S. HRG. 119–359

TRUTH IN LABELING: AMERICANS DESERVE TO KNOW WHERE THEIR DRUGS COME FROM

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

ONE HUNDRED NINETEENTH CONGRESS

SECOND SESSION

WASHINGTON, DC

JANUARY 29, 2026

Serial No. 119–23

Printed for the use of the Special Committee on Aging

Available via the World Wide Web: http://www.govinfo.gov

U.S. GOVERNMENT PUBLISHING OFFICE
63–403 PDF WASHINGTON : 2026

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C O N T E N T S

TRUTH IN LABELING: AMERICANS DESERVE TO KNOW WHERE THEIR DRUGS COME FROM

Thursday, January 29, 2026

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

The Committee met, pursuant to notice, at 9:30 a.m., Room 608, Dirksen Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

Present: Senator Scott, Johnson, Moody, and Gillibrand.

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. The U.S. Senate Special Committee on Aging will now come to order. Last year, this Committee exposed the public health risk and national security threat posed by America's over-reliance on Communist China and India for generic drugs and the drug ingredients that make them, known in the medical industry as APIs.

Together, Ranking Member Gillibrand and I led a bipartisan effort to demand accountability. We sent letters to the Food and Drug Administration, the Department of Veteran Affairs, and key industry stakeholders, including large drug purchasers, distributors, and major pharmacies.

The Aging Committee sounded the alarm and exposed the dangers in Americans' medicine cabinets. Our Committee also released a bipartisan report detailing the extent of these threats and held three hearings. In the first hearing, we heard from experts about the problems we face due to our massive over-reliance on foreign made generic drugs. We heard horrifying stories from a former FDA Inspector about how dangerous and unregulated these drugs from Communist China and India can be.

We learned about the tragic deaths caused by failures to make sure the medicines Americans rely on to heal and treat them are actually safe. In the second hearing, we discussed solutions that create safer medicines, secure supply chains, so we aren't dependent on adversaries like Communist China for our medicines and create good paying American jobs by bringing back drug manufacturing back to America.

In the third hearing, we heard from American drug manufacturers about the hurdles they face when they try to ramp up domestic production. What we uncovered during this investigation will shock

you. Ninety-one percent of prescriptions in the United States are generic drugs.

Of those drugs, almost 94 percent use APIs, produced and processed overseas in factories predominantly in Communist China and India that have little to no FDA oversight. When the FDA does make it abroad to inspect these facilities, they often warn them in advance, which gives them time to cover up any outstanding issues before inspectors see them. That is crazy. Somehow, even with all this time to prepare, we still see reports of skittering lizards and birds flying around foreign facilities. Does that sound safe and sanitary to anybody here? Absolutely not.

Here is the deal, we face two problems that every American needs to understand. One is that foreign manufactured generic drugs are made with untested and dangerous APIs from countries like India and Communist China. That means we can't trust these drugs because we know they are less safe than those made in America.

The second is that fixing that problem is made difficult by our own Government bureaucracy that blocks American drug manufacturers and fuels our over-reliance on Communist China and India to make generic drugs. We face not just a serious public health risk, but a massive national security risk as well.

Think about it. If the government of Communist China, a self-described enemy of the United States, or India wants to stop the supply of prescription drugs to the United States, they can do so at any moment. If that happens, the United Sates has absolutely no plan to keep these generic, life-saving drugs needed by millions of Americans available.

This may sound far-fetched, but we are seeing it play out in real time. Communist China has already limited exports of items like rare earth minerals during the COVID pandemic. India blocked the export of critical pharmaceutical ingredients, so, it can happen again. If we can't solve this problem, it is only a matter of time before more American lives are unnecessarily lost. We cannot allow that to happen.

We must act now. This is why I am taking action to address these threats immediately with the introduction of my CLEAR LABELS Act. This bill will require country of origin labeling for pharmaceuticals so that physicians, pharmacists, and most importantly the American families taking these medicines know where these essential drugs are coming from.

Every American deserves honesty and transparency about what they are putting into their bodies. We label food, clothes, and other products, but we don't require that same standard of medicines that Americans and especially our aging population rely on. Can anybody really disagree with that? It is wholly irresponsible that we are living in the dark when it comes to where our medicines are made.

My bill changes that. Under my bill, finished drug products prescribed and sold in the United States would need to identify the name and location of each, including API's original manufacturer, as well as the packer or distributor, right on the label or through a searchable electronic portal. This is a simple and common-sense

reform that will bring transparency and accountability to our generic drug industry.

The fact is, most Americans would prefer to buy American when they can. Unfortunately, with drugs, too often the information about the country of origin isn't readily available. They want to know what they are taking is safe, and they want to support American jobs. By labeling these essential drugs, Americans will have more information to help them make well-informed decisions for themselves and their families.

It will also encourage more domestic drug manufacturing, making sure generic medicines that our aging population and all Americans rely on are more effective and readily available. Country of origin transparency is not just a consumer right, it is a matter of national security, public health, and American pride.

I invite all members of the Committee to join me and co-sponsor this legislation. We can get country of origin labeling done now to allow stakeholders at every stage of healthcare, especially the patient, to be confident, informed about the medications they take. I look forward to hearing from witnesses today on how we can empower patients to make the best choices for themselves and their families when it comes to where their medicines come from.

Now, I am going to turn it over to Senator Moody. I have to go to a Foreign Relations Committee for a few minutes, and she will take over and she is my colleague from Florida and as a mom, she has to worry about not only the drugs she puts in her body, but what her kids are putting in their body.

Senator MOODY. Thank you, Chairman. Good morning. Thank you so much for being here. I would like to welcome all of our witnesses and everyone that is here today to witness this hearing. Our witnesses are leading experts on generic drugs and generic drug supply chains and can speak to how we ensure Americans have access to medications that are safe and high quality.

I would now like to introduce our first witness and if you would like to, after I introduce you, go ahead and begin your introduction and we will go from there. We will begin with Dr. John Gray. Dr. John Gray is a Dean's Distinguished Professor of Operations at the Ohio State University's Fisher College of Business. Go ahead.

Mr. GRAY. Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for this opportunity, and thank you very much for bringing so much attention to this important——

Senator MOODY. Well, I am not Chairman Scott. I have more hair than he does. [Laughter.]. Thankfully.

You may go ahead.

STATEMENT OF JOHN GRAY, PH.D., DEAN'S DISTINGUISHED PROFESSOR OF OPERATIONS, FISHER COLLEGE OF BUSINESS, THE OHIO STATE UNIVERSITY, COLUMBUS, OHIO

Dr. GRAY. I want to start by saying I strongly support giving consumers, doctors, pharmacists, and other stakeholders' access to basic drug level information, including country of origin and some valid assessment of drug quality risk.

This kind of transparency would allow generic manufacturers to compete on something other than price, and it could help slow or

even stop the race to the bottom that has been present in this industry for the past several years. For many years, the FDA has emphasized that all generic drugs patterned after the same original drug are exchangeable. That may have been largely true decades ago, but today it is no longer a defensible assumption.

There is now substantial evidence, both anecdotal and academic, that meaningful quality differences exist among generic drugs. Investigative reporting, academic research, and testimony to this Committee have made clear—have made that clear. These problems are the predictable result of intense cost pressure combined with a highly opaque supply chain, a product where quality is difficult to detect by touch or feel, and as mentioned, the exchangeability assumption.

The FDA's traditional approach to ensuring quality is focused on inspecting manufacturing process to verify compliance with good manufacturing practices. That approach is necessary but has become much harder as manufacturing has moved offshore, especially when foreign inspections are often pre-announced. From my own experience, 8 years working as an engineer and manager in an FDA regulated manufacturing facility, I can say that consistent compliance is genuinely difficult.

Day to day variability in materials, equipment, environments, and human decision-making creates constant risk. When firms are under pressure to deliver on time and compete on price, it can be tempting to overlook small compliance issues rather than investigate them fully. Over time, even well-intentioned organizations can go down that slippery slope. Indeed, in my research with co-authors over a decade ago, we found that pharmaceutical compliance tends to erode over time, absent a clear observable reason to refocus on quality.

Transparency can help change this dynamic. A congressionally mandated National Academies Report in 2022 recommended country of origin labeling. In our research testing that recommendation, we found that both consumers and hospital pharmacists showed a clear preference for drugs manufactured domestically or near shore and away from drugs manufactured in India or China, even when told that all drugs were FDA approved.

That same report also recommended public facing quality scores. When we tested quality scores alongside country of origin, we have found something important. While consumers preferred domestic drugs on average, high-quality offshore drugs were preferred over moderate quality domestic ones.

This tells us that transparency can promote competition on quality, not just location or cost. While the industry remains opaque, some progress has been made, my co-authors and more recently ProPublica investigative journalists have been able to link many drugs to their finished dosage form manufacturing facilities using mostly public data.

These efforts are valuable, but they are incomplete, difficult to maintain, and require enormous effort. In the case of ProPublica, even including a lawsuit of the FDA for some data. Critically, even with these efforts, we still lack reliable public data on active pharmaceutical ingredient manufacturing locations. There is real momentum for broader transparency.

The FDA has requested the authority to release manufacturing location information in its upcoming authorization. HHS has emphasized radical transparency, and the current FDA Commissioner was a leader in creating transparency in hospital quality years ago, as described in his book, Unaccountable. I am part of a Pentagon-funded team developing drug-level quality scores using existing data, while a parallel team is conducting laboratory testing of drugs in the market.

These efforts have already identified meaningful variation in quality, and the resulting scores should be available later this year. Variation in manufacturing quality has real consequences for patient outcomes. Research in this area has been slow, not only because supply chains were long overlooked as a cause, but also because linking manufacturers to drugs was previously nearly impossible.

As discussed in your September hearing, and in many recent news articles, low quality drugs have human consequences. My specific recommendation is this, require a QR code on all public facing drug packaging that links to a website searchable by NDC, showing the manufacturing locations of both the finished dosage form and the active ingredient, along with the drug level quality score.

The site should also allow the same information for other exchangeable versions of the same drug, enabling informed comparison. For consumer facing use, quality scores should be designed carefully to avoid discouraging patients from taking necessary medications. One option would be a five-star scale where all marketed drugs are at least three stars.

Transparency should be one part of a broader policy approach. I support stronger foreign inspections, increased testing, especially of imported drugs, and consideration of a legally accountable, U.S. based qualified person for imported batches. Federal purchasing decisions that incorporate quality and country of origin would send a powerful signal to the market.

Transparency alone will not solve every problem, particularly in the complex private market, but is a necessary foundation. By allowing manufacturers to compete on quality and location and not just price, we can begin to reverse the race to the bottom and improve drug quality for patients. Thank you.

Senator MOODY. Technical problems]—can speak to drug quality and shortages. Dr. Michael Ganio is Senior Director of Pharmacy Practice and Quality with the American Society of Health System Pharmacists, or ASHP.

ASHP is the largest association of pharmacy professionals in the United States, representing its 65,000 members in hospitals, ambulatory systems, and health system community pharmacies. ASHP also maintains a drug shortages list and has worked with Congress and a variety of stakeholders on supply chain resiliency. Thank you for being here, and you can begin your testimony.

STATEMENT OF MICHAEL GANIO, PHARM.D., SENIOR DIRECTOR, PHARMACY PRACTICE AND QUALITY, ASHP, BETHESDA, MARYLAND

Dr. GANIO. Thank you, Senator Moody, Chair Scott, Ranking Member Gillibrand, Senator Johnson, and members of the Special

Committee on Aging. Thank you for the invitation to today's hearing.

ASHP appreciates the Special Committee on Aging's comprehensive work over the past several months on creating a more resilient and reliable drug supply chain. For over 20 years, ASHP has worked to strengthen the drug supply change by publicly reporting drug shortages, providing resources to support patients and clinicians who are affected by supply disruptions, and advocating for policies that support a more reliable and resilient drug supply chain.

Every American has a right to know where their prescription drugs are manufactured. Today, that information can be voluntarily provided by manufacturers, but it is not required. Drug labels may include a name and address for a company marketing a product, but not the name and the address of a manufacturing location. ASHP strongly supports transparency in the pharmaceutical supply chain, including manufacturer and country of origin labeling for prescription drugs.

Research that Dr. Gray and I participated in, that he alluded to, and with other colleagues, has shown that patients and pharmacy purchasers prefer to buy drugs manufactured in the U.S. or Canada compared to products from India or China when the country of origin is made available.

Disclosure of this information on the label has the potential to realign incentives in the supply chain away from price and may increase market share for products manufactured domestically.

Research also conducted by Dr. Gray and other colleagues reveal there may be a correlation between drug quality and country of origin. These studies provide motivation to increase domestic manufacturing and manufacturing in countries with high reliability and FDA accessibility.

However, country of origin alone is not a reliable proxy for drug product quality. There are many examples of manufacturers, both domestic and foreign, that have faced quality challenges in recent years. Our research also ignores key factors that affect purchasing decisions in practice. For example, patients will receive a product in an amber bottle that may not have the country of origin on the label.

Choice is often an illusion. Patients who have received medications in hospitals and clinics and surgery centers are often—the drugs are often prepared and administered without a patient ever seeing the label. I do want to reiterate ASHP's support for this legislation.

This is basic information that every American has a right to know. I urge the Committee to consider additional policies to directly incentivize domestic manufacturing, improve regulatory oversight or inspections of manufacturing facilities to ensure Americans have access to high quality pharmaceuticals.

Chronic drug shortages, concern over drug product quality, and threats to national security are all related to the resilience and reliability of our pharmaceutical supply chain. Policies to address each of these risks and vulnerabilities can actually solve multiple root causes and result in a resilient supply chain of high quality pharmaceuticals that can withstand demand and supply shocks.

There are two separate drug supply chains in the United States, brand name, single source products and older generic multi-source products. Financial incentives and challenges separate these two supply chains. Brand name manufacturers have a strong market incentive to invest in the resiliency of their supply chains and produce high quality drugs.

However, price erosion and race to the bottom market dynamics result in a brittle supply chain for older generic drugs. For context, nearly every drug on the FDA's 2020 list of essential medicines is generic. With slim to negative profit margins, generic manufacturers are less likely to invest in resiliency and quality management.

Generic manufacturers that are capable and willing to make those investments often lose market share due to drug price competition from manufacturers that unwilling or unable to invest in resiliency and quality management. The narrow profit margins also result in the offshoring of our drug supply chain, API manufacturing to countries with cheaper labor and less rigorous regulatory oversight.

Without a public mechanism to evaluate quality and resiliency investments, purchasers have no information other than price to leverage when buying drugs. This reinforces the race to the bottom market dynamics and erodes market resiliency, resulting in a fragile supply chain, concerns about product quality, and chronic drug shortages.

To strengthen the drug supply chain, ASHP also recommends additional policies that are available in the written testimony submitted to the Committee. These policies are focused on improving transparency into manufacturing quality, encouraging new manufacturers and new manufacturing sites, supporting economic stability by encouraging long-term guaranteed volume purchasing contracts, and diversifying the manufacturing base.

ASHP greatly appreciates the Senate Special Committee on Aging's leadership in working to ensure America's seniors have access to safe and effective drugs. Thank you, and I look forward to today's discussion.

Senator MOODY. Thank you. Now, I would like to introduce Dr. Stephen Schondelmeyer. Dr. Schondelmeyer is a Professor of Pharmaceutical Economics and Management at the University of Minnesota, as well as the Director of the PRIME Institute, which conducts research on policies related to pharmaceuticals.

Through his decades of research experience as a published researcher on pharmaceutical economics and the pharmaceutical market, Dr. Schondelmeyer has conducted research for the Centers for Medicare and Medicaid Services and the Food and Drug Administration, as well as this Committee. We thank you for being here today, and we ask that you begin your testimony.

STATEMENT OF STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D., PROFESSOR OF PHARMACEUTICAL MANAGEMENT & ECONOMICS, COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MINNESOTA

Dr. SCHONDELMEYER. Thank you, Senator Moody, and Ranking Member Gillibrand, and members of the Special Committee on Aging. I am pleased to be here today to talk about truth in label-

ing. It is an important topic to our marketplace and to consumers and to health care.

Historically, we have had drug shortages in the U.S. market. We understand that. We have characterized them, and we are beginning to deal with that issue. Those shortages have occurred for a variety of reasons, including quality issues with drug products and concerns related to market economics.

However, the advent of COVID–19 made us aware of and brought to the forefront another issue that causes drug shortages and lack of product in the market, and that is geopolitical risk—the behavior of other countries in the world can affect our access to supply of drugs and even some countries, in an effort to maintain sufficient supply for their own populations, prohibited export of drugs from their country to other countries during the COVID–19 process.

Now we have seen now drug supply used as a weapon or as a leverage in the marketplace, and that could affect the U.S. dramatically. We are dangerously dependent on foreign sources for our drug supply in the U.S., with India and China dominating the market for active pharmaceutical ingredients and key starting materials.

The U.S. health care system is quite vulnerable to this geopolitical risk. If a dominant sourcing country decides to withhold drugs from our supply chain, we would face a major health care crisis precipitously. That brings us to the issue of how do we deal with this?

We need to change our drug supply system and our drug shortage response process from a ″find and fix″ mentality—that is, we will wait till it occurs then we will fix it—to a ″predict and prevent″ approach. Let's predict where the shortages are going to be and prevent them from occurring in the first place, so we don't have people that go without necessary medications. I think ″country of origin labeling″ is an essential, foundational component of that process. It is standard practice for many consumer goods.

As Chairman Scott pointed out, there is country of origin labeling for food and clothing and automobiles and other things in our consumer goods market. As you know, when an American goes to the grocery store to buy a T-bone steak, or they go to the department store to buy a T-shirt, there is a label on the product that tells them where the product was really was made, where it was sourced.

Consumers do read and respond to that information and use it. I find it unconscionable though that we require transparency for our dinner and for our denims, but not for the critical drugs that save people's lives, cancer drugs, diabetes drugs, and a variety of other medications.

Real country of origin labeling for pharmaceuticals must be clear, specific, and transparent. We should know where the drug product was actually made, not just where it was packaged, or warehoused, or marketed. Clear labeling must disclose two things, where the finished dosage product was made, and where the active pharmaceutical ingredient was made.

Currently, finding information about where a drug was made, by the pharmacist who has to provide that information to the con-

sumer, is very difficult, if not impossible. To find this information, a pharmacist can go to sources like the National Library of Medicine's DailyMed website, and if they dig around enough they can find, for some products, the country of origin. You can't find it for all products. It is not always there.

It may take up to 30 minutes to find the answer for one drug, and pharmacists can't operate a pharmacy efficiently if they have to spend 30 minutes for each prescription chasing down what is the country of origin.

Furthermore, manufacturers hide behind claims of confidentiality. FDA allows a drug company the option to declare that the information of where their product is made is confidential and a trade secret and I understand trade secrets are important, but a couple of things come to mind that suggest that this may not be as much of a trade secrets as we think.

For example, the major blockbuster drugs today, like Mounjaro and Zepbound for weight loss and diabetes, are products that are labeled—if you look on the box or the package, it says ″marketed by Eli Lilly,″ and that is good. It tells us who marketed it. It doesn't tell us who made it or where it was made.

Lilly may well make these products, from other data bases I was able to find that Lilly really does make their products, For the Lilly case, and for many other drugs, the product labeling says who the product is ″marketed by″ but it does not tell you where it was made. However, if you go to Google, you can find press releases from the company announcing their investment in a new production facility, and they tell you where the product was actually made.

What the company told FDA was confidential, they turn around and issue public press releases to say, look at what we are doing and I applaud Lilly for building a new plant in the U.S., but the point is it can't be confidential when you are giving it to FDA, and not confidential when the drug company puts out press releases on same product and the same plant where it is made.

There is a little bit of duplicity in their approach to what confidentiality really is. There has been a recent change in the regulation of consumer product labeling. In June 2024, the U.S. Customs and Border Protection issued a new regulation, and they shifted their position.

They said the consumer is really the patient at the pharmacy counter, not the pharmacy when it buys the product. They used to interpret that manufacturers had to represent to the pharmacy where the drug was made, and the pharmacy was viewed as the end consumer. I am a pharmacist. We work in the marketplace, and we know that the pharmacist is the last point at which the product gets to the patient.

The pharmacist is the face of the drug product to the patient. I do think there is a proven transparency process, and that is in the country of New Zealand. New Zealand has a process, a public transparent online website that publishes the API source and the address where it was made in the factory, the finished dose form, and many other things.

I encourage you to look. I have given references in my written testimony about where to find that and look at that and see what

is there and New Zealand's experience has been that transparency has not harmed the commercial interest of companies. Three things I recommend to Congress.

One, mandate country of origin transparency. We need to amend Federal statutes to require country of origins labeling for manufacturers at both the API and the finished dosage form level. Don't allow companies to hide behind that confidentiality claim.

Senator MOODY. Sir, if you could wrap up your testimony——

Dr. SCHONDELMEYER. I am——

Senator MOODY [continuing]. in just 30 seconds, that would be great.

Dr. SCHONDELMEYER. Yes.

Senator MOODY. Thank you.

Dr. SCHONDELMEYER. Labeling for consumers is not an end unto itself. It is a foundational building block of a broader data base that helps the Government, and the country strategically plan for a secure drug supply and manage it. Labeling for the consumer is important, but building that broader supply is important.

In other words, we need to build a market wide supply map, and I encourage you to look at the United States Pharmacopeia's Medicine Supply Map which does that and Congress needs to engage with, and fund building this and bring it within the work of the Government.

Finally, empowering consumers. The consumer is the ultimate purchaser, and we need to make sure that this law is implemented and enforced, not just passed.

Senator MOODY. Thank you, sir. Thank you so much and I am sure that the questions will elicit a lot more of what you have to say today. We appreciate you. I am going to turn it over to Ranking Member Gillibrand now to introduce her witness.

Senator GILLIBRAND. Thank you, Chairwoman Moody. I want to introduce Stephen Colvill.

Mr. Colvill is an Assistant Research Director at the Duke-Margolis Institute for Health Policy where he leads the Duke-Margolis Revamp Drug Supply Chain Consortium and policy work on other supply chain and biomedical innovation topics.

Previously, Mr. Colvill served in the White House Domestic Policy Council as Senior Policy Advisor for Medical Supply Chains. You may begin.

STATEMENT OF STEPHEN COLVILL, ASSISTANT RESEARCH DIRECTOR, DUKE-MARGOLIS INSTITUTE FOR HEALTH POLICY, WASHINGTON, D.C.

Mr. COLVILL. Thank you, Ranking Member Gillibrand, Senator Moody, and Chairman Scott, and members of the Committee for holding this hearing. I am Stephen Colvill, and as Ranking member mentioned, I lead the Revamp Drug Supply Chain Consortium at the Duke-Margolis Institute for Health Policy.

I have seen the drug supply chain from many different angles. I have worked at one of the largest drug manufacturing plants in the U.S., and then on the commercial business side of that drug manufacturer.

I co-founded a drug supply chain certification organization, where I worked with health systems to help them identify reliable suppliers.

Then moved to the policy side where I have served in the White House Domestic Policy Council, and then my current role and throughout all this, one common thread has been obvious, we need to revamp how our supply chain works to better care for patients.

Before discussing solutions, we need to identify the distinct yet overlapping problems in the drug supply chain. First, chronic drug shortages. These occur when a drug is simply not available, usually because of a supply chain breakdown like a manufacturing delay. Second, questions around pharmaceutical quality assurance.

This is when a drug is available, but there are questions around if it was manufactured and tested appropriately. Then third, addressing geopolitical and national health security risks from foreign dependency and fourth, a desire to grow the economy through domestic manufacturing.

As a Nation, we obviously need to address all of these. At the Revamp Consortium, we focus on policy solutions to the chronic drug shortages that have been causing devastating impacts to patient care for 20 plus years. We focus where shortages have been most prevalent, inexpensive generic sterile injectables, which are usually administered by healthcare providers such as in a hospital setting.

Generic drug prices are on average about 33 percent lower in the U.S. than in other high income countries. Generics are cheap here, yet too frequently not available because the current provider payment system set by CMS and private insurers encourages providers to seek low cost generic drugs without enough consideration for reliable availability.

Providers are not adequately rewarded when they take steps to prevent shortages. However, there is an alternative, aligning incentives to focus more on reliable availability for critical generics. I coauthored a proposal in October on how to make this happen.

Our proposal offers up a simplified version of a Medicare incentive payment program originally outlined in the 2024 Senate Finance Committee discussion draft. The proposal would incentivize health care providers to do two things. One, purchase through committed contracting models.

Second, identify and purchase drugs that meet reliability or resiliency benchmarks. Addressing chronic drug shortages in this way is clearly aligned with CMS's mission to improve health outcomes.

CMS is also well positioned to move the needle, particularly in the inpatient setting where Medicare and Medicaid together account for about 75 percent of inpatient days. Since 2023, CMS has taken several actions to incentivize domestic production, including a notice earlier this week—just this week about a potential upcoming hospital incentive program.

CMS actions should also encourage the reliable availability of critical generics by supporting committed contracts and reliability benchmarks. I encourage this Committee to collaborate with the Finance Committee on that. In the meantime, it is great that this Committee is considering legislation to make better information available about suppliers. My top priority here would be to kickstart reliability benchmarking pilots.

Three prominent examples of such programs include the Healthcare Industry Resilience Collaborative's Resiliency Badging Program, U.S. Pharmacopeia's Resiliency Benchmarking Program,

and FDA's Quality Management Maturity Program. These voluntary programs evaluate confidential data about various manufacturer supply chains.

They then can communicate findings to the market about the reliability of those manufacturers. Uptakes of approaches like these has been relatively limited but could be significantly increased through HHS and DOD funding and support.

This could also set a foundation for future CMS reform. Regarding pharmaceutical labeling, Americans deserve to know where their drugs come from, and effective labeling changes could, over time, possibly drive some more demand to domestic manufacturers. However, labeling reforms alone are likely to have a limited impact.

Many decisionmaker already know where API and finished dosage forms are made, and patients have limited influence over what drugs are stocked. Also, just because a drug is made in the U.S. doesn't necessarily mean it is always the best choice. Some of the most significant shortages have resulted from manufacturing issues in U.S. plants.

Other assessments are also needed, such as from reliability benchmarking programs, like I mentioned. My written testimony provides additional points on how potential unintended consequences of labeling reforms could be mitigated. Before I close, two specific considerations on labeling.

Place of business may not be the best term to use in labeling requirements, as place of business is not necessarily the same as the location of manufacturing.

It may be more beneficial as FDA requested in their legislative proposals under the prior Administration, and again in the current Administration, to require manufacturers to include in their digital labeling information unique facility identifier numbers for the original API manufacturer and original finished drug product manufacturer.

Finally, to summarize, one, we need to clearly define the problems. Two, I would focus first and foremost on CMS payment reforms to support committed contracting models between purchasers and manufacturers that meet reliability benchmarks and third, consider requiring unique facility identifiers to be included in digital labeling information. Thank you, and I look forward to the discussion.

Senator MOODY. Thank you very much for your testimony and without any objection, I am going to let Senator Johnson kick us off with questions.

Senator JOHNSON. Thanks, Senator Moody. I supplied plastic packaging materials to the medical device industry for about 30 years and, you know, fully understand good manufacturing process, GMPs, benchmark of that is traceability.

You know, we need to know, you know, what rail car, what box of resin produced that roll of sheet stock that went into packaging that particular medical device, okay and that is just for packaging material.

Dr. Gray, does the FDA not require that level of traceability on drugs, I mean, things we actually put in our bodies versus just a package that surrounds a medical device?

Dr. GRAY. My understanding is within the facility, they have requirements, and GMP requirements like you are talking about. The manufacturer itself does have to trace lots and things from its suppliers, but—and Mike can help me with this one—but when the hospitals receive the drugs——

Senator JOHNSON. They don't have the information.

Dr. GRAY. They don't have the information. The buyers don't have the information.

Senator JOHNSON. Does the FDA require that traceability back to the precursor chemicals—to the API, to the actual compounding of the drug, to the marketer?

Dr. GRAY. My understanding is API, yes. Precursor chemicals, no, is my understanding. At least—and I am not 100 percent sure on that.

Senator JOHNSON. Anybody who can answer that question to me. How critical would be for us to know where the precursor chemicals come from, or is it okay just to focus on API? Dr. Schondelmeyer.

Dr. SCHONDELMEYER. Yes. Certainly, it is important to know where the KSM came from for purposes of, is it quality, is it a product that we want to put in human bodies in America, but it is also important to see how dependent we are on specific sources of supply and countries of supply so they may be putting quality product in there, but if we find that 30, 40, 50 percent of our API supply is from China, and China is an adversary——

Senator JOHNSON. I got to—so I understand the supply chain issue, the precursor chemical. What about a quality issue? I mean, do we need to know what the—you know, where that precursor chemical came from, or can we do the quality check on the API before it gets compounded into a drug?

Dr. SCHONDELMEYER. Well, I would describe it this way. A lot of that is based on voluntary compliance with the Continuous Good Manufacturing Practices Act. It is not required, and FDA doesn't—it is not like a meatpacking plant where they inspect everybody, you know——

Senator JOHNSON. Mr. Ganio, you want to answer this again?

Dr. GANIO. Sure.

Senator JOHNSON. It is not required by the FDA?

Dr. GANIO. The key starting materials, no and to answer your question about quality, I would be less concerned about the quality and more of the national security vulnerabilities associated with it. The API is tested by manufacturers. They will confirm that what they receive from an API manufacturer is suitable for production. Anything that is manufactured up to that point should be okay from a quality perspective, but the vulnerabilities that need to be revealed are important.

Senator JOHNSON. We had the 2008 heparin contamination issue. Have we done anything to address what went wrong there?

Dr. GANIO. Scientifically, United States Pharmacopeia revised the monograph for that to make sure that oversulfated chondroitin sulfate would be detected when testing. From a national security standpoint, that should address if the GMPs are being followed and record keeping is being followed.

Senator JOHNSON. If we—you know, Mr. Colvill, you mentioned that U.S. generic drugs are about 33 percent less expensive than in other countries, you know, first world nation countries. Why is that? Is it just greater competition, or are there rules and regulations in place in those countries that increase that cost of drug?

Mr. COLVILL. It could be a result of incentives in the market. What are the purchasers incentivized to value? I think in the U.S., there is an emphasis on low cost, which is important, of course, but there is not enough emphasis on other things that are important too—reliable availability, quality, you know, everything else that goes into the full value proposition for these products.

Senator JOHNSON. I mean, in general generic drugs are pretty cheap, correct? I mean, where we have problems with high drug prices in the patentable drugs that, you know, until they go off patent and become generic.

When we are talking about—and I think, you know, what Senator Scott is proposing, labeling, I think that is an incredibly important first step. I think all the witnesses are saying that as well, but you know, there may be rules and regulations in terms of quality, and testing, and statistical sampling, and GMPs, and following those things and making those available as well, that would add a price to that.

Anybody want to opine in terms of, would that increase prices by 33 percent? Which still, when you look at the total drug buy in the U.S.—you know, we don't have extremely expensive health care here because of drugs. It is a component of it, but it is a small component.

If you want—I personally think most consumers would pay a little bit more to be assured of quality, so they don't get—so they won't die from a heparin contamination or something like that. Anybody want to opine in terms of what the right rules and regulations and laws to ensure quality, how much that would increase the price of generic drugs? Would it be the 33 percent? Would it double it? Mr. Ganio, you look like you want to answer.

Dr. GANIO. I couldn't give you an exact number. That would vary by manufacturer, but as you mentioned, and as I mentioned in my testimony, the two supply chains—there is instances where we probably don't pay enough for generic drugs, and this is the result, the questionable quality, but all we have to value when we buy drugs is the price.

Everything is pass, fail, which is clearly not sufficient. If additional information about quality is made available, then purchasers would have a reason to spend 10 percent, 15 percent more. We conducted a survey in 2023 and found our members are willing to spend about 10 to 15 percent on drugs.

You have to look on the other side that the supply chain issues, the shortages, what they cost—over almost $900 million in labor expenses alone, according to a report from Vizien, a group purchasing organization. Our research also shows increased costs of drug supply chain concerns.

If you make that tradeoff, pay a little bit more for guaranteed supply chain high quality drugs, it theoretically could pay for itself.

Senator JOHNSON. By the way, I will say that having been a manufacturer, had to follow GMP, got ISO audits every 6 months,

it costs a little bit more but not that much more. What you end up being is just a far better manufacturer.

You have higher quality. You have higher level customer service, greater reliability, less scrap. You know, so I wouldn't believe any manufacturer or any of these marketers saying, well, it is going to increase our cost dramatically. It really shouldn't. It is just good manufacturing practices. That ought to be insisted on again. I really appreciate what Senator Scott is doing here with these hearings. Thank you.

The CHAIRMAN. Thank you, Senator Johnson. Ranking Member Gillibrand.

Senator GILLIBRAND. Thank you, Mr. Chairman. Dr. Schondelmeyer and Dr. Colvill, we have been talking about, we talked about terms of art, that we have to get the terms of our correct. People say marketed for, distributed by, repackaged by. What is the best term of art for this labeling? I would like all the witnesses to answer this question, but starting with you, Dr. Schondelmeyer.

Dr. SCHONDELMEYER. I think the simplest is ″product of″ or ″made by″ and then it should specify, are they talking about the finished dosage form or the API? Both should be disclosed. FDA may well have all of this information and other information on quality, but they either aren't authorized, or as a matter of policy don't choose, to release a lot of it.

Just having the information at FDA doesn't necessarily improve the quality and the ability of decisionmakers to make decisions, whether it is the consumer, or the prescriber, or the pharmacist, or the purchaser.

They need to know what FDA knows to make those decisions, so ″made by″ or ″product of,″ and ″API product of,″ ″finished dosage form product of″ and the country.

Senator GILLIBRAND. Mr. Colvill.

Mr. COLVILL. Dr. Schondelmeyer, you are referring to what is on the physical label, which is important, obviously. I think we also should think about the digital information. We live in a digital world.

What is the information that is provided digitally? You can have a lot more information that is provided that way. There is limited real estate on these labels. Some of them are really, really tiny. As I mentioned in my opening remarks, unique facility identifier numbers could be considered to be required.

Senator GILLIBRAND. I think that it would be very smart for the digital labeling to say exactly where the plant was in India or where the plan was in China.

Mr. COLVILL. If that was done, it would all be listed on DailyMed, the data base that several others have mentioned. Third parties could easily put together publicly available, user-friendly data bases where patients and others could easily look up where these drugs were made.

Senator GILLIBRAND. Doctor Ganio.

Dr. SCHONDELMEYER. I would quickly comment that I agree, the DailyMed is a great source, but if you look at their data—they do sometimes have API manufacturer and finished dosage form manufacturer for some products, and they have an entity identifier on

there for the ones that are named, but it is pretty complex, and consumers have a difficult time sorting out what is there.

I included as an appendix to my written testimony printouts from the New Zealand MedSafe data base that report the same information, but it is much more easily understandable by a consumer if they look it up with a QR code or other things.

I encourage you to look at the way it's presented in the New Zealand MedSafe data base. It is much more consumer and user friendly, and easier to follow.

Senator GILLIBRAND. Okay, and Dr. Ganio.

Dr. GANIO. Yes, I completely agree with both—I agree with both Dr. Schondelmeyer and Mr. Colvill. The physical label should be easy to understand and easy to read. It should say manufactured by the name of the facility.

Having the unique facility identifiers in a searchable data base can help identify vulnerabilities, choke points, things where we are all relying on the same site, where right now might be under a contract and not necessarily easily discernible, but stakeholders could find out where those choke points are and invest.

Senator GILLIBRAND. Thank you. Dr. Gray.

Dr. GRAY. Finished dosage manufacturing location, active pharmaceutical ingredient manufacturing location should both be on the label and then I agree with the searchable data, the easy to access data base that includes more details on that, and also as I mentioned in my testimony, quality ratings.

Senator GILLIBRAND. Thank you. In several of the testimonies today, there have been mentions of the data that is collected by the Customs and Border Protection and the Food and Drug Administration when pharmaceuticals are imported into the U.S. However, what is required to be listed on the label by CPB is different than what's required to listed on a label by FDA.

There also been allusions to country of origin disclosures being voluntary provided rather than mandated by the current CPB regulations. At times, disclosure regulations required by CPB seem to be in direct odds with those by the FDA.

For any or all of the witnesses, how should Congress work to harmonize the information gathered by the FDA and the CBP to ensure that the information received by them is not duplicative, but also provides consumers with clear understanding of a product's country of origin?

Dr. GRAY. I will just say quickly, and hopefully this will sort of answer your question, that FDA has requested authorization to be able to release a bunch of manufacturing location, API, active ingredient—API finished dosage form, excipients, critical excipient, etcetera—allowing them to do that. The FDA feels bounded to not be able do that by company confidential information. That would align them, I think.

Dr. SCHONDELMEYER. I think as policymakers, you need to look across both the CPB and FDA, and what their regulations are, and integrate them. This—CBP is limited only to imports. They don't even require listing on the label ″made in the USA″ when it is made in the USA because that is not an import.

Senator GILLIBRAND. I see.

Dr. SCHONDELMEYER. That needs to be cleaned up. I think do it under one set of regulations, probably placed at FDA rather than CBP because of that and then make it really clear what the language is, you know, what goes—as important as the made or manufactured is the preposition that follows it. Made ″by″ is different than made ″for.″

Senator GILLIBRAND. Yes. Understood.

Dr. SCHONDELMEYER. Very different and so, clear that up and put clear definitions for it and then also, don't allow companies to declare that where it is actually made as confidential or trade secret.

Senator GILLIBRAND. Correct.

Dr. SCHONDELMEYER. Declare that is public information that needs to be disclosed.

Senator GILLIBRAND. Understood. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Moody.

Senator MOODY. Thank you, Chairman Scott and Ranking Member Gillibrand for convening this hearing to examine what sounds like a very urgent need for transparency in our drug supply chain. Every day, millions of Americans rely on a wide range of medications to maintain their health and quality of life.

As parents, we often take prescriptions to the pharmacy and get medications that we then tell our children to take, trusting that there are no quality control issues. I think this should be top of mind for every American and certainly every parent.

Unfortunately, throughout the hearings that we have had on this issue and this Committee on drug supply transparency, it has become increasingly clear there's simply not enough transparency and what is worse, FDA import alerts routinely cite carcinogenic impurities, falsified batch records, and non-sterile conditions from manufacturers in China and India.

Roughly one-third of all FDA import alerts target Chinese facilities, and another 16 percent target Indian producers. Just last year, I and many of my colleagues on this Committee sent a letter to the FDA raising the alarm at problems with drug quality due to poor foreign inspections in countries like China and in India who together account for 60 percent of APIs globally.

That doesn't even include, as we have discussed already, the key starting materials. Many Americans who rely on prescription medications, particularly seniors, which is why this Committee is paying such close attention, have no reasonable way to determine where their medications are manufactured, effectively denying them an opportunity to choose American made drugs.

What we found is that this failure stems from a combination of loopholes and insufficient FDA enforcement, which allows foreign adversaries such as China to exert control over the production of drugs that Americans depend on to stay alive.

It is crucial, and what I am hearing from every witness today, that we take immediate action to increase transparency in our drug supply chain so that consumers can make informed decisions about the medications they use. Important, a study from 2022 found that 83 percent of top 100 generic drugs consumed by U.S. citizens have no U.S. based source of active pharmaceutical ingredients.

With that said, I would like to turn to one of the witnesses that I had to cut short when we were getting to time limits on introductions. Mr. Schondelmeyer, in your testimony, you wanted to further explain, I believe, about how in New Zealand they have a model for providing drug supply chain transparency.

That the New Zealand MedSafe program maintains updated information regarding active ingredients which is available to the public. What aspects of that model would you say are most crucial to be included if the United States were to ever enact transparency measures on our drug supply chain?

Dr. SCHONDELMEYER. The New Zealand system collects all of the information we have talked about, where are the key starting materials from, what are the inactive ingredients, where is the active ingredient made, and the factory name and address, the finished dosage form, manufacturer name and address, who packages the product, and who labels it.

Every step along the way is transparent and for every prescription drug on the market in New Zealand, it is put in a data base and any consumer in New Zealand, or the rest of the world, can look up those products at the product-specific level and identify where did it come from. We should have nothing less in America.

In fact, these days the pharmaceutical supply system is really a global supply system. We talk about the U.S. drug supply, but if we take that, the same sources are probably 70 or 80 percent of the worlds global supply.

It really is the same system. We need a system equivalent to New Zealand. I applaud FDA and the DailyMed website that is maintained, but it is not nearly as consumer friendly as New Zealand's system is and we need to look at, and emulate their process, and then make transparent the information that FDA does have.

Senator MOODY. Do you believe that the New Zealand model for transparency, the things that they have enacted, do you believe that has decreased the amount of contaminated drugs that are consumed by the public there?

Dr. SCHONDELMEYER. I believe it has and I haven't seen studies from New Zealand about the number and types of shortages, but I think if they were at the same level as we see in the U.S., we would probably have seen studies of that type.

I wouldn't draw a conclusion from it yet, but I don't think they have as severe a drug shortage problem as we do in the U.S. for a variety of reasons and I have talked with the officials at MedSafe in New Zealand, and they say they aren't aware of any commercial problems in the marketplace from making that information public.

Senator MOODY. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Moody. I guess to start, maybe each of you, when we go to the pharmacy and we have a choice between a generic drug and a brand name drug, are they exactly—we are taking the exact same drug? If each of could respond.

Dr. GRAY. Yes. Generics typically do not follow the same production process. The excipients can be different, and there is a range of bioavailability that is allowed even upon approval. Generics do go through an approval process that is somewhat rigorous and includes in-vitro testing on a small number of individuals, but it is a lot less than the original drug and that is at approval.

Then I think what I have researched most and thought about is after approval, when the manufacturing facility has been operating for years under light regulation, how things go, you know, how consistent is compliance, but no, it is not the same excipients necessarily. It is not same process and there is—again, there is a range of availability.

Dr. GANIO. I would agree that they are not the same. However, they should behave the same in the body. When I talk to my family, I myself, I have no problem taking a generic. I will tell you that if the label shows where it is made, I will opt for domestically manufactured, or ″French,″ or ″friend-shored″ manufacturing because I am not sure the quality of where the product is made.

However, I don't think there's any issue with generic equivalency. There are, as Dr. Gray mentioned, a battery of tests that are done to make sure that it behaves in the body the exact same way as the brand name product does.

Dr. SCHONDELMEYER. Embedded in your question is, are they the same drug? What do we mean by drug? On the one hand, a drug can be the molecule, the active ingredient that causes the positive effects in the body that we are after in the healthcare system.

We also use the word drug to mean the drug product. That is the active ingredients, plus all of the extra things we added in to make the tablet hold together and to preserve it. The excipients, as Dr. Gray described, so there may be differences in the excipients and other things.

Think about it when you are baking cookies. You know, each cook has their own recipe, their secret ingredient in making their cookies and they may be a little bit different. They may all taste similar. They may be all chocolate chip cookies, but there are slight differences across them.

They all have the same ingredients, they have chocolate chips in them, and they are chocolate chip cookies. The molecule, I think, is essentially the same in almost all cases. The other things you add into it may differ, and some of those may have an effect positively or negatively on the health of a patient.

Our current process of inspecting and evaluating equivalency of products doesn't take into account all of those other things perhaps as well as it should.

Mr. COLVILL. Thank you for the question, Chairman. For myself, I don't have any problem taking generics. These two are pharmacists, so I, you know, would—I am very interested in, you know—glad that they shared their perspective.

I think the most stark difference between a branded drug and a generic drug isn't the chemical properties themselves of the drug, but it is the supply chain, the robustness of the supply chain. A branded drug has every incentive to have redundancy, extra manufacturing capacity, backup plans, buffer stock. They take all these steps to make sure they avoid shortages.

Whereas generic supply chains are very lean. If there is a disruption in the supply chain, frequently that leads to patient issues, and, you know, issues with patient care being impacted. I think that is the most stark difference.

The CHAIRMAN. Dr. Gray, would you take—you don't care if it is a generic or branded drug?

Dr. GRAY. At the moment, I don't take any drugs, but I would generally take a generic drug if prescribed but would try to investigate where it is from, but again, some of my family do, and ProPublica's Rx Inspector, which came out just a month ago, allows you to find out where the finished dosage form of your drug is made easily, unlike the DailyMed approach.

I would certainly investigate. I do pay more for brand over-the-counter drugs. I wouldn't take a generic eye drop. It kind of depends on what it is, right. If it is going directly into the bloodstream, or the eyes, or a tablet.

The CHAIRMAN. Good. Dr. Ganio, so, do pharmacists know where the active ingredients of the drugs are made? If so, do they tell their customers?

Dr. GANIO. No, in general, the pharmacist would not know where the active pharmaceutical ingredient is from. It is possible to research and find that and there is nothing on a prescription label that would tell the patient. I have never been asked as a pharmacist where the API was from by anyone that I have dispensed the medication to.

Dr. GRAY. Can I just say, I have asked my pharmacist, and they look at me like I have two heads, so.

The CHAIRMAN. Oh, no, I ask them every time.

Dr. GRAY. Yes.

The CHAIRMAN. I have done enough ads. They all know who I am, so and I have told them about our hearings. They now expect it. They actually have more information now than before. Mr. Colvill, why is supply chain mapping important to country of origin labeling?

Mr. COLVILL. Well, a few different reasons. Supply chain mapping would be important because you want to identify if there is redundancy in the supply chain or if there is concentration. If there is concentration, that can cause issues. For example, you know, from a natural disaster or any sort of disruption.

Being able to identify where there is diversification versus concentration, and also just identifying vulnerabilities. There is different problems, like I mentioned earlier, different problems that we need to assess.

If you are thinking about national security issues or geopolitical risks, then obviously mapping the supply chain to determine where drugs that are heavily reliant on more adversarial countries are coming from is important.

The CHAIRMAN. Dr. Schondelmeyer, what county of origin labeling—would country of origin labeling encourage investment in U.S. pharmaceutical manufacturing?

Dr. SCHONDELMEYER. Would it encourage what?

The CHAIRMAN. U.S. manufacturing.

Dr. SCHONDELMEYER. I think it will provide some encouragement for U.S. and for nearshoring manufacturing in Canada, perhaps Mexico, or our neighbors in Latin America may be encouraged.

Issues that come to play—one reason why China and India have become dominant is because they had lower environmental regulations, lower labor laws, and lower pay, and many other restrictions are eliminated in those countries and the companies take advan-

tage of that and make it—and they also have an economy of scale larger than the U.S. or the Western Hemisphere.

I think we can overcome those though and with advanced manufacturing that is being developed in the U.S., they can make products leaner and greener and I think, we could get to a point where we could compete in the U.S. and in our nearshore neighbors and recall, Puerto Rico used to be a hotbed of production. It has declined over time, but I think that could be reinvigorated along with other neighboring countries.

The CHAIRMAN. Ranking Member Gillibrand, do you have any other questions?

Senator GILLIBRAND. Just a couple more. Dr. Ganio, I want to explore a little bit more about your testimony about supply chain. You specifically mentioned fragile supply chains and the need for buffer inventory to insulate the United States from potential drug shortages in times of geopolitical conflict. Can you discuss some of the national security risks in more detail?

Dr. GANIO. Yes, I think we have covered some of it today but thank you for the question. I keep forgetting to unmute my microphone. Thank you for that question. We know, based on data out of the United States Pharmacopeia, that we have an overreliance on China for key starting materials, API sources in China and in India also.

In the event of escalating trade conflict, in the event an armed conflict, if China decides to make a move on the Taiwanese territory, for example, and that things escalate, we are extremely vulnerable to sources in China and they could hold those supplies from the United States, which would cut us off from essential medicines.

Knowing exactly where those vulnerabilities are—the data and transparency only gives you enough to act, and we can't take action until we have that data. We think—we believe strongly that the transparency—to help the United States understand how much we rely on those sources and how to find alternative sources is critical to our national health care security.

Senator GILLIBRAND. We have had a hearing on this topic before, but we talked a lot about FDA's ability to inspect foreign domestic manufacturing process very significantly, creating concerns about oversight and quality of imported drugs. Can you talk a little bit about that? That is same question for all the witnesses.

Dr. GANIO. Yes. Thank you for the hearing in September. I cannot say that that hearing did not keep me up at night after hearing testimony about some of the inspections, but this is where I think it is important. Domestic manufacturing is great.

FDA has the ability to walk in unannounced, but I also think in other countries that are considered allies, we should be investing in a diverse supply chain, both in the U.S., in other countries where—we have vulnerabilities, we have hurricanes here, we have other disruptions that can happen.

More diversity geographically creates a more robust supply chain, so by incentivizing it in countries where the FDA has that ability to walk in unannounced, I think is important.

Senator GILLIBRAND. Yes. Because it was interesting when asked by the Chairman, would you guys take generics? You all said, well, if I could figure out where it is from, I would maybe consider that.

Obviously, for you as the most knowledgeable stakeholders, where things are manufactured is highly relevant to you and it is highly relevant to me because we don't have the same inspections. Just to close out the testimony, if each of the other witnesses could just add whatever you think is relevant to add on these topics. Go ahead, Dr. Gray.

Dr. GRAY. On the inspections, I would like to also add that one big difference is the legal ramifications for the individuals, the managers, the quality manager, the plant manager of sending adulterated drugs in the U.S., you can go to jail. If you are overseas, you can't, right. We can't prosecute.

I think that is another incentive. I think the—you know, you heard a lot from Peter Baker on the unannounced inspection pilot, and that shows the need to do unannounced inspections globally. I think—I have a research paper now exploring the current pilot.

I think you are aware that the Congress mandated an unannounced inspection pilot in India that began in late 2022, and we are finding three to four times more likely to issue a warning letter of the unannounced inspections relative to the pre-announced inspection, meaning things weren't being found.

Some of the worst—the worst things you have read about the last few years were plants that had had clean inspections years prior to the unannounced inspection pilot. I was thinking about that. I will stop there.

Senator GILLIBRAND. Dr. Schondelmeyer.

Dr. SCHONDELMEYER. Yes. A couple of points I would make. First of all, India is our major supplier of generic pharmaceuticals and in India, certainly, there are good quality products that come out of India. Not all of them, but some of them. One of the issues is India does not participate in the International Council on Harmonization of Regulation, FDA type regulations.

Most all of our other suppliers, including China, collaborate in that. We should begin to pressure and encourage India to participate in the ICH. Second, within India, they regulate manufacturing of drugs, not at the national level, but at the equivalent of the state level, and they have like 40 states.

Even within India, they know that some states have pretty poor quality production and others have better quality. They differentiate internally in the country, yet we don't as a country when we buy from India. We need to encourage India to step up within their system, the quality, and make it more consistent and uniform.

Senator GILLIBRAND. Thank you.

Mr. COLVILL. Thank you, Senator. Two thoughts from me. The first is, you mentioned location of production and that is an important thing to consider. I think the best thing to address that issue is leveling the playing field, and one of the best things that can be done to do that is ensure FDA has the resources to do foreign inspections at the level that is needed.

Then second point is location of production is only one thing that should be considered. You also need to consider reliable supply

chains and quality and so, you can do that through reliability benchmarking programs.

I mentioned a few examples of programs that are early on in doing that and then also you could do independent quality testing to ensure a high level of quality assurance.

Senator GILLIBRAND. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Well, I want to thank each of you for being here. It has been enlightening. Today's hearing made one thing unmistakably clear, Americans are being asked to trust a system that refuses to tell them the truth. We label our food, we label our clothes.

When it comes to lifesaving medicine, patients are kept in the dark about where they are made. I mean, that doesn't make any sense. This isn't about banning drugs or raising prices. This could actually lower prices for American families, while delivering needed transparency and support American jobs. Manufacturing location matters. Oversight isn't equals. Secrecy doesn't protect patients. It protects the status quo and bad actors.

Americans deserve to know what they are putting in their bodies and whether their medicine is truly made in America. Honesty and transparency strengthens markets, accountability, and national security.

My staff will be reaching out to share the bill text with everybody's office in the coming days. I just want to thank Ranking Member Gillibrand. Her team has been great to work with, and this has been a great bipartisan effort to try to come up with a solution that is going to be workable.

If any Senators have additional questions for the witnesses or statements to be added, the hearing record will be open until next Wednesday at 5:00 p.m. Thanks everybody.

[Whereupon, at 10:35 a.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

Written Testimony of John V. Gray
Dean's Distinguished Professor, Operations and Business Analytics
Fisher College of Business, The Ohio State University

Submitted January 26, 2026

Abridged version to be read at the hearing

Before the
U.S. Senate Special Committee on Aging
hearing titled:
"Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From"
January 29, 2026

Senator Scott, Ranking Member Gillibrand, and distinguished members of the committee. Thank you for this opportunity and thank you very much for bringing so much attention to the issue of pharmaceutical supply chains.

I will start by saying I support a requirement for consumers, doctors, pharmacists, and any other stakeholders to be readily able to access key information about their drug, at the unique National Drug Code (NDC) [1] level. Specifically, they should be able to access information about the location of both the finished dosage form, or FDF, manufacturer, as well as the Active Pharmaceutical Ingredient, or API, manufacturer.[2] I consider it important to also include a valid drug-level quality score alongside this. Finally, I believe that the same information about other drugs deemed exchangeable by the FDA also be readily available. Taken together, this transparency would allow generics manufacturers to compete on something other than cost and help to slow or even halt the race to the bottom that has ensued in this industry for some time.

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[1] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

[2] I focus this testimony on transparency's effect on the generic drug market. I do not focus on national security. For that purpose, for critical drugs, supply chain mapping should include Key Starting Materials (KSMs), critical excipients and packaging (e.g., vials). I do not believe KSM and excipient transparency to consumers is necessary. The mechanisms for dealing with identified supply risks for critical drugs may include one or more of stockpiling, direct investment in capacity (domestic or friend/nearshore), guaranteed demand, pre-determined allocation procedures, etc.

For years, the FDA has espoused the notion that all generic drugs are fully exchangeable, and this may have been mostly true two or three decades ago. However, the notion that all generic drugs are created equal is no longer tenable. There are meaningful quality differences. Anecdotes have abounded for years. Joe and Terry Graedon of The People's Pharmacy have long raised concern, based on anecdotes from listeners. Katherine Eban's 2019 best-selling book *Bottle of Lies* provided more clear evidence. Bloomberg's Anna Edney[3] and The New York Times' Farah Stockman[4] have written great pieces on this issue. More recently, ProPublica[5] has written several articles in the last year, and Sinclair Broadcasting Group[6] did a multi-part series. As was made clear in your September hearing, there is ample anecdotal and now academic[7] evidence that all generic drugs are not created equal, with the most problematic drugs, on average, being older drugs manufactured offshore. The combination of intense cost pressure [8] and the opacity of the industry have been key factors enabling this race to the bottom.

The FDA's regulatory strategy to ensure quality has long been to focus on the *process* by inspecting facilities to ensure adequate adherence to good manufacturing, lab, and distribution practices. Consistent process compliance with validated procedures is necessary to ensure that the approved drug product always meets the standards that were deemed met when the drug was initially approved. It has become more difficult for the FDA to ensure this compliance as manufacturing has moved offshore,[9] especially given that foreign inspections are typically preannounced.[10]

It is important to understand the day-to-day challenges and trade-offs that manufacturers face when trying to operate consistently in compliance with regulations. From my own eight years of experience as an engineer and manager in a highly compliant FDA-regulated

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[3] e.g., https://www.bloomberg.com/news/newsletters/2025-01-08/generic-drug-poses-dangers-when-potency-falls-short-of-brand-name
[4] https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html
[5] e.g., https://www.propublica.org/article/fda-hides-drug-names-contaminated-factories
[6] e.g., https://wjla.com/features/i-team/the-deadly-consequences-of-americas-reliance-on-foreign-made-drugs-medication-prescriptions-health-fda-inpesctions-generics-medicine-united-states-pills-cough-syrup-eye-drops
[7] https://journals.sagepub.com/doi/10.1177/10591478251319691
[8] A recent RAND study found that, while the U.S. does pay more for branded drugs than the rest of the world, we pay substantially less than the rest of the world for our generic drugs.
[9] See, e.g., Almeter, Philip J., et al. "FDA approaches in monitoring drug quality, forces impacting the drug quality, and recent alternative strategies to assess quality in the US drug supply." *Journal of Pharmaceutical Innovation* 17.2 (2022): 269-282.
[10] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5252874

facility, I can say that consistent compliance is difficult. Variability in raw material properties, the environment, equipment functioning, and personnel decision-making can all lead to noncompliance. Faced with pressure to deliver products on time and to operate at low enough costs to compete, it is tempting for managers and frontline employees to look the other way in the face of noncompliance, versus dealing with the time-consuming and potentially costly consequences of properly investigating. Over time, this tendency can lead to a slippery slope, even for managers with the best intentions. Since consumers cannot observe quality and are told that all drugs are exchangeable, firms are left to compete almost solely on cost, titling the trade-off in favor of looking the other way. In research in the pharmaceutical industry, co-authors and I documented an overall, on average, tendency for manufacturing compliance to decay over time, absent an observable trigger to renew focus on quality.[11]

Country of origin labeling can serve to partially reverse the race to the bottom. Country of Origin labeling was called for by a 2022 Congressionally mandated National Academies of Science, Engineering, and Math (NASEM) Report.[12] Co-authors and I experimentally tested the recommendation and found a significant preference among both American consumers and hospital pharmacists with buying experience towards drugs produced domestically or nearshore, and away from those produced in India or China.[13] It is notable that we informed participants that all the drugs under consideration were FDA approved.

The NASEM Report also recommended public-facing quality scores. In our study, we tested the influence of quality scores in addition to country of origin for a subsample of participants. Interestingly, while there was still a preference for domestic manufacturing among consumers, the highest-quality rated offshore-made drugs were preferred over moderate-quality domestic-made drugs. Thus, the combination of country of origin *and* quality ratings will prevent unjustly rewarding lower-quality domestic manufacturers and unjustly punishing strong foreign ones, allowing global competition not just in cost, but quality.

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[11] Anand, G., J.V. Gray, E. Siemsen. 2012. Decay, Shock, and Renewal: Operational Routines and Process Entropy in the Pharmaceutical Industry *Organization Science* **23**:6, 1700-1716

[12] https://www.nationalacademies.org/publications/26420

[13] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4639108 ; note that I do not cite literature in this statement on the effect of country of origin or quality ratings on demand; several such citations can be found in this paper.

I note that while the industry is still opaque, recent work has led to some transparency. A Ph.D. student of mine was able to use public data to link most drugs to their manufacturing facility for the research discussed in your September 17 hearing. About a month ago, ProPublica released its RxInspector tool.[14] Using largely the same approach we did, supplemented by some additional data obtained through a lawsuit of the FDA, they also linked most, but not all, drugs to their finished dosage manufacturing facilities. They used this data to create a public-facing interface to allow stakeholders to find out the facility where their drugs are made, and the facility's recent inspections and any compliance action. Last week, they made the database itself public.[15]

While these are positive steps, it seems less than ideal to need teams of academics and journalists to spend countless hours to create incomplete and difficult-to-maintain databases linking drugs to facilities while the FDA already has all the necessary information in its databases. Further, none of these efforts have yielded reliable information about where the API, one step upstream and arguably the most important step in drug manufacturing,[16] is produced.

It seems there is momentum for full manufacturing location and quality transparency in this industry. Notably, the FDA itself has requested the authority to release manufacturer location information for finished dosage form, API, and more in their 2026 authorization request.[17] HHS is promoting "radical transparency." The FDA commissioner, as described in his book, *Unaccountable,*[18] promoted transparency of hospital outcomes years ago.[19] I am part of a team, funded by the Pentagon, charged with developing drug-level quality scores based on attainable data. A separate team under the same broad funding is performing lab tests of market sweeps of critical drugs, finding meaningful variation in dissolution, contaminants, and active ingredient. The goal of both teams is to provide valid drug-level quality scores (ideally, one score based on both historical data and the results of tests)[20] which can directly impact federal government purchasing decisions and hopefully

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[14] https://www.propublica.org/article/rx-inspector-prescription-drug-lookup
[15] https://www.propublica.org/article/rx-inspector-reshaping-decisions-generic-drugs
[16] The debate around the Acetris ruling is relevant to the discussion about where the most important step in drug manufacturing occurs: https://apicenter.org/policy-recommendations/acetris-loophole
[17] https://www.fda.gov/media/187068/download
[18] https://www.bloomsbury.com/us/unaccountable-9781608198382/
[19] Here is the history of hospital ratings, which actually pre-date the book *Unaccountable*. https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-compare
[20] As in: https://www.sciencedirect.com/science/article/abs/pii/S1544319122003272

influence sourcing decisions more broadly.[21] These scores should be available by the end of the year.

As transparency leads more entities to source from relatively higher-quality manufacturers, there will be real positive consequences for the health of the population. While mostly unmeasured, there is increasing evidence of that quality variation among manufacturers has real consequences to clinical outcomes.[22] Such research has taken so long to emerge both because most medical researchers until recently did not think about operations and supply chains as a source of variation and risk in drugs, and because for those who wished to study such questions, it has not been possible to link drugs to specific manufacturers.

The specific recommendation I make related to country of origin, the main focus of this hearing, is this: A QR-code on all public-facing packaging that leads to a website (also searchable by NDC) that provides the manufacturing location/locations of both the finished dosage form and the active pharmaceutical ingredient, as well as a drug/NDC-level quality score. I recommend for anything public facing that quality is scored in a way that minimizes the likelihood that consumers choose to not take drugs with low scores, as skipping the drug may be worse than possible contamination, sub- or superpotency, or fast or slow dissolution in many, if not most, cases. One option may be to use a five-star scale but have all drugs on the market be scored three stars or higher. I also recommend that the site provide the same information for other manufacturers of the same drug, for comparison, so consumers who are willing and able to do so can search for other ways to get higher rated and/or domestic drugs. There are non-insurance options that are often affordable, [23] especially for older drugs which, as mentioned earlier, tend to be those with the highest quality risk. Even if consumers are unable to acquire a substitute, they can at least raise concern to their pharmacy or insurer, which hopefully would also eventually move the market. I believe that this transparency will slow, or even halt, the race to the bottom by allowing manufacturers to compete on something other than cost: specifically, manufacturing location and quality.

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[21] The FDA already has, at least, facility level compliance scores (e.g., Figure 4 on page 5 of this: https://www.fda.gov/media/135046/download?attachment); they may also have internal drug level quality scores. They do not release these scores at the level of facility or drug; only occasionally in aggregate.
[22] e.g., https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4120736 ; https://pubmed.ncbi.nlm.nih.gov/39574836/
[23] e.g., DiRx, Mark Cuban Cost Plus Drugs

Location and quality transparency should, in my opinion, be just one of several aspects of comprehensive legislation to promote a higher quality, more domestic pharmaceutical manufacturing supply base. Your October report and other hearings cover many other important aspects, including improving foreign inspections, more testing, especially of imported drugs, and the possibly of having a "qualified person" with legal responsibility in the U.S. who signs off on any imported batch.[24] I support all these layers of protection.

Direct purchasing incorporating country of origin and quality by the federal government (i.e., the Veterans Administration [VA], the Pentagon, and federal prisons) will send a powerful signal to the market. However, the private market, including that with CMS oversight, is of course much larger and very complex. I am unsure how much transparency will affect the market, absent additional work. While the Federal Trade Commission[25] and the Senate Finance Committee[26] have active work in this area, robust solutions seem elusive, and I also cannot provide one. I can only say that there is significant value capture in the middle of the supply chain by a web of often integrated intermediaries; i.e., the entities between the manufacturers and the doctors/ pharmacists/ consumers. It is not clear to me the degree to which transparency would affect the sourcing decisions of these entities without some additional legislation.

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[24] This helps to address the fact that personal liability for producing adulterated products is much more easily enforceable for domestic plant and quality managers than for foreign managers, another factor that tilts attention away from strict compliance and towards cost in foreign facilities.

[25] https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen

[26] https://www.finance.senate.gov/chairmans-news/crapo-wyden-introduce-bipartisan-pharmacy-benefit-manager-legislation

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AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS STATEMENT FOR THE RECORD

"Truth in Labeling – Americans Deserve to Know Where Their Drugs Come From"

U.S. Senate Special Committee on Aging

January 29, 2026

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

Introduction: The American Society of Health-System Pharmacists (ASHP) appreciates the Special Committee on Aging's comprehensive work on creating a more resilient and reliable drug supply chain. For over 20 years, ASHP has worked to strengthen the drug supply chain by publicly reporting drug shortages, providing resources to support patients and clinicians affected by supply disruptions, and advocating for a stronger drug supply chain.

America's drug supply chain is currently challenged by hundreds of ongoing drug shortages and concerns about drug reliability and quality.[1][2][3] These challenges, along with geopolitical risks to our drug supply chain, threaten our national healthcare security. These are decades-old problems with multiple causes.

Every American should have the right to know where their pharmaceuticals are manufactured. Today, that information can be voluntarily provided by manufacturers, but it is not required. While ASHP supports transparency in the pharmaceutical supply chain, including country-of-origin labeling, no single policy will fix the underlying problems that have led to the current fragile supply chain.

Over the last few months, the committee has thoroughly investigated the pharmaceutical supply chain: manufacturers, wholesalers, group purchasing organizations, distributors, and pharmacies. I ask that the committee consider that the drug supply chain in the United States is composed of two distinct supply chains: brand-name, single-source products, and older, generic, multisource products. Financial incentives and challenges separate the two supply chains.

Brand-name manufacturers have a strong market incentive to invest in the resiliency of their supply chains and to produce high-quality drugs. However, price erosion and race-to-the-bottom market

[1] ASHP Drug Shortages Statistics: https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[2] Written testimony, Peter Baker: https://www.aging.senate.gov/imo/media/doc/ab6519c3-c1ce-3adb-a0a9-0d3992a936d5/Testimony_Baker%2009.17.25.pdf
[3] Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Adverse Events: https://journals.sagepub.com/doi/10.1177/10591478251319691

dynamics result in a brittle supply chain for older, generic products. With slim-to-negative profit margins, generic manufacturers are less likely to invest in resiliency and quality maturity. Generic manufacturers that are capable and willing to make those investments often lose market share due to pricing competition from manufacturers that are unwilling or unable to invest in resiliency and quality maturity. Without a public mechanism to evaluate quality maturity and resiliency investments, purchasers have no information, aside from price, to leverage when buying drugs, reinforcing race-to-the-bottom market dynamics and undercutting market resiliency. The lack of market recognition for these investments reduces incentives for manufacturers to commit to quality and resiliency, contributing to a fragile supply chain and resulting in drug shortages.

While there may be a correlation between country of manufacture and drug product quality, the country of origin alone is not a reliable proxy to evaluate drug product quality. There are many examples of manufacturers, both domestic and overseas, that have faced quality challenges in the recent past. We support public disclosure of where our drugs are made, but we ask that the committee consider additional policies if the intended result is to improve the overall reliability and resiliency of America's drug supply chain. Drug shortages, product quality, and national healthcare security are all related to the resiliency and reliability of our pharmaceutical supply chain (Figure 1). Policies to address each of these risks and vulnerabilities can solve multiple root causes and result in a resilient supply chain of high-quality pharmaceuticals that withstands demand and supply shocks.

Figure 1: Policies to address drug product quality, national healthcare security vulnerabilities, and drug shortages support a resilient and reliable supply chain

ASHP's Role in the Pharmaceutical Supply Chain: ASHP is the largest association of pharmacy professionals in the United States, representing over 65,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. Our members manage drug shortages in hospitals, ambulatory clinics, and various other healthcare settings. As part of our mission, we have publicly reported national drug shortages for over two decades. We collect public reports of drug shortages from clinicians, patients, and caregivers. Through a partnership with the University of Utah Drug Information Service, ASHP maintains a drug shortages list that includes active and resolved drug shortages.[4] We post every prescription drug shortage report we receive to our database as soon as it is investigated and confirmed with the manufacturer, usually within 24-72 hours. The ASHP Drug Shortages List includes information down to the individual manufacturer and national drug code level and reflects any supply interruption that affects how a pharmacy prepares or dispenses a drug product.

[4] ASHP Drug Shortages List: https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages

We also provide practitioner-focused resources to help the healthcare community manage shortages. Examples include guidelines for managing drug shortages, specific recommendations and clinical considerations for therapeutic alternatives to drugs in shortage, comparisons within individual drug classes, and safety information to reduce the risk of medication errors during shortages.

Current and Long-Term Trends in Drug Shortages: Our current data indicate that drug shortages are improving.[5] Eighty-nine new drugs were added to the ASHP Drug Shortages List in 2025, the fewest additions since 2006. However, we continue to track over 200 ongoing drug shortages, including lifesaving and life-sustaining drugs used in critical care and surgical settings. Solutions targeted at these root causes include promoting quality and transparency, ensuring diversity in the manufacturing base, and directly incentivizing new manufacturing. As noted, a critical component to promoting quality, transparency, and diversity is providing information so manufacturers and purchasers know where the active pharmaceutical ingredients (APIs) and finished products are produced.

Causes of Drug Shortages: The causes of drug shortages can range from raw material availability to natural disasters disrupting infrastructure. Most often, shortages are caused by manufacturing delays or declines in manufacturing quality.[6] [7] [8] The root causes behind these shortages are a lack of incentive to produce older, generic drugs with slim profit margins, and limited market recognition of manufacturers with reliable supply chains and high-quality systems.[9]

Country-of-Origin Labeling Can Improve Transparency and May Influence Purchasers: Research has shown that patients and pharmacy purchasers prefer to buy drug products manufactured in the U.S. or Canada compared to products from India or China when the country of origin is made available to them.[10] But our research misses key factors that affect purchasing decisions in practice. Choice is often an illusion. Patients receive whichever product is on a pharmacy contract from a wholesaler, pharmacy

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[5] ASHP Drug Shortages Statistics: https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[6] National Academies of Sciences, Engineering, and Medicine Building Resilience into the Nation's Medical Product Supply Chains: https://nap.nationalacademies.org/catalog/26420/building-resilience-into-the-nations-medical-product-supply-chains
[7] ASHP Virtual Summit on Safe, Effective, and Accessible High-Quality Medicines as a Matter of National Security: https://academic.oup.com/ajhp/article/78/6/511/6009025
[8] FDA Drug Shortages: Root Causes and Potential Solutions: https://www.fda.gov/media/131130/download?attachment
[9] Ibid
[10] Generic Drug Transparency: Testing a Regulatory Proposal: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4639108

benefit manager, or group purchasing organization. At the pharmacy counter, a patient is likely to receive their prescription in an amber bottle dispensed by the pharmacy and will never see the manufacturer's container. In hospitals, clinics, and surgery centers, medications are prepared and administered without patients seeing them beforehand.

While patient and buyer behavior may not change directly because of country-of-origin labeling, increased transparency about where our drugs and ingredients are manufactured can help government agencies, private investors, and researchers better understand the drug supply chain and decide where to invest resources to address vulnerabilities. With this in mind, we urge the committee to consider requiring disclosure of sources of APIs and key starting material (KSMs) so that agencies have information to identify critical dependencies and vulnerabilities.

While ASHP strongly supports supply chain transparency, we urge the committee to consider the goal of country-of-origin labeling and directly address deficiencies or apply incentives to achieve the desired outcomes. For example, if the goal is to improve overall supply chain quality, consider more transparency in manufacturer quality to provide market recognition for manufacturers with strong quality systems. Strengthening the Food and Drug Administration's (FDA) capabilities to conduct overseas and surprise inspections and enhancing enforcement authority for recalls of adulterated or contaminated drug products can also improve the overall quality of the drug supply chain.

Reliance on potential geopolitical adversaries can also be addressed more directly. The Agency for Strategic Preparedness and Response has undertaken a Strategic Active Pharmaceutical Ingredients Reserve to build onshore stockpiles of essential medicines.[11] Building buffer inventories of finished dosage forms, APIs, and KSMs can allow critical parts of the supply chain to withstand supply and demand shocks, improving national healthcare security and reducing drug shortages. The United States relies heavily on China for raw materials needed to manufacture pharmaceuticals.[12] Trade tensions and the threat of armed conflict between China and Taiwan may threaten access to these KSMs and other inputs needed to maintain access to life-sustaining and lifesaving drugs. Financial incentives and supply

[11] Ensuring American Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve: https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/

[12] Concentrated Origins, Widespread Risk: New USP Insights on Key Starting Materials: https://qualitymatters.usp.org/concentrated-origins-widespread-risk-new-usp-insights-key-starting-materials

chain transparency can help stakeholders identify vulnerabilities and accelerate the de-risking of supply chains from Chinese sources.

ASHP's Additional Recommendations to Address Drug Shortages[13]: We agree with the committee that a comprehensive approach is needed to solve the nation's drug shortages. In addition to labeling transparency and the aforementioned policies, we also make the following recommendations to the committee to effectively address drug shortages through quality, transparency, and direct economic incentives:

- **Enforce Existing Drug Shortage Requirements:** Congress should amend section 510(j) of the Food Drug and Cosmetic Act (FDCA) 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.
- **Improve Transparency into Manufacturer Quality:** Congress should require FDA to finalize and make public metrics of quality management maturity (QMM) so that purchasers can buy from manufacturers less likely to experience a shortage. In the absence of publicly reported QMM metrics, FDA should make unredacted manufacturing inspection reports publicly available so that purchasers have a better understanding of supplier manufacturing challenges and which products are made at facilities with records of manufacturing quality and compliance problems.
- **Encourage New Manufacturers and Manufacturing Sites:** Congress should give FDA authority to waive generic drug user fees for drugs described in 506C(g) of the FDCA, for which FDA may prioritize and expedite review of an abbreviated new pharmaceutical drug application (ANDA) or related supplement to mitigate a shortage. The fee waiver would apply only to manufacturers that commit to promptly market their generic pharmaceutical drug if it is approved.
- **Encourage Long-Term, Guaranteed-Volume Contracts:** Congress should authorize the Centers for Medicare & Medicaid Services to provide an add-on payment to providers for critical generic pharmaceutical drugs determined by the Department of Health and Human Services (HHS) to be at risk of experiencing a shortage, if those providers certify that they have entered an agreement to

[13] ASHP Policy Solutions to Address the Drug Shortage Crisis: https://www.ashp.org/-/media/assets/advocacy-issues/docs/2023/ASHP-Drug-Shortage-Recommendations.pdf

acquire at least 50% of their historical purchase volume for those products via long-term contracts. To ensure investment in supply chain stability and quality, the agreement must include a requirement that manufacturers maintain a six-month buffer supply of finished product as well as meaningful penalties for failure to supply contracted products, including when manufacturing disruptions result from regulatory violations or supplier disruptions. To be eligible for pass-through payments, providers must demonstrate that their suppliers participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[14]

- **Diversify the Manufacturing Base:** Congress should require the federal government to use its purchasing power to encourage greater diversity and redundancy in the supply chain by spreading purchase volume from federal agencies across at least three different manufacturers with approved ANDAs for any critical generic pharmaceutical drug determined by HHS to be at risk of experiencing a shortage. Federal purchasers should require that manufacturers not rely on the same contract manufacturers, as this would do little to diversify the manufacturing base. Federal contracts should require manufacturers to maintain a six-month buffer supply of finished product and include meaningful penalties for the failure to supply, including when manufacturing disruptions result from regulatory violations or supplier problems. As noted earlier, to ensure quality and transparency, federal agencies should give preference to manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[15]

ASHP greatly appreciates the Senate Special Committee on Aging's leadership in working to ensure America's seniors have access to safe and effective drugs without hindrance or delay. Such efforts are critical to ensuring patients have continuity of care. We look forward to working with the committee to provide greater transparency into the drug supply chain and ensure patients and providers have ready and uninterrupted access to safe and effective drugs required to ensure optimal patient care.

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[14] Healthcare Groups Release Drug Supply Chain Recommendations: https://news.ashp.org/news/ashp-news/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations

[15] Ibid

Thank you for the opportunity to appear before this committee.

Michael Ganio

American Society of Health-System Pharmacists

Senior Director, Pharmacy Practice and Quality

Statement on

Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply

at the Senate Hearing on

Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From

Statement before the

Special Committee on Aging
United States Senate
Congress of the United States
Thursday, January 29, 2026, at 9:30 a.m.
Dirksen Senate Office Building, Room SD-608

Statement of

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Real COOL (Country-Of-Origin-Labeling) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply

Thank you, Chairman Scott, Ranking Member Gillibrand, and other members of the Senate Special Committee on Aging, for the opportunity to provide information and insights at this hearing on "Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From." My remarks will address "Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market as a Foundation for a Secure & Resilient Drug Supply.

I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Co-Principal Investigator for the Resilient Drug Supply Project in the Center for Infectious Disease Research and Policy (CIDRAP). In addition, I am Director of the *PRIME* Institute which focuses on research and policy issues related to the pharmaceutical market and its impact on society. These remarks are my own views based upon my research and experience in studying the pharmaceutical marketplace for over fifty (50) years. Thank you for the opportunity to testify at this hearing. During my career I have had the opportunity to interact with many of the federal entities that shape and influence our nation's healthcare system including the Department of Health and Human Services and many of its divisions such as FDA, CMS, ASPE, ASPR, BARDA and with other federal agencies such as the Department of Commerce, FTC, GAO, and OMB.

This hearing on the role of transparency and country-of-origin-labeling (COOL) in securing the U.S. drug supply comes at a critical time for the United States. The U.S. pharmaceutical market is facing ongoing challenges with economic and quality concerns and with new challenges from geopolitical risk that may precipitously interrupt pharmaceutical trade, distribution and the supply chain.

Challenges Impacting the U.S. Drug Supply

Prescription drugs are a cornerstone of American healthcare, with virtually all Americans needing and using prescription medications and related pharmacy services during their lifetime. Nearly one-half (45.8%) of all Americans and 85% of older adults (aged 60+) reported taking one or more prescription drugs in the last month.[1] Americans

[1] "Americans Take Prescriptions a Large Portion of Their Lives." U.S. Pharmacist, October 25, 2023. Accessed 01-24-2026 at: https://www.uspharmacist.com/article/americans-take-prescriptions-a-large-portion-of-their-lives#:~:text=University%20Park%2C%20PA%E2%80%94Over%20a,all%20Americans%20said%20the%20same; see, also, Jessica Ho. "Life Course Patterns of Prescription Drug Use in the United States." Demography (2023) 60(5):1549–1579, published September 20, 2023, DOI 10.1215/00703370-10965990

count on critical and essential medications for serious and life-threatening diseases such as diabetes, chronic heart disease, asthma, epilepsy, cancer, and almost every other condition or disease. Indeed, access to prescription drugs is a foundational component of a safe and effective healthcare system.

Historical Challenges to Drug Supply: Quality & Market Economic Issues. Americans expect essential medications to be available at a nearby community pharmacy, or at the local hospital, when they are needed. However, drug shortages have been, and still are, "a serious and recurring problem resulting from a web of factors rooted in an opaque drug production and drug supply chain, underfunded and underperforming government agencies, and a drug purchasing and distribution system with product allocation practices that are often secretive, unknown, and at times counterproductive."[2] Historically, drug shortages have been attributed to a variety of quality issues and market economic factors[3] including "manufacturing difficulties; quality problems and [drug] recalls; supply and logistic disruptions; unexpected demand surges; low prices for older, well-established generic drugs due to 'over-competition'; market [concentration and] manipulation by various stakeholders; and other factors."[4]

For more than three decades, there has been a substantial number of drug shortages in the U.S. market.[5,6] Both the FDA and the American Society of Health System Pharmacists (ASHP) routinely track and report on these drug shortages.[7,8] While the number of drug shortages has been growing over time, there are several relatively recent developments that have improved our understanding of, and response to, drug shortages. For example, organizations such as Angels for Change[9] and End Drug

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[2] Schondelmeyer S, Siefert J, Margraf D, et al, COVID-19: The CIDRAP Viewpoint, Part 6: Ensuring a Resilient US Prescription Drug Supply, October 21, 2020, available on the Resilient Drug Supply Project website at: https://www.cidrap.umn.edu/rds or directly at: https://www.cidrap.umn.edu/sites/default/files/public/downloads/cidrap-covid19-viewpoint-part6.pdf

[3] FDA. Drug Shortages: Root Causes and Potential Solutions. Report. Oct 2019.

[4] Stephen W Schondelmeyer. Statement on Strategic Assessment of the Resilience of the U.S. Drug Supply with Lessons from the Pandemic & Recommendations for Moving Beyond. Presented at Senate Hearing on COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps before the Committee on Homeland Security and Governmental Affairs, United States Senate, May 19, 2021. Accessed online on January 24, 2026 at: https://www.hsgac.senate.gov/wp-content/uploads/imo/media/doc/Testimony-Schondelmeyer-2021-05-19-13.pdf.

[5] FDA. Drug Shortages, Oct 2019.

[6] Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. Am J Health Syst Pharm 2009 Aug 1;66 (15):1399-406; and, ASHP website: https://www.ashp.org/Drug-Shortages/Current-Shortages.

[7] FDA reported drug shortages can be found at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

[8] ASHP reported drug shortages can be found at: https://www.ashp.org/Drug-Shortages/Current-Shortages

[9] Angels for Change. Our Mission. "Our focus is to advocate on behalf of any patient in a life-saving drug shortage, while building relationships with patients and members of the pharmaceutical supply chain ending all healthcare crises created by drug shortages." Angels for Change was founded in 2019. Accessed online on January 24, 2026 at: https://www.angelsforchange.org/ourmission.

Shortages Alliance (EDSA)[10] have emerged to work with patients, healthcare providers and health systems, the pharmaceutical industry, and supply chain stakeholders. In addition, the United States Pharmacopeia (USP) has developed and maintains the USP Medicine Supply Map which is an innovative digital platform "powered by AI technology and predictive analytics."[11] Using previous drug shortage data and other factors, the USP Medicine Supply Map employed predictive analytics to identify, characterize, and forecast shortage risks. In 2024, the USP model was able to predict a high risk of shortage for more than 98% of the sterile injectable drugs that later experienced an actual shortage in the U.S. market. Clearly, this historical, experience-based model works for predicting drug shortage risk driven by quality and market economic issues and it has improved our ability to anticipate and mitigate many drug shortages.[12]

New Challenges to a Secure Drug Supply: Trade Restrictions & Geopolitical Risk. With the advent of COVID-19, the global market for pharmaceuticals faced a new reality: trade restrictions and barriers for pharmaceuticals. There was a sudden global demand for a COVID-19 vaccine. Even when vaccines were developed and began to enter the market, the demand far outstripped the supply leading to intense global competition for the limited supplies of the vaccine. Vaccine-producing and high-income countries wanted to assure sufficient supply for their own populations before allowing export of the vaccine to other nations.[13] Countries such as those in the European Union, the United States, and India imposed export restrictions on the COVID-19 vaccine.[14] In addition, India was so concerned about having enough critical drugs to meet the needs of the Indian market that it restricted for a time the export of 26 APIs and finished drug

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[10] End Drug Shortage Alliance (EDSA). About Us. Mission. EDSA was founded in December or 2021.

[11] United States Pharmacopeia, USP Medicines Supply Map, USP. Accessed online on January 24, 2026 at: https://www.usp.org/supply-chain/medicine-supply-map; the USP Medicines Supply Map was initiated in 2018 and made public in 2022. Mary Van Beusekom. RDSP maps medicine supply to US to predict, prevent shortages (Part 1 of 2). CIDRAP News, University of Minnesota. March 31, 2022. Accessed on May 23, 2025 at: https://www.cidrap.umn.edu/supply-map-created-predict-drugshortages-find-solutions-part-1-2.

[12] United States Pharmacopeia. USP Annual Drug Shortages Report: Longstanding drug shortages persist in 2024. May 2025/ Accessed on January 24, 2026 at: https://go.usp.org/2025drugshortagesreport?_gl=1*zlzl4g*_gcl_aw*R0NMLjE3NjkzODA2MDAuQ2owS0NRaUFtOWZMQmhDUUFSSXNBSm9OT2N0NnlscUZPaDBpTnpWbWlXMFJGamxrVXlqMk1tX0d5TmVlaEpBZFFNNnhlUWxMNEZ1bDRPQWFBdTBuRUFMd193Y0I.*_gcl_au*NDQ3ODc4MTQxLjE3Njg5OTI3OTQuMTA2MzA4OTQ4Ny4xNzY5MDQxMjM5LjE3NjkwNDEyNzE.*_ga*NTgxOTMxNzIuMTc2ODk5Mjc5NA..*_ga_DTGQ04CR27*czE3Njk0MDEzODUkbzckZzAkdE3Njk0MDEzODYkajU5JGwwJGgw/

[13] Victoria Pilkington Sarai Mirjam Keestra, Andrew Hill. "Global COVID-19 Vaccine Inequity: Failures in the First Year of Distribution and Potential Solutions for the Future." Frontiers in Public Health, PERSPECTIVE, March 1, 2022, Volume 10, doi: 10.3389/fpubh.2022.821117.

[14] Ibrahim, Imad Antoine. "Overview of Export Restrictions on COVID-19 Vaccines and their Components." American Society of International Law, Issue: 10, Volume: 25, June 01, 2021

products to prevent shortages in India.[15] More recently, the Trump administration has introduced tariffs on the trade of certain pharmaceutical products.[16]

Although geographic concentration of pharmaceutical production had been growing gradually for more than two decades, COVID-19 exposed the vulnerability of a highly concentrated supply chain. The dominant market share of India and China in certain pharmaceutical markets gives these countries significant leverage to raise price or, if hostilities exist, to withhold supply from the U.S. market.[17] With the current level of U.S. dependency upon drugs whose active pharmaceutical ingredients (APIs) were made in China or India, if either country decides for any reason to block export of pharmaceuticals to the U.S., the American healthcare system would face a major supply crisis.[18]

Geopolitical risk and trade restrictions are both factors that are largely independent from, and external to, the pharmaceutical market. However, these new types of risk can have a sudden and major impact on the U.S. drug supply chain. One analyst noted that "A major geopolitical conflict could compromise many supply chains, potentially ones quite different from those currently at high risk of shortage."[19] Such geopolitical risk and trade restrictions are new forces in the global pharmaceutical market that are likely to cause supply issues and shortages with a different set of drugs than are traditionally seen due to quality issues and market economic factors. Because of recent changes in the dynamics of global relationships, overall, both geopolitical risk and trade restrictions on pharmaceuticals have become real and are much more likely to impact the supply of drugs in the United States. The U.S. population, in general, does not have much visibility into the geographic source of the medications they take every day and the risk of disruptions to the supply chains for those medications.

What Is COOL (Country-of-Origin-Labeling)?

What is the Purpose of COOL? Country-Of-Origin-Labeling (COOL) is an established practice for important consumer goods including food, textiles, automobiles, and certain

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[15] PTI, BloombergQuint. India restricts drug exports as threat of coronavirus rises. Mar 3, 2020.

[16] American Hospital Association, "President announces new tariffs, including for certain pharmaceuticals, set to begin Oct. 1." Sep 26, 2025. Accessed on January 24, 2025 at: https://www.aha.org/news/headline/2025-09-26-president-announces-new-tariffs-including-certain-pharmaceuticals-set-begin-oct-1.

[17] Stephen W Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities" at the U.S.-China Economic and Security Review Commission Hearing on Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security Panel II: Preparing for China's Counterpunch: Vectors for Supply Chain Coercion, June 5, 2025. p. 19

[18] Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply." P. 19.

[19] Marta E. Wosińska. "Drug shortages: A guide to policy solutions." Brookings, March 13, 2024. Accessed on January 24, 2026 at: https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/.

other consumer goods. When buying a T-bone steak, or a new t-shirt and blue jeans, the consumer is provided with a label on the end-product that clearly identifies the country where the product was "made." In general, COOL in the consumer market serves as a mechanism to inform buyers about the product's origin, thereby influencing perceptions of quality, safety, economics, or even the presumed patriotism of the purchaser. With respect to pharmaceuticals, the safety, efficacy, and quality assurance of the medication are paramount. Knowing the country of origin for the product can directly affect consumer trust and regulatory scrutiny. Furthermore, COOL reflects the regulatory frameworks, economic strategies, environmental conditions, and international trade policies that may have surrounded and influenced the making of the end-product. COOL is a tangible means to provide transparency, support consumer decision-making, and encourage a fair and competitive market.

Public policy regarding a variety of consumer goods requires the manufacturer to inform the purchaser about where the product being acquired and consumed was actually made. In a market where public policy requires that the consumer be informed about where their T-bone steak was raised or where their blue jeans were made, it seems unconscionable that society would consider it any less important to know where their life-saving cancer drug or diabetes medicine was made.

What Is COOL? COOL is the acronym for "Country-Of-Origin-Labeling" which means to provide the ultimate purchaser—the American patient—with pharmaceutical product labeling that clearly indicates where their medication was made. COOL has emerged as a critical element in the contemporary landscape of consumer goods, in general, and prescription pharmaceuticals, in particular. COOL involves marking the drug product received by the end-consumer with the name of the country in which the product was actually manufactured or made. For some industries, and in some trade agreements, the concept of COOL is the place where the product was "manufactured, processed, or substantially transformed." The definition of where a pharmaceutical product is made is critical and should be clearly defined. For pharmaceutical products, the essence and value of the drug product is embodied in its active pharmaceutical ingredient(s) (API), and not necessarily in how it was processed or packaged.

For most pharmaceutical products, the API is typically made in a different location from where the final drug product is formed. Consequently, one can argue that "transformation" of the raw API material into the final form of the actual physical product such as a tablet, capsule, liquid, or other dosage form is relevant to the integrity and use of the end-product. In other words, the COOL for pharmaceutical products should account for both the country where the API is made and the country where the final pharmaceutical product is formed. In some cases, both the API and the finished product may have been made at the same plant and in the same country, although more often than not, the API and the finished drug product are made in different plants or even different countries.

Additionally, the production of the API for a pharmaceutical product typically involves combining 2 to 5 or more key starting materials (KSMs) and may require up to a dozen or more supporting materials such as catalysts, solvents, enzymes and other agents.[20] Some have advocated that COOL should be required for the KSMs used in making the API for a pharmaceutical product. Other drug products require peripheral devices, or ancillary materials, to facilitate their safe and appropriate use. This would include devices such as an auto-injector pen for epinephrine or insulin, or an inhaler for an asthma medication, or glass vials and rubber stoppers for sterile injectable drugs. Some have advocated that COOL should be required for these peripheral devices and ancillary materials as well.

In summary, *Country-Of-Origin-Labeling* (COOL) for prescription pharmaceutical products is defined as "The mandatory disclosure of the specific country of the geographic location where a finished pharmaceutical product was made, and the country where its critical components (*i.e.*, the active pharmaceutical ingredient(s) (API)) were physically manufactured and made." At a minimum, the COOL for a prescription pharmaceutical product must include the country where the finished product was made and the country where the API was made. In some cases, where appropriate, the COOL may also require disclosure of the country where a peripheral device was made (*e.g.,* an auto-injector pen for epinephrine or insulin, or an inhaler device for an asthma medication) or the country where ancillary materials were made (*e.g.*, a glass vial and rubber stopper for a sterile injectable drug).

As global pharmaceutical supply chains become increasingly complex and as intermediary goods and products move across multiple borders before reaching the end consumer, COOL has taken on greater importance and significance.

What Is Not COOL? With respect to prescription pharmaceutical products, it is not sufficient for the COOL-compliant label to name the country of: (1) the warehouse shipping the product; (2) the corporate headquarters of the firm marketing, selling, or distributing the product; (3) the U.S. address of a foreign-owned company operating in the United States; (4) the facility repackaging or relabeling the product; or (5) the pharmacy or healthcare entity dispensing the medication. The location and country of these additional facilities may be of interest or required for other reasons, but they are not COOL. If a finished pharmaceutical product is made using API from a factory in China and then the powder is shipped to New Jersey where it is pressed into a tablet, it is not sufficient to label this product as simply "Made in the USA." Such a label would be a material misrepresentation of where the functional component of the product was actually made. This product should be labeled as active ingredient "Made in China" and finished product "Made in the USA."

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[20] Wosińska. "Drug shortages: A guide to policy solutions." Brookings, March 13, 2024.

What Are the Rules for COOL? U.S. law[21] currently requires that "all products of foreign origin imported into the United States must be marked with their country of origin."[22] The intent of this requirement is to protect the consumers' interests by informing the "ultimate purchaser" as to the "country of origin" of the goods that are being purchased, which includes prescription medications purchased at the retail level. The implementation of this provision was clarified on June 14, 2024 by the U.S. Customs and Border Protection (CBP) Headquarters in a letter (HQ H283420) to CVS Health.[23] This letter clarified that the 'consumer at retail,' rather than the pharmacy (or dispenser/repackager/seller) is the 'ultimate purchaser.' This change means that "the outermost container that ordinarily reaches the ultimate purchaser of a J-List article [includes prescription drugs] must be marked with the country of origin of the article."[24] This new interpretation means that "when a customer fills a prescription order for a medication, and purchases it at a retail pharmacy such as CVS, we [the CBP] find[s]that the customer, as the purchaser of the medication at retail, is the ultimate purchaser." Prior to this ruling the retail pharmacy had been considered the ultimate purchaser.

After this ruling, CBP made it clear that manufacturers (*i.e.*, importers) were expected to provide the country of origin for their product to the downstream purchaser to enable that information to be placed on the prescription bottle at the time it is dispensed to the 'ultimate consumer.' In order to comply with this ruling, retail pharmacists must rely upon the importer (*i.e.*, or proxy for the manufacturer) to disclose and report this information. The pharmacist must search for the 'country of origin' information, although there is no standardized format or place where it must be reported.

Where Can You Find COOL Information? The first place for the pharmacist to look is on the actual label attached to the bulk prescription bottle as purchased from the importer (manufacturer) or wholesaler. If the 'country of origin' is not on the label, then the pharmacist would need to look at the outer packaging surrounding the bulk container when it was shipped. If the 'country of origin' still is not found, the pharmacist

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[21] 19 U.S.C. § 1304 and 19 C.F.R. § 134.11.

[22] U.S. Customs and Border Protection. "Fact Sheet: Marking of Prescription Medication for Retail Sale." CBP Publication No. 3812-0824. Accessed on January 24, 2026 at: https://www.cbp.gov/sites/default/files/2024-08/FACT%20SHEET%20Marking%20Prescription%20Medication%20for%20Retail%20Sale.pdf.

[23] U.S. Customs and Border Protection, Letter from Yuliya A. Gulis, Director, Commercial and Trade Facilitation Division to JoAnne Colonnello, Center Director, Pharmaceuticals, Health, and Chemicals, Center of Excellence and Expertise, U.S. Customs and Border Protection, 6747 Engle Road, Middleburg Heights, OH 44130, dated June 14, 2024; HQ H283420, OT:RR:CTF:CPMMA H283420 RRB, CATEGORY: Marking; RE: Internal Advice; Country of origin marking requirements for repackaged prescription medication sold by CVS Health; ultimate purchaser; 19 U.S.C. § 1304; 19 C.F.R. § 134.1(d)(1); 19 C.F.R. § 134.25. Accessed on January 24, 2026 at: https://rulings.cbp.gov/ruling/H283420.

[24] U.S. Customs and Border Protection, Letter to Yulia A. Gulis, June 14, 2024.

could log onto the National Library of Medicine's website, known as DailyMed,[25] that has a profile for each drug product at the national drug code level using the FDA's Structured Product Labeling database.[26] Once on the DailyMed website, one can search for a specific drug product using its brand or trade name, if it has one, or the generic name plus the manufacturer name. Then, one would need to search the extensive DailyMed profile of the drug product for the 'country of origin' in one or more of the following places: (1) a jpg image of the drug product label; (2) a jpg image of the outer carton surrounding the bulk package; (3) near the end of the section under the heading "Patient Counseling Information;" (4) near the end of the section under the heading "Patient Package Insert"; (5) on the jpg image titled "PACKAGE LABEL PRINCIPAL DISPLAY PANEL;" or, (6) near the end of the section under the heading "INGREDIENTS AND APPEARANCE" in the sub-heading titled "Establishment". If there is a firm named under the Business Establishment section, it may be indicated as the MANUFACTURER—the firm that made the finished dosage form (FDF) or finished drug product; or as the API MANUFACTURER—the firm that made the API. If found in this section, the firm name will be followed by an FEI (Federal Establishment Identifier) or a DUNS number[27] which would need to be looked up to find the firm address and its Country of Origin. As one can tell after reading this list of places to look for Country of Origin information, this process is labor-intensive and very time consuming. It may take a pharmacist 10 minutes to 30 minutes or more per prescription drug to search for this information, and they still may not find the Country of Origin as presented by the manufacturer.

While this process works theoretically, there are a number of practical problems. First, this process is dependent upon the importer (*i.e.*, manufacturer) reporting the Country of Origin as required and in a clearly understood manner. Second, if there is information on the Country of Origin one must interpret what it really means—for example, is it the finished product manufacturer, the API manufacturer, or something else. Third, there is not a uniform place to look for this information across products and manufacturers.

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[25] DailyMed is a database that contains labeling submitted to the Food and Drug Administration (FDA) by drug companies and as of January 25, 2026 included contains 154,512 products and their respective labels. Accessed on January 24, 2026 at: https://dailymed.nlm.nih.gov/dailymed/.

[26] U.S. Food and Drug Administration, Structured Product Labeling (SPL). Accessed on January 24, 2026 at: https://open.fda.gov/data/spl/. "Drug manufacturers and distributors submit documentation about their products to FDA… There is considerable variation between drug products, since the information required for safe and effective use varies with the unique characteristics of each drug product."

[27] U.S. Food and Drug Administration, Business Entity Identifiers. Last updated on March 27, 2018. Guidance for Industry Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing. U.S. Department of Health and Human Services, Food and Drug Administration, Office of the Commissioner, May 2009, p. 10, FN 22; "D-U-N-S® Numbers are proprietary to and controlled by Dun & Bradstreet (D&B). Where practicable, the customer will refer to the number as a "D-U-N-S® Number" and state that D-U-N-S is a registered trademark of D&B." Source: Dun and Bradstreet D-U-N-S Number. Accessed on January 24, 2026 at: https://www.fda.gov/industry/structured-product-labeling-resources/business-entity-identifiers.

Fourth, after searching for the Country of Origin on hundreds of drug products in DailyMed profiles, one realizes that the terminology used is not well-defined, and it is not consistent or standardized.

The specific drug product labels use inconsistent and unclear language to precede the name of the firm and its country of operation. Labels use language such as: "Marketed by..."; "Distributed by..."; "Manufactured for..."; "Mfg. for..."; "Repackaged by..."; "Relabeled for..."; and a variety of other phrasing. Even when followed by a firm name or country of operation, none of these represents the country of origin for the importer (or manufacturer) of the finished drug product or the API. Such labeling of these drug products does not appear to comply with the COOL requirement if this is the only manufacturer information provided. Other drug products may have language such as: "Manufactured by..."; Manuf. by..."; "Product of..."; "Made in..." or numerous other somewhat similar phrases preceding the name of a firm, and sometimes the country or location of the firm. These labels may appear to comply with the COOL requirement, although even if a country is named, it is not clear whether this country is for the finished product manufacturer, the API manufacturer, a corporate headquarter, or some other site that is different from the actual manufacturing site.

What Can Be Done to Improve COOL Information? The requirement for COOL should specify the location for where the Country of Origin for the finished product manufacturer is to be reported and it should have a clearly-defined and consistent phrase to be used preceding the firm name and Country of Origin to eliminate the potential for confusion with free-form company-specific phrasing. Similarly, the COOL requirement for Country-of-Origin labeling of the API manufacturer should also have a clearly-defined and consistent phrase to be used preceding the drug product's API manufacturer and its Country of Origin.

For some drug products the only information about the manufacturing firm is provided in a jpg image of the drug product label or the outer box container. However, for some jpg images on the DailyMed website, the quality is so poor that one cannot clearly read the fine print with the name or country of the product's marketer, distributor, repackager, manufacturer, or other description. When the only place the information is found is in a jpg image on the DailyMed website, the jpg image must be of sufficient quality so that the words related to the drug company and its location can be clearly read. The FDA should establish a minimum readable level of pixilation for label jpgs that can be clearly read.

To the best of my knowledge, there is no compiled electronic-format list of NDCs for drug products with the associated Country of Origin for both the finished product manufacturer and the API manufacturer. Such a list should be compiled by FDA and/or a commercial database that would be readily available to pharmacies to facilitate compliance with the COOL provisions. While the pharmacist, and the pharmacy, are the

last point of contact where the ultimate purchaser receives the prescription drug, it does not make sense to hold the pharmacist accountable for reporting the Country of Origin for the drug product's manufacturer, if the manufacturer is not required to always and consistently report this information to the FDA and the FDA is not required to make this information readily available to pharmacists in an efficient manner. For most other types of consumer goods with COOL requirements, it is the manufacturer and not the retailer that attaches the COOL compliant label to the product.

Why Is COOL Information Hidden? Another major concern regarding the COOL provision as currently implemented is that the FDA allows drug sponsors who report the manufacturer name and location for a drug product to specify that this information is 'confidential' or 'proprietary' or a 'trade secret'. When the drug sponsor declares the information to be 'confidential', the FDA does not report the information in their public-facing records including the SPL database used to populate a drug product's profile on the NLM's DailyMed website.[28] FDA Regulations (21 CFR § 20.61) define Confidential Commercial Information (CCI) as valuable data that is "customarily held in strict confidence." For example, the FDA traditionally treats the specific factory location of an Active Pharmaceutical Ingredient (API) as CCI. In other words, the manufacturer can request that information not be made public, yet the pharmacist is still responsible for reporting the Country of Origin for the finished product manufacturer—even though the necessary information is not provided. Ironically, many times when a firm declares the name and location of the drug manufacturer to be confidential and does not report the information, it is not unusual to find that the same firm has issued a public press release announcing details of who the actual manufacturer is and where its production facility is located.

For example, the blockbuster drug products (*i.e.*, Mounjaro for diabetes and Zepbound for weight loss) are both made with the same active ingredient—tirzepatide. When one looks up these drug products on the DailyMed website[29], you find that the Sections of the drug profile which provide information on who makes each drug product are: (1) Patient Counseling Information; (2) Principal Display Panel; and (3) Ingredients and Appearance. In all three places for both Mounjaro and Zepbound, the labeling on the DailyMed website shows that these drugs are: "Marketed by: Lilly USA, LLC, Indianapolis, IN 46285. USA." Note that all sources report "Marketed by" and not "Manufactured by". Apparently, Lilly indicated that the information on the finished product manufacturer and on the API manufacturer is "Confidential". However, if one

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[28] U.S. Food and Drug Administration. Step-by-Step Instructions for Creating SPL Files For Electronic Drug Establishment Registration and Drug Listing v2.0. Accessed on January 24, 2026 at: https://www.fda.gov/media/76331/download.

[29] National Library of Medicine, DailyMed website: tirzepatide. Accessed on January 24, 2026 at: https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=tirzepatide&pagesize=20&page=1.

does a Google search for "Who Makes Zepbound?", you will find a Press Release[30] for Eli Lilly announcing investment in a new manufacturing facility "to manufacture active pharmaceutical ingredients (API) for Zepbound® (tirzepatide) injection and Mounjaro® (tirzepatide) injection." The purpose of this example is to illustrate that information which may have been represented as "Confidential" to the FDA for labeling purposes often has actually been made public by the medicine company for another purpose.

The labeling (marking) statute (section 304 of the Tariff Act of 1930) as amended (19 U.S.C. § 1304), provides that unless excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or its container) will permit, in such a manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article. The Congressional intent of 19 U.S.C. § 1304 was "that the ultimate purchaser should be able to know by an inspection of the markings on the imported goods the country of which the good is the product. The evident purpose is to mark the goods so that at the time of purchase the ultimate purchaser may, by knowing where the goods were produced, be able to buy or refuse to buy them, if such marking should influence his will."[31]

The statutes for FDA should be amended to allow, or require, that the Country of Origin for the manufacturer of the finished drug product and for the API should be made transparent for all prescription drug products. The manufacturers of drug products actually made in the United States should also be required to indicate that their drug product and/or API, if appropriate, was "Made in the USA." If the products made in the USA are not labeled with the Country of Origin, the pharmacist will not know whether the Country of Origin for a given product is missing (not reported) or the United States. This could lead to making a (sometimes) false assumption that products without a Country of Origin on the label are Made in the USA.

What Changes are Needed to COOL Policy? *Full transparency of the Country of Origin for the finished product manufacturer and the API manufacturer should be required for all prescription drugs*. The "Ultimate Purchaser" Rule[32] is a landmark change for transparency related to Country-of-Origin labeling for prescription drugs. The Country of Origin must be disclosed on the prescription container. CBP argues that trade secrets cannot override the statutory requirement (19 U.S.C. § 1304) to inform consumers of a product's origin. However, the FDA statutes, regulations, and guidance need to be changed to make sure that FDA makes public the information pharmacists

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[30] Eli Lilly and Company, "Lilly Increases Manufacturing Investment to $9 Billion at Newest Indiana Site to Boost API Production for Tirzepatide and Pipeline Medicines", Press Release, May 24, 2024. Accessed on January 24, 2026 at: https://investor.lilly.com/news-releases/news-release-details/lilly-increases-manufacturing-investment-9-billion-newest.

[31] United States v. Friedlaender & Co., 27 C.C.P.A. 297, 302 C.A.D. 104 (1940).

[32] Customs & Border Protection Ruling HQ H283420/H346255

will need to put the Country of Origin on the prescription container for every customer. Transparency facilitates public safety and allows patients to track recalls and adverse effects that may have come from their specific drug product such as the recalls for the 'sartans' (e.g., the 2018–2025) involving nitrosamine impurities from specific Chinese and Indian plants. Transparency also supports national security. Both the U.S. Pharmacopeia (USP) and the Department of Defense have argued that "confidentiality" hides the fact that the U.S. is dangerously over-reliant on foreign adversaries for critical medicines, which is a matter of public interest, not private profit.

Real Transparency for the Drug Supply Chain

The country of New Zealand serves as a real example of full transparency for the prescription drug supply chain. Medsafe is a unit in the Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health. MedSafe is the authority responsible for the regulation of therapeutic prescription products in New Zealand. All prescription drug products (at the equivalent of the NDC level) on the market in New Zealand have a transparent drug supply chain that is accessible through an online website.[33] This public database allows any person to search for a medication and see exactly which manufacturing sites are approved for that product. There is no "proprietary" or confidential shield for the factory's name or location.

Among the reported categories in the supply chain are: active ingredients; excipients; finished product testing sites; manufacturer(s) of active ingredients; manufacturer(s) of finished dosage forms; packing; secondary packing; and NZ site of product release. The database also reports all package sizes, indications, and the regulatory action history for each product. The profiles of two drugs are attached in Appendix B. Compare these MedSafe Product Detail profiles to the DailyMed Drug Product Ingredients profiles in Appendix A. There are strengths to each of the formats; however, the drug supply chain format in MedSafe appears easier to use, more consumer friendly, and does not require additional look up of codes in other databases to interpret. *The FDA and DailyMed should consider revising the format for their drug supply chain information to be similar to the format in MedSafe.*

New Zealand has demonstrated the feasibility and utility of a market-wide drug product database with detailed information on the upstream supply chain and they maintain the database on an ongoing basis. "The public transparency of this information does not appear to have commercially harmed the manufacturers or marketers of drug products

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[33] MedSafe, Product Application Search, New Zealand. Accessed on January 23, 2026 at: https://www.medsafe.govt.nz/regulatory/DbSearch.asp

in New Zealand."[34] Many of the corporate entities marketing drugs in New Zealand are marketing the same, or very similar, drug products in the United States and they often use the same supply chain sources. The information for all drug products and their sites of manufacturer are transparent and accessible to all who can access New Zealand's MedSafe website. Clearly, New Zealand has been able to prioritize consumer and patient access, while still respecting truly proprietary information.

Building a COOL & Secure Drug Supply Foundation

Building a secure foundation for the U.S. drug supply requires re-framing our approach to understanding the U.S. drug supply and the challenges that it faces in the years ahead. The FDA is charged to review and approve drugs that are safe and effective for treating patients in the U.S. healthcare market. FDA has a tremendous amount of information about clinical and safety aspects of drug products in the market. In general, however, the FDA has not been empowered, authorized or appropriated resources to assess and manage the U.S. drug supply on a market-wide industrial and commercial basis. There is a need for an assessment of the data sources and analytics necessary to assure the security of the U.S. drug supply from a market-wide perspective that embraces, and goes beyond, the safety, effectiveness, and approval of individual drug products. This effort should be built using the cornerstone of the FDA drug data platforms while enabling integration with data from the business and consumer sectors as well as the global economy.

There is a need for an entity at the national level that can coordinate and stimulate the robustness of the entire pharmaceutical market at all levels and in all corners of the healthcare system. Drug data and systems are fragmented and a framework is needed for integration of data across federal and state agencies (including the FDA, CDC, DOD, VA, FTC, and others) as well with the private sector. Market-wide mapping is needed to integrate siloed drug approval data into a comprehensive, transparent system to ensure life-saving medicines remain available, affordable, secure, and of high quality. A core drug supply map needs to build new strengths and methods for understanding the national and global dynamics of the upstream drug supply chain and its vulnerabilities.

The recent changes to the COOL requirements have facilitated getting more complete information from drug companies about the origin of KSMs, APIs, and finished drug products. This information is now being provided to the FDA and has been used to enrich the drug product profiles on NLMs DailyMed platform. The U.S. government

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[34] Stephen W Schondelmeyer, "Statement on Designing A Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities" at the U.S.-China Economic and Security Review Commission Hearing on Dominance by Design: China Shock 2.0 and the Supply Chain Chokepoints Eroding U.S. Security Panel II: Preparing for China's Counterpunch: Vectors for Supply Chain Coercion, June 5, 2025. p. 6

needs to build upon the rich databases of the FDA, CMS, the Department of Commerce, the Department of Defense, Homeland Security, the Veterans Administration, and other entities as well as the quasi-governmental standard-setting body known as USP and its innovative USP Medicine Supply Map. Collaborations need to be encouraged across the whole of government and with the private sector.

Both the mapping and the transparency of this market-wide drug data system should be built with a three-tiered layering of access. The most complete and open access would be at the national level for specialized analysts and policy makers in government and key think tank participants who can think strategically about building and protecting a secure pharmaceutical market. The second level would provide access to integrated data and working projects at functional levels in federal agencies, academia, and with industry stakeholders. The third layer of this tiered access would be for the private sector, consumers, and the general public to have insights into data that facilitate their safe, effective and affordable use of prescription drugs.

At the top-tier level, the paradigm needs to shift from a reactive "fail and fix" drug supply framework to a proactive "predict and prevent" paradigm. Central to this top tier of the drug supply is a core medicine supply map that interfaces drugs with health, the economy, society, and other domains including the geopolitical realm. A mechanism to embrace and build upon the unique work of the USP Medicine Supply Map as the foundation of the whole of government strategic pharmaceutical industrial policy makes sense. USP is accustomed to working at the interface of government and the private sector and has a 200-year track-record of doing so.

Congress is encouraged to authorize and fund a national entity to maintain this master drug database for the whole of government market-wide approach to industrial pharmaceutical policy analysis. This work could be done by a new independent Congressional commission similar to MedPac or through a hybrid approach with USP and other selective contracting and collaborations across various government agencies and private entities. Funding for the core medicine supply map should have an initial annual appropriation and additional funds for a public-private research program to develop sentinel systems that use big data to detect signals for strategic change and to address security challenges in the pharmaceutical supply system of the United States.

****

Appendix A
DailyMed Labeling & Packaging for Mounjaro & Zepbound

Mounjaro 15 mg NDC 00002-1657-80

17 PATIENT COUNSELING INFORMATION

What are the ingredients in MOUNJARO?

Active ingredient: tirzepatide

Inactive ingredients: sodium chloride, sodium phosphate dibasic heptahydrate, and water for injection. Hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust the pH.

MOUNJARO® is a registered trademark of Eli Lilly and Company.

Marketed by: Lilly USA, LLC Indianapolis, IN 46285, USA

For more information, go to www.MOUNJARO.com or call 1-800-545-5979.

This Medication Guide has been approved by the U.S. Food and Drug Administration

Revised: December 2025

Zepbound 15 mg NDC 00002-2457-80

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling *(Medication Guide and Instructions for Use)*.

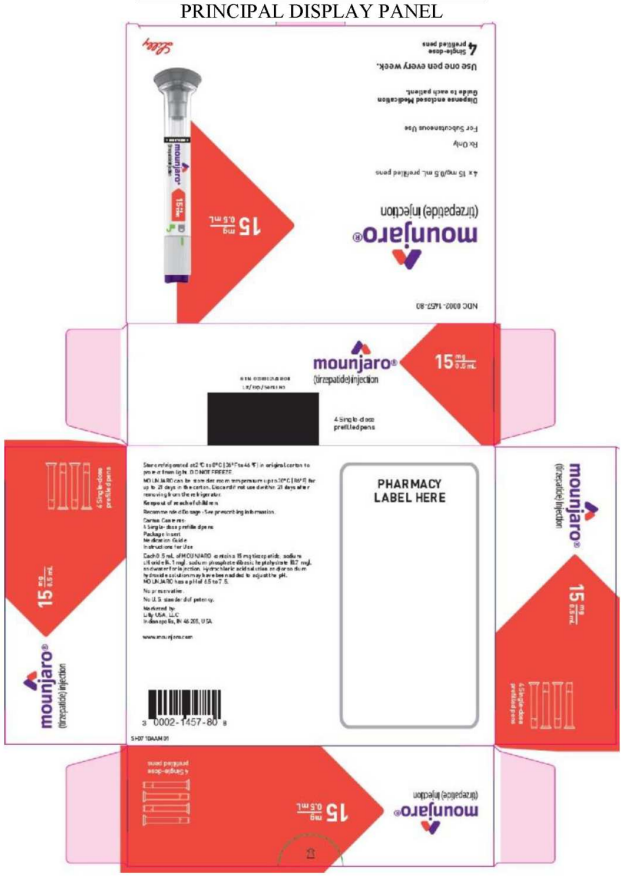
Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA

Pat.: www.lilly.com/patents

ZEP-0011-USPI-20260107

Mounjaro 15 mg NDC 00002-1657-80

PRINCIPAL DISPLAY PANEL



Zepbound 15 mg NDC 00002-2457-80

PRINCIPAL DISPLAY PANEL

Mounjaro 15 mg NDC 00002-1657-80

INGREDIENTS AND APPEARANCE

ZEPBOUND
tirzepatide injection, solution

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0002-2002
Route of Administration	SUBCUTANEOUS		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
tirzepatide (UNII: OYN3CCI6QE) (tirzepatide - UNII:OYN3CCI6QE)	tirzepatide	15 mg in 0.5 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	4.1 mg in 0.5 mL
Sodium Phosphate, Dibasic, Heptahydrate (UNII: 70WT22SF4B)	0.7 mg in 0.5 mL
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

PACKAGING				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0002-2002-01	1 in 1 CARTON	03/28/2024	
1		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0002-2002-04	4 in 1 CARTON	07/07/2025	
2		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA217806	11/08/2023	

Zepbound 15 mg NDC 00002-2457-80

INGREDIENTS AND APPEARANCE

ZEPBOUND
tirzepatide injection, solution

PRODUCT INFORMATION			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0002-2002
Route of Administration	SUBCUTANEOUS		

ACTIVE INGREDIENT/ACTIVE MOIETY		
Ingredient Name	**Basis of Strength**	**Strength**
tirzepatide (UNII: OYN3CCI6QE) (tirzepatide - UNII:OYN3CCI6QE)	tirzepatide	15 mg in 0.5 mL

INACTIVE INGREDIENTS	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	4.1 mg in 0.5 mL
Sodium Phosphate, Dibasic, Heptahydrate (UNII: 70WT22SF4B)	0.7 mg in 0.5 mL
Hydrochloric Acid (UNII: QTT17582CB)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

PACKAGING				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0002-2002-01	1 in 1 CARTON	03/28/2024	
1		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		
2	NDC:0002-2002-04	4 in 1 CARTON	07/07/2025	
2		0.5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

MARKETING INFORMATION			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
NDA	NDA217806	11/08/2023	

Lilly Increases Manufacturing Investment to $9 Billion at Newest Indiana Site to Boost API Production for Tirzepatide and Pipeline Medicines

May 24, 2024

Largest investment in active pharmaceutical ingredient manufacturing of synthetic medicines in U.S. history

Since 2020, the company has committed more than $18 billion to build, upgrade and acquire facilities in the U.S. and Europe

INDIANAPOLIS, May 24, 2024 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it has more than doubled its investment in its Lebanon, Indiana, manufacturing site with a new $5.3 billion commitment, increasing the company's total investment in this site from $3.7 billion to $9 billion. This expansion will enhance Lilly's capacity to manufacture active pharmaceutical ingredients (API) for Zepbound® (tirzepatide) injection and Mounjaro® (tirzepatide) injection so that more adults with chronic diseases like obesity and type 2 diabetes may benefit from these important treatments.

Since 2020, Lilly has committed more than $16 billion to develop new manufacturing sites in the U.S. and Europe. New locations outside Indiana include Research Triangle Park and Concord, North Carolina; Limerick, Ireland; and Alzey, Germany. Separately, the company has invested an additional $1.2 billion to update existing manufacturing facilities in Indianapolis and recently acquired an injectable manufacturing facility in Pleasant Prairie, Wisconsin, from Nexus Pharmaceuticals. Together, these manufacturing investments total more than $18 billion.

"Today's announcement tops the largest manufacturing investment in our company's history and, we believe, represents the single largest investment in synthetic medicine API manufacturing in U.S. history," said David A. Ricks, Lilly's chair and CEO. "This multi-site campus will make our latest medicines, including Zepbound and Mounjaro, support pipeline growth and leverage the latest technology and automation for maximum efficiency, safety and quality control. Importantly, we are investing in our home state of Indiana, creating high-wage, advanced manufacturing, engineering and science jobs for hundreds of current and future Hoosier families."

Lilly embarked on a significant manufacturing expansion in 2020, driven by the research results for tirzepatide. The company made this strategic investment decision at risk so that upon the approval of Mounjaro (2022) and Zepbound (2023), it could make these medicines available to adults living with type 2 diabetes and obesity, respectively. Since then, the strong demand for these medicines – the only approved treatments activating two incretin hormone receptors, GIP and GLP-1 – underscores the urgent unmet need for treatments in both type 2 diabetes and obesity.

As part of this additional investment in the Lebanon site, located within Indiana's LEAP Research and Innovation District, Lilly expects to add 200 full-time jobs for highly skilled workers such as engineers, scientists, operating personnel and lab technicians, resulting in an estimated 900 full-time employees when the facility is fully operational. Additionally, there will be more than 5,000 construction jobs during the site's development.

"Lilly continues to play a transformational role in shaping Indiana's opportunity economy, and I couldn't be more proud about their pole position leadership in developing the LEAP Research and Innovation District in Lebanon, Indiana. Lilly has long been driving global innovation and economic growth that will be felt for decades here at home," said Indiana Governor Eric J. Holcomb. "As an international company, headquartered in Indiana, Lilly had a world of options to consider before making this investment, and choosing Indiana once again reinforces the incredible environment we've cultivated and the talented workforce we have to carry Lilly's success forward. I can't wait to see the incredible benefits this investment leads to for patients around the world, knowing they were made in Indiana."

To support Lilly's expansion project, the state will partner on infrastructure solutions – road improvements, water, electric and other utilities – as well as workforce development commitments and certain economic incentives tied to the company's achievement of investment and employment goals. The state's workforce development support includes the contribution of land, pending approval, for the construction of a learning and training center that will be part of the larger LEAP industrial development, along with a commitment to work with Lilly to raise capital for its completion. The new training center aligns with Lilly's previously announced financial support for scholarship and training programs with Purdue University and Ivy Tech Community College, and the BioCrossroads-led training center at 16 Tech – part of Indiana's recent Tech Hub designation.

"Lilly's commitment to meeting the demand for our life-changing medicines goes beyond buildings and extends to improving education opportunities and upskilling a global workforce of the future," said Edgardo Hernandez, executive vice president and president, Lilly Manufacturing Operations. "Academia is a critical partner to both industry and government as we work together to advance innovation in our state and communities around the globe."

Since breaking ground at its Lebanon manufacturing site in 2023, Lilly has transformed a significant portion of the nearly 600 acres within the complex into an active construction site. The company expects to begin making medicines in Lebanon toward the end of 2026 – with operations scaling up through 2028.

Appendix B
MedSafe Product Detail
Profile for Mounjaro & Paxlovid

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Medicines *Revised: 31 May 2019*

Medsafe Product Detail

File ref: TT50-11479/1e

Trade Name	*Dose Form*	*Strength*	*Identifier*
Mounjaro	Solution for injection	15 mg/0.5mL	Pre-filled Pen
Sponsor	*Application date*	*Registration situation*	*Classification*
Eli Lilly and Company (NZ) Limited P O Box 109 197 Newmarket AUCKLAND 1149	8/1/2025	Consent given Approval date: 22/12/2025 Labelling exemption expires 11/12/2027	Prescription

Composition

Component	*Ingredient*	*Manufacturer*
solution for injection	Active	
	Tirzepatide 30 mg/mL	Corden Pharma Colorado Inc 2075 North 55th Street Boulder Colorado 80301 UNITED STATES OF AMERICA Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Excipient	
	Dibasic sodium phosphate heptahydrate	
	Hydrochloric acid	
	Sodium chloride	
	Sodium hydroxide	

Water for injection

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Eli Lilly Italia SpA Via Gramsci 731-733 Sesto Fiorentino Florence 50019 ITALY
	Eurofins Lancaster Laboratories Inc 2425 New Holland Pike Lancaster Pennsylvania 17601 UNITED STATES OF AMERICA
	Vetter Pharma-Fertigung GmbH & Co KG Eisenbahnstrasse 2-4 Langenargen D-88085 GERMANY
	Vetter Pharma-Fertigung GmbH & Co KG Helmut-Vetter-Str. 10 Ravensburg Baden Wurttemberg 88213 GERMANY
	Vetter Pharma-Fertigung GmbH & Co KG Mooswiesen 2 Ravensburg D-88214 GERMANY
	Vetter Pharma-Fertigung GmbH & Co KG Schuetzenstrasse 87, 99-101 Ravensburg D-88212 GERMANY
Manufacture of Active Ingredient	Corden Pharma Colorado Inc 2075 North 55th Street Boulder Colorado 80301 UNITED STATES OF AMERICA

	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
Manufacture of Final Dose Form	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Vetter Pharma-Fertigung GmbH & Co KG Mooswiesen 2 Ravensburg D-88214 GERMANY
Packing	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Vetter Pharma-Fertigung GmbH & Co KG Mooswiesen 2 Ravensburg D-88214 GERMANY
Secondary Packaging	Eli Lilly and Company Inc Lilly Corporate Center Indianapolis Indiana 46285 UNITED STATES OF AMERICA
	Eli Lilly Italia SpA Via Gramsci 731-733 Sesto Fiorentino Florence 50019 ITALY
NZ Site of Product Release	Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics 6 Te Kapua Drive Mangere Auckland 2022

Packaging

Package	*Contents*	*Shelf Life*

Syringe, glass, type I glass, elastomeric plunger, single-use pen with 29G needle	2 dose units	24 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) protect from light 21 days not refrigerated stored at or below 30°C protect from light
Syringe, glass, type I glass, elastomeric plunger, single-use pen with 29G needle	4 dose units	24 months from date of manufacture stored at 2° to 8°C (Refrigerate, do not freeze) protect from light 21 days not refrigerated stored at or below 30°C protect from light

Indications

Type 2 Diabetes Mellitus: MOUNJARO is indicated for the treatment of adults with insufficiently controlled type 2
diabetes mellitus as an adjunct to diet and exercise
" as monotherapy when metformin is not tolerated or contraindicated.
" in addition to other medicinal products for the treatment of type 2 diabetes.

Chronic Weight Management: MOUNJARO is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management, including weight loss and weight maintenance, in adults with an initial body mass index (BMI) of:
" NLT 30 kg/m2 (obesity) or
" NLT 27 kg/m2 to <30 kg/m2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, prediabetes or type 2 diabetes mellitus).

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
8/1/2025	New Higher-risk Medicine Application	Abridged new higher-risk medicine containing one or more new active substance; Additional strength - Grade 1; Additional strength - Grade 3	Withdrawn 10/2/2025		
17/3/2025	New Higher-risk Medicine Application	New higher-risk medicine containing one or more new active substances; Additional strength - Grade 1; Additional strength - Grade 3; Additional strength - Grade 5	Granted 22/12/2025	22/4/2025	Y

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-10969

Trade Name	*Dose Form*	*Strength*	*Identifier*
Paxlovid	Film coated tablet		150 mg/100 mg
Sponsor	*Application date*	*Registration situation*	*Classification*
Pfizer New Zealand Limited P O Box 3998 AUCKLAND 1140	10/11/2021	Consent given Approval date: 12/11/2024	Prescription

Composition

Component	*Ingredient*	*Manufacturer*
film coated tablet, Nirmatrelvir 150 mg film-coated tablets	Active	
	Nirmatrelvir 150mg	Esteve Quimica SA C/ Ter 94, Poligon Industrial Celra Girona 17460 SPAIN
		Pfizer Ireland Pharmaceuticals Unlimited Company Ringaskiddy Active Pharmaceutical Ingredient Plant Ringaskiddy County Cork P43 X336 IRELAND
		Changzhou SynTheAll Pharmaceutical Co. Ltd 589 North Yulong Road Xinbei District Changzhou 213127 CHINA
		Jilin Asymchem Laboratories Co. Ltd. No. 99, Hongda Road, Economic Development Zone Dunhua Jilin 133700 CHINA
	Excipient	
	Colloidal silicon dioxide	
	Croscarmellose sodium	
	Lactose monohydrate	
	Microcrystalline cellulose	
	Opadry pink 05B140011	
	Purified water	
	Sodium stearyl fumarate	
film coated tablet, Ritonavir 100 mg film-coated tablets	Active	

Ritonavir 100mg	AbbVie S.r.l S.R. 148 Pontina Km 52 Snc Campoverde di Aprilia Latina 04011 ITALY

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	AbbVie Deutschland GmbH & Co KG Knollstrasse Ludwigshafen 67061 GERMANY
	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Italia SrL Localita Marino del Tronto Ascoli Piceno (AP) I-63100 ITALY
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
	Quinta-Analytica sro Prazska 1486/18c Prague 10 CZ-102 00 CZECH REPUBLIC
	Quinta-Analytica sro Provozovna Brno Karasek 2296/1n Brno-Reckovice 621 00 CZECH REPUBLIC
Manufacture of Active Ingredient	AbbVie S.r.l S.R. 148 Pontina Km 52 Snc Campoverde di Aprilia Latina 04011 ITALY
	Changzhou SynTheAll Pharmaceutical Co. Ltd 589 North Yulong Road Xinbei District Changzhou 213127 CHINA
	Esteve Quimica SA C/ Ter 94, Poligon Industrial Celra Girona 17460 SPAIN

	Jilin Asymchem Laboratories Co. Ltd. No. 99, Hongda Road, Economic Development Zone Dunhua Jilin 133700 CHINA
	Pfizer Ireland Pharmaceuticals Unlimited Company Ringaskiddy Active Pharmaceutical Ingredient Plant Ringaskiddy County Cork P43 X336 IRELAND
Manufacture of Final Dose Form	AbbVie Deutschland GmbH & Co KG Knollstrasse Ludwigshafen 67061 GERMANY
	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
Packing	Pfizer Ireland Pharmaceuticals Unlimited Company Little Connell Newbridge County Kildare W12 HX57 IRELAND
	Pfizer Italia SrL Localita Marino del Tronto Ascoli Piceno (AP) I-63100 ITALY
	Pfizer Manufacturing Deutschland GmbH Mooswaldallee 1 Freiburg Im Breisgau 79108 GERMANY
Secondary Packaging	DHL Supply Chain (New Zealand) Ltd 6 Manu Tapu Drive Mangere Auckland 2022
NZ Site of Product Release	Pfizer New Zealand Limited Level 10, 11 Britomart Place Auckland CBD Auckland 1010

Packaging

Package	*Contents*	*Shelf Life*
Blister pack, Nirmatrelvir 150mg in OPA/Al/PVC blisters	10 tablets	24 months from date of manufacture stored at or below 25°C
Blister pack, Ritonavir 100 mg in OPA/Al/PVC blisters	10 tablets	24 months from date of manufacture stored at or below 25°C
Blister pack, Nirmatrelvir 150mg in OPA/Al/PVC blisters	20 tablets	24 months from date of manufacture stored at or below 25°C
Combination pack, OPA/Al/PVC combination	20 tablets	24 months from date of manufacture stored at or below 25°C
Combination pack, OPA/Al/PVC combination	30 tablets	24 months from date of manufacture stored at or below 25°C

Indications

Paxlovid is indicated for the treatment of coronavirus disease 2019 (COVID- 19) in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
10/11/2021	Provisional Consent (Section 23)	New higher-risk medicine containing one or more new active substances	Granted 2/3/2022	1/12/2021	Y
30/8/2023	New Higher-risk Medicine Application	Provisional to full approval (clinical need) higher-risk NCE	Granted 12/11/2024	20/9/2023	
29/11/2024	CMN 24(5)	Formulation - G4; Active ingredient manufacture - G3; Finished product manufacture - G3	Additional evaluation started 06/11/2025	11/12/2024	
30/6/2025	Changed Medicine Notification	Indications/dosage - G2; Contraindications, warnings and precautions - G1; Data sheet - G2	Granted 1/10/2025	9/7/2025	

Testimony of Stephen Colvill, MBA
Assistant Research Director and ReVAMP Drug Supply Chain Consortium Lead
Duke-Margolis Institute for Health Policy

Presented before the
United States Senate Special Committee on Aging
Hearing on:
“Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From”
January 29, 2026

Summary of Testimony

Pharmaceutical Supply Chain Problem Areas

- **Clearly defining the distinct, yet overlapping, pharmaceutical supply chain problem areas is critical.** Different solutions are needed to address each area.
    - Problem Area 1: Chronic drug shortages
    - Problem Area 2: Questions around pharmaceutical quality assurance
    - Problem Area 3: Geopolitical and national health security risks
    - Problem Area 4: A desire to grow the economy through domestic manufacturing
- **My testimony focuses on the solutions needed to address chronic drug shortages**, which most frequently impact generic sterile injectable drugs that are usually administered by health care providers such as in a hospital setting.
- **Chronic drug shortages are caused by a race-to-the-bottom for critical generics.** Health care provider payment systems, which are set by CMS and private payers, encourage health care providers to seek the lowest short-term cost for generics without adequate consideration for reliable availability.

Potential Solutions

- **I propose an alternative to the race-to-the-bottom for critical generics: policymakers can adjust CMS payment policy to better align market incentives towards reliable availability, rather than focusing too much on lowest cost.**
    - Building on a 2024 bipartisan Senate Finance Committee Discussion Draft, I propose a Medicare incentive payment program that would reward health care providers when they 1) purchase through committed contracting models and 2) identify and purchase drugs that meet reliability or resiliency benchmarks. Costs from such a program would likely equate to <0.1% of total U.S. drug spending.
- **I also propose other steps that Congress could take to create more resilient and secure drug supply chains.** Congress could utilize CMS payment policy and other incentives to bolster domestic manufacturing, and Congress could support international collaboration efforts with trusted partner countries.
- **Lastly, regarding pharmaceutical labeling reforms, I outline potential positive and negative impacts and offer two important considerations:**
    - “Place of business” is likely not the best term to use when specifying what location(s) are required to be listed in pharmaceutical labeling information.
    - Legislation could require manufacturers to include unique facility identifiers for both the original API manufacturer and original finished drug product manufacturer in their digital SPL labeling information (not the physical labels).

Full Testimony

Introduction and Background

Thank you Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee for holding this critical hearing on medicine supply chain challenges that directly impact millions of Americans, particularly seniors.

My name is Stephen Colvill, and I am Assistant Research Director at the Duke-Margolis Institute for Health Policy, where I lead the ReVAMP Drug Supply Chain Consortium. I also serve on the board of the End Drug Shortages Alliance and as a volunteer advisor for Angels for Change.

Throughout my career, I have seen the drug supply chain from many different angles. I worked at one of the largest drug manufacturing plants in the U.S. and then worked my way up the commercial business side of one of the largest generic injectable drug manufacturers in the U.S. In 2019, I co-founded RISCS, a nonprofit drug supply chain rating and certification organization with a mission to prevent drug shortages. At RISCS, I worked with health systems, group purchasing organizations, and others to help them identify reliable manufacturers of critical generic injectable drugs. I then moved to the policy side, where I have served both in the government as senior policy advisor for medical supply chains in the White House Domestic Policy Council and outside the government in my current role.

Throughout these experiences, I have witnessed drug shortages frequently inhibit patient access to life-saving and life-sustaining medications and leave health care providers unable to provide the highest level of care. As a result, one takeaway has become obvious: we need to ReVAMP how our drug supply chain works.

At Duke-Margolis, our ReVAMP Consortium brings together supply chain experts from manufacturers, group purchasing organizations, wholesalers, health systems, patient advocacy organizations, and elsewhere to develop and implement policy solutions to drug supply chain challenges, with a focus on reducing the frequency and severity of chronic drug shortages. The four tenets of the ReVAMP Consortium are: a **Re**liable Drug Supply, **V**aluing Availability, **A**dvanced **M**anufacturing Technologies, and a **P**atient-Centered Focus.

This testimony reflects my own recommendations, analysis, and perspective. As part of Duke University, Duke-Margolis honors the tradition of academic independence on the part of its faculty, researchers, and scholars. This testimony may not represent the opinions of every ReVAMP Consortium member and is not intended to limit the ability of ReVAMP Consortium members to provide their own perspective on behalf of their independent organizations.

Defining the Problems

In efforts related to pharmaceutical supply chains, policymakers seek to address distinct, yet overlapping, problems. Clearly defining the four problem areas below is critical, as different policy steps are needed to address each area.

1) Chronic drug shortages

Severe, chronic shortages of critical generic drugs in recent decades are associated with higher mortality rates, medication errors, delays in life-saving treatment, and significant financial costs to the health care system. These chronic drug shortages have most frequently impacted inexpensive and older generic drugs, particularly generic sterile injectable drugs that are usually administered by health care providers such as in a hospital setting. Supply chain disruptions, such as from manufacturing delays, product discontinuations, and natural disasters, too frequently result in drug shortages that impact patient care. Supply chain reliability[1], which can be built and sustained through investments in modernized manufacturing infrastructure and quality culture, redundancies, buffer stocks, strong risk management plans, and other steps, is lacking for many critical generic drugs.

2) Questions around pharmaceutical quality assurance

Pharmaceutical supply chain stakeholders frequently raise questions around pharmaceutical quality assurance. In this problem area, the relevant drug is available to patients, but questions exist around whether the drug is consistently produced in accordance with Current Good Manufacturing Practices (CGMP), whether the drug is consistently produced to appropriate specifications, whether the drug might contain dangerous contaminants or defects, and/or whether the drug consistently underwent adequate quality control testing prior to each batch's release into the supply chain. These questions around pharmaceutical quality assurance are a distinct issue from chronic drug shortages. In this problem area, the relevant drug is available to patients. However, during a shortage, the relevant drug is not available (to some or all patients).

3) Geopolitical and national health security risks

The medicines that Americans rely on every day are often products of complex global supply chains. While global supply chains create efficiencies through economies of scale and increase access to global expertise and capabilities, they also create vulnerabilities to

[1] This testimony frequently refers to "supply chain reliability" (strong routine performance), but "supply chain resilience" (bouncing back from unexpected shocks) and "supply chain robustness" (withstanding unexpected shocks) are also important.

geopolitical conflict, challenges with regulatory oversight in some countries, and other risks. Some areas of foreign dependence that may represent particularly high risks include certain categories of API (for example, certain antibiotics) for which production is concentrated in China, key starting material production that is concentrated in China, and finished dosage form production for solid oral drugs that is concentrated in India. Notably, while pharmaceutical export restrictions imposed by foreign governments have been rare and have not been a major contributing factor to past shortages, foreign dependence certainly poses a risk for future shortages and other supply chain issues.

4) **A desire to grow the economy and create high-paying jobs through domestic manufacturing**

Domestic manufacturing can create high-paying jobs in the U.S., develop a skilled U.S. workforce, and potentially help to increase U.S. Gross Domestic Product.

As a nation, we obviously need to address all four of these areas. At the ReVAMP Consortium, we focus primarily on policy solutions to address chronic drug shortages. The American Society of Health-System Pharmacists has listed over 3,000 drug shortages[2] since 2001. Over one hundred studies over the past several decades have clearly documented the negative impacts to health and patient care that result from chronic drug shortages. In one example, the societal cost from hundreds of excess deaths associated with a prior shortage of norepinephrine, a drug used to treat septic shock, was estimated at over $13 billion.

Without substantive policy changes to address root causes, chronic drug shortages will likely persist. Effective solutions to chronic drug shortages would likely also have positive effects on the other problems listed above.

The Race to the Bottom

Generic drug prices are on average about 33% lower in the U.S. than in other high-income countries. In 2024, the average price of an injectable drug in shortage was $9, while the average cost of an injectable drug not in shortage was $118. The U.S. market for already-inexpensive generic drugs, which make up a small fraction of U.S. drug spending, often emphasizes achieving the lowest price at a point in time over ensuring reliable drug availability over time. While limiting costs is important, low-cost generic drugs do not benefit patients if they are not available.

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[2] Many drugs have reoccurred multiple times on the ASHP drug shortage list, and those drugs are counted multiple times in this figure.

Health care providers, and the group purchasing organizations (GPOs) that contract for and wholesalers that distribute drugs on their behalf, usually have a choice of several manufacturers from which they can source a given generic drug. These generic manufacturers vary in their pricing and their ability to supply the drug reliably over time. However, the Centers for Medicare and Medicaid Services (CMS) through Medicare Part A and Part B[3], and many private payers, generally pay the same amount to providers regardless of which generic manufacturer is chosen. This payment system creates strong price competition but does not create an incentive for providers to select more reliable manufacturers.

Health care providers care deeply about providing quality care to their patients. They also are rational economic actors that often operate in challenging financial environments with significant economic constraints. Health care providers have some financial incentives to prevent shortages, but these financial incentives are limited and uncertain. For example, providers experience some increased costs from shortages, such as costs from additional labor spend[4], longer patient stay times, and negative impacts to health care quality incentive payment programs. Providers may also experience decreased revenue if shortages lead to reduced patient volumes. However, shortages sometimes impact patient care without having a significant impact on provider costs or revenue. For example, a patient who received a suboptimal therapy due to a shortage may experience complications that are not identified or apparent in the short-term, and health care quality incentive payment programs may not fully internalize some patient impacts from shortages. Patients bear the brunt of the impact of many shortages in the form of worse health outcomes.

Because the financial impacts on providers from shortages are limited and uncertain, the demand signal for reliability transmitted from many providers to others upstream – such as GPOs, wholesalers, and manufacturers – is weak and ambiguous. The result is a race-to-the-bottom for many generic drugs: manufacturers compete intensely on price but too frequently do not supply reliably and consistently.

While the totality of financial and patient care impacts from shortages is uncertain and very challenging to measure, it is clear that current market incentives driven by the current drug

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[3] In Medicare Part A, providers receive Diagnosis Related Group (DRG) payments that include a set rate for cases based on the patient's diagnosis. In Medicare Part B, providers receive a payment based on the drug's Average Sales Price (ASP), which is a blended rate across all generic suppliers of the particular drug.

[4] The average cost to U.S. hospitals from the additional labor spend needed to manage drug shortages has been estimated at $900 million per year ($150,000/hospital/year). This is small compared to the societal cost from hundreds of excess deaths associated with one prior shortage of norepinephrine, a drug used to treat septic shock, which has been estimated at over $13 billion.

reimbursement and provider payment structure have not been sufficient to address the chronic drug shortage crisis.

An Alternative: Aligning Incentives Towards Reliable Availability

Drug shortages are not inevitable. Policymakers can shift the market to focus more on ensuring a reliable supply of generic drugs, while keeping costs low. CMS payment policy is the most appropriate and influential tool that policymakers can use to accomplish this aim.

Addressing chronic drug shortages is clearly aligned with CMS' mission to improve the health outcomes of CMS beneficiaries. CMS, as the primary source of revenue for many U.S. hospitals, is well-positioned to meaningfully change market incentives. CMS influence is particularly pronounced in the inpatient setting – in 2023, Medicare accounted for 48% of all inpatient days in the U.S., and Medicaid accounted for another 26%.

Recognizing the need for CMS to play a central role in addressing drug shortages, the Senate Finance Committee released a bipartisan Discussion Draft in 2024 that proposed a Medicare Drug Shortage Prevention and Mitigation incentive payment program designed to combat shortages of critical generic drugs. Importantly, participation in this Program would be entirely voluntary, and providers could choose not to participate or to participate for only a subset of their purchases.

Building on the Senate Finance Committee proposal, we at Duke-Margolis recently published a white paper on "Addressing the Root Causes of Drug Shortages: Next Steps for Congress". In this white paper, we propose a simplified version of the Medicare Drug Shortage Prevention and Mitigation incentive payment program that would reward health care providers when they 1) purchase through committed contracting models and 2) identify and purchase drugs that meet reliability or resiliency benchmarks.

1) Purchase through committed contracting models

In recent years, some health care providers have begun entering into new committed contracting models, such as through Civica Rx or other similar programs. These committed contracting models are designed to offer greater assurance of demand for manufacturers and assurance of supply for providers. The committed nature of these models creates a greater incentive for purchasers to vet suppliers and for manufacturers to ensure reliable delivery of products over time. However, while such committed contracting models have demonstrated some success, they currently represent a small share of generic drug contracts in the U.S., and drug shortages persist as many resource-constrained providers continue to seek out the lowest cost short term suppliers. Our proposed Medicare Drug

Shortage Prevention and Mitigation Program would incentivize health care providers to more frequently purchase their generic drugs through committed contracting models.

2) Identify and purchase drugs that meet reliability or resiliency benchmarks

Our proposal also would tie Medicare Drug Shortage Prevention and Mitigation Program incentive payments to purchases of drugs that meet reliability or resiliency benchmarks. The first step in accomplishing this is assessing which manufacturers and drugs actually have reliable supply chains. To that end, we propose that Congress should direct CMS, in collaboration with other relevant HHS operating divisions, to authorize one or multiple drug supply chain reliability (DSCR) benchmarking programs for this purpose. To qualify for our proposed Medicare incentive program payments, providers would need to buy products that have been evaluated through at least one of the CMS-authorized benchmarking programs. At the outset, qualification for these incentive payments could be binary (either the product was evaluated or it was not). As the accuracy and utility of benchmarking programs are assessed and potentially verified over time, CMS could adjust the incentive payments to provide higher payment amounts for products that are deemed more reliable through the benchmarking programs.

Three prominent examples of such benchmarking programs include the Healthcare Industry Resilience Collaborative's resiliency badging program, US Pharmacopeia's resiliency benchmarking program, and FDA's Quality Management Maturity program. Uptake of approaches such as these has thus far been limited, especially among generic injectable drug manufacturers and products, but could be significantly increased through government funding and support.

The proposed Medicare Drug Shortage Prevention and Mitigation Program would be a logical extension of other Medicare quality and safety measures that are adequately reflected in Medicare provider payments today. After the incentive payments are incorporated in baseline purchasing prices in the future, the payments could potentially be discontinued – similar to Medicare payments for important new technologies or previously for electronic heath record adoption.

The Potential Cost of a Medicare Drug Shortage Prevention and Mitigation Program

Health care providers spend about $15 billion per year on physician-administered generic sterile injectable (GSI) drugs. Assuming a 20% bonus incentive payment (based on Average Sales Price) and inclusion of all GSI drugs, the proposed Medicare Drug Shortage Prevention and Mitigation Program could cost less than $3 billion per year.

If targeted towards the top 50 most essential GSIs[5], the proposed Medicare Drug Shortage Prevention and Mitigation Program would likely cost **less than $1 billion per year[6].**

Because not all purchases would qualify for the incentive, program costs would likely be well under $1 billion per year. Costs to administer the program would need to be considered as well but could be negligible. $1 billion in incremental spending is equal to ~0.1% of total annual drug spending in the U.S.

Other Potential Reforms

Supporting Domestic Pharmaceutical Manufacturing

A critical and bipartisan priority, bolstering domestic pharmaceutical manufacturing capabilities can help to reduce geopolitical and national health security risks, ensure a sustained industrial base for emergency events, reduce regulatory oversight challenges, increase economic growth, create jobs, and more. While increased domestic manufacturing could have positive spillover effects in reducing chronic drug shortages, other steps described above are likely more well-targeted to address the misaligned economic incentives driving chronic drug shortages. Some of the most significant past drug shortages have resulted from manufacturing issues in U.S. plants.

The drugs for which increased domestic manufacturing would be the most beneficial are not necessarily the same drugs that pose chronic drug shortage risks. For example, while increasing domestic manufacturing for some innovative branded drugs may be beneficial for sensitive intellectual property and economic impact reasons, innovative branded drugs are historically unlikely to experience shortages. On the other hand, IV fluids have been notoriously prone to shortage, both due to hurricanes and other issues. However, IV fluids are largely already produced in the U.S. and thus likely do not need domestic manufacturing support.

To bolster domestic drug manufacturing, policymakers need to prioritize the most important drugs for onshoring and then create incentives for purchasers to select domestically-made versions of those drugs. As described previously, Medicare and Medicaid together account for ~75% of all inpatient days in the U.S. Congress could partner with CMS to incentivize purchasers to source from domestic manufacturers of critical medical supplies such as personal protective equipment and essential medicines. For example, CMS could revise their existing Domestic N95 Respirator Payment Adjustment policy, including by expanding the policy to essential medicines. While the existing policy

[5] The ASPR Downselected Essential Medicines Needed for Acute Patient Care List includes 66 essential generic sterile injectable drugs.
[6] Author's analysis.

has had limited uptake thus far, Duke-Margolis recently released three recommendations that could significantly increase uptake: simplify the reimbursement and reporting methodology, expand to other product types (including essential medicines), and publish a list of eligible domestically-made products. Congress could also direct CMMI to pilot various approaches to preference domestically-made drugs as proposed in the American Made Pharmaceuticals Act.

Although direct federal procurement accounts for less than 10% of the total pharmaceutical market, creating a federal buyer's market that prioritizes domestically-made drugs would be another important step. While maintaining preference for drugs sourced from Trade Agreements Act (TAA) compliant countries over non-TAA compliant countries is important, Congress could prioritize preference for drugs that meet Buy American Act requirements over any foreign-made drugs from TAA compliant and non-TAA compliant countries. Legislation could also close the "Acetris loophole" by directing revision of the Federal Acquisition Regulation definition such that country-of-origin would be determined only by where a drug is "substantially transformed" rather than where a drug is "manufactured". This would refocus country-of-origin determinations for the purposes of direct federal procurement on the most important production step.

International Collaboration

Collaboration with trusted international partners (with important safeguards in place for national security and emergency preparedness) should be a critical complement to onshoring efforts. Duke-Margolis recently published a white paper on "Building a Resilient and Secure Pharmaceutical Supply Chain: The Role of International Collaboration" that proposes how the U.S. should prioritize international regulatory harmonization and international economic partnerships to effectively and cost-efficiently secure our pharmaceutical supply chain. International regulatory harmonization can create efficiencies and reduce barriers to sourcing from trusted sources, which can reduce risks associated with concentrated production in more adversarial countries. International economic partnerships, such as through the Bio-5 Consortium model, can also reduce these risks through purchase commitments and coordination among partner countries. For example, if one partner country is specializing in building resilient alternate sources of antibiotics, another could specialize in a different product class, such as oncology drugs, rather than duplicating efforts. Rather than taking an antagonistic approach towards allied countries, the U.S. should focus on these kinds of international collaboration efforts.

Pharmaceutical Labeling Reform

Pharmaceutical labeling reforms, if effectively designed, could have a positive, yet limited, impact. Americans deserve to know where their drugs come from, and better availability of information about manufacturing locations of drugs might, over time, cause more drugs to be sourced domestically. However, for provider-administered drugs, impacts of labeling reforms are likely to be limited, as many decision makers already know where API and finished drug products are made or can acquire this information if desired. For retail drugs, impacts of labeling reforms are also likely to be limited, as patients have minimal influence over what drugs the retail pharmacies and retail GPOs decide to stock.

The Committee should carefully weigh any negative consequences that may arise from labeling reforms and consider how to mitigate them. Just because a drug is made in the U.S. does not necessarily mean that it is the best choice – some of the most significant past shortages have resulted from manufacturing issues in U.S. plants. Site location alone is not necessarily indicative of reliability or quality. Other assessments of reliability and quality, such as through the benchmarking programs described previously, are also needed. Pharmaceutical labels also may illuminate certain stages of production while obscuring other risks, such as from upstream key starting material (KSM) dependencies. KSM mapping and vulnerability assessment exercises will remain critical. The Committee should also consider that any labeling reforms may impact the information that is ultimately available to institutional buyers, health care providers, and patients in different ways. Other potential negative consequences include increased regulatory burden, potential impacts to patient medication adherence, and potentially more easily enabling bad actors to identify potential targets[7].

As the Committee considers potential pharmaceutical labeling reforms, I offer two additional specific considerations:

- **"Place of business" is likely not the best term to use when specifying what location(s) are required to be listed in pharmaceutical labeling information.** Current labeling requirements in the Federal Food, Drug, and Cosmetic Act dictate that a drug label must include the name and "place of business" of the manufacturer, packer, or distributor. Requiring only the "place of business" of a manufacturer to be listed on a label enables the actual location of manufacturing to be obscured. For example, the "place of business" listed on a drug label may be a company's U.S. corporate headquarters, while that drug's manufacturing facility might be in a foreign location. If any new requirements only require a "place of business" to be listed, those new requirements may result in limited to no additional transparency.

- **Legislation could require manufacturers to include unique facility identifiers, such as the FDA Establishment Identifier (FEI) number or the DUNS number, for both the original API manufacturer and original finished drug product manufacturer in their labeling information**[7]**,** as FDA requested in the prior Administration's legislative proposals and again in the current Administration's FY26 legislative proposals. Requiring unique facility identifiers only in digital Structured Product Labeling (SPL) metadata, and not on the physical labels, could eliminate the complexities that would arise from the updating of physical labels and product inserts whenever a manufacturing location changes or is added, while still enabling online public access to data that for the first time could be easily used to connect National Drug Codes with unique manufacturing facilities.

As mentioned previously, the most critical step that is needed, both in the provider-administered and retail drug settings, is to implement financial incentives for pharmacies and other purchasers to select more reliable and/or domestic suppliers.

Conclusion

I encourage the Committee to prioritize financial incentive reforms that can meaningfully address the various drug supply chain challenges we face, particularly by partnering with the Senate Finance Committee on Medicare payment reforms to address chronic drug shortages. I also encourage the Committee to prioritize international collaboration opportunities and to consider incentives that would encourage drug purchasers to select domestically-made drugs. The Committee should carefully think through important considerations around pharmaceutical labeling reforms to ensure positive impact and mitigate any negative consequences. Absent new incentives to encourage pharmacies and other purchasers to select reliable and/or domestic manufacturers, any positive impacts from pharmaceutical labeling reforms are likely to be limited.

Thank you to the Committee for holding this hearing on this critical topic and for inviting me to testify. I look forward to your questions.

[7] The Committee could consider whether FDA should be provided with the authority to exempt some drugs from a requirement to disclose unique facility identifiers if there is a compelling safety or national security reason to do so, such as for some controlled substances.

Questions for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"TRUTH IN LABELING: AMERICANS DESERVE TO KNOW WHERE THEIR DRUGS COME FROM"

JANUARY 29, 2026

QUESTIONS FOR THE RECORD

Dr. Michael Ganio

There were two questions during the hearing that I'd like to expand on.

The first was Chairman Scott's question about brand and generic being exactly the same. I would like to affirm my response during the hearing, but add that the question we should be considering is whether generic drugs, as originally approved by the FDA, are exactly the same as manufactured decades later. The generics approved under an abbreviated new drug application (ANDA) must match the characteristics of the brand-name product approved under the new drug application (NDA), even if the inactive ingredients are different. What we have seen through recent research and from FDA inspections is that not all generics are manufactured to the same high quality standards, especially older generic drugs.

The second was Senator Johnson's question about the 2008 heparin issue. Again, my response to the question is accurate-that specific issue has been resolved. However, I would like to add that the circumstances that led to that issue still exist today. If a manufacturer knowingly included an impurity or a false active ingredient in a pharmaceutical, it may not be detected immediately. Only regular testing of pharmaceuticals could catch or prevent that. To be 100% transparent, I'm not sure that a regular testing program would have caught the heparin contamination in 2008 -- the heparin test at the time was not designed to detect the oversulfated chondroitin sulfate contaminant. Regardless, the U.S. relies extensively on the manufacturer's own testing programs. Falsified results or knowingly contaminated products very likely would reach patients before detected.

Senator Jon Husted

Question:

How do large purchasers of medicines such as hospitals, and health systems currently assess supply-chain risk when selecting drugs?

Response:

Large purchasers base buying decisions almost exclusively on price. Purchasing contracts can also influence decisions, but buying is still based solely on financial evaluation and not differences in the drug product. Occasionally, specific buyers may avoid a product due to past experiences, for example, problems with vial stoppers when inserting a needle.

In most cases, generic drugs are all assumed to be the same. All are evaluated and approved through the FDA's abbreviated new drug application process. Because this is a pass-or-fail method of approval, there is no reason to expect differences between generic products. However, based on outcomes research and on FDA inspection reports, there are clearly differences in the quality of manufacturing.

Question:

Beyond transparent information on a medicine's country of origin, what other information would be meaningful to large purchasers as it relates to how a purchaser evaluates the resiliency of a manufacturer's supply chain?

Response:

Currently, the only information readily available to purchasers is the price. In the current environment, manufacturers compete on a pass/fail system with the FDA, so all products available on the market are assumed to be equal. That puts an overemphasis on price and will shift purchasers away from manufacturers able to invest in quality and resiliency and toward higher risk manufacturers.

If purchasers had more information about a manufacturer's quality management and investments in resiliency, it could realign incentives toward reliability and away from buying the cheapest product.

Question:

Given the recent shortage of cancer drugs such as carboplatin and cisplatin, why did the market for these drugs end with such little redundancy despite the importance of these drugs for cancer patients?

Response:

With most generic drugs that have been around for decades, the manufacturer with the cheapest price is likely to win most of the market share. In the case of cisplatin, a single manufacturer had 50% of the market. Unfortunately, an FDA inspection revealed that manufacturer was cutting corners, leading to a halt in production and shortage of an essential cancer treatment.

It's difficult for high-reliability manufacturers to compete with companies that cut corners or are subsidized by foreign governments. If they are continually undercut on price, they will eventually stop making a product, leading to less resiliency in the marketplace for that drug. This happens regularly with generic drugs that have been around for decades.

Question:

How does the low reimbursement for these drugs shape the supply chain fragility?

Response:

Hospitals and providers are not separately paid for older generic drugs by Medicare or Medicaid. When a hospital or provider submits a claim for older generic drugs, like decades-old chemotherapy drugs, the drugs are reimbursed as part of a bundled payment that is assumed to account for the cost of care.

This type of reimbursement overemphasizes low price when determining which products to buy for patients. Buying the cheapest product generally results in a more favorable margin-a margin that is often negative, but less negative than buying and billing a more expensive version of that same generic product.

Question:

What vulnerabilities exposed by these shortages still exist today?

Response:

Several vulnerabilities - concentrated market share anywhere can be a vulnerability, both geographically (see Hurricanes Maria and Helene) or with quality-related disruptions (cisplatin).

Concentrated market share in a country that can be challenging for FDA inspections is another vulnerability.

The underlying market dynamics (described in previous answers) also still exist today and will continually reinforce purchasers buying the cheapest product.

Additional vulnerabilities that may or may not exist related to the upstream supply chain (i.e. active pharmaceutical ingredients or key starting materials) for cisplatin and other essential drugs. Not knowing how much the supply chain relies on sources of API and key inputs that are in countries at risk of trade wars or geopolitical tensions is an unknown vulnerability.

Question:

According to recent reporting, the number of ongoing prescription drug shortages rose slightly in the last quarter of 2025, but remained significantly lower than the all-time high reached in the beginning of 2024. Moreover, the number of new shortages identified last year was just 89, the lowest figure since 2006, and considerably less than 130 medicines that were in shortly supply in 2024, according to a new report from the American Society of Health-System Pharmacists (ASHP). And notably, long-standing shortages are beginning to resolve; 75% of all the active shortages started in 2022 or later.

Could new mandates on companies with respect to either the label or labeling contribute to new drug shortages? Could any new requirements and their associated penalties for non-compliance create a situation in which certain manufacturers prematurely leave the U.S. market and, as such, create new drug shortages?

Response:

I don't foresee this being a significant contributor to future drug shortages. New mandates on label or labeling requirements should have realistic timelines for compliance. Otherwise, this should not result in manufacturers leaving the U.S. market.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"TRUTH IN LABELING: AMERICANS DESERVE TO KNOW WHERE THEIR DRUGS COME FROM"

JANUARY 29, 2026

QUESTIONS FOR THE RECORD

Dr. Stephen Schondelmeyer

Senator Raphael Warnock

Question:

Dr. Schondelmeyer, you emphasized the role of advanced data analytics in identifying vulnerabilities before crises and mitigating pharmaceutical drug shortages.

How can Congress improve the employment of predictive analytics across federal agencies to forecast drug shortages for scenarios such as natural disasters or international trade disruptions?

Response:

The Current Landscape and Supply Chain Vulnerabilities

The resilience of the United States prescription drug supply is a matter of critical national security and public health. Currently, the U.S. reacts to drug shortages rather than proactively forecasting them. Congress has the opportunity to authorize systematic changes across federal agencies, specifically by permitting data to be shared across agencies and by improving the employment of predictive analytics. Through comprehensive supply chain mapping and enhanced predictive analytics with data transparency, the U.S. can transition to a "predict and prevent" paradigm to forecast and mitigate drug shortages resulting from natural disasters, pandemics, or international trade disruptions.

The U.S. pharmaceutical market is heavily dependent on foreign sources for key starting materials (KSMs), active pharmaceutical ingredients (APIs) and finished dosage forms (FDFs). This geographically concentrated reliance introduces substantial vulnerabilities during geopolitical disruptions. Currently, the U.S. Food and Drug Administration (FDA) is tasked with reviewing and approving drug products to ensure they are safe and effective for the market. While the FDA possesses a tremendous amount of information regarding the clinical and safety profiles of these drugs, it has not been tasked with, or given resources for, managing economic and commercial data to conduct a comprehensive, market-wide analysis of the U.S. drug supply.

While the federal government has the authority to collect certain types of information to assist in managing drug shortages, other critical intelligence gaps prevent the effective construction of a comprehensive drug supply database. Although the FDA can request details concerning the manufacturing processes, as well as lists of active and inactive ingredients used, it remains unclear whether the FDA actually receives all of this data or the extent to which this information can be integrated internally or with external datasets. Most alarmingly, the FDA acknowledges that it lacks the requisite information to assess how quickly U.S.-based manufacturers could scale up domestic production of APIs or finished dose forms if a primary supplying nation-such as China or India-were to suddenly cease supply to the U.S. market.

For decades, the pharmaceutical supply chain has operated under a reactive "fail and fix" framework, leaving the nation vulnerable to disruptions stemming from manufacturing failures, natural disasters, or geopolitical tensions. To be sure, these "fail and fix" efforts are a necessary part of mitigating the impact of drug shortages, but they will not change the trajectory or magnitude of future drug shortages and their prevention. In order to shift toward a "predict and prevent" model, a multifaceted approach is required: (1) construct and maintain a dynamic and comprehensive national drug supply map; (2) overhaul data collection to ensure seamless coordination between all government agencies and appropriate private entities; (3) proactively manage market demand and use data and risk management plans on a market-wide basis; and (4) deploy advanced artificial intelligence and predictive analytics to forecast disruptions, implement structural changes, and circumvent the impact of potential new and recurring threats.

To effectively employ predictive analytics, federal agencies require reliable inputs, inter-agency coordination, and comprehensive market visibility and strategic visioning. Congress should enact legislation to implement the following structural and data-driven improvements.

A. Authorize, Fund, and Build an Ongoing, Comprehensive National Drug Supply Map

Predictive analytics algorithms cannot forecast disruptions in a supply chain that is undocumented or poorly understood. To address this, an in-depth, comprehensive, and ongoing map of the U.S. drug supply chain is needed to pinpoint exactly where each drug product-including its key starting materials, APIs, and finished products-are manufactured. Congress should authorize and fund a national agency or entity responsible for: (1) building this comprehensive supply map; (2) making transparent to the public appropriate data elements; (3) linking to commercial sources with prescription drug use and expenditure data; and (4) analyzing the data to estimate the probability and risk of consequences of specific events that can lead to drug shortages.

The foundation of a resilient pharmaceutical market is a comprehensive, real-time map of the drug supply chain. An in-depth mapping initiative is required to identify the precise manufacturing pathways and geographical origins of key starting materials (KSMs), active pharmaceutical ingredients (APIs), and finished dose forms (FDFs).

•The USP Medicine Supply Map: The United States Pharmacopeia (USP) has developed a global Medicine Supply Map that aggregates insights from over 22,000 global sites. This tool successfully maps 91% of FDFs and 55% of APIs, calculating vulnerability scores to offer quantifiable risk metrics. The federal government should support, fund, expand, and utilize such initiatives to ensure that it has a real-time, comprehensive drug supply map. The government should collaborate with and build upon the USP Medicines Supply Map.

•Identifying Geographical Vulnerabilities: The U.S. market relies heavily on foreign manufacturing, particularly in China and India, which creates acute geographical vulnerabilities and ″single points of failure″. A robust supply map must pinpoint these dependencies to facilitate priorities for re-shoring, near-shoring, and friend-shoring among critical drug products.

•Adopting the ″New Zealand Transparency Model″: To maximize the utility of the supply map, the U.S. should adopt transparency standards akin to New Zealand's MedSafe, which maintains a public, searchable database of every approved manufacturing site for every drug product on the market. This transparency enables analysts to use product-specific, market-wide, real-time data to provide insight into the potential and real market impact of a quality failure, factory closure, climate disaster, trade barriers, or other market disruptions.

B. Collect and Coordinate Data from Government and Private Sources

A drug supply map is only as effective as the data supporting it. Currently, pharmaceutical data is highly fragmented across various federal and state agencies, including the FDA, DEA, CDC, Department of Defense (DOD), Veterans Affairs (VA), Department of Commerce, the Federal Trade Commission (FTC) and a variety of other government entities.

•Legislative Mandates for Data Collection: The CARES Act significantly expanded the FDA's authority to collect supply chain data. It expanded requirements for manufacturers to notify the FDA of permanent discontinuances or interruptions in manufacturing that could disrupt U.S. supply. Furthermore, Section 510(j)(3) mandates annual reports from drug manufacturers on monthly production totals for APIs and finished drug products, providing the FDA insight into national production capacity and output.

•Upstream Sourcing Transparency: Drug manufacturers must be required to report all sources of APIs and major excipients. When an FDF manufacturer utilizes APIs from multiple sources, they should disclose the percentage of the API originating from each distinct source to facilitate accurate utilization, excess capacity estimates, risk management, and remediation efforts.

•COOL and Technological Integration: To effectively utilize this data, the industry should integrate Country-Of-Origin Labeling (COOL) into the digital supply chain. By leveraging the 2D DataMatrix barcodes and Blockchain systems already implemented for the Drug Supply Chain Security Act (DSCSA), the origin data of every drug product can be tracked securely from the factory to the patient. While pieces of this data are known at various points in the market, it is not aggregated

comprehensively across the U.S. market to analyze for structural and functional factors that can lead to market and supply disruptions.

C. Prospectively Monitor and Manage the U.S. Drug Supply

Data collection must be paired with proactive data management and interpretation. The U.S. government needs a centralized infrastructure to analyze, predict, and coordinate supply chain structure and function to minimize, prevent, and mitigate real and potential drug shortages.

•Establishing a Centralized Coordination Entity: The U.S. should authorize a dedicated entity-such as a new Strategic Pharmaceutical Policy Advisory Commission (Strategic PharmPAC), an independent commission, or a public-private hybrid model. This effort should work in coordination with the United States Pharmacopeial Convention (USP)-to oversee the market-wide health and security of the drug supply chain. This entity and its efforts would integrate data across the federal government and the private sector.

•Prioritizing Critical Medications: Management efforts should first focus on defining the set of ″Critical Acute Drugs″ (drugs necessary in acute care, where a lack of substitutes leads to severe health outcomes or death) and ″Essential Chronic Drugs″ (drugs necessary to prevent patients from seriously deteriorating from lack of therapy). The list of critical drugs also needs to be regularly maintained and updated.

•Mandatory Risk Management Plans (RMPs): Under the CARES Act, manufacturers of critical drugs and associated APIs are required to develop, maintain, and implement Risk Management Plans. Reporting of these RMPs to the FDA is mandatory for critical drug products and the data from these plans should be used to contribute to a comprehensive, ongoing data set and related analysis to proactively identify and mitigate hazards that could cause supply disruptions.

•Develop and Adopt an OSCR Model for Drug Products: The FDA's Office of Supply Chain Resilience (OSCR), which monitors medical device supply chains, uses a structural model that employs advanced analytics to identify risks, maintains a Critical Medical Device List (CMDL), and enacts proactive interventions to preserve availability. A similar, expanded approach to supply chain resilience is needed for prescription pharmaceuticals.

D. Predictive Analytics to Prepare for Challenges and Threats

The final pillar of a resilient supply chain is the employment of predictive analytics. Congress must fund public-private research programs to develop ″sentinel systems″ that can access and utilize big data to detect signals of strategic change and security threats in the pharmaceutical network serving the U.S. market.

•AI and Machine Learning for Demand Forecasting: Artificial intelligence and machine learning algorithms are revolutionizing most industries by analyzing vast datasets of historical trends, real-time supply chain updates, changes in demand, and expected as well as unanticipated external factors. Used effectively these tools can accurately forecast medication demand, allowing companies and the market to anticipate seasonal variations and demand surges, thereby reducing or preventing stockouts.

•Network-Level Intelligence Platforms: Modern predictive analytics rely on massive, multi-enterprise data networks. Platforms like TraceLink analyze flow data from over 38 billion serialized units across 283,000 healthcare organizations to predict drug shortages up to 90 days in advance with high accuracy.

•Pharmacy-Level Data Modeling: Predictive models can also assess downstream vulnerabilities by evaluating data at the level of individual National Drug Code (NDC) and Drug Identification Number (DIN). Machine learning algorithms assess variables such as the average days of supply (DOS) per patient and month-to-month changes in the ratio of drugs dispensed within therapeutic classes to signal impending clinical shortages.

•Sentinel and Early Warning Systems (EWS): Advanced cognitive models can identify drugs at risk of shortage far earlier than manual reporting. For instance, Premier Inc.'s CognitiveRx AI model has reported an average accuracy of 75% in early shortage detection, identifying at-risk drugs by an average of 128 days before they were officially announced on the FDA shortage list. The federal government should encourage, fund, and develop sentinel models and systems based on historical drug shortages patterns as well as systems to detect new root causes for drug shortages such as geopolitical risk or other new sources of disruption.

Summary

Assuring the resilience and security of the U.S. drug supply requires an unprecedented level of data, transparency, and technological integration. By establishing a

National Drug Supply Map, enforcing stringent upstream data reporting, centralizing market-wide analysis and oversight, and leveraging AI-driven predictive analytics, the United States can transcend the inherent vulnerabilities of the globalized pharmaceutical market. A framework for ″Building a Strategic Pharmaceutical Policy Advisory Commission″ to accomplish these tasks is presented in Appendix A. This integrated framework (when properly authorized, funded, and managed) can ensure that patients consistently receive life-saving medications, regardless of manufacturing and quality failures, natural events and disasters, or international trade disputes.

Question:

Dr. Schondelmeyer, you mentioned that 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:

Thank you for this important and relevant question. Everyone needs, or uses, prescription drugs at various points during their lifetime. The quality and security of the prescription drug supply in the United States is a critical part of the national infrastructure that assures the availability of effective drug therapy for all in America. Seniors and other vulnerable populations, in particular, rely heavily on daily medications to manage chronic conditions and to improve their health status. The U.S. drug supply faces serious challenges with respect to quality, recalls, and shortages affecting many critical medicines. In addition, the drug supply chain has become highly concentrated economically and geographically and is heavily dependent upon two countries, China and India, for key starting materials (KSMs), active pharmaceutical ingredients (API), and finished dosage forms (FDFs).

A senior filling a prescription in Georgia for a generic blood pressure medication has no way of knowing whether their tablets were manufactured in a state-of-the-art facility in the United States or a sweat-shop facility in China or India with a history of FDA warning letters or ″Official Action Indicated″ (OAI) safety violations.[1]

Prescribing physicians and pharmacists in Georgia could actively choose to source drugs from manufacturers with superior safety records, if this information was reliably and publicly available. Thus, protecting seniors from recurring risk due to economically-motivated adulteration or contamination-such as the deadly global recalls of tainted heparin from China or the generic blood pressure medications (e.g., valsartan) made in India that were found to have carcinogenic impurities.[2]

Under the current opaque system, when a foreign manufacturing plant suffers a catastrophic failure, quality breach, or natural disaster, the U.S. market often experiences cascading, panic-driven shortages. The exact origin of the drugs dispensed to the patient are invisible to the physician, the pharmacist, and the patient. Therefore, an FDA recall of a drug product from a specific plant in China or India can cause a nationwide panic, as pharmacists struggle to identify which of their drug products are actually affected. Mandatory country of origin labeling (COOL) transparency helps to correct this market failure. By making a product's origin visible, it allows group purchasing organizations (GPOs), Medicare plans, physicians, pharmacists, and consumers to actively prefer and reward resilience. This can provide the financial incentives necessary for companies to ″re-shore″ or ″near-shore″ their manufacturing, ultimately reducing the U.S. supply chain's dangerous over-reliance on geopolitical rivals for life-saving drugs. With clear labeling of the manufacturing source, pharmacists could pull the tainted batches while confidently dispensing the safe, unaffected batches to seniors, thereby preventing substantial risks and disruptions of care.

U.S. law[3] currently requires that ″all products of foreign origin imported into the United States must be marked with their country of origin.″[4] The intent of this re-

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[1] Schondelmeyer, S.W. (2026, January 29). Statement on Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply. Testimony before the U.S. Senate Special Committee on Aging. See, also, Schondelmeyer, S.W. (2024, February 6). Statement on A Resilient U.S. Drug Supply: Current & Emerging Vulnerabilities. Testimony before the U.S. House Committee on Ways & Means.

[2] Schondelmeyer, S.W. (2025, June 5). Designing A Resilient U.S. Drug Supply: Efficient Strategies to Address Vulnerabilities. Testimony before the U.S.-China Economic and Security Review Commission.

[3] U.S.C. ⧫ 1304 and 19 C.F.R. ⧫ 134.11.

[4] U.S. Customs and Border Protection. ″Fact Sheet: Marking of Prescription Medication for Retail Sale.″ CBP Publication No. 3812-0824. Accessed on January 24, 2026 at: https://

quirement is to compel the manufacturer to disclose to the public the country where their drug product is made. On June 14, 2024, a ruling by the U.S. Customs and Border Protection (CBP) Headquarters in a letter (HQ H283420) to CVS Health[5] declared that the 'consumer at retail' is the 'ultimate purchaser', rather than the previous interpretation that it is the 'manufacturer selling to a pharmacy' This change makes sense; however, it means that pharmacists are now responsible to report the 'country of origin' on the prescription label when the medication is dispensed to a patient.[6] Although this is a good policy on its surface, its weakness comes because the pharmacist is held responsible for labeling a prescription with the 'country of origin' which is information that must ultimately come from the manufacturer who may, or may not, report that information to the FDA, the pharmacist, or the public.

When a customer in Georgia fills a prescription at their retail pharmacy such as CVS or their independent community pharmacy, the pharmacist must provide the 'country of origin' for the drug product on the prescription label. This process sounds simple enough; however, not all drug companies marketing prescription drugs in the U.S. report the 'country of origin' identifying where their drug product is actually made. And, some manufacturers report this information only to the FDA who may, or may not, make the data public. If the manufacturer does not report the 'country of origin', the pharmacist is still responsible to find and report the 'country of origin' to their patients. The large chain pharmacies such as CVS can assign staff at their corporate office to research and compile this information across the 70,000 to 100,000 drug products on the market, so that their in-store pharmacists can comply with this requirement. However, for an independent community pharmacy, the process to search for the ″country of origin″ for each prescription drug product may take the pharmacist 10 minutes to 30 minutes or more per prescription to search for this information. And, the pharmacist may not be able to find the 'country of origin' if it is not made public by the manufacturer.

While this policy appears workable in theory, it simply is not practical. First, this process is dependent upon the importer (i.e., manufacturer) to publicly report the 'country of origin' to the FDA as required and in a clearly understood manner. Second, it is dependent upon the FDA passing the information on to the public in a useable format. Third, the search process by a pharmacist, at the store level, to find the 'country of origin' for many thousands of drug products so it can be included on the prescription label is very time consuming and is clearly not sustainable economically. Even though the FDA may have this information for each specific prescription drug product in its files or in electronic data sets, if the data is not made public, the pharmacist cannot report what he or she does not have and cannot obtain.

Clearly, this policy-no matter how well intended-will have a severe differential negative impact on independent community pharmacies and their patients. In a state, like Georgia, where more than one-third of its pharmacies are locally and independently owned, the economic burden of chasing 'country of origin' data that manufacturers may, or may not, have reported to the FDA or the public is overwhelming. Absence of this information will mean that physicians, pharmacists, and patients cannot make purchase decisions that take into account the geographic origin of a drug product. This impact will be especially noticed by Georgians in rural and distressed urban areas which often have a higher share of independent pharmacies. This will also have a greater impact on seniors and other vulnerable populations served in these communities.

While chain pharmacies dominate the overall share of pharmacies in Georgia, especially in densely populated metro areas (like Atlanta), independent pharmacies carry the vast majority of the burden in rural and stressed regions of Georgia. According to Georgia's Rural Center, 25% of all Georgia counties (42 counties) have no corporate [chain] pharmacies and rely entirely on local, independently owned

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www.cbp.gov/sites/default/files/2024-08/
FACT%20SHEET%20Marking%20Prescription%20Medication%20for%20Retail%20Sale.pdf.

[5] U.S. Customs and Border Protection, Letter from Yuliya A. Gulis, Director, Commercial and Trade Facilitation Division to JoAnne Colonnello, Center Director, Pharmaceuticals, Health, and Chemicals, Center of Excellence and Expertise, U.S. Customs and Border Protection, 6747 Engle Road, Middleburg Heights, OH 44130, dated June 14, 2024; HQ H283420, OT:RR:CTF:CPMMA H283420 RRB, CATEGORY: Marking; RE: Internal Advice; Country of origin marking requirements for repackaged prescription medication sold by CVS Health; ultimate purchaser; 19 U.S.C. ⧫ 1304; 19 C.F.R. ⧫ 134.1(d)(1); 19 C.F.R. ⧫ 134.25. Accessed on January 24, 2026 at: https://rulings.cbp.gov/ruling/H283420.

[6] U.S. Customs and Border Protection, Letter to Yulia A. Gulis, June 14, 2024.

community pharmacies for their prescription drug access.[7] Other types of pharmacies (such as Federally Qualified Health Centers (FQHCs), hospital outpatient pharmacies, and specialized clinics) are expected to have 'country of origin' labeling problems similar to those experienced by independent community pharmacies. When these other pharmacy types are taken into account, nearly one-half of all Georgia pharmacies could be impacted by these short-comings and lack of public data on 'country of origin' information needed to support the prescription labeling requirements. Only with two pre-requisite obligations can community pharmacies meet the otherwise impossible task of placing the 'country of origin' on each prescription label.

(1) Manufacturers (and marketers) should be required to report to the FDA the 'country of origin' for both the active pharmaceutical ingredients and the finished dose form for all prescription products marketed in the United States.

(2) The FDA should be required to compile this 'country of origin' information into easily machine-readable digital files and publicly report the data through online web sites.

In summary, Georgia and other states, would benefit from publicly disclosed 'country of origin' on prescription labels. This information can: (1) empower prescribers, pharmacists, and patients to make wise purchase decisions based on the quality history and geographic origin of drug products; (2) enable rapid and targeted identification and removal of drug products made in specific locations with known quality or contamination problems; (3) support market-based incentives intended to encourage and reward domestic or friend-shored production of pharmaceuticals; and (4) utilize existing infrastructure and data that has been reported in an opaque system including the data collected under the Drug Supply Chain Security Act (DSCSA).

Routine provision of ″country of origin labeling″ for prescription medications would greatly improve transparency for physicians and pharmacists, as well as purchasers and payers, and most importantly for patients. Transparency regarding where one's medications are actually being made is not merely a matter of consumer preference; it is a matter vital to public health and national security. Knowing where a drug comes from can build trust in the quality and dependability of our U.S. drug supply.

That trust begins with ″truth and openness″ from CLEAR LABELS.

Question:

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

Response:

A number of recommendations are reported in my written comments provided to the Senate Special Committee on Aging at its Hearing on: ″Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From″ on January 29, 2026.[8] Those recommendations, and others, are re-stated and further described here. Many of these recommendations can be implemented as administrative actions and regulatory guidance, while other recommendations may require statutory revisions or additions. The Senate Special Committee on Aging members and their staffs should work with FDA to identify the necessary and most efficient way to accomplish the intent of the recommendations described herein.

The overall intent of the recommendations provided here is to require country of origin labeling that provides the ultimate purchaser-the American patient-with pharmaceutical product labeling that clearly indicates where their prescription medication was made. The term 'country of origin' may be abbreviated as COO, while the term 'country of origin labeling' may be abbreviated as COOL.

As noted in my written testimony, 'country of origin labeling' has emerged as a critical element in the contemporary landscape of consumer goods, in general, and prescription pharmaceuticals, in particular. COOL involves marking the drug prod-

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[7]Georgia's Rural Center. Rural Pharmacies and Patients at Risk: PBM Practices Pose Risks to Independent Pharmacies, Updated Feb. 6, 2025. Accessed on February 12, 2026 at the website: https://www.ruralga.org/post/rural-pharmacies-and-patients-at-risk-pbm-practices-pose-risks-to-independent-pharmacies#:text=the20National20Community20Pharmacy20Association,a20pharmacy20(Figure%201).

[8] Schondelmeyer Stephen, ″Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply, presented at the Senate Hearing on Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From, Statement before the Special Committee on Aging United States Senate, Congress of the United States, Thursday, January 29, 2026, Washington, DC.

uct received by the end-consumer with the name of the country in which the product was actually manufactured or made. For some industries, and in some trade agreements, the concept of COOL is the place where the product was ″manufactured, processed, or substantially transformed.″ The definition of where a pharmaceutical product is made is critical and should be carefully and clearly defined. For pharmaceutical products, the primary essence and value of the drug product is embodied in its active pharmaceutical ingredient(s) (API), and not necessarily in how or where it was processed or packaged. For prescription drug products, the 'country of origin' for the API should be clearly defined as ″the country which contains the geographical location where the API is actually made.″ Similarly, the 'country of origin' for the finished product should be clearly defined as ″the country which contains the geographical location where the finished product is actually made.″

First, Section 502 of the FD&C Act (21 U.S.C. ⧫352) should be reviewed and revised, if necessary, to ensure that it includes a requirement that ″the country of origin for the API and the country of origin for the finished drug product must be clearly marked on the label of the container in which the finished product is sold in the U.S. market.″ Both the COO for the API and the COO for the finished product are required. This requirement for labeling of a drug product with both the COO for the API and the COO for the finished product should apply to any drug product at the National Drug Code (NDC) level being sold by any labeler in the U.S. market. Recall that a 'labeler' ″may be either a manufacturer, including a repackager or relabeler, or, for drugs subject to private labeling arrangements, the entity under whose own label or trade name the product will be distributed.″[9]

Failure to include the country of origin for either the API or the finished product should render a drug product as 'misbranded' and it should be subject to any and all remedies available including, but not limited to, civil penalties and fines, product seizures and destruction, injunctions to stop manufacturing or distribution, refusal to import, voluntary or mandatory recalls, and criminal prosecution including misdemeanor to felony charges against the corporation and its executives. In particular, misbranded products with respect to lack of COO for either API or finished product on the end product label should result in refusal to import to the U.S. or recall and removal from the market for product originating in, or otherwise being sold in, the U.S. market.

The intended net effect of the 'country of origin labeling' policy is that:

•Any labeler of a prescription drug product at the NDC level being marketed in the U.S. is responsible for placing the COO for the API on the label of the end product container.

•Any labeler of a prescription drug product at the NDC level being marketed in the U.S. is responsible for placing the COO for the finished product on the label of the end product container.

•The FDA or the Department of Justice may pursue civil penalties and fines, product seizures and destruction, injunctions to stop manufacturing or distribution, voluntary or mandatory recalls, and criminal prosecution including misdemeanor to felony charges against the corporation and its executives of labelers not complying with the COO labeling requirement for either the API or the finished product.

•The Customs and Border Protection agency may refuse to import any drug product not complying with the COO labeling requirement for either the API or the finished product.

•The requirement to comply with COOL for the API and COOL for the finished drug product applies not only to a prescription drug product manufacturer, but also to any labeler, repackager, relabeler, marketer, distributor, or private labeler of a drug product at the NDC level.

•Simply reporting another drug product's NDC or FDA approval number does not suffice for providing the COO for the API or the finished product on the actual label for the container holding the end product.

•FDA sponsors, manufacturers, labelers, repackagers, relabelers, marketers, distributors, private labeler of products, or any other firm responsible for a prescription drug product at the NDC level in the U.S. market is responsible to report the COO for the API and for the finished product to the FDA and its Structured Product Label (SPL) electronic listing file system.

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[9] U.S. Food & Drug Administration. NDC Package File Definitions. Content current as of July 21, 2022 and found on February 12, 2026 at the website: https://www.fda.gov/drugs/drug-approvals-and-databases/ndc-package-file-definitions.

•The COO for the API and the COO for the finished product are required public information for marketing a prescription drug product in the U.S. market, and this information may not be declared as ″Confidential Commercial Information″.

•The requirement for COOL for the API or the finished product is not met by a manufacturer, labeler, marketer, distributor, repackager, relabeler, or private labeler who reports only the location of:

(1) the warehouse shipping the product;

(2) the corporate headquarters of the firm labeling, marketing, selling, or distributing the product;

(3) the U.S. address of a subsidiary of a foreign-owned company operating in the United States;

(4) the facility repackaging or relabeling the product; or

(5) the pharmacy or healthcare entity dispensing the medication.

Second, the labeler of any drug product at the NDC level in the U.S. market should be required to report to the FDA, the COO for the API and the COO for the finished product. The FDA should be authorized, and required, to collect in text form the COO for the API and the COO for the finished product. FDA should add, or include data variables, if not already present for reporting this required information in text form in its Structured Product Labeling (SPL)[10] electronic file for each drug product at the NDC level.

The FDA has traditionally treated the specific factory location of an Active Pharmaceutical Ingredient (API) as ″Confidential Commercial Information″ (CCI).[11] FDA Regulations (21 CFR § 20.61) define ″Confidential Commercial Information″ (CCI) as valuable data that is ″customarily held in strict confidence.″ As noted in my testimony, there are numerous examples of drug firms (i.e., manufacturers and labelers) issuing public press releases about building new facilities for production of specific API and finished products to be sold as prescription drugs in the U.S. market. The public and widespread disclosure of such information clearly contravenes the current FDA definition of ″Confidential Commercial Information″. This regulation, and related FDA guidance, regarding ″Confidential Commercial Information″ should be reviewed and revised, if necessary, to exclude COO for the API and COO for the finished product from the definition of CCI. Both the COO for the API and the COO for the finished product should be defined as 'required public information' that must be disclosed at the NDC level for any prescription drug product marketed in the United States. Consequently, labelers reporting prescription drug product information to the FDA's SPL electronic file system should not be permitted to declare the COO for the API and the COO for the finished product as ″Commercial Confidential Information″ resulting in this information being suppressed or withheld from the public.

The data submitted by labelers to the FDA's SPL electronic file system is used by the National Library of Medicine (NLM) to populate a drug profile on the consumer-facing DailyMed website.[12] The 'About DailyMed' section on the website describes that it provides to the public ″the most recent labeling submitted to the Food and Drug Administration (FDA) by companies and currently in use (i.e., ″in use″ labeling).″[13] As of February 12, 2026, the DailyMed database contained 154,834 products with labeling information submitted to the FDA by the product's labeler.[14] For each drug product, with related NDC numbers grouped together, there are 17 enumerated sections as well as several other sections including: SPL Unclassified

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[10] U.S. Food & Drug Administration. Structured Product Labeling Resources. Content current as of January 8, 2025 and found on February 12, 2026 at the website: https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources.

[11] U.S. Food & Drug Administration. FDA Fact Sheet: Information Sharing: 20.88 Agreements & Commissioning. Content current as of February 12, 2026 and found on February 12, 2026 at the website:https://www.fda.gov/media/109437/download.

[12] National Library of Medicine, DailyMed. About DailyMed. Content accessed on February 12, 2026 at the website: dailymed.nlm.nih.gov/dailymed/about-dailymed.cfm.

[13] The FDA-approved Prescribing Information (PI) for approved human prescription drug and biological products contains a summary of the essential scientific information needed for the safe and effective use of the product. The PI includes boxed warnings, indications, dosage and administration, contraindications, warnings and precautions, adverse reactions, drug interactions, information about use in specific populations, and other important information for healthcare practitioners. FDA-approved patient labeling (e.g., Patient Information, Medication Guide, Instructions for Use) is directed to the patient, family, or caregiver. FDA-approved carton and container labeling communicate information that is critical to the safe use of prescription drug and biological products from the initial prescription, to procurement, to preparation and dispensing of the drug, to the time it is given to the patient.

[14] National Library of Medicine, DailyMed. Content accessed on February 12, 2026 at the website: dailymed.nlm.nih.gov/dailymed/index.cfm.

Section; Medication Guide; Package/Label Principal Display Panel; and Ingredients and Appearance.

Looking on the DailyMed website for information related to 'country of origin' for the API or the finished dose form is somewhat like playing 'Hide and Seek'-the information may, or may not, be there but you have to look for it; and, it is not always contained in the same location for each drug product or DailyMed profile. The DailyMed website reports various types of information in each of the 17 enumerated sections of the FDA-approved Prescribing Information. Typically, none of the first 16 sections contain any country of origin (COO) information, and only sometimes do Section ″17 PATIENT COUNSELING INFORMATION″ or later sections contain country of origin information. If there is COO information in Section 17 it is usually found only at the very end of the FDA-approved Patient Labeling information where the 'Medication Guide' is presented.

The drug product, Revlimid (lenalidomide), was used as an example from the DailyMed website to show what information is provided with respect to the 'country of origin' for the manufacturer of the API and the manufacturer of the finished product for this specific drug product[15] (See Appendix B). At the very top of the DailyMed Profile is a heading that indicates the ″Packager″ of the Revlimid product is ″Celgene Corporation″ and no country is reported as the location for this corporate entity (Appendix B.1.). Eight different sections on the DailyMed website (i.e., Section ″17 Patient Counseling Information″; ″Medication Guide″; and six versions of the ″Package/Label Display Principal Panel″ with one label (as only a jpg image) for each of 6 different strengths of Revlimid) report that the product is ″Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA″ (Appendix B.2., B.3., and B.4). One additional place at the very end of the DailyMed website (i.e., the Ingredients and Appearance section) indicates that the ″Labeler″ for this product is ″Celgene Corporation (174201137)″ (Appendix B.5.). In the DailyMed profiles for other drugs, this section sometimes lists specific 'Establishments' or companies involved in the supply chain for the specific drug product such as Revlimid. Among the 'Business Operations' listed are 'API Manufacture' and 'Manufacture' (of finished dose form). There was no list of 'Establishments' or manufacturing functions on the DailyMed website for Revlimid. This implies that the 'Labeler' for Revlimid has indicated in the SPL electronic submission system that information on the API manufacturer and the finished dose form manufacturer were considered 'Commercial Confidential Information' or that they were not reported at all, thus suppressing this information from being reported on the DailyMed profile. An example of a DailyMed profile showing business operation information is provided using the generic version of lenalidomide (Cipla USA Inc.) to illustrate what types of information are available and are sometimes reported (Appendix B.6.).

The overall finding from examining the Revlimid profile on the DailyMed website is that the public information included identifies the 'Packager' as Celgene Corporation; that it is 'Marketed by' Bristol-Myers Squibb Company; that it is a 'Product of Switzerland'; and that the 'labeler' is Celgene Corporation. The Revlimid DailyMed profile did not identify the source of the API or the country of origin for the 'API Manufacturer', although a generic version of this drug (lenalidomide) does identify both the source of the API and the country of origin for the 'API Manufacturer'. Because there was no standardized location for the 'country of origin' information in the DailyMed profile and there was a lot of text material to be reviewed, it took about an hour to read through and search the entire DailyMed profile of Revlimid to check for information on the 'country of origin' for the API and the 'country of origin' for the finished product.

From experience reviewing DailyMed profiles and looking for country of origin information, the locations where this information is most likely to be found were:

(1) near the end of the section titled ″17 PATIENT COUNSELING INFORMATION;″

(2) near the end of the section titled ″Patient Package Insert″, if present;

(3) in the section titled ″PACKAGE LABEL PRINCIPAL DISPLAY PANEL;″ which may have jpg images of the drug product label; or jpg images of the outer carton surrounding the bulk package; or

(4) near the end of the section under the heading ″INGREDIENTS AND APPEARANCE″ under the sub-heading titled ″Establishment″ and listing 'Business Operations'.

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[15] National Library of Medicine, DailyMed, LABEL: REVLIMID-lenalidomide capsule. Content updated as of March 24, 2023 and found on February 12, 2026 at the website: dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5fa97bf5-28a2-48f1-8955-f56012d296be.

In contrast to searching for the 'country of origin' information on the DailyMed profile and website, as described above, a similar search was performed on the New Zealand MedSafe website.[16] The information found on the MedSafe website for Revlimid capsules 10 mg (Bristol-Myers Squibb (NZ) Limited is shown in Appendix C. Within 2 minutes this information was found and it reported not only the country of origin for API and the finished dose form, but also the name of each manufacturing company and its address. This MedSafe example demonstrates that the 'country of origin' information can be provided in a more consumer-friendly and easy to find format. Also, the disclosure of the 'country of origin' information is, and can be, made available in a public-facing environment.

One final comment on the information found in the DailyMed product profiles concerns the quality of the jpg images published on the site. The FDA and NLM rely on the product sponsor and/or labeler to provide jpg images of the container, carton, and label for prescription products listed in the SPL database and presented on the DailyMed website. Some of the jpg images are of such poor quality that they cannot be accurately read or understood. One such example is provided in Appendix D. Appendix D first shows the DailyMed listing for the Metformin Hydrochloride-Tablet, Extended Release (Appendix D.1.). In Appendix D.2. the jpg image of the product label is shown. Upon examining this label: Can you read the NDC number of the product? Can you find the Labeler Name? Can you find the Manufacturer for the API or the Finished Product? Can you find the 'Country of Origin' for the API or the Finished Product? Not all of this information is on the label provided. However, even if all of this information was there, clearly one cannot read it. The point is, if the FDA SPL electronic data system is going to request label images (and they should), the images are of no value if they are not readable. At present, some information on the label images (such as 'country of origin" for the API or the finished product) is found nowhere else in the data presented on the DailyMed product profile. The FDA should require submission of label images through its SPL electronic data system, and it should require that jpg images meet minimum readability and pixel density requirements.

The FDA should address the following issues to facilitate making 'country of origin' labeling publicly accessible including reporting of the information on the NLM DailyMed profiles of prescription products:

•The 'country of origin' for the API should be required, publicly accessible, and reported in a text format in a standard place on the DailyMed website.

•The 'country of origin' for the finished product should be required, publicly accessible, and reported in a text format in a standard place on the DailyMed website.

•The 'country of origin' for API should be reported using the phrase: "API Made in ————————" immediately preceding the country where the API is actually manufactured and no variation in this preceding phrase is acceptable.

•The 'country of origin' for finished product should be reported using the phrase: "Product Made in ————————" immediately preceding the country where the finished product is actually manufactured and no variation in this preceding phrase is acceptable.

•FDA should add a text field variable for the API 'country of origin' to its National Drug Code Directory[17] NDC product file[18] list of variables.

•FDA should add a text field variable for the finished product 'country of origin' to its National Drug Code Directory NDC product file list of variables.

•FDA should encourage commercial databases such as MediSpan and First DataBank to add text variables for the API 'country of origin' and the finished product 'country of origin' in their drug product reference and dispensing system data files.

•FDA should require reporting of both API and finished product 'country of origin' in a standard location in the FDA-approved Prescribing Information (PI).

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[16] New Zealand Medicines and Medical Devices Safety Authority. MedSafe. MedSafe Product Detail. Revlimid Capsule 10 mg. Accessed on February 12, 2026 at the website: https://www.medsafe.govt.nz/DbSearch/ProductDetail.asp?ID=13399.

[17] U.S. Food and Drug Administration. National Drug Code Directory. Content current as of February 5, 2026 and accessed on February 12, 2026 at: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

[18] U.S. Food and Drug Administration. NDC Product File Definitions. Content current as of March 12, 2024 and accessed on February 12, 2026 at: https://www.fda.gov/drugs/drug-approvals-and-databases/ndc-product-file-definitions.

•FDA should require reporting of both API and finished product 'country of origin' in a standard location in the FDA-approved Patient Medication Guide.

•FDA should require reporting of both API and finished product 'country of origin' in a standard location in the FDA-approved product carton labeling.

•FDA should require reporting of both API and finished product 'country of origin' in a standard location in the FDA-approved product package labeling.

•FDA and NLM should report in the ″Ingredients and Appearances″ Section of the DailyMed profile the API Manufacturer firm name, the ID/FEI, and the 'Country of Origin'.

•FDA and NLM should report in the ″Ingredients and Appearances″ Section of the DailyMed profile the finished product Manufacturer firm name, the ID/FEI, and the 'Country of Origin'.

The intent of the 'country of origin' labeling (COOL) requirement is to provide the consumer (i.e., the patient) with easily accessible and understandable information about where their prescription medications were made. Both the country of origin for the active pharmaceutical ingredient (API) and the finished product should be disclosed to the public so that they, along with their physician and pharmacist, can make a conscious selection of the medicines they choose and use. When a prescription medicine is made using API from a factory in China and a finished product prepared in India, that is then marketed by a business entity in the United States; it is misleading to give the impression that the product is made in the USA. Yet, this is the situation for many prescription products in the U.S. market, and they are assumed to be made in the USA when actually they are not. If all prescription products are not clearly labeled with the true 'country of origin', consumers may lose trust in the quality and confidence in the effectiveness of the U.S. medicines supply.

'Country of origin labeling' (COOL) serves as a mechanism to inform buyers about their product's origin and to inform their perceptions of quality, safety, economics, or even their presumed patriotism and support of free markets. With respect to pharmaceuticals, safety, efficacy, and quality assurance of the medication are paramount. Knowing the country of origin for the product can directly affect consumer trust in the regulatory scrutiny and oversight of pharmaceutical production. Furthermore, COOL indicates the regulatory frameworks, economic strategies, environmental conditions, political systems, and international trade policies that may have surrounded and influenced the making of the end-product. COOL is a tangible means to provide transparency, support consumer decision-making, and encourage a fair and competitive market.

Knowing where a drug comes from can build trust in the quality and dependability of our U.S. drug supply. That trust begins with ″truth and openness″ from CLEAR LABELS.

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Appendix A

Building a Strategic Pharmaceutical Policy Advisory Commission

Prescription drugs represent a significant part of the U.S. economy (as much as 4% of the entire GDP) and are a cornerstone for our health care system in order to assure productive workers and a ready and able military force. Historically, the lack of information on upstream drug product supplies has resulted in growing drug shortages with serious health consequences and substantial additional healthcare costs. Drug shortages can appear with little or no warning to healthcare providers (e.g., azithromycin, vincristine) and may require prescribers to look for alternatives, if any. At times, all or most of the suppliers of a given drug product (e.g., ranitidine) may face recalls at about the same time, leaving little or no drug product on the market due to inadequate production, inventories, or quality control measures. Business decisions can also deprive patients of critical drugs (e.g., vincristine). Public health events and natural disasters may lead to sudden or unexpected changes in drug demand. More recently, trade conditions and international hostilities have introduced new and troubling concerns about external forces that can disrupt the availability of key starting materials (KSMs), active pharmaceutical ingredients (APIs), and finished dosage forms (FDF) of prescription drug products. These external forces of supply disruption can be sudden, wide spread, and independent of traditional drug supply factors. The decades-long persistence of critical drug shortages demonstrates that a more systematic, comprehensive approach to ensuring a continuous, resilient supply of critical drugs is needed.

As described in my written testimony before the Senate Special Committee on Aging on January 29, 2006:[19] "Building a secure foundation for the U.S. drug supply requires re-framing our approach to understanding the U.S. drug supply and the challenges that it faces in the years ahead. The FDA is charged to review and approve drugs that are safe and effective for treating patients in the U.S. healthcare market. FDA has a tremendous amount of information about clinical and safety aspects of drug products in the market. In general, however, the FDA has not been empowered, authorized or appropriated resources to assess and manage the U.S. drug supply on a market-wide industrial and commercial basis. There is a need for an assessment of the data sources and analytics necessary to assure the security of the U.S. drug supply from a market-wide perspective that embraces, and goes beyond, the safety, effectiveness, and approval of individual drug products. This effort should be built using the cornerstone of the FDA drug data platforms while enabling integration with data from the business and consumer sectors as well as the global economy."

"There is a need for an entity at the national level that can coordinate and stimulate the robustness of the entire pharmaceutical market at all levels and in all corners of the healthcare system. Drug data and systems are fragmented and a framework is needed for integration of data across federal and state agencies (including the FDA, CDC, DOD, VA, FTC, and others) as well with the private sector. Market-wide mapping is needed to integrate siloed drug approval data into a

[19] Schondelmeyer Stephen, "Real Country-Of-Origin-Labeling (COOL) Transparency in the U.S. Pharmaceutical Market: Foundation for a Secure & Resilient Drug Supply, presented at the Senate Hearing on Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From, Statement before the Special Committee on Aging United States Senate, Congress of the United States, Thursday, January 29, 2026, Washington, DC.

comprehensive, transparent system to ensure life-saving medicines remain available, affordable, secure, and of high quality. A core drug supply map needs to build new strengths and methods for understanding the national and global dynamics of the upstream drug supply chain and its vulnerabilities."

Congress should authorize and fund a single, focused national entity to be known as the Strategic Pharmaceutical Policy Advisory Commission (or Strategic PharmPAC) to advise Congress on policies that will strengthen and assure a resilient and secure drug supply for the United States.

The following discussion outlines, in no particular order, recommended characteristics and functions of the Strategic PharmPAC.

This federal entity should be a specific single national entity to: (1) build an in-depth map of the US drug supply chain; (2) publish selected and appropriate information on each drug's supply chain; (3) acquire and analyze data on the volume and expenditures for prescription drug products in the US market, including Medicaid, Medicare, other government programs, managed care and commercial insurance, and cash pay markets; (4) identify critical and top priority drugs with the most serious consequences if drug shortages occur; and (5) coordinate development and implementation of national policy related to the pharmaceutical market and ensuring a high-quality, resilient drug supply.

This federal entity should be structured as a governmental advisory commission with reporting to, and oversight from, the United States Congress. This Commission should function in a manner similar to the Medicare Payment Advisory Commission (MedPAC) or the U.S. China Economic and Security Review Commission (USCC) with responsibility for reporting to, and oversight from, the U.S. Congress. This Strategic PharmPAC should be established and tasked with "developing and implementing a forward-looking and ongoing process to formulate and propose pharmaceutical industrial policy to assure a safe, affordable, and secure U.S. drug supply." The Strategic PharmPAC should collaborate and coordinate with all other federal government entities including the FDA, CMS, NIH, NLM, DHHS, DHS, U.S. trade and commerce, FTC, CBP, DEA, DOD, VA, CDC, and any other agencies that interface with pharmaceutical products. One possible approach would be to designate an expanded role for an organization such as the United States Pharmacopeial Convention—an entity that has a long-standing track record with explicit statutory authority to establish standards for regulation of the pharmaceutical market. Another alternative would be to establish a new entity for the purposes described above.

This federal entity should design, develop, maintain, enhance, analyze, and publish information on the supply chain for all drug products (at the NDC level) in the US market. The manufacturing, quality, clinical, and safety data of the FDA regulatory process should be combined with commercial data on market demand, economic factors, distribution, and delivery systems of critical drug products. This combined data set needs to reach across all government entities and to relevant private sector sources. The supply chain patterns and as well as external risk factors need to be assessed to determine which drugs to prioritize and which products will have the greatest risk of a supply shortage.

This federal entity should monitor the changing landscape of pharmaceutical manufacturing and supply chain policy for prescription drugs, including steps to: (1) modernize drug production and

quality; (2) monitor the safety, security and resilience of the drug supply chain; (3) track and trace the drug supply; (4) oversee trade policies and shipping security and safety; (5) require and enforce transparent country-of-origin labeling for prescription drug products; and (6) implement appropriate levels of supply chain transparency. This monitoring effort should lead to policy proposals to improve and ensure drug product quality and to incentivize increased and improved drug manufacturing (both API and FDF) based in the United States, or friend-shoring sites, in order to increase the quality, security, and resilience of the US drug supply.

This federal entity should use a three-tiered, layered approach to transparency of its market-wide drug data system. The most complete and open access would be at the national level for specialized analysts and policy makers in government and key think tank participants who can think strategically about building and protecting a secure pharmaceutical market. The second level would provide access to integrated data and working projects at functional levels in federal agencies, academia, and with industry stakeholders. The third layer of this tiered access would be for the private sector, consumers, and the general public to have insights into data that facilitate their safe, effective and affordable use of prescription drugs.

This federal entity should prepare a readiness and response plan for managing and mitigating drug shortages and other supply chain disruptions that arise in the US market. This plan should involve a nationally coordinated effort to tally and manage limited supplies including: set priorities for allocation, establish allocation procedures, implement plans for distribution, define roles of drug stockpiles and repositories; identify alternative supplies or alternative drug products; and establish other appropriate methods and responses for managing a drug shortage in order to provide critical drug therapy to patients in need.

This federal entity should have a national process and a comprehensive ongoing infrastructure for describing, analyzing, predicting, managing, and preventing shortages of critical medications to better inform policymakers and to better serve the American public. While the U.S. government has on occasion stood up a drug supply chain tracking system in the past, such as the control tower approach used by ASPR during the early days of the COVID pandemic, these efforts were undertaken only after there was a supply problem. The control tower team then had to pull together limited and targeted sets of data from disparate and isolated sources. Basically, this represents a "Fail and Fix" approach to drug supply tracking and drug shortage management.

This federal entity should develop a strategic pharmaceutical database resource that uses experience with 'big data' systems and artificial intelligence and draws upon experience from the financial, agricultural, energy, defense, computer, social networks, and other sectors. This prospective approach can create a "Predict and Prevent" approach to planning and maintaining the U.S. drug supply, rather than waiting until the supply chain fails and must be fixed. Building an in-depth map of the US drug supply chain will help identify where each drug product (at the National Drug Code [NDC] level) in the US market was made, including where the key starting materials, APIs, and finished drug products were produced. The supply map should also track how the drug product is shipped from manufacturer to labeler (or marketer) to wholesaler and to the pharmacy or provider and consumer. This supply map should incorporate production data from the manufacturer, logistical date from shipping records and importers, regulatory data from the FDA, commercial data from suppliers, manufacturers, wholesalers, and other sources. The drug supply map should use the collected data to map networking patterns and interdependence of

suppliers at all levels in the supply chain and to identify, report, assess, and monitor its vulnerabilities.

This federal entity should conduct strategic industrial base assessment and infrastructure planning for the U.S. pharmaceuticals market. This national entity should collaborate with, but be separate from, the U.S. Food and Drug Administration. FDA is authorized and has appropriation for evaluating drug product manufacturing, quality, safety and clinical effectiveness. This data is collected and evaluated one product at a time in the drug approval process. The FDA does not have in their scope of legislative authorization, or in their institutional experience, assessment of economic, market, and industrial base policy from a commercial or trade perspective, let alone from a national health system and national security basis.

This federal entity should create prescription drug profiles for each drug product (at the NDC level) and they should be publicly available on a consumer-friendly website. Much of the information gathered could be made transparent, as it already is, through a website such as the NLM's DailyMed database. This website could update its database with new Congressional authority using data elements and presentation formats similar to New Zealand's MedSafe website. The profile for any prescription product in the U.S. market should include, but not be limited to:

(1) major steps in the supply chain (*e.g.*, KSMs, APIs, FDFs, quality testing, and packaging);
(2) the site of API manufacture and the site of finished dose form manufacture;
(3) FDA labeling and any black box and warning letters;
(4) facility inspections and Form 483 reports;
(5) manufacturer recall, and FDA seizure history;
(6) import holds;
(7) marketing and advertising letters and warnings;
(8) other regulatory actions;
(9) public and private assessments of product quality using validated measures;
(10) quality assurance reports; and
(11) other relevant information.

This federal entity should support ongoing intramural and extramural research programs on the resilience and security of the US drug supply chain including, but not limited to: (1) application of artificial intelligence and predictive analytics to identify and mitigate the risk of drug shortages and (2) development of a sentinel system that can detect signals that may precede a supply chain disruption or drug shortage. Predictive analytics should be applied to the national drug supply map and database to test expected and unexpected relationships and patterns that explain risks and threats to the resilience and security of the U.S. drug supply. Sentinel analysis systems may use big data modeling, artificial intelligence tools, and statistical techniques to look for potential and probable trigger events that are highly likely to lead to a drug supply shortage. Additional analysis should be performed to determine if the precipitating trigger events and predictive models for drug shortages are similar for all types of drugs or if different models and signals are needed for different types of drug products (*e.g.*, critical acute drugs vs critical chronic drugs, injectable drugs vs oral solid dosage forms vs inhalers, or various therapeutic categories).

This federal entity should develop and regularly update lists of essential drugs to be used for ensuring a high quality, resilient drug supply for (1) the active military, (2) triage during a natural disaster for a large population and for simultaneous disasters, (3) the critical acute drug needs of the general population, and (4) the critical chronic drug needs of the American public. An essential

function is the continual assessment, identification and prioritization of the critical acute and chronic medications that are most needed to ensure the security and resilience of the U.S. drug supply. This ongoing maintenance, updating, and monitoring of the list of critical acute and chronic drug molecules needs to be done through a collaborative process with various stakeholders including the FDA, Department of Defense, National Security Agency, drug firms, wholesalers, retail and hospital pharmacies, physicians, pharmacists, nurses, first responders, and others. Critical Acute Drugs are those that, "when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious outcomes which may include disability or death." Also, the "absence of a Critical Acute Drug, or even the lack of availability of an effective substitute, may also lead to serious health outcomes or limited ability to provide humane care." Critical chronic drug molecules have been defined as drugs that "when medically needed must be available and used within a few days or weeks or the patient's health will deteriorate, worsen substantially, or lead to serious outcomes such as hospitalization or death." Keep in mind that the vast majority of medical conditions are chronic diseases such as diabetes, high blood pressure, asthma, epilepsy, thyroid problems, autoimmune conditions, and cancer. If a critical chronic medication is not available because of a drug shortage, some patients, such as type 1 diabetics without insulin, may experience serious problems or loss of life.

Overall, the United States should have a national process and a common ongoing infrastructure for describing, analyzing, predicting, managing, and preventing shortages of critical medications to better inform policymakers and the public. This national effort should include certain public data elements on critical acute and critical chronic drugs that will be made transparent and will be provided through a public communication interface such as a website. The drug supply map and related databases will also include a confidential and comprehensive archival database for critical drugs with certain strategic information limited and accessible only to secure governmental and authorized industry stakeholders. This national effort will involve collaboration of multiple public and private stakeholders to deploy strategic analytics and security tools to predict, prevent, and respond to future critical drug supply disruptions, shortages, and related consequences. The Strategic PharmPAC will serve as the focal point *for development and recommendation to Congress of policies to ensure a resilient and secure supply chain for prescription drugs in the United States.*

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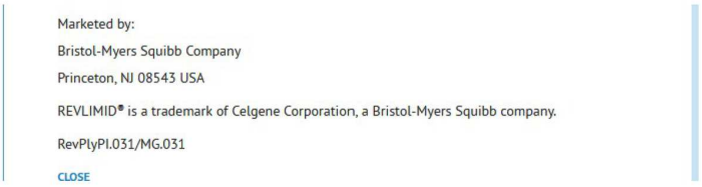
Appendix B

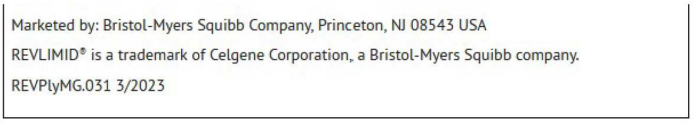
Information on Country of Origin for Manufacturing and Related Activities of the Drug Product Revlimid (lenalidomide capsule) as Found on the National Library of Medicines DailyMed Website

B.1. DailyMed: Revlimid-lenalidomide capsule
Packager: Celgene Corporation

B.2. Section 17 PATIENT COUNSELING INFORMATION
Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA



B.3. MEDICATION GUIDE
Marketed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA



B.4. PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

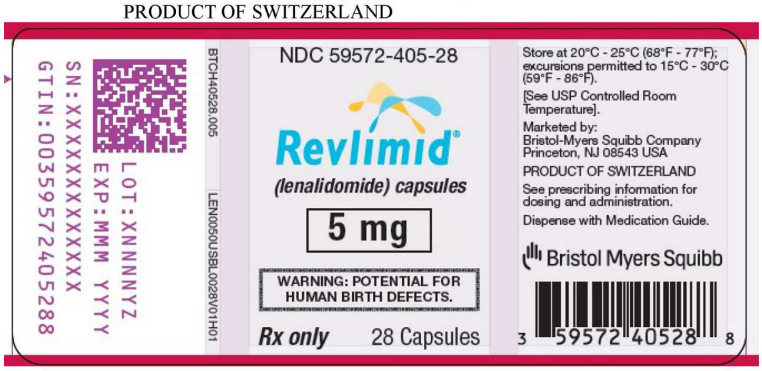
NDC 59572-405-28, Revlimid (lenalidomide) Capsules, 5 mg

The label indicates:

Marketed by:

Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

PRODUCT OF SWITZERLAND



B.5. LABLER

Celgene Corporation is identified as the 'Labeler'. There are no listings of 'Establishments' and their 'Business Operations' under this section for Revlimid. [This section sometimes includes a listing of ESTABLISHMENTS and their Business Operations such as 'API Manufacture' or 'Manufacture' (for finished product).]

LABELER - CELGENE CORPORATION (174201137)

[No additional information appeared below this heading.]

Source: National Library of Medicine, DailyMed, LABEL: REVLIMID-lenalidomide capsule. Content updated as of March 24, 2023 and found on February 12, 2026 at the website: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5fa97bf5-28a2-48f1-8955-f56012d296be.

B.6. LABLER

[NOTE: This example is NOT for Revlimid, but rather for a generic version of lenalidomide labeled by Cipla USA Inc. This DailyMed profile lists the 'Business Operations' including 'Manufacture' as being done in Canada and 'API Manufacture' as being done at Bommasandra (in India).]

LABELER - CIPLA USA INC. (078719707)

REGISTRANT - CIPLA USA INC. (078719707)

ESTABLISHMENT

Name	Address	ID/FEI	Business Operations
Genvion Corporation 500 Camiel Sys Street, Winnipeg, Manitoba R2J 4K2, Canada		245221226	ANALYSIS(69097-604) , LABEL(69097-604) , PACK(69097-604) , MANUFACTURE(69097-604)

ESTABLISHMENT

Name	Address	ID/FEI	Business Operations
Cipla Ltd-Bommasandra		650442440	API MANUFACTURE(69097-604) , ANALYSIS(69097-604)

Source: National Library of Medicine, DailyMed, LABEL: lenalidomide capsule, Cipla USA Inc. Content updated as of May 31, 2022 and found on February 12, 2026 at the website: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=96df285d-dd13-4083-b2c6-e5c799e7587b.

Appendix C

Information on Country of Origin for Manufacturing and Related Activities of the Drug Product Revlimid (lenalidomide capsules 10 mg) as Found on New Zealand's MedSafe Website

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Search

Medicines | Devices | Safety | Compliance | Publications | Consultations | Committees | About Medsafe | Contact Us

Medicine Information | Approval Process | Regulatory Guidance | Manufacturing

Related Information
- Guidelines and Codes
- Categorisation of Products
- Data Sheets
- Consumer Medicine Information
- Consumer Information Leaflets
- Product/Application Search
- Label Statements Database
- Credit Card Payment
- Classification Database
- Suspected Medicine Adverse Reaction Search
- Importing Medicines
- Report a Problem

Home ▶ Medicines ▶ Related Information ▶ Product/Application Search ▶ Product Detail

Medicines

Revised: 31 May 2019

Medsafe Product Detail

File ref: TT50-8057a

Trade Name	*Dose Form*	*Strength*	*Identifier*
Revlimid	Capsule	10 mg	
Sponsor	*Application date*	*Registration situation*	*Classification*
Bristol-Myers Squibb (NZ) Limited Private Bag 92518 Auckland 1141	23/1/2008	Consent given Approval date: 16/10/2008	Prescription

Composition

Component	*Ingredient*	*Manufacturer*
capsule	Active	
	Lenalidomide 10mg	Siegfried AG Untere Bruhlstrasse 4 Zofingen CH-4800 SWITZERLAND Lonza AG Lonzastrasse Walliser Werke Visp CH-3930 SWITZERLAND
	Excipient	
	Capsugel yellow 4035	
	Capsule blue-green 6579	
	Croscarmellose sodium	
	Lactose	
	Magnesium stearate	
	Microcrystalline cellulose	
	TekPrint black SW-9008	
	TekPrint black SW-9009	

Production

Manufacturing step	*Manufacturer*
Finished Product Testing	Celgene International Sarl Route de Perreux 1 Boudry CH-2017 SWITZERLAND Jetpharma SA via Sottobisio 42a Balerna CH-6828 SWITZERLAND STA Pharmaceutical Switzerland SA Rue du Pre-Jorat 14 Couvet 2108 SWITZERLAND
Manufacture of Active Ingredient	Lonza AG Lonzastrasse Walliser Werke Visp CH-3930 SWITZERLAND Siegfried AG Untere Bruhlstrasse 4 Zofingen CH-4800 SWITZERLAND
Manufacture of Final Dose Form	Celgene International Sarl Route de Perreux 1 Boudry CH-2017 SWITZERLAND STA Pharmaceutical Switzerland SA Rue du Pre-Jorat 14 Couvet 2108 SWITZERLAND

Micronisation	Catalent Micron Technologies Limited Crossways Crossways Boulevard Dartford Kent DA2 6QY UNITED KINGDOM
	Jetpharma SA via Sottobisio 42a Balerna CH-6828 SWITZERLAND
Packing	Celgene International Sarl Route de Perreux 1 Boudry CH-2017 SWITZERLAND
	STA Pharmaceutical Switzerland SA Rue du Pre-Jorat 14 Couvet 2108 SWITZERLAND
Secondary Packaging	DHL Supply Chain (Australia) Pty Limited 25 Ottelia Road Kemps Creek NSW 2178 AUSTRALIA
NZ Site of Product Release	DHL Supply Chain (New Zealand) Ltd 6 Manu Tapu Drive Mangere Auckland 2022

Packaging

Package	*Contents*	*Shelf Life*
Blister pack, PVC/PCTFE(Aclar)/Al	21 capsules	36 months from date of manufacture stored at or below 25°C
Blister pack, PVC/PCTFE(Aclar)/Al	28 capsules	36 months from date of manufacture stored at or below 25°C

Indications

Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma patients whose disease has progressed after one therapy.

Revlimid is indicated for treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

Revlimid is indicated for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation

Latest Regulatory Activity

Application Date	*Application Type*	*Change(s)*	*Status*	*Payment Date*	*Priority*
23/1/2008	New Higher-risk Medicine Application	New higher-risk medicine containing one or more new active substances; Additional strength - Grade 2	Granted 16/10/2008	23/1/2008	
6/5/2025	Self-Assessable Change Notification	Editorial updates to Module 3 documents (Self assessable)	Notified	14/5/2025	

Source: New Zealand Medicines and Medical Devices Safety Authority. MedSafe. MedSafe Product Detail. Revlimid Capsule 10 mg. Accessed on February 12, 2026 at the website: https://www.medsafe.govt.nz/DbSearch/ProductDetail.asp?ID=13399.

Appendix D

JPG Image for Metformin 850 mg Tablets as Found on NLM's DailyMed Website

D.1. DailyMed: Metformin Hydrochloride, Tablet, Extended Release RPK Pharmaceuticals, Inc.

D.2. Label for DailyMed: Metformin Hydrochloride, Tablet, Extended Release RPK Pharmaceuticals, Inc.

D.3. Enlarged Label for DailyMed: Metformin Hydrochloride, Tablet, Extended Release RPK Pharmaceuticals, Inc.

Can you read the NDC #? Can you find the Labeler Name?
Can you find the Manufacturer for the API or the Finished Product?
Can you find the 'Country of Origin' for the API or the Finished Product?

Source: National Library of Medicine, DailyMed, Metformin Hydrochloride Extended Release. RPK Pharmaceuticals, Inc. Content updated as of October 23, 2023 and found on February 12, 2026 at the website: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=179a4a21-1541-4f96-834f-e80731b62d92.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"TRUTH IN LABELING: AMERICANS DESERVE TO KNOW WHERE THEIR DRUGS COME FROM"

JANUARY 29, 2026

QUESTIONS FOR THE RECORD

Stephen Colvill

Senator Raphael Warnock

Question:

The Federal Trade Commission and the U.S. Department of Health and Human Services launched an investigation into group purchasing organizations (GPOs) in 2024 to understand their potential contribution to generic drug shortages, which affected Georgians' access to cancer and rheumatoid arthritis medications.

What role do GPOs play in the stability of the domestic pharmaceutical supply chain?

Response:

Distinguishing between various health care settings, including the health system setting, independent oncology clinic setting, and retail setting, is important to understand the roles of various types of GPOs and other entities in the generic drug supply chain. Drug reimbursement methodologies, contracting practices, and other market dynamics differ in each of these settings.

In the health system setting, traditional GPOs (Vizient, Premier, HealthTrust) negotiate contract prices and terms between their member health systems and manufacturers. These traditional GPOs do not take possession of or title to the drugs and do not markup the drugs. Traditional GPO contracts impact drug usage in hospitals along with other sites of care.

In the independent oncology clinic setting, wholesalers (Cencora, McKesson) and wholesaler-affiliated GPOs often negotiate contracts with manufacturers of oncology drugs used in community oncology clinics. Wholesalers take possession of and title to the drugs before distributing them.

In the retail setting, retail GPOs (RedOak, Walgreens Boots Alliance, ClarusOne) negotiate contracts with manufacturers on behalf of retail pharmacies. Pharmacy benefit managers (PBMs) are most influential in this retail setting, but PBMs are markedly different from GPOs.

In all these settings, GPOs have significant negotiating power, in part due to consolidation, and they use that power to secure favorable contract pricing and terms from manufacturers. My professional experience has mostly involved the hospital and health system setting, where I have observed contract negotiations from both the manufacturer and GPO perspective. In this setting, I have observed traditional GPOs use their market power to pursue the interests of their health system members.

The "Race to the Bottom" section of my full written testimony provides a detailed overview of the interests of health systems related to generic drug purchasing. In summary, for already-inexpensive generic drugs, resource-constrained health systems focus significant efforts on obtaining the lowest cost at a point in time without adequate consideration for reliable availability over time. These health system priorities shape the actions of their GPOs.

In recent years, some limited progress has been made on better valuing reliable availability of critical generics. Some health care providers have begun entering into new committed contracting models that have been pioneered by new entities such as Civica Rx, and traditional GPOs and wholesalers also now offer committed contracting models. These committed contracting models are designed to offer greater assurance of demand for manufacturers and assurance of supply for providers. The committed nature of these models creates a greater incentive for purchasers to vet suppliers and for manufacturers to ensure reliable delivery of products over time. However, while such committed contracting models have demonstrated some success, they currently represent a small share of generic drug contracts in the U.S., and drug shortages persist. Many resource-constrained health systems opt not to participate in committed contracting models (or participate minimally) and instead continue to seek out the lowest cost short term suppliers. In addition, health sys-

tems and their GPOs could also take other important steps to identify and purchase from reliable manufacturers. For example, health systems and their GPOs could require manufacturers to be evaluated through third-party drug supply chain reliability benchmarking programs. However, uptake of such benchmarking programs has also thus far been limited.

In the ″An Alternative: Aligning Incentives Towards Reliable Availability″ section of my full written testimony and the response to Question 2 below, I outline how Congress could address drug shortages by aligning health care provider incentives to better value the reliable availability of critical generic drugs.

Question:

How can Congress keep GPOs accountable and improve older adults' access to quality and affordable drugs?

Response:

Congress should enact Medicare payment reforms to incentivize health care providers to take steps to support the reliable availability of critical generic drugs.

In a recent white paper, Duke-Margolis proposed a simplified version of the Medicare Drug Shortage Prevention and Mitigation Program originally outlined in a 2024 Senate Finance Committee Discussion Draft. Our proposal would reward health care providers when they 1) purchase through committed contracting models and 2) identify and purchase drugs that meet reliability benchmarks. If this proposal is implemented, GPOs would be well-positioned to support a shift towards a more reliable supply chain. Rather than focusing their negotiating power too much on obtaining the lowest cost, GPOs could instead use that same negotiating power to demand reliable availability and higher levels of quality assurance from manufacturers. The market could also use reliability benchmarking programs to observe the extent to which GPOs and health systems contract with reliable manufacturers.

Lastly, healthy competition is essential for a well-functioning market. Congress should ensure that health care providers have the opportunity to select from a range of different competing GPOs and other service providers and that new entrants (both new GPO entrants and new manufacturer entrants) have an opportunity to succeed in a competitive market. Levels of market concentration and consolidation should be continually assessed.

Senator Andy Kim

Question:

Current Requirements for Country-of-Origin Information

There are current requirements for country-of-origin information involving multiple government entities, however, this could also lead to confusing or conflicting requirements. Currently drug manufacturers must comply with label and labeling requirements of the Food and Drug Administration, country of origin information requirements by Customs and Border Protection (CBP) (which is further influenced by trade agreements such as the USMCA), and government procurement requirements.

Can you detail the current regulatory environment and where there may be gaps and potential overlap?

Response:

Customs and Border Protection (CBP) generally relies on a ″substantial transformation″ standard to determine country-of-origin for the purpose of determining tariffs and other requirements that apply to U.S. imports. The final ″substantial transformation″ for drugs most commonly (but not always) occurs when the active pharmaceutical ingredient (API) is produced. The Tariff Act of 1930 also requires that imported goods be marked with the country-of-origin in a manner visible to the ″ultimate purchaser″ in the United States. A controversial 2024 CBP ruling determined that the ″ultimate purchaser″ in the retail pharmacy setting should be the patient rather than the dispensing pharmacy.

Direct federal procurement, such as purchases by VA and DoD governed by the Federal Acquisition Regulation (FAR), generally preferences pharmaceuticals that have a country-of-origin in a Trade Agreements Act (TAA) compliant country. Prior to the U.S. Federal Appeals Court decision in Acetris Health, LLC v. United States, federal agencies generally deferred to CBP's ″substantial transformation″ country-of-origin determinations for the purposes of direct federal procurement. However, following the Acetris decision in 2020, country-of-origin determinations for the purposes of direct federal procurement may now be based on where the product is ″manufactured″. This is different from CBP's standard and means that a product with an API from China that is ″manufactured″ into its final dosage form in a TAA-

compliant country may now be considered TAA-compliant for the purposes of direct federal procurement, even if the most important production step occurred in China.

FDA labeling requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) currently dictate that a drug is misbranded unless its label includes the name and ″place of business″ of the manufacturer, packer, or distributor. In many cases, the ″place of business″ of the final manufacturer, packer, or distributor differs from the country-of-origin as determined by the CBP and direct federal procurement standards described above. The ″place of business″ may be a company's corporate headquarters and may not be a manufacturing site at all. The CLEAR Labels Act introduced by Sen. Scott and Sen. Gillibrand in February 2026 would require unique facility identifiers for both the original API manufacturer and the original finished drug product manufacturer to be listed in the drug's labeling information. This CLEAR Labels Act approach would provide much more useful public information regarding locations of production than the current FD&C Act requirements.

Potential Next Steps on Labeling

Requiring manufacturers to include unique facility identifiers in their labeling information would make it fairly straightforward for third parties to create user-friendly databases that allow patients, purchasers, researchers, and the public to identify where drugs are made. Congress should note that exempting manufacturers from the labeling requirements in the Tariff Act of 1930 may cause patients picking up a prescription at a retail pharmacy to not be able to see the country-of-origin on the physical drug label. That said, having one common set of labeling requirements through the FD&C Act (rather than divergent requirements from FDA and CBP) that enables the creation of user-friendly databases that patients and others can use to identify where drugs are made could be a common-sense approach. Ensuring the right information is available digitally may be more important than what is listed on the physical label.

Country-of-origin determinations for the purposes of direct federal procurement would need to be addressed separately. Legislation could close the ″Acetris loophole″ by directing revision of the FAR definition such that country-of-origin would be determined only by where a drug is ″substantially transformed″ rather than where a drug is ″manufactured″. This would refocus country-of-origin determinations for the purposes of direct federal procurement on the most important production step.

Question:

Accessible Country-of-Origin Information

Information about where prescription drugs are manufactured is not always visible to patients or policymakers, and purchasing decisions for prescription drugs are often made be entities other than the end user, including hospitals, pharmacies, and group purchasing organizations. These dynamics affect the potential impact of pharmaceutical labeling reforms in both provider-administrated and retail drug settings. Additionally, as we consider increasing transparency, we must also balance how we achieve more accessible information with security risks from sharing too much about key manufacturing sites. What practical changes should pharmaceutical labeling reforms be expected to achieve on their own? Beyond country-of-origin labeling, are there additional reforms we can focus on here in Congress to strengthen our domestic supply chain of quality active pharmaceutical ingredients and drugs and protect our national security?

Response:

Pharmaceutical labeling reforms, if effectively designed, could have a positive, yet limited, impact. Americans deserve to know where their drugs come from, and better availability of information about manufacturing locations of drugs might, over time, cause more drugs to be sourced domestically. However, for provider-administered drugs, impacts of labeling reforms are likely to be limited, as many decision makers already know where API and finished drug products are made or can acquire this information if desired. For retail drugs, impacts of labeling reforms are also likely to be limited, as patients have minimal influence over what drugs the retail pharmacies and retail GPOs decide to stock.

The Committee should carefully weigh any negative consequences that may arise from labeling reforms and consider how to mitigate them. Just because a drug is made in the U.S. does not necessarily mean that it is the best choice - some of the most significant past shortages have resulted from manufacturing issues in U.S. plants. Site location alone is not necessarily indicative of reliability or quality. Other assessments of reliability and quality, such as through the benchmarking programs described previously, are also needed. Pharmaceutical labels also may illuminate certain stages of production while obscuring other risks, such as from upstream key starting material (KSM) dependencies. KSM mapping and vulnerability assessment

exercises will remain critical. The Committee should also consider that any labeling reforms may impact the information that is ultimately available to institutional buyers, health care providers, and patients in different ways. Other potential negative consequences include increased regulatory burden, potential impacts to patient medication adherence, and potentially more easily enabling bad actors to identify potential targets. The Committee could consider whether FDA should be provided with the authority to exempt some drugs from a requirement to disclose unique facility identifiers if there is a compelling safety or national security reason to do so, such as for some controlled substances.

Regarding other steps to more meaningfully improve the reliability of our domestic supply chain, financial incentives for purchasers is the most important area to focus. See more in the answer to Question 3 below.

Question:

Financial Incentives for Purchasers

Purchasers of prescription drugs, including pharmacies and providers often, face financial pressure that influence which products are selected and stocked. Without targeted incentives, efforts to encourage the use of more reliable or domestic suppliers may be limited. Financial incentives for purchasers are a critical component of addressing drug shortages and maintaining a resilient supply chain. What limitations remain as we think through how to meaningfully reduce chronic drug shortages?

Response:

I agree that targeted financial incentives for purchasers are needed to meaningfully address drug shortages and create a resilient supply chain for critical generic drugs.

In a recent white paper, Duke-Margolis proposed a simplified version of the Medicare Drug Shortage Prevention and Mitigation Program originally outlined in a 2024 Senate Finance Committee Discussion Draft. Our proposal would create new CMS incentives for health care providers to 1) purchase through committed contracting models and 2) identify and purchase drugs that meet drug supply chain reliability benchmarks. Costs from such a program would likely equate to <0.1% of total U.S. drug spending.

An additional limitation to meaningfully addressing chronic drug shortages is that drug supply chain reliability benchmarking programs are not yet widely adopted. Supply chain reliability benchmarking programs can objectively assess aspects of manufacturer supply chains such as redundancies, available manufacturing capacity, buffer stock, risk mitigation plans, and commitment to quality culture. These programs can then communicate insights to the market regarding which manufacturers, product supply chains, and/or manufacturing facilities are more reliable than their competition. Unfortunately, these benchmarking programs are not yet widely adopted on the supply-side or the demand-side. Wide supply-side adoption would entail a substantial share of manufacturer supply chains for critical products being evaluated through the programs. Wide demand-side adoption would entail the incorporation of resulting program insights into a substantial share of purchasing and contracting decisions.

To address this limitation, Congress could provide funding to HHS and DoD to de-risk the development, testing, and adoption of reliability benchmarking programs. This could set a foundation for future CMS payment reform that could target incentive payments to providers that purchase from reliable suppliers.

Statements for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN CHINA, PAID BY SENIORS: STOPPING THE SURGE OF INTERNATIONAL SCAMS"

JANUARY 14, 2026

STATEMENT FOR THE RECORD

Opening Statement of Senator Kirsten E. Gillibrand, Ranking Member

Chairman Scott, thank you for calling today's hearing and thank you to our witnesses for being here.I'm looking forward to continuing our conversation on how we can improve the quality and reliability of our generic drug supply chain, particularly the role of increased transparency.

As we have heard in our previous hearings, these supply chains are vulnerable to disruption, and with decreased domestic manufacturing, we are putting ourselves in an increasingly perilous position.

Given recent instability in geopolitics and international trade policy, this reliance on foreign drugs increases the risk that Americans may not have access to life-saving drugs in times of crisis, threatening our national security.

However, we must approach strengthening and reforming this extremely complex supply chain thoughtfully and thoroughly.

One piece of this puzzle is increasing supply chain transparency through country-of-origin labeling.Country-of-origin labeling is a common tool that is used on thousands of products, most prominently in textiles and food.

It gives consumers clear information on the origins of their products, providing them with additional information that may influence whether they purchase an item.

Pharmaceuticals are also required to disclose this information; however, it may be difficult for patients to track it down.

As we will hear from our witnesses today, providing transparency to consumers is extremely important, but it is not the only solution to improve the reliability and quality of the drug supply chain.

Country-of-origin labeling does not necessarily equate to higher or lower quality drugs, and there are additional steps that Congress can take to ensure that all drugs in our supply chain, both domestic and foreign, are of the highest quality.

We must examine the underlying economic dynamics in the current marketplace and adjust incentives to fix the "race to the bottom" in generic drug pricing, which can create drug quality issues, drive manufacturing outside of the United States, or cause companies to stop production of certain drugs or chemicals altogether.

Transparency must also be coupled with expanded supply chain mapping as well as quality benchmarking.Coupled together, these proposals will create a more resilient drug supply chain that can lead to improved stability for manufacturers and purchasers, increased consumer confidence in the quality of their medications, and a potential resurgence of domestic production.

While the vast majority of the medications that patients use are both safe and effective, increased transparency and supply chain mapping will improve long-term decision making for manufacturers to invest in quality and reliability.

I am excited to hear from our witnesses today as they are discussing policy proposals that can be undertaken by Congress.

I look forward to working with Chairman Scott and other committees of jurisdiction as we work to increase the transparency and reliability of our drug supply chain.

Association for Accessible Medicines
Statement for the Record
U.S. Senate Special Committee on Aging Hearing
"Truth in Labeling: Americans Deserve to Know Where Their Drugs Come From"
January 29, 2026

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 represents the manufacturers of finished generic and biosimilar pharmaceutical products, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM works to expand patient access to safe, quality, and effective generic and biosimilar medicines by promoting a positive regulatory, reimbursement, and policy environment and advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

Generics add value to the American healthcare system. In the last decade, Americans were prescribed and received nearly 2 trillion doses of generic oral solids.[1] In our healthcare system, generic drugs are the only sector that consistently results in decreased spending. The overall value of all generic sales in the U.S. has **declined** by $6.4 billion since 2019, despite increased volume and new generic launches.[2]

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[1] Association for Accessible Medicines (September 2025). The U.S. Generic & Biosimilar Medicines Savings Report. https://accessiblemeds.org/wp-content/uploads/2025/09/AAM-2025-Generic-Biosimilar-Medicines-Savings-Report-WEB.pdf.
[2] IQVIA Contributors. (May 2023). The Use of Medicines in the U.S. 2023. https://www.iqvia.com/insights/the-iqviainstitute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023.

But the generic market is facing hurdles. A recent analysis focused on generic prices over the last three decades found that, over that last 30 years, generics are launching at lower prices and bottoming out at lower prices.[3] This price deflation is driven by consolidation among generic drug-buying organizations. In the retail market, three purchasing consortiums (wholesaler/retail chain combinations) collectively control 80-90 percent of the retail prescription market.[4,5] As such, fewer buyers means fewer markets for the more than 200 generic drug manufacturers with FDA approval in the U.S., and the constant downward contractual pressure used by the supply chain purchasers can result in lower prices.

While lower prices mean more savings for patients and the healthcare system, they present additional challenges for generic manufacturers that can result in manufacturer-exit and associated drug shortages, which can be deleterious for patients. Imposing additional labeling requirements to reflect country of origin simply will result in more costs industry-wide by requiring revision and reprinting of labels and labeling for thousands of products. This will total hundreds of millions of dollars of cost for manufacturers, just for reprinting alone.

Compounding these concerns is that additional labeling requirements, including enhanced country-of-origin labeling, imposes significant costs in exchange for limited returns. This is because drug manufacturers already disclose finished product and API country of origin information under Customs and Border Protection (CBP) statutes and regulations. Indeed, 19 U.S.C. § 1304 requires that "every article of foreign origin . . . imported into the United States shall be marked in a conspicuous place . . . to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article."[6]

More specifically, current law set forth in both the federal Customs marking statute (19 U.S.C. 1304) and its implementing regulations (19 C.F.R. Part 134) require the packaging for imported finished dosage form (FDF) pharmaceuticals foreign active pharmaceutical ingredient (APIs) to bear a label stating their country of origin. Under longstanding customs principles, FDF products are generally considered to originate, for purposes of 19 USC 1304 and 19 CFR Part 134, in the country in which their API is manufactured. In other words, an FDF with Israeli API is generally marked “Product of Israel” for customs purposes.

Further, the origin disclosure must be flowed down to the packaging in which the “ultimate purchaser” of the pharmaceuticals will receive them – including retail pharmacy bottles in

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[3] Op cit.
[4] 5 Fein, Aj. “The 2022-23 Economic Report On Pharmaceutical Wholesalers And Specialty Distributors” (October 2022) Drug Channels Institute. Available at: https://drugchannelsinstitute.com/products/industry_report/wholesale/
[5] Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report, July 2024, U.S. Federal Trade Commission Office of Policy Planning, Available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf, Accessed 8/12/2024.
[6] 19 U.S.C. § 1304.

which prescriptions are delivered to individual patients.[7] Failure to include country of origin labeling can also be considered false and misleading labeling.[8]

As of today, CBP actively enforces these requirements in the U.S. pharmaceutical supply chain by requiring importers such as generic and biosimilar companies to:

- notify downstream recipients that will repack the goods in new containers that they are legally required to ensure that the pharmaceuticals' country of origin is included on new the containers
- certify that, if the importer itself processes and/or repacks the articles, the country of origin will be provided on the new containers; and
- imposing additional duties and penalties on importers that do not comply.

There is no reason that FDA requirements should be imposed on top of these.[9]

Imposing additional country-of-origin-restrictions on pharmaceuticals, even if it were feasible, would contribute to higher prescription drug costs. Rather than impose costs on industry, the Committee should consider opportunities to attract manufacturing of medicines to the U.S. To accomplish that goal, it will be critical for the federal government to provide both financial support to industry and implement regulatory reforms. Examples of this support include:

- Providing grants and low-cost loans for plant construction or refurbishment in the U.S.;
- Ensuring that significant new investments in the U.S. production of medicines are not undermined by imported products that make the medicines produced in those plants non-competitive; and
- Streamlining regulatory and environmental requirements to allow new or refurbished facilities to come online quickly.

AAM and its members stand ready to work with policymakers on how best to achieve these goals and enhance patient access to safe, effective and affordable generic medicines.

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[7] 19 C.F.R. § 134.1(d).

[8] *See* CPG 560.200 ("It is possible that a violation of *CBP's* requirement concerning country of origin labeling, whether by omission or deviation, could also result in false or misleading labeling that violates the FFD&C Act and FDA regulations.")

[9] FDA has stated as much in Citizen Petition response. FDA noted that "the Federal agency tasked with implementing and enforcing 19 U.S.C. 1304 and related regulations is not FDA but rather Customs and Border Protection (CBP) (formerly the U.S. Customs Service), within the Department of Homeland Security. Accordingly, we defer to CBP to interpret and enforce its regulations...." FDA, Citizen Petition Response, Docket No. FDA-2018-P-0625 (July 30, 2019).

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