encourage Congress to protect and build on this progress to deliver further relief to families across the country.

AARP thanks the Senate Aging Committee for your efforts to focus on ensuring older Americans have access to the medications they need to stay healthy. If you have any additional questions, feel free to contact Gidget Benitez on our Government Affairs team.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

American Society of Health-System Pharmacists (ASHP) Statement

September 17, 2025

The Honorable Chairman Rick Scott
The United State Senate
Special Committee on Aging
G 16 Dirksen Senate Office Building
Washington, DC 20510-6050

The Honorable Ranking Member Kirsten Gillibrand
The United State Senate
Special Committee on Aging
G 16 Dirksen Senate Office Building
Washington, DC 20510-6050

Re: ASHP Statement on the Senate Special Committee on Aging hearing, entitled, "*Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans*."

Dear Chair Scott and Ranking Member Gillibrand:

Thank you for holding this hearing on the status and root causes of generic drugs shortages and their impacts on America's seniors. The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies.

Generic drug shortages affect American seniors whether they are seeking critical lifesaving care in inpatient and outpatient facilities or simply trying to pick up medications at their community pharmacies. These shortages include sterile fluids used for injection or irrigation, and critical oncology drugs, such as cisplatin, carboplatin, methotrexate, and vinblastine — medications commonly used by seniors. While these drug shortages may be attributed to multiple factors, the root causes can be directly linked to economic factors that erode the resilience of the supply chain. We appreciate the committee's commitment to strengthening the generic drug supply chain.

ASHP's Role in Addressing and Managing Drug Shortages: Our members manage drug shortages in health systems and pharmacies throughout our nation's supply chain. We use public submissions, in conjunction with the University of Utah Drug Information Service, to maintain a drug shortage list that tracks drug availability across the nation. Information submitted is verified with drug manufacturers before it is posted on the ASHP Drug Shortages List. Drug shortage information gathered is also shared with the Food and Drug Administration (FDA). We list every drug shortage reported on our drug shortage database as soon as it is investigated and confirmed, usually within 24-72 hours.[1] We also provide practitioner-focused resources to help the healthcare community manage shortages. Examples include information on unapproved drugs and unlabeled uses (when well-researched and reported to be safe and effective); recommendations for therapeutic alternatives; drug-to-drug comparisons and comparisons within individual drug classes; and safety recommendations.

[1] https://www.ashp.org/drug-shortages/current-shortages

Status of Drug Shortages: As of the second quarter of this year, the number of active drug shortages is 253.[2] While this is the lowest number since early 2022, and down from an all-time high of 323 in the first quarter of 2024, it remains abnormally high and indicates that seniors' access to medications may be at risk. Certain trends warrant highlighting. Drugs in shortage are primarily older, generic medications which are well established and commonly used by seniors. Patients with chronic pain are also struggling to fill prescriptions for oral opioids due to ongoing shortages. Most of these medications are low-cost generics, such as sterile injectable generic drugs used in hospital procedures with major impacts on patient care. These medications have no alternatives, forcing hospitals and clinicians to ration medication or even delay care. What is clear from the data is that while medication shortages are slightly improving, it is the low-cost generic drugs, typically used widely, that are the bulk of drugs that remain in shortage, and are likely to remain so unless policy changes are undertaken.

Underlying Causes of Generic Drug Shortages: While spikes in demand can cause short-term drug shortages, the most severe and persistent shortages are driven by economic factors that undermine investment in manufacturing capacity, manufacturing quality,[3] and supply chain reliability. These economic challenges are driven by extreme price competition among generic manufacturers. For example, the lower profitability of generic drug manufacturing has caused companies to completely stop manufacturing certain less-profitable drugs.[4] To effectively address drug shortages, the United States needs to focus on the key drivers of generic drug shortages, including manufacturer reliability and supply chain issues and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generic drugs.

Impact of Generic Drug Shortages on Seniors: Seniors are particularly vulnerable to drug shortages due to their higher prevalence of chronic conditions that require consistent and ongoing treatment.[5] Furthermore, due to their higher risk of hospitalization, they are particularly vulnerable to shortages of commonly used generic drugs in hospitals, particularly sterile, injectable generics used during medical procedures. A 2023 Office of the Assistant Secretary of Health and Human Services for Planning and Evaluation report found that the average drug shortage affects at least a half a million consumers, and that a disproportionate amount; more than two thirds of those impacted, were consumers ages 65 to 85 (32 percent), 55 to 64 (24 percent) and 45 to 54 (17 percent) [6] Addressing the economics of the generic drug supply chain will help ensure seniors' healthcare is not disrupted.

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[2] ASHP - National Drug Shortages Report (Q2 - 2025)
[3] https://news.nd.edu/news/extreme-price-competition-in-pharmaceutical-industry-may-put-patients-at-serious-health-risk-study-shows
[4] https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg
[5] https://www.cdc.gov/nchs/data/hestat/hestat105.htm
[6] https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs#:~:text=Drug%20shortages%20impact%20consumers%20through,to%2054%20(17%20percent).

Recommended Solutions: To effectively address drug shortages and protect seniors' access to care, we strongly urge policymakers to focus on the key drivers of generic drug shortages — quality and supply chain issues that enable more clarity in purchasing based on quality and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generics.

ASHP has developed the following recommendations designed to directly address the root causes of generic drug shortages which can be applied to both foreign and domestic manufacturers:

Improve Transparency into Manufacturer Quality to Enable Purchasing Based on Quality as Opposed to Cost: Healthcare providers and pharmacies currently have very little ability to select manufacturers based on the reliability of their supply chain. This lack of transparency undermines their ability to source products from the most reliable manufacturers.

- We recommend that FDA finalize, and make public, metrics of quality manufacturing maturity (QMM), so that purchasers can buy from manufacturers less likely to experience a shortage.
- In the absence of publicly reported QMM metrics, we recommend FDA make unredacted manufacturing inspection reports publicly available so that purchasers have a better understanding of supplier manufacturing challenges, and what products are made at facilities with a history of manufacturing quality and compliance problems.

Encourage New Manufacturers and New Manufacturing Sites: Entering the market to manufacture a generic drug is a multi-year process that requires investment in scientific, manufacturing, and regulatory functions. This makes it difficult for new manufacturers to enter the market and increase supply when shortages occur.

- We recommend that FDA waive generic drug user fees for generic drugs described in 506C(g) of the Federal Food Drug and Cosmetics Act, for which FDA may prioritize and expedite review of an abbreviated new drug application (ANDA) or related supplement to mitigate a shortage. This fee waiver should apply only to manufacturers that commit to promptly market their generic drug if it is approved.

Enforce Existing Shortage Prevention Requirements: Congress previously passed legislation requiring manufacturers to report information about their manufacturing and supply chains to the FDA and to develop risk management plans to help prevent disruptions to drug manufacturing. FDA has raised concerns that manufacturers have failed to provide this information for more than 4,000 manufacturing facilities — greater than half of registered facilities.[7] This disregards Congress' intent, increases the risk of manufacturing disruptions, and prevents FDA from responding to shortages.

- We recommend Congress amend section 510(j) of the Federal Food, Drug, and Cosmetics Act to include meaningful penalties for manufacturers that fail to develop risk management plans or report manufacturing and supply chain data as required by this section.

[7] https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-20230511-SD006.pdf

Encourage Long-Term, Guaranteed-Volume Contracts: Medicare payment policy for inpatient and provider-administered generic drugs, particularly inclusion of inpatient drug costs in diagnosis-related groups (DRGs) and the absence of a mechanism to evaluate quality, leaves healthcare providers with cost as the differentiating attribute when making purchasing decisions. This encourages healthcare providers and their group purchasing organizations (GPOs) to aggressively negotiate the price of generic drugs. To encourage greater investment in manufacturing capacity and quality, both in the United States and abroad, federal policy should provide manufacturers of critical generic drugs who make this commitment with greater certainty of their ability to recover their investment and receive purchase volume for these products. Such policy should also give healthcare providers certainty that they can rely on the manufacturer to provide a particular level of supply for the term of the contract.

- We recommend that the Centers for Medicare & Medicaid Services provide an add-on payment to providers for critical generic drugs determined by the U.S. Department of Health and Human Services (HHS) to be at risk of experiencing a shortage if those providers certify that they have entered a contract to acquire at least 50% of their historical purchase volume for those products via long-term contracts.
    - To ensure manufacturers invest in supply chain stability and quality, the contract must include a requirement that the manufacturer will maintain a six-month buffer supply of finished product, and include meaningful penalties for failure to supply contracted products, including when manufacturing disruptions result from regulatory violations or supplier disruptions.
    - To receive add-on payments, providers must ensure that they enter long-term supply contracts with manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[8]
    - Providers and manufacturers could attest to meeting these requirements rather than providing proprietary contract information to HHS.
    - Providers should be free to delegate long-term supply contracting to their GPO to meet these requirements.
    - To minimize the administrative burden, add-on payments should be made based on the provider's total Medicare spend on the contracted drug product, rather than requiring per beneficiary accounting for medication use.

Diversify the Manufacturing Base: The federal government should use its purchasing power to ensure that at least a minimum number of manufacturers remain in the market and maintain active manufacturing capacity for critical medications. While this would not prevent any given manufacturer from experiencing a supply disruption, it would increase the likelihood that another existing manufacturer would be able to respond when a shortage occurs.

- We recommend the federal government encourage greater diversity and redundancy in the supply chain by spreading purchase volume from federal agencies across at least three different manufacturers with an approved ANDA for any critical generic drug determined by HHS to be at risk of experiencing a shortage.

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[8] Recommendations from ASHP and other healthcare providers in 2021 called for FDA to make these metrics public. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

- The federal government could leverage its purchasing through the Department of Veterans Affairs, the Department of Defense, the Indian Health Service, the Bureau of Prisons, and the Administration of Strategic Preparedness/the Strategic National Stockpile.
- Federal purchasers should ensure that manufacturers under this program do not rely on the same contract manufacturers, as this would not actually diversify the manufacturing base.
- To ensure manufacturers invest in supply chain stability and quality, the federal contracts must include a requirement that the manufacturer will maintain a six-month buffer supply of finished product, and include meaningful penalties for the failure to supply, including when manufacturing disruptions result from a regulatory violation or supplier disruption.
- Federal agencies should give preference to manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.

Finance Private Sector Buffer Supplies: Encouraging healthcare providers and their distributors to maintain a buffer supply of critical medicines would reduce the impact of manufacturing disruptions on patient care.

- We recommend that the federal government provide low- or no-cost financing to encourage private sector maintenance of a buffer inventory of critical drugs.[9]
  - Providers and distributors should continue to have discretion to determine what products they stockpile.
  - Providers should continue to be free to contract with GPOs, drug distributors, or manufacturers to manage storage and rotation of drugs stockpiled on their behalf.
  - Access to financing should phase in slowly, to minimize the risk of a demand surge that could result in shortages as providers and distributors build their stockpiles.

ASHP thanks you for your efforts to strengthen America's health care supply chain. We look forward to continuing to work with you to ensure American seniors have access to the life-saving medications they need. If you have questions or if ASHP can assist your office in any way, please contact Frank Kolb.

Sincerely,

Tom Kraus
American Society of Health-System Pharmacists

[9] Recommendations from ASHP and other healthcare providers in 2021 called for incentivizing the creation of private-sector reserves of essential medicines, medical devices, and supplies not adequately provided by the SNS. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

Amneal Pharmaceuticals LLC Statement

The Honorable Rick Scott
Chairman Special Committee on Aging
U.S. Senate
Washington D.C. 20515

The Honorable Kirsten Gillibrand
Ranking Member Special Committee on Aging
U.S. Senate Washington D.C. 20515

Re: **Amneal Pharmaceuticals LLC Statement for the Record: United States Senate Special Committee on Aging; Hearing on "Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans," September 17, 2025**

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

I am writing on behalf of Amneal Pharmaceuticals LLC (Amneal), a leading accessible medicines company committed to improving health outcomes and ensuring that medicines remain available to those who rely on them most. We appreciate the opportunity to provide written testimony on behalf of the millions of American patients, particularly seniors, who depend on safe, affordable, and reliable medicines every day.

Amneal is a New Jersey-based integrated pharmaceutical company that provides millions of American patients with access to innovative, affordable medicines. We are powered by a robust generics segment, as well as growing portfolios of biosimilar and branded treatments. We are the leading U.S.-domiciled company that manufactures generics, with approximately 2,500 U.S.-based employees and over 290 Food and Drug Administration (FDA)-approved products on the market today. Amneal has best-in-class in-house generic pharmaceutical development and manufacturing capability, with a network of 16 sites, six of which are in the United States, ensuring patients have access to quality medicines manufactured close to home.

Our mission is to prioritize patient needs by manufacturing innovative, quality medicines that are both accessible and affordable. For the aging Americans on fixed incomes who fill 91% of their prescriptions with generics, a disruption in supply or spike in costs can be devastating. We share the Committee's concern that nearly 75% of America's essential drug supply depends on overseas manufacturers, leaving patients vulnerable to sudden shortages. We also share the Committee's focus on the quality of generic medicines, which must remain paramount. Every patient in each of our families deserves to know that their medicine is safe and effective.

Antibiotics and National Security

We agree with the Committee that the lack of manufacturing capacity is particularly dire for antibiotic active pharmaceutical ingredients (APIs), which directly threaten our national security interests due to China's dominance in their manufacture. Currently, China is responsible for almost 100% of the global antibiotic supply chain of APIs, and key starting materials (KSMs). Data on the top 57 antibiotics used in the U.S. show that >95% of volume comes from abroad. Only 2% of API and less than 1% of finished antibiotic products are manufactured domestically, leaving patients and providers with few alternatives in times of crisis.

Incentivizing a Stable Marketplace for Domestically Manufactured Medicines is Essential to Ensuring U.S. Supply Chain Resilience

While competition among multiple generic manufacturers is the cornerstone of a healthy marketplace, the current generic market disincentivizes robust and resilient competition. The fundamental challenge we face is one of economics and sustainability: U.S. manufacturers cannot sustain or expand operations when forced to compete with overseas manufacturers who benefit from significantly lower production and labor costs, weaker labor protections, and government subsidies.

Policy Solutions for Sustained Domestic Manufacturing

- Amneal believes that Congress must act urgently to re-establish U.S. leadership in generic drug manufacturing. Real, lasting policy must involve sustained, meaningful market-based solutions to retain and expand domestic manufacturing. For example, Congress can pass legislation requiring the federal government to prioritize U.S.-manufactured essential medicines, with CMS conditioning participation on meeting minimum thresholds of domestic sourcing for the most-pressing essential medicines.

Several bipartisan and bicameral bills already before Congress also offer an opportunity to incentivize U.S. generic manufacturing, ensuring it cannot only survive but succeed in the United States for American seniors:

- **The PILLS Act (H.R. 1396, 119th Congress**) (establishing tax incentives);
- **The MAPS Act (S. 1784 / H.R. 4191, 119th Congress)** (strengthening supply-chain transparency and resilience); and
- **The RAPID Reserve Act (H.R. 3955, 119th Congress)** (establishing mid-term strategic reserves of essential generic medicines and critical ingredients).

Together, these policies will do more than strengthen supply chains, they will protect patients. By lowering the cost of essential generics through direct procurement, incentivizing domestic investment, and ensuring long-term stability, Congress can guarantee that seniors and families across the country continue to have uninterrupted access to the medicines they depend on.

In closing, Amneal believes that a comprehensive approach, combining long-term market incentives and bipartisan/bicameral legislation such as the PILLS Act, MAPS Act, and RAPID Reserve Act, will ensure that patients always have access to safe, affordable, and domestically manufactured medicines. We are committed to playing an active role in these efforts and collaborating with Congress and other stakeholders to safeguard patient access and ensure the resilience of America's healthcare system.

Thank you for your continued attention to this critical issue and for the opportunity to provide input. Please contact me with any questions or requests for additional information.

Sincerely,

Maryll W. Toufanian
Senior Vice President – Regulatory Strategy and Government Affairs
Amneal Pharmaceuticals LLC

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

Association for Accessible Medicines Statement

Association for Accessible Medicines
Statement for the Record
United States Senate Special Committee on Aging
Hearing on "Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"
September 17, 2025

The Honorable Rick Scott
Chairman
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

The Honorable Kirsten Gillibrand
Ranking Member
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

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

AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Our members provide more than 36,700 jobs at nearly 150 facilities and manufacture more than 61 billion doses in the United States.[1] AAM's core mission is to improve the lives of patients by advancing timely access to safe, affordable and high-quality generic and biosimilar medications.

Patient safety is the number one priority for AAM and its member companies. Generics and biosimilars are just as safe and effective as their brand-name drug counterparts. Through its rigorous approval process, manufacturing regulations, and continuous inspections of manufacturing facilities, FDA ensures that "medicines at all

[1] AAM, State Advocacy (available at https://accessiblemeds.org/advocacy/state-advocacy/#:~:text=What%20is%20the%20economic%20impact,Model%20B (last visited Sept. 20, 2025)).

levels of the supply chain, from active pharmaceutical ingredients (API) to the finished product sold to consumers at the pharmacy counter are safe, effective and high quality."[2]

As a result of FDA oversight and the daily commitment to quality from AAM's member companies, the U.S. has one of the safest and most resilient drug supply chains in the world.

It is also important to emphasize that generics and biosimilars are part of the same global pharmaceutical supply chain as that for brand-name drugs. And the scrutiny applied to the manufacturers of generic and biosimilar medicines must also be applied to the manufacturers of brand-name pharmaceuticals. We strongly encourage the committee to take a comprehensive and inclusive approach in its examination of the pharmaceutical supply chain.

In examining the pharmaceutical supply chain, one must also consider the underlying economic realities of the generic and biosimilar markets. Prices for generic drugs are plummeting and creating a market in which many drugs are simply not economical to manufacture given low margins and business unpredictability. As Richard Saynor, CEO of Sandoz told the Wall Street Journal, "You sell a packet of antibiotics more cheaply than a packet of M&M's.[3] Moreover, the biosimilars market is relatively nascent, with only 67 launched products and 84 FDA-approved biosimilars licensed for only 21 Reference Products. Biosimilar manufacturers are increasingly looking to provide Europe's patients with access first, rather than the U.S., due to the barriers to competition and use domestically.[4]

In the retail generic drug market, three buying groups account for nearly 80% of drug purchases.[5] Similarly, three major players dominate purchases for hospitals, accounting for at least 80% of that market.[6] In the retail market, there has been extensive vertical integration between wholesale distributors and buying groups with equally consolidated PBMs—another market in which the three largest players (i.e., CVS Health, Optum, and Express Scripts) control roughly 80% of the market. In some cases, all of these groups

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[2] Statement from FDA Commissioner Scott Gottlieb, M.D., and Director of FDA's CDER Janet Woodcock, M.D., "FDA's continuing efforts to maintain its strong oversight of generic drug quality issues domestically and abroad," February 2019.
[3] Jared Hopkins, WSJ, June 17, 2025.
[4] Biosimilars Council, "Failure to Launch: Barriers to Biosimilar Market Adoption," September 2019; Alana Hippensteele, EU Leads in Biosimilar Market Access While US Lags Behind, Faces Challenges in Adoption, Pharmacy Times, June 29, 2024.
[5] Letter from AAM to Chair Fed. Trade Comm'n and Sec'y U.S. Dep't of Health and Human Servs., re: Request for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages, May 2024 at 2 (available at https://accessiblemeds.org/wpcontent/uploads/2024/11/AAM-Response-to-FTC-HHS-RFI-on-Drug-Shortages-5-30-2024.pdf).
[6] *Id.* at 3.

share financial and referral relationships, effectively owning the entire drug distribution channel. Studies have increasingly found that generics have recently experienced slower adoption than normal based on PBM behavior, with PBMs preferring high-priced drugs with high rebates over lower- list priced generics.[7]

This consolidation has enabled buyers to exert downward pricing pressure resulting in extremely low profit margins and one-sided contract terms including "most-favored-nation" clauses. These clauses allow a buyer to terminate a generic manufacturer's contract if a competitor in China, for example, can underprice by one cent, without regard to whether that Chinese competitor is a reliable supplier. This has driven purchases to the lowest cost producers, creating long-term disincentives for U.S. investments in manufacturing capacity.

With this in mind, we understand why the committee would be concerned about information that paints a distorted picture of a global supply chain that is heavily reliant on China, India, and other countries for API.[8] As detailed below, the US generic supply chain is strong and resilient.

Generics and Biosimilars Are Integral to Patient Health

Generic medicines play an integral role in health care and enhance patient access to life-saving treatments. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price result in significant savings for patients and the health care system. Over the last 10 years, generic manufacturers have delivered savings of nearly $3.4 trillion—including $467 billion in 2024 – to patients and the health care system.[9]

Biosimilar medicines represent another critical step forward in reducing high drug prices. Biosimilars are safe, effective and more affordable versions of costly brand biologics. Currently, between 25 and 40 percent of drug approvals are biological products.[10] Experts estimate that FDA-approved biosimilars could save more than $180 billion over the next 5 years.[11]

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[7] AAM, Middlemen Increasingly Block Patient Access to New Generics, Association for Accessible Medicines," Jan. 2023 (available at https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Middlemen-Block-Patient-Access-New-Generics-2023-1.pdf).
[8] *See* USP, Medicine Supply Map (available at https://www.usp.org/supply-chain/medicine-supply-map (last visited Sept. 20, 2025))
[9] AAM, "Generic & Biosimilar Medicines Savings Report 2025," Sept. 2025.
[10] de la Torre BG, Albericio F. The Pharmaceutical Industry in 2023: An Analysis of FDA Drug Approvals from the Perspective of Molecules. Molecules. 2024 Jan 25;29(3):585.
[11] IQVIA, "Biosimilars in the United States 2023–2027," January 2023.

The introduction of generic and biosimilar competition significantly reduces the price of medicine, and patients benefit from greater, more affordable access to FDA-approved drugs. Experience shows prescription drug prices decline by more than 40 percent the first year that generics enter the market.[12] However, these savings are only possible because of the scrupulously maintained commitment to quality, safety and efficacy throughout the generic drug supply chain.

FDA's Oversight of the Pharmaceutical Supply Chain

FDA ensures all pharmaceuticals meet the same high-quality standards regardless of where brand-name drugs, generics and biosimilars are manufactured. All drug products, including biologics, whether generic or brand, must be manufactured in accordance with rigorous regulatory requirements that mandate high levels of diligence, and accompanying documentation.[13] Governmental mandates cover each of the following areas:

- Acquisition of raw materials and drug packaging components, including audits by manufacturers of suppliers of critical ingredients;[14]
- Testing of active ingredients using qualified equipment and validated methods;[15]
- Manufacturing equipment and facilities that have been constructed and maintained to provide sanitary conditions and to protect against contamination;[16]
- Appropriate and documented training of manufacturing personnel;[17]
- Validation of manufacturing processes to ensure that they consistently produce safe, effective, and uniform drug products;[18]
- Thorough contemporaneous documentation of each manufacturing step, with oversight by an employee other than the operator for significant manufacturing steps;[19]
- Taking samples of drug products during the manufacturing process at predetermined intervals, and testing the samples for potency and, where appropriate, sterility;[20]

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[12] AAM, "Generic & Biosimilar Medicines Savings Report 2025," Sept. 2025.
[13] 21 Code of Federal Regulations ("CFR") Parts 210, 211, 600-680; Inspection of Biological Drug Products, FDA Compliance Program Guidance Manual, Chapter – 45 Biological Drug Products, Section 7345.848 (available at https://www.fda.gov/media/73834/download).
[14] 21 CFR §211.184.
[15] 21 CFR §211.84.
[16] 21 CFR §§211.42, 211.56 (facilities); 21 CFR §§211.65, 211.67, 211.182 (equipment).
[17] 21 CFR §211.25.
[18] 21 CFR §211.100.
[19] *Id.,* 21 CFR §§211.101(c), 211.180(a), 211.186, 211.188(b).
[20] 21 CFR §211.110.

- Rigid controls over labels placed on drug containers, to ensure the correct labels are placed on every package;[21]
- Thorough testing of drug products before packaging to ensure that they are free of microbial contamination or other defects, and that they meet tight specifications for uniformity, potency and lack of impurities;[22]
- Retention of samples of all manufactured batches of drug products;[23]
- Routine stability testing to ensure that drug products, including biologics, will remain safe and effective for the duration of their shelf lives;[24]
- Release of each batch of drug products for distribution only upon review of all batch records and testing data by a quality unit that is independent of manufacturing personnel;[25]
- Continuous oversight by management and regular audits by an independent quality unit of the manufacturer or outside consultants;[26]
- Rigorous documentation of every step in the storage and distribution of manufactured drug products;[27] and
- Prompt reporting to FDA and thorough investigation of any complaints about distributed products, or any reports that products that may have failed to remain safe and effective.[28]

When FDA finds deviations from the strict standards of production, FDA can sanction manufacturers by pressuring manufacturers to recall products,[29] by issuing public Warning Letters,[30] by imposing import alerts barring the admission into the United States of violative Active Pharmaceutical Ingredients or finished drug products,[31] by seeking court orders suspending distribution of drug products until FDA approves resumption of operations,[32] and by pursuing criminal prosecution of individuals and companies.[33] FDA does not hesitate to exercise these powers, imposing sanctions not only where products are determined to be defective, but when FDA believes that the system of manufacturing is insufficient to guarantee that all drug products are safe, effective, and uniform.

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[21] 21 CFR §§211.122, 211.125, 211.130, 211.134.
[22] 21 CFR §§211.113, 211.165, 211.194.
[23] 21 CFR §211.170(b).
[24] 21 CFR §211.166.
[25] 21 CFR §§211.22, 211.142, 211.167, 211.192.
[26] 21 CFR §211.180(e),(f).
[27] 21 CFR §§211.150(b), 211.196; Drug Supply Chain Security Act, 21 U.S.C. 351 *et seq.*
[28] 21 CFR §211.198.
[29] Drug Recall database (available at https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls).
[30] Warning Letter database (available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters).
[31] Import Alert database (available at https://www.fda.gov/industry/import-alerts/search-import-alerts).
[32] 21 U.S.C. §332.
[33] Speech by FDA Commissioner Scott Gottlieb, M.D. (11/14/17) (available at https://www.fda.gov/news-events/speeches-fda-officials/remarks-fda-office-criminal-investigations-meeting-11142017).

Indeed, contrary to the assertions at the hearing, FDA can and does use its enforcement authority to address violative products coming into the U.S. market from abroad. On September 19, 2025, for example, FDA updated its Import Alert list for drug products that have not met cGMPs, with hundreds of companies subject to detention without physical examination.[34] And FDA has been assiduously issuing Warning Letters, with one issued to a Chinese company based on a 2025 inspection as recently as June 2025 and another in August 2025.[35]

The Generic Industry Has Funded Foreign Inspections Through GDUFA

The Generic Drug User Fee Amendments (GDUFA) of 2012 and reauthorizations in 2018 and 2023 included a $4 billion commitment from the generic drug industry.[36] One of the reasons that industry (especially AAM's predecessor, the Generic Pharmaceutical Association) requested the imposition of fees was the imbalance between frequency of inspections for domestic manufacturers and foreign manufacturers, especially those in China and India. Statistics at the time showed that large generic drug manufacturers in the United States could expect to be inspected by FDA once every two to three years, while even large Chinese and Indian manufacturers supplying huge quantities of prescription drugs distributed in the United State were inspected, if at all, on an average of less than once every ten years.

GDUFA has significantly increased and continues to augment the funding of FDA's generic drug review and inspection programs. GDUFA substantially increased FDA's review capacity and the frequency of inspections. FDA hired nearly 1,200 employees to strengthen oversight and 120 additional employees were added in FY 2023 as a result of GDUFA III.[37] Indeed, GDUFA fees and the foreign drug manufacturer inspections by FDA that the fees enable have dramatically changed where FDA has taken enforcement actions, including import alerts that can completely shut down imports from a troubled plant overseas. Up until about 2012, the majority of FDA Warning Letters relating to manufacturing violations issued to mainstream drug manufacturers were issued for inspections at facilities located in the United States. In 2011, for instance, 45% of FDA Warning Letters for drug manufacturing violations were issued based on inspections of facilities outside the United States. In FY2024, 61% of such Warning Letters were issued

[34] IA 66-40 (Sept. 18, 2025).
[35] FDA, Warning Letter to Zhejiang Huahai Pharmaceutical Co., Ltd. (June 6, 2025); FDA, Warning Letter to Anhui Hanbon Daily Chemical Co., Ltd. (August 11, 2025).
[36] FDA, Five-Year Financial Plan for the Generic Drug User Fee Amendments, 2018; AAM, GDUFA and BSUFA User Fees, https://accessiblemeds.org/advocacy/gdufa-bsufa-user-fees/#:~:text=After%20more%20than%20a%20decade,approved%20generic%20and%20biosimilar%20medicines (last visited Sept. 20, 2025).
[37] FDA, FY2024 Performance Report to Congress for GDUFA, June 2025.

to facilities located outside the United States.[38] In other words, the uptick in enforcement sanctions against drug manufacturing facilities outside the United States is directly attributable to an increase in the number and aggressiveness of FDA inspections.

The FDA utilizes a risk-based inspection strategy, established under the GDUFA I Commitment Letter, to maintain a robust inspections footprint around the world, including in China and India. In recent years, the FDA has established offices in China and India as a result of funding from the GDUFA user fee program. The FDA's global inspection efforts focus on higher risk facilities to prevent, uncover and combat data integrity issues and manufacturing problems. Using a risk-based site selection surveillance inspection model, the FDA prioritizes domestic and foreign inspections based on multiple factors carefully selected to appropriately target the agency's resources.

In fiscal year 2024, the FDA conducted 774 inspections of generic drug manufacturing facilities in the U.S. and around the world.[39] This includes 570 international inspections and 204 domestic inspections. In addition, FDA has mutual recognition agreements (MRAs) with the European Union (EU), SwissMedic, and the United Kingdom (UK) that allow drug inspectors to rely upon information from drug inspections conducted within each other's borders.

Meanwhile, AAM and its members remain committed to ensuring FDA continues to have the resources to perform thorough inspections of facilities that manufacture all medicines approved in the United States.

Our Industry's Commitment to Quality and Patient Safety

As noted, patient safety is the number one priority for AAM and its member companies. AAM's members adhere to a Code of Business Ethics and the "Safety of Medicines" is its first principle.[40] Every AAM member company pledges to "conform to high standards of quality, safety and efficacy as determined by regulatory authorities in each economy in which they operate."[41] This commitment to quality, safety and efficacy applies regardless of where medicines are manufactured.

Chairman Scott expressed concern about quality and safety of generic drugs and, as one example, referenced Indian eye drops that caused bacterium that killed patients. He also referenced contaminated heparin from 2007-08. There are over 200 manufacturers of

[38] FDA, FY2024 Report on the State of Pharmaceutical Quality, September 2025.
[39] FDA, FY2024 Performance Report to Congress for GDUFA, June 2025.
[40] AAM, Code of Business Ethics, March 2018.
[41] Ibid.

generic products and, importantly, these products were not manufactured by AAM member companies.

Patients should know and be confident in the quality of the generic medicines prescribed and picked up at the pharmacy. Generics and biosimilars are just as safe and effective as their brand-name drug counterparts. Independent research consistently demonstrates the clinical equivalence of generic medicines compared to the brand-name drug.[42]

Patients can trust the safety and effectiveness of generic medicines. And it is important that patients take their medicines as prescribed by their physicians. While it is not always possible to combat the misinformation that exists, we encourage lawmakers to avoid, to the extent possible, repeating and sometimes promoting inaccurate information on quality. Additionally, and as FDA has emphasized, not taking one's medicine as prescribed by a doctor or as instructed by a pharmacist, due to unsubstantiated claims on quality, could prolong a patient's disease or lead to worse health outcomes.

Moreover, FDA provides regulatory oversight of the manufacturing of generic and biosimilar medicines. Manufacturing facilities located overseas, as well as in the U.S., are routinely inspected by the FDA to ensure the medicines are of the highest quality for patients. A standardized, transparent and dynamic system is in place and is working for doctors, pharmacists and patients.

Indeed, between 2022 and May 2024, FDA conducted 94 unannounced pilot inspections in India and, between 2023 and 2024, 16 in China.[43] In FY 2024, 12% of foreign inspections were unannounced.[44] A new policy is in place that is expected to significantly increase such visits.[45]

Quality is Standard

Exacting standards ensure the reliability of the medicines we take. These standards make it possible for us to trust that a pill dispensed from a pharmacy in Oregon in the spring will match, in every way that matters, a pill picked up at a drug store counter the following winter in Miami.

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[42] FDA, Generic Drugs: Questions & Answers, June 2018.
[43] NSF, US FDA: Expanded use of unannounced inspections outside of the USA, May 6, 2025 (available at https://www.nsf.org/au/en/life-science-regulatory-news/us-fda-expanded-use-of-unannounced-inspections-outside-of-the-usa).
[44] Public Meeting on Reauthorization of GDUFA IV, July 11, 2025.
[45] FDA, FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities, May 2025.

Dr. Jeremy Greene, professor of medicine and the history of medicine at Johns Hopkins University and author of *Generic: The Unbranding of Modern Medicine*, explained in a recent interview with United States Pharmacopeia (USP):

> "There's a mutual interest among manufacturers, whether they are brands or generics, for establishing and disseminating a public standard that helps us determine if a drug is what it says it is."[46]

The various stakeholders – health care professionals, industry, and government – that keep our drug supply safe agree upon the standards, and USP publishes the methods that manufacturers and regulators can employ to demonstrate that medicines are what they should be. These standards apply to a drug's molecular structure, and to the amount of active and inactive ingredients it contains to ensure a drug's efficacy and safety.

USP strives for comprehensive standards, which is no small task. As detailed by Dr. Ronald Piervincenzi's testimony, USP has over 6,000 standards for active pharmaceutical ingredients, drug products, and inactive ingredients used throughout the supply chain[47] Indeed, USP "work[s] with hundreds of scientific experts to set thousands of quality standards for medicines."[48] "USP works to strengthen medicine supply chains to ensure that patients, and especially older Americans managing the chronic conditions, can access the generic medicines they need when they need them, and very importantly, to trust in their consistent quality, low cost generic drugs. . . ."[49] USP's collaborative work with FDA to set drug quality standards for nearly 80 years has made FDA the gold standard worldwide for safety and quality.

Transparency Enhances Quality

All of the links along the supply chain have an obligation to be open and transparent about issues related to safety and quality. This is how the system secures the accountability necessary to earn and retain the trust of the medical profession and, ultimately, the patients.

FDA has a robust around-the-clock program for inspecting pharmaceutical manufacturing facilities worldwide. The Office of Regulatory Affairs (ORA) conducts assessments, inspections, research and surveillance of pharmaceutical manufacturing facilities. AAM's member company manufacturing facilities, all over the world, must be ready for FDA

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[46] Jeremy Greene, "Similarity and difference in the world of drugs," USP, accessed October 2019.
[47] Statement of the U.S. Pharmacopeia, United States Senate Special Committee on Aging (Sept. 17, 2025).
[48] Testimony of Ronald Piervicenzi, United States Senate Special Committee on Aging (Sept. 17, 2025).
[49] *Id.*

inspection whenever they are operating, 365 days a year. Our member companies have established interlocking processes and procedures to ensure the quality and integrity of the medicines manufactured in these facilities.

Generic manufacturers not only readily comply with inspections audits; they also fund this oversight through GDUFA, which support FDA staffing and best practices in protecting public health and accelerating innovation. These fees (totaling over $630 million annually) support timely review of generic drug applications.[50] Foreign as well as domestic companies identify and register all facilities involved in the manufacturing of generics and their active ingredients. BsUFA operates on similar principles.

Reports from the public, health care professionals and the industry of potentially defective drug products help the FDA identify sites for inspection or investigation. Most companies that are inspected are found to be fully compliant with the regulations.[51] In addition, Post-marketing Surveillance Programs are in place to identify adverse events, such as adverse reactions, that did not appear during the drug approval process.

Critics may point to product recalls to draw attention to issues in the supply chain, but we believe the rarity of these events demonstrates the system's effectiveness. Indeed, as noted above, recalls occasionally are required not when a flaw or defect is identified in a product, but when FDA believes that there is inadequate assurance of adequate quality systems at a plant because manufacturing does not strictly comply with the rigorous regulatory requirements. We would also note that while 90 percent of prescriptions filled in the U.S. are generic medicines, generic drugs account for only 56 percent of any prescription drug recalls.[52] Brand products on the other hand account for only 10 percent of prescriptions filled, but 44 percent of the total recalls.[53]

When an issue is discovered, the proper mechanisms are activated and industry works with FDA to appropriately address the issue. In the unlikely event that flawed medication does reach a patient, we should take comfort that all medicines can be traced to the manufacturer. The manufacturer of the product immediately notifies stakeholders in the supply chain, and then pharmacists or physicians reach out to notify patients and to determine alternative prescription options. Obviously, these recalls are widely publicized; transparency contributes to quality.

Innovation is Dynamic

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[50] FDA, "GDUFA III Five Year Financial Plan , FY2025 Version," accessed September 20, 2025.
[51] FDA, "Facts about the Current Good Manufacturing Practices (CGMPs)," June 2018.
[52] FDA database, "Recalls, Market Withdrawals, and Safety Alerts," 2011-18.
[53] Ibid.

FDA and industry are constantly adapting to manufacturing innovations. Current Good Manufacturing Practice (cGMP) regulations address methods, facilities and controls used in manufacturing, processing and packaging. The globalization of the supply chain, which is a fact of life for brand, generic and biosimilar drugs, is often mentioned as a matter of concern, but in fact, the record bolsters confidence in the system. While it is true that so-called fake drugs circulate in developing nations through mail-order and online pharmacies, U.S. regulations, guidance and legislation are in place to minimize the possibility that they could reach our patients.[54] Further, the only additional method of preventing counterfeit or unapproved medications from reaching the United States market would be to rigorously examine and test all incoming parcels and packages that could contain medications, a measure that AAM would wholeheartedly support. Currently, only a tiny fraction of incoming parcels and packages are examined.

These factors ensure patients can take their medications with confidence. Michael Kopcha, director of the OPQ in the FDA's Center for Drug Evaluation and Research (CDER), may have put it best when he said:

> "The quality of our drug supply is better than ever before. There is no difference in the quality of drugs based only on where they are made."[55]

Claims of Carcinogens Are Based on Flawed Testing

The Committee also expressed concerns over carcinogens seen in third-party testing. Over the last several years, a third-party company alleged safety concerns with the medication ranitidine (Zantac). The third party claimed that ranitidine had the potential to degrade into a carcinogen known as NDMA. This claim served as the basis for what became a products liability litigation alleging that Zantac was not safe for consumers. Those assertions, however, were based on flawed testing rejected by a federal judge.

Indeed, Robin Rosenberg of the Southern District of Florida rejected the plaintiffs' case on summary judgment, and in her order, she raised concerns with the third-party testing results on which the plaintiffs' claims were premised. For instance, while the tests found NDMA in ranitidine in excess of 3,000,000 nanograms (ng) (compared to the FDA's guidance limiting NDMA in a drug to 96 ng), Judge Rosenberg concluded that the third-party testing *created* the environment in which NDMA was produced.

Judge Rosenberg explained:

As the Court and FDA observed, "the laboratory equipment that [third party] used to test for NDMA actually *created* NDMA. In other words, [the third party's] laboratory equipment

[54] Fight the Fakes, "US FDA Gives Tips on Spotting Fake Medicines," June 2014.
[55] Michael Kopcha, "CDER Conversation: Assuring Drug Quality Around the Globe," FDA, May 2019.

created the very substance for which it was testing."[56] And, when the FDA conducted its own tests, some of the drug products showed no NDMA or almost no NDMA.[57]

Data Confirms A Resilient Global Supply Chain

We understand why the committee would be concerned about data that paint a distorted picture of the generic supply chain. We wish to provide the Committee with more accurate analysis of the global location of where generic finished product manufacturing facilities and API facilities are located.

USP data assess U.S. dependence on foreign API. Its Medicine Supply Map shows that a significant number API DMFs originate outside of the U.S..[58] While not all drug products utilize APIs referencing DMFs, the geographic analysis of DMFs can provide a perspective on where API manufacturing is trending:

API DMF Facilities

- 48 percent of the API DMF facilities are located in India and 16 percent in China.
- 17 percent of API DMF facilities are located in the EU.
- 10 percent of API DMF facilities are located in the U.S.

USP also looked at FDF based on its Medicine Supply Map and IQIVIA data and found that very little FDFs are from China. Most FDF manufacturing occurs in the U.S.:

FDF Facilities

- 31 percent of the manufacturing footprint for FDF facilities are located in India and 2 percent in China as of 2024.
- Overall, 38 percent of the manufacturing footprint for FDF facilities are located in the U.S. and 62 percent are located outside of the U.S.

Considering this analysis of USP data, it is important to accurately depict where API DMF FDF facilities are located.

Conclusion

Patients can and should trust in the safety and effectiveness of generic medicines. The FDA ensures all pharmaceuticals meet the same high-quality standards regardless of

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[56] *Zantac*, 644 F. Supp. 3d at 1092.
[57] *Id.*
[58] USP, Global manufacturing capacity for active pharmaceutical ingredients remains concentrated, November 6, 2024.

where medicines are manufactured. Globalization of the supply chain – a market reality for brand-name drug companies and generic and biosimilar manufacturers – is often mentioned as a matter of concern, but the record in fact should bolster confidence in the system. FDA's oversight and the daily commitment to quality from AAM's member companies has resulted in the U.S. having one of the safest drug supply chains in the world.

There are, of course, a number of steps this committee can take to address the very real sustainability challenges facing generic and biosimilar manufacturers. The first is to do no harm and avoid policies that further exacerbate the problem. This includes:

- **Fix the Medicaid Generics Penalty.** The Medicaid Generics Penalty threatens the viability of low-cost generics who are now subject to additional rebates even when the generic drug price does not increase. These unpredictable, onerous penalties on often low-margin medicines create significant risk for manufacturers.
- **Immediately Enact Interchangeability and Q1/Q2 Transparency.** Currently, biosimilar uptake and generic development is delayed by the additional testing and guess work necessary to demonstrate "sameness." By alleviating these burdens in development, uptake of lower-cost follow-ons would occur more rapidly, decreasing the costs for consumers.
- **Enact meaningful patent reform that caps the number of duplicative patents that can be asserted.** Currently, patent litigation—particularly in the biosimilar space—is inundated with duplicative or "double" patents. Congress should enact legislation cabining patent litigation and requiring brands limit their assertions. The lesser the burden of patent litigation on generic and biosimilar manufacturers, the more access to affordable medicines is possible.
- **Direct the Federal Trade Commission (FTC) and Department of Justice (DOJ) to investigate and issue new guidance on anticompetitive monopsony practices by group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs).** This would address onerous contract terms and race-to-the bottom pricing in the generic industry.

We would also be glad to discuss proactive measures the committee could consider to strengthen the generics and biosimilars markets.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

Indian Pharmaceutical Allicance (IPA) Statement

Statement for the Record

United States Senate Special Committee on Aging Hearing
"Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"
Hearing Date: September 17, 2025
Response Statement: Indian Pharmaceutical Alliance

The Honorable Rick Scott
Chairman
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

The Honorable Kirsten Gillibrand
Ranking Member
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

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

The Indian Pharmaceutical Alliance (IPA), representing the world's leading global generic manufacturers, submits these comments to the Senate Special Committee on Aging in response to the September 2025 hearing, *"Drug Safety and Supply Chain Risks to Aging Americans."* We share the Committee's commitment to ensuring America's seniors have uninterrupted access to safe, affordable, and high-quality medicines.

Executive Summary: Over the last decade, India's pharmaceutical industry has undergone a profound transformation. FDA's most recent *State of Pharmaceutical Quality* reports confirm that Indian facilities perform on par with U.S. and global peers in inspection outcomes. This progress has also been validated independently: in April 2025, DoD-funded Valisure testing found nearly two-thirds of generics scored "Green" (highest quality), with several Indian suppliers achieving a perfect score of 100 -- equal to or better than U.S. peers. These findings underscore what FDA and IPA's decade of collaboration has built -- a culture of continuous quality improvement and regulatory alignment.

IPA members also have welcomed stronger FDA oversight, including unannounced foreign inspections, neutral translators, and even the establishment of an FDA inspection office in India steps -- that ensure transparency and parity with U.S. facilities. IPA members also support country-of-origin disclosure, already required under U.S. law and reinforced by Executive Order 14293 (May 2025), provided implementation is phased and risk-based to avoid disruptions.

The tremendous impact of the U.S.- India partnership on America's healthcare system is clear. Indian generics saved American patients and the healthcare system an estimated $219 billion in 2022 along; and between 2013 and 2022, Indian generics contributed more than $1.4 trillion in cumulative U.S. savings. These contributions demonstrate that IPA members -- most which are global companies -- are trusted partners embedded in America's healthcare system.

Lastly, IPA and the U.S. government share the same national security imperative: ensuring resilient, affordable, and secure access to generic medicines. For over a year and half -- well before tariff debates began -- IPA has advanced a concrete partnership proposal titled, U.S.–India Affordable Medicines Partnership (AMP) for API/KSM joint investment, production and stockpiling to drive security and supply chain resilience. These efforts reflect a long-standing commitment to work with the U.S. government as a strategic ally.

I. IPA GLOBAL COMPANIES WITH STRONG U.S. FOOTPRINTS

IPA's leading members are global pharmaceutical leaders with deep and growing roots in the U.S. These companies are indispensable to the security and resilience of America's healthcare system and are fully embedded in the U.S. economic and regulatory fabric.

IPA members rank among the top manufacturers of generics in the U.S. by prescription volume, directly underpinning access for millions of American patients. They have made significant investments in U.S. operations, operating 31 FDA-approved facilities across 14 states. These companies generate substantial direct employment for American workers, and create wider supply chain and community level jobs nationwide. These facilities manufacture a wide range of critical medicines in the U.S. -- from oral solids and injectables to inhalation therapies and complex generics -- helping to address shortages and ensuring a secure domestic supply.

The U.S. footprint of IPA members is expanding, strategic, and aligned with community development and national security goals. These are not foreign manufacturers looking in from the outside — they are global companies already integrated into U.S. healthcare system, and to drive better health for their communities and patients they serve. They employ American workers, follow U.S. law, operate FDA-inspected facilities, and supply half of the affordable medicines on which 9 out of 10 prescriptions in America depend.

By recognizing IPA members for what they are - **trusted partners with significant U.S. footprints** - policymakers can shift the conversation from outdated stereotypes to the reality of a resilient, deeply integrated supply chain that strengthens both U.S. healthcare and U.S. national security.

II. CORRECTING THE RECORD.

Much of the testimony presented at the September 2025 hearing relied on outdated narratives that no longer reflect the state of Indian pharmaceutical manufacturing. Fraud cases like Ranbaxy's DOJ settlement date back more than a decade to 2013. The question is not where a company is based, but whether it complies. When it does not, FDA already has the tools- - and IPA supports strong enforcement against any firm, brand or generic, U.S. or overseas.

Since then, India's manufacturers doing business in the U.S. have fundamentally reformed their systems, and invested heavily in compliance and quality infrastructures, ushering in a new era of transparency and accountability. At the same time, FDA oversight is much stronger. In May 2025, the FDA announced the expanded use of unannounced foreign inspections, eliminating the perception of unequal standards abroad. IPA companies have not resisted this change; on the contrary, they have welcomed unannounced inspections, supported the use of neutral translators, and endorsed the establishment of a permanent FDA inspection office in India. These steps ensure parity with U.S. oversight and affirm industry's commitment to full transparency.

The results are visible in the data. FDA's most recent *State of Pharmaceutical Quality* reports demonstrate that inspection outcomes for Indian facilities are now on par with U.S., EU, and other global peers, underscoring that quality is not a function of geography but of systems and oversight. This progress has been confirmed by independent validation as well: in April 2025, DoD-funded Valisure (3rd party laboratory) phase I testing found that nearly two-thirds of generics scored "Green" (highest quality), with several Indian suppliers achieving a perfect score of 100 -- equal to or better than U.S. manufacturers.

It is also worth clarifying that the eye-drop incident cited is one of incident during testimony involved a product never intended for the U.S. market and therefore outside FDA jurisdiction. This underscores the importance of strengthening India's domestic infrastructure for safety and quality — a process already underway — with FDA playing a supportive role.

Finally, transparency around origin is already the law of the land. Under long-standing CBP regulations, imported prescription drugs must declare their country of origin on the outermost container. In May 2025, Executive Order 14293 went further, directing FDA to enforce API source reporting and consider public disclosure of noncompliant facilities. IPA supports these new labeling requirements.

Together, these facts establish a clear record: the outdated fraud narrative no longer reflects today's reality. India's pharmaceutical sector operates under robust oversight and welcomes transparency. IPA members meet the same stringent FDA requirements as any manufacturer doing business in the U.S. When companies - whether the be brand or generic -- anywhere in the U.S. and world fail to meet those standards, enforcement action is the appropriate remedy. The issue is not geography but ensuring consistent oversight and accountability across the entire supply chain.

From 2013 to 2025: A Decade of Transformation in IPA–FDA Collaboration

Year / Event	Details
2013 – DOJ Settlement (Ranbaxy)	🔴 Settlement for data falsification and manufacturing violations. 🔴 Symbol of a 'problem era' that placed Indian pharma under scrutiny. ➡️ Catalyst for reform across the industry.
2015 – Launch of Global Pharma Quality Summit (GPQS)	🟢 IPA establishes dedicated Quality Forum to embed quality excellence and improve quality culture. 🟢 25,000+ professionals trained; 20+ best practice guides published. 🟢 Regular engagement with FDA, USP, EDQM, MHRA WHO, and regulators worldwide.
2015–2024 – A Decade of Measurable Improvements	🟢 50% reduction in FDA OAI outcomes for Indian facilities. 🟢 27% reduction in EMA noncompliance rates.

	● India now leads globally with 752 FDA-approved facilities, 2,050 WHO-GMP and 286 EDQM-certified plants.
2025 – Independent Validation & U.S. Policy Alignment	● Valisure/DoD testing: ~⅔ of generics rated 'Green'; Indian firms among those scoring 100. ● FDA Quality Report: Indian plants perform on par with global peers. ● Executive Order 14293: Country-of-origin & API source transparency now mandatory; IPA supports phased rollout.

Takeaway: In 2013, Indian pharma was under heavy scrutiny. By 2025, after a decade of IPA–FDA collaboration, regulatory reform dedicated focus on quality excellence and more, Indian companies are global players, fully embedded in U.S. supply chains, validated for quality, and essential to America's medicine security.

III. A DECADE OF IPA–FDA COLLABORATION DRIVING QUALITY IMPROVEMENTS

Over the last decade, IPA and U.S. FDA have worked side by side to strengthen quality systems and drive measurable improvements. This partnership has helped transform India's pharmaceutical industry.

Since its launch in 2015, IPA's Quality Forum acts as a driver of change through thought leadership, knowledge development, and best-practice sharing. It's objective is to measure, benchmark, to expand and develop India's quality talent base, strengthen engagement with key stakeholders in India and abroad; and to provide platforms for members and stakeholders to interact and network. IPA organizes Global Pharma Quality Summit (GPQS)every year which has served as the premier platform for advancing quality. With active participation from FDA, USP, WHO, and other regulators, GPQS has trained more than 25,000 professionals and issued over 20 technical best practice guides. These sustained efforts have directly contributed to a 50 percent reduction in FDA Official Action Indicated (OAI) outcomes for Indian facilities over the past decade. Most recently, IPA held its 10th GPQS Summit, demonstrating that IPA is proactively building capacity, disseminating best practices, and creating cultures of quality and continuous learning.

IPA also has been an active partner in FDA's evolving Quality Metrics and Quality Management Maturity (QMM) frameworks. Through close engagement with FDA's India Office, IPA members have provided input, piloted approaches, and shared operational learnings to help shape practical, meaningful quality measurement tools. This collaboration underscores that Indian firms are not operating at arm's length from U.S. regulators; they are at the table, engaged in shaping the future of global pharmaceutical quality oversight. The scale and sophistication of India's pharmaceutical infrastructure today is unmatched outside the U.S. As of 2024, India hosts 752 FDA-approved facilities, alongside 2,050 WHO-GMP and 286 EDQM-certified plants.

U.S. FDA data on inspection confirms a 50 percent decline in FDA OAI outcomes and a 27 percent reduction in EMA noncompliance rates over the past decade. See Indian Pharma Report_27 Feb (2025). These are not anecdotes -- they are measurable, independent indicators of sustained improvement, which aligns with FDA's 2024 quality findings.

Companies are further leveraging advanced digital tools (AI), analytics, and lean systems to minimize variability, enhance investigations, and improve root-cause analysis. These investments align closely with

FDA's Quality Management Maturity framework, demonstrating that Indian firms are not just meeting today's standards but are building the systems that will define tomorrow's quality and efficiency expectations.

IV. INDIA AS A PARTNER, NOT A RISK

India supplies nearly **half of all generic medicines used in the United States**, doing so safely, affordably, and reliably. These products span the therapeutic areas most critical to American seniors and families. According to IQVIA's 2024 Report, Indian manufacturers account for the majority of prescriptions across the top 10 therapeutic categories in the U.S., often representing 60–90 percent of total volume. The table below provides category-by-category shares with example medicines.

Indian Share of U.S. Generics – Top 10 Therapeutic Categories (IQVIA 2024)

Therapeutic Area	% of U.S. Prescriptions Supplied by Indian Manufacturers	Example Medicines (Generic Name)
Cardiovascular	~85–90%	Amlodipine, Losartan, Metoprolol
Central Nervous System	~80–85%	Sertraline, Gabapentin, Escitalopram
Diabetes & Endocrine	~70–80%	Metformin, Glimepiride
Infectious Diseases	~70–75%	Amoxicillin, Azithromycin
Oncology (supportive)	~60–70%	Letrozole, Imatinib
Respiratory	~65–70%	Albuterol inhalers, Montelukast
Gastrointestinal	~75–80%	Omeprazole, Pantoprazole
Pain & Musculoskeletal	~60–70%	Ibuprofen, Naproxen
Mental Health	~80–85%	Sertraline, Risperidone
Women's & Children's Health	~70–80%	Oral contraceptives, Pediatric antibiotics

These categories are the backbone of everyday care for America families with generics produced by IPA members underpin the therapy areas where seniors account for the highest prescription volumes, directly supporting Medicare, Medicaid, the VA, and community pharmacies nationwide.

Undermining IPA members would not just disrupt "generic supply" broadly — it would create vulnerabilities across the core therapeutic areas of U.S. healthcare. Worse, it would increase America's reliance on China, which provide state-backed subsidies to drive global health dominance. Moreover, India is already reducing its reliance on China through the Government of India's Production Linked Incentive (PLI) program, which is expanding domestic API and KSM production and strengthening allied supply chains.

By contrast, India is a trusted direct ally and QUAD member, aligned and engaged with major U.S. defense, technology, and energy security goals — from joint production of Apache and Chinook helicopters and BrahMos missiles, to collaboration on semiconductors and critical minerals, to expanding civil nuclear energy cooperation. See Chart – Appendix.

In its 2025 *Section 232 Comments to the U.S. Department of Commerce*, IPA reiterated its April **2024 U.S.–India Affordable Medicines Partnership (AMP)** — a structured, multi-phased collaboration to:

- Co-invest in API/KSM production to diversify away from China.
- Stockpile essential medicines and inputs for national emergencies.
- Expand U.S. domestic capacity while leveraging India's scale and capabilities.

This partnership model recognizes a simple fact: India is not the risk — India is part of the solution. Through shared investment, regulatory alignment, and strategic collaboration, the U.S. and India can ensure that seniors and families have secure, affordable access to the medicines they rely on most.

V. COMMITMENT TO QUALITY

Quality is the foundation of trust. Over the past decade, IPA and its members have invested heavily in systems, training, and technology to ensure that medicines supplied to the U.S. meet the highest standards regardless of whether the medicine is made in the U.S. Europe or India. This commitment is ongoing and central to IPA's identity as a trusted global partner.

IPA and its members affirm:

- **Zero tolerance for lapses.** Quality failures — whether in India, the United States, or anywhere else — must be met with strong enforcement action. Indian companies hold themselves to the same high standards expected of any FDA-regulated manufacturer.
- **FDA Collaboration.** IPA has worked hand-in-hand with FDA on inspections, Quality Metrics, and the Quality Management Maturity (QMM) program, building cultures of quality and transparency.
- **Continuous improvement through innovation.** IPA members are embedding digital tools, analytics, and lean systems into manufacturing and quality processes to reduce variability, strengthen investigations, and improve reliability year after year.
- **Shared responsibility.** Quality is not defined by geography; it is defined by systems and oversight. IPA recognizes a shared responsibility with U.S. regulators to ensure that affordable medicines remain safe, reliable, and available for America's seniors and families.

This track record and ongoing commitment make clear: Indian pharmaceutical companies are not a weak link — they are partners dedicated to sustaining America's medicine security.

VI. RECOMMENDATIONS FOR THE COMMITTEE

Quality is paramount — the foundation of trust. It is the non-negotiable core of IPA companies, and the anchor for any reforms Congress considers.

The record already shows that IPA members supplying the U.S. meet the same stringent FDA oversight as any other manufacturer. Adding another layer of assurance, quality and reliability are continuously measured within the U.S. wholesale distribution system.

Many of the most important reforms mentioned during the recent hearing are already underway:

- FDA has expanded unannounced inspections abroad,
- Country-of-origin disclosure is mandated by U.S. law and reinforced by Executive Order 14293, and
- IPA members have publicly supported neutral translators to ensure transparency.

The task before the Committee is how to build on these reforms. IPA believes the path forward lies not in punitive tariffs that risk destabilizing the generic market further, but in incentives and partnerships — the same formula that has worked in defense co-production, semiconductors, critical minerals, and nuclear energy.

- **Inspection Parity.** Provide FDA with the resources and tools to expand and maintain a significant inspection team with unannounced inspections abroad and institutionalize the use of neutral translators and digital forensics. These tools ensure parity and confidence across all domestic and global sites supplying the U.S.
- **Procurement Reform.** Shift CMS, VA, and DoD procurement practices to provide fair reimbursement and reward quality and resilience, not just lowest price. Ending the "race to the bottom" driven by GPO and PBM consolidation will help ensure a sustainable market for affordable generic medicines. See 232 Comments and FTC: Drug Shortage Comments submitted by IPA.
- **U.S.–India API Partnerships.** Launch co-investment / co-production programs to expand API and KSM production in both the U.S. and India, reducing reliance on China. Scale up advanced manufacturing and green chemistry solutions to modernize and diversify supply.

America's medicine security will not be strengthened by punitive tariffs or blunt instruments -- like tariffs or DoD exclusions -- that will most risk driving generics out of the market. It will be secured by incentives, partnerships, and pragmatic use of oversight tools to ensure quality, resilience, and affordability together.

APPENDIX

Area	Example	Details & Source
Helicopters (Defense Cooperation)	India purchased **22 AH-64E Apache attack helicopters** and **15 CH-47F Chinook heavy-lift helicopters** from Boeing / U.S. in 2015, including production, training, support components.	Boeing: *Boeing Receives Order from India for 22 Apache and 15 Chinook* (Sep 29, 2015) MediaRoom
Helicopters – Recent Deliveries	As of July 2025, India has received the first batch of Apaches from the U.S. under a contract worth ten of hundreds of millions, adding to its Army Aviation Corps capability.	*Indian Army receives first 3 Apache attack helicopters ordered from US* (Jul 22, 2025) The Times of India+1
Semiconductor Supply Chain & Technology	U.S. is partnering with India's Semiconductor Mission (Ministry of Electronics & IT) to explore joint opportunities in the semiconductor supply chain.	U.S. Department of State – *New Partnership with India to Explore Semiconductor Supply Chain Opportunities* (Sep 9, 2024) U.S. Department of State
Technology / Strategic Initiatives	The "TRUST Initiative" — U.S.–India initiative to advance semiconductor, innovation, and technology cooperation under their strategic bilateral relationship.	*India-US TRUST Initiative: Advancing Semiconductor Supply Chain Cooperation* (Carnegie Endowment, Apr 24, 2025) Carnegie Endowment
Energy / Nuclear	India and the U.S. committed to civil nuclear energy cooperation — building U.S.-designed nuclear reactors in India. Also, joint statements have reaffirmed shared goals around energy security and small modular reactors.	Several sources: *Modi, Trump commit to US-India partnership* (World Nuclear News, 2025) World Nuclear News; and *U.S.-India Joint Leaders' Statement Feb 2025* (White House) The White House
Clean Energy Collaboration	In a U.S.–India joint statement (Sep 2024), leaders committed to expanding manufacturing and deployment of clean energy (solar, wind, nuclear), including small modular reactor technologies.	*Joint Fact Sheet: The United States and India Continue to Expand Comprehensive & Global Strategic Partnership* (Sep 21, 2024) The White House

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

National Consumers League Statement

NATIONAL CONSUMERS LEAGUE
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September 17, 2025

The Honorable Rick Scott
Chair, Senate Select Committee on Aging
G16 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Kirsten Gillibrand
Ranking Member, Senate Select Committee on Aging
628 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Scott and Ranking Member Gillibrand:

The National Consumers League (NCL) is a private, nonprofit consumer national consumer organization that, since its founding in 1899, has been a vocal advocate for policies to improve the health and well-being of Americans. Thus, we write to thank the Select Committee for holding the hearing, *Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans,* and to offer our perspective on a critical safety issue affecting many seniors today – the serious health risks posed by compounded GLP-1 medicines made with unregulated active pharmaceutical ingredients (API) from foreign sources (primarily China), many of which are not registered or inspected by the FDA.

On May 1, 2025, the National Consumers League launched The Weight Truth, a national anti-disinformation effort to alert consumers to the warnings from the Food and Drug Administration (FDA) and medical societies that compounded GLP-1 drugs are not reviewed for safety, effectiveness or quality by FDA,[1] are not approved medicines, and "can be risky for patients"[2] because compounded versions differ in ways that may increase the risk of medication errors. Among the differences, compounded GLP-1 drugs may contain too much or too little of the API, be at a different dosage level, and have drug quality problems, such as contamination with bacteria or a harmful substance – all of which can be detrimental to patient safety.

Underscoring the potential health consequences from dosing errors and exposure to the wrong ingredients, as of September 9, 2025, the FDA has received 1,424 reports of adverse events associated with compounded GLP-1 drugs, 329 hospitalizations, and 23 deaths.[3] Moreover, poison control centers have seen a nearly 1,500 percent increase in calls since 2019 related to overdose or side effects of injectable weight loss drugs and have managed 3,633 GLP-1 agonist related exposure cases as of April 30, 2025.[4]

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[1] Food and Drug Administration. Human Drug Compounding Laws. December 17, 2024. Accessible at: https://www.fda.gov/drugs/human-drug-compounding/human-drug-compounding-laws
[2] Food and Drug Administration. FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss. September 5, 2025. Accessible at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss
[3] Food and Drug Administration. FDA Adverse Events Reporting System Public Dashboard,data on compounded September 9, 2025
[4] America's Poison Centers. Glucagon-Like Peptide-1 (GLP-1) Agonists.

However, older adults face added safety challenges when taking a compounded GLP-1 drug. Compared to younger adults, seniors metabolize drugs differently due to age-related physiological changes, such as reduced liver and kidney function. These age-related changes increase the likelihood that a dosing error from taking a compounded GLP-1 medicine will lead to a severe adverse effect, like pancreatitis, gallbladder issues, and gastroparesis.[5] Additionally, older adults may be more susceptible to the medication's known side effects, such as muscle mass loss and dehydration, and are at higher risk for harmful drug interactions due to taking multiple medications.

These concerns are especially relevant as the Select Committee considers the risks to seniors from compounded GLP-1 drugs that rely on foreign sources for the supply of API. Federal law requires that API used in any product sold in the U.S., including compounded drugs, must be sources from entities that are properly registered with the FDA. However, a recent report citing publicly available data finds that most of the API used in making compounded GLP-1 drugs is from entities that are either not registered with the FDA or have never been inspected by the FDA to ensure compliance with good manufacturing practices and other safety requirements.[6] Moreover, an analysis from the Brookings Institution detailed that the vast majority of these foreign API shipments come from China and have not been inspected for safety or quality.[7]

To address this situation, on September 5, the FDA announced the establishment of a "green list" import alert that will include GLP-1 APIs from facilities the agency has inspected or evaluated and, according to the agency, "appear to be in compliance" with FDA's standards that apply to all API's manufactured in the US. Further, FDA has stated that APIs from other sources are subject to detention without physical examination. The National Consumers League applauds this action as a proactive measure to help stop the entry of unverified foreign APIs into the US, but we remain concerned that more will need to be done to address the quality issues posed by foreign-manufactured compounded GLP-1 drugs and more generally, to reduce pharmaceutical supply chain risks.

Speaking for America's consumers, and especially older adults who are at greater risk for harm if drugs contain potentially unsafe ingredients, the National Consumers League thanks the Select Committee for seeking solutions to reduce the serious threats posed by quality issues in foreign-manufactured pharmaceutical products. We appreciate the opportunity to share our insights and hope these comments will be helpful.

Sincerely,

Nancy Glick

Nancy Glick, Director, Food & Nutrition Policy
National Consumers League

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[5] Are GLP-1 Weight Loss Medications Safe for People Over Age 65? Harbor Health. February 28, 2024. Accessible at: https://harborhealth.com/blog/health-tips/are-glp-1-weight-loss-medications-safe-for-people-over-65

[6] Center for Medicine in the Public Interest. FDA Regulatory Failures in Enforcing Limits on GLP-1 Compounding Puts Patients at Risk. July 22,2025.

[7] Brookings Institution. Wosińska, ME et al. US drug supply chain exposure to China: Myths, omissions and related insights. July 28, 2025. Accessible at: https://www.brookings.edu/articles/us-drug-supply-chain-exposure-to-china/

U.S. SENATE SPECIAL COMMITTEE ON AGING

"PRESCRIPTION FOR TROUBLE: DRUG SAFETY, SUPPLY CHAINS, AND THE RISK TO AGING AMERICANS"

SEPTEMBER 17, 2025

STATEMENTS FOR THE RECORD

Partnership for Safe Medicines Statement

The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Comments to the Senate Aging Committee for the hearing
"Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans"
Wednesday, September 17th, 2025

Who We Are

The Partnership for Safe Medicines (PSM) is a public health group committed to the safety of the prescription drug supply chain and protecting consumers against the dangers of counterfeit, substandard or otherwise unsafe medicines. Our membership are not-for-profit organizations representing healthcare professionals, patient advocacy groups, law enforcement, and industry stakeholders who are committed to prioritizing American patient safety, promoting the integrity of our American pharmaceutical supply chains, and protecting our pharmaceutical border security.

The supply chain risks to American seniors

Though the U.S. drug supply chain is the envy of the world, it still contends with clever criminals who occasionally pierce it in all the ways we describe below. Americans in every demographic, including older Americans, are tempted by illegal online pharmacies that promise convenience and cost savings but sell substandard medicines.

The Alliance for Safe Online Pharmacies has surveyed older Americans about their online medicine purchasing habits:

- 26% of Americans aged 55-64 years old have previously purchased prescription medicines online for themselves or someone in their care.
- 21% of Americans aged 65+ have previously purchased prescription medicines online for themselves or someone in their care.

While their research doesn't confirm how many of these seniors purchased from illegal online pharmacies, given the fact that the National Association of Boards of Pharmacy determined that 96% of all online pharmacies are operating illegally, it seems likely there has been significant exposure for older Americans to this danger.

The Partnership for SAFEMEDICINES.org®
WORKING TOGETHER TO PROTECT THE SAFETY OF YOUR PRESCRIPTION DRUGS

Problem: Illegal imports of finished drug products or compounding ingredients flooding into the U.S.

Streamlining the seizure and destruction processes for unapproved and adulterated medicines and medical devices by border inspectors from either U.S. Customs and Border Protection (CBP) or the Food and Drug Administration (FDA) must be a priority to protect patients from malicious bad actors who aim to harm American patients and consumers.

Sometimes, when dangerous medical products are detained and refused entry into the U.S., FDA lacks the authority to order them destroyed. Refused shipments are returned to customs brokers, which ask original shippers their preference for what to do with them. Rogue manufacturers sometimes request they be returned to them. After this return, the rogue manufacturers reship them back to the U.S. through a different port, again aiming to breach our pharmaceutical border security and harm American patients.

Proposed solution: Provide the FDA with the authority to mandate destruction of products that have been refused entry and pose a danger to public health. FDA has requested this in the FY26 Appropriations budget, and a letter from patient safety advocates to Congress supporting the FDA request is available.

Patients exposed to illegally compounded medication

The FDA has issued myriad public warnings about counterfeits and knock-offs of branded drugs. The manufacturers' anticounterfeiting teams have also shut down 250 sites selling the violative products.

PSM has documented sales of counterfeit and illegally compounded weight-loss injectables on Etsy, the popular ecommerce platform. Etsy is not a licensed pharmacy, and neither were the sellers on their platform, who did not require the buyer to provide a prescription before purchase. The injectables have also been dispensed to Americans from foreign, fake online pharmacies, and in the U.S., from poorly regulated medspas and weight loss clinics.

Illegally compounded and counterfeit weight loss injectables look realistic enough to fool consumers and may have deadly consequences.

Proposed solution: Now that the shortage of GLP-1 products is over, compounding of GLP-1 products should also have ended, and with it, the use of "last resort" compounded medications by patients. It has not. The FDA should enforce the statutory limits on compounding of medication and its marketing by telehealth companies.

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Patients exposed to deceptive marketing may be deceived into thinking compounded medication is as safe as generic or branded medication

Millions of Americans, including older Americans, are exposed to deceptive advertising for compounded medications provided by telehealth companies every day. These ads present non-FDA-approved compounded versions of medicines as equivalent to FDA-approved versions.

Hims & Hers aired a particularly egregious example of these ads during the Super Bowl in February. Public health experts called the commercial "incredibly irresponsible" and and the Commissioner made remarks about Hims & Hers recently confirming our concerns.

Proposed solution: Ensure the FDA enforces the rules around drug advertising equally for telehealth companies.

Lack of visibility into the volume of compounding / traceability of compounding

Ever-growing amounts of compounded GLP-1s are making their way into the drug supply, but FDA has limited visibility into how much is being made. This lack of visibility contributed to the deadliest compounded drug scandal in history ("New England Compounding"). 503A compounding pharmacies, as differentiated from large compounding outsourcing facilities (503Bs), are generally regulated by State Boards of Pharmacy and do not report production volumes to the FDA. This is typically not needed when a 503A compounding pharmacy makes a small amount of product. But in recent years some industry players have scaled up their 503A compounding pharmacies to resemble high volume outsourcing facilities. As a regulator, FDA is blind to the volumes of production coming out of these entities and, therefore, is unable to adequately monitor for risks and patient safety.

Additionally, some dispensers have found ways to purchase compounded GLP-1s from compounding facilities and deliver them to patients. This compounder-to-dispenser-to-patient delivery is the most basic form of a drug supply chain. To protect patient safety, the Drug Supply Chain Security Act (DSCSA) generally provides a framework to ensure that prescription medicines are traceable as they move through the supply chain, requiring that these drugs contain a unique identifier, and records be kept by all trading partners in the chain.

However, the DSCSA does not apply to drugs compounded in accordance with 503A or 503B of the Federal Food, Drug, and Cosmetic Act. This lack of traceability poses a danger to consumers because there's no easy way to answer the question, "Where did this medication come from and where has it been?"

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Proposed solution: Require FDA to enforce current requirements on limits for 503A compounding pharmacies.

Predatory business practices by pharmacy benefit managers (PBMs) that encourage counterfeit sales in the secondary wholesale market

PBM business practices, like under-reimbursements, have broken the economics of the pharmaceutical supply chain in America, creating pressures that criminals are actively exploiting, to the detriment of patients.

How does this happen? For example, a pharmacy may buy a month's supply of GLP-1 medicine for $1,100 from the licensed wholesaler, but after dispensing it to patients, the PBM only reimburses the pharmacy $1,050, which is a loss of $50. Consistent losses like these are not viable, and they are driving pharmacies out of business. However, this business practice also undermines the safety of our drug supply chain.

Criminals who sell diverted and counterfeit medicine know that pharmacists are being under-reimbursed, and have taken to selling unsafe, diverted, and counterfeit medicines to pharmacies at a price low enough to be enticing, but not low enough to look suspicious. These criminals are thorough, and they often obtain state-issued wholesale licenses to reassure pharmacies that they are legitimate, because pharmacies are careful about who they order medicine from. This crime is so profitable that one gang moved $240mm of unsafe HIV medicines through the supply chain; the largest drug counterfeiting and diversion case we've seen in at least two decades.

Proposed solution: Pass PBM reform, which would prohibit under-reimbursement practices and remove the loophole criminals are exploiting to sneak diverted and counterfeit medicines into our drug supply. Ending under-reimbursements will benefit pharmacies but **it will also improve the safety of patients**.

Impediments to access and insurance coverage drive Americans to illegal online pharmacies selling counterfeit medicines

Insurance companies and PBMs often place access impediments to GLP-1 medication, such as refusing coverage or by requiring onerous copays. These restrictions drive Americans, especially older Americans, to seek bargains from dangerous illegal online pharmacies.

Proposed solution: Require insurance companies and PBMs to provide coverage of medicines like these at reasonable terms to reduce Americans' exposure to illegal online pharmacies that sell dangerous counterfeits.