S. HRG. 119–483

POISONED PILLS: THE HUMAN COST OF DANGEROUS FOREIGN DRUGS

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

ONE HUNDRED NINETEENTH CONGRESS

SECOND SESSION

WASHINGTON, DC

JUNE 3, 2026

Serial No. 119–31

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
64–196 PDF WASHINGTON : 2026

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C O N T E N T S

POISONED PILLS: THE HUMAN COST OF DANGEROUS FOREIGN DRUGS

Wednesday, June 3, 2026

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

The Committee met, pursuant to notice, at 3:29 p.m., Room 216, Hart Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

Present: Senator Scott, McCormick, Tuberville, Gillibrand, and Alsobrooks.

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. Thank you. The U.S. Senate Special Committee on Aging will now come to order. This country has a big drug problem, and it is not the one most people are thinking about when they say it. America's drug supply is not secured, and American patients are in danger as a result.

Congress needs to do everything it can to change that. Ninety-one percent of prescriptions in the United States are for generic drugs, and many older Americans will rely on one or more medications to lead healthy and happy lives. This Congress, I have worked closely with Ranking Member Gillibrand to push the Federal Government to do everything it can to ensure older Americans have access to safe and high-quality drugs.

We sent letters to the Secretaries of HHS, the Department of War, and the VA about our reliance on Communist China and India for generic drugs. We sent a letter to the FDA asking about foreign inspections and the quality of drugs coming into our country. We also wrote letters to group purchasing organizations, distributors, and pharmacies asking where they source their drugs and the information they have about low-quality foreign generics.

Last year, this Committee held three hearings on the quality of the medication's seniors rely on. First, we held a hearing on the quality problems with foreign generics and our reliance on Communist China and India for drugs.

We followed that up with a hearing on solutions on how to bring drug manufacturing back to the United States. Then we heard from American drug manufacturers on the problems they face and what the Federal Government can do to help them. This January, we held a hearing where I was proud to announce the CLEAR LABELS Act with ranking member Gillibrand, a bipartisan bill that

would require manufacturers to disclose where the drug and drug ingredients, or API, are manufactured.

You know where your car is made, where the food you eat is from, but you don't know where the medications you or a loved one takes comes from. That doesn't make any sense. I encourage all members of this Committee to co-sponsor this bill so that all Americans can know where their medications are manufactured.

At our last hearing on generic drugs in March, we brought in experts on Communist China to discuss how our over-reliance on foreign drugs was no accident, but a very deliberate policy by the CCP and also Washington politicians choosing profits over patients. Today, we want to focus on the real Americans that these low-quality foreign drugs are harming.

A researcher from Indiana University testified before this Committee that generic drugs made in India have 54 percent more serious adverse events than equivalent drugs made the U.S., including hospitalization, disability, and death.

That means American patients and their family members taking medications to manage health conditions or recover from illnesses or procedures are ending up in the hospital, potentially even dying. This should never happen in our country, but it has been going on for decades. In 2008, contaminated heparin from Communist China killed nearly 100 Americans. This was a lifesaving blood thinner medication that these people needed, and it killed them.

Leroy Hubley lost his wife of 48 years, Bonnie, and his son, Randy, because of contaminated heparin from Communist China. They relied on this medication for their dialysis treatment they were undergoing due to a genetic kidney disease, and it killed them. Those drugs never should have been made into our country, but these are sadly too many—there are sadly too many such stories.

In 2023 contaminated eye drops from India killed four people and blinded 14 others. This cannot keep happening. As long as we are not regularly testing drugs coming from Communist of China and India, and lag behind in foreign inspections, poor quality drugs from these countries will keep coming into America. Under the current framework, we simply cannot rely on the drugs coming from Communist China and India to be the same quality as drugs made right here in America.

It has been almost two decades since the heparin incident, and we are even more reliant on Communist China and India for our medications than we were then. The bottom line is foreign manufacturers are not being held to the same standards as domestic manufacturers. This lets bad actors cut corners. When it comes to patient safety, patients' lives are on the line.

Here in the U.S., the FDA doesn't announce when it goes to inspect a manufacturing facility, but overseas, in Communist China and India, the majority of inspections are pre-announced so they can cleanup any problems they have got. While I support the FDA's efforts to increase unannounced foreign inspections, inspections alone can't solve this problem.

The problem is the FDA relies on manufacturers to submit data on an honor system. Foreign manufacturers know this, and bad actors are taking advantage of gaps in the FDA's oversight. We saw

this in 2013 when Ranbaxy settled with the Department of Justice for $500 million for falsifying data and systemic violations of FDA good manufacturing practices.

The FDA cannot trust foreign manufacturers that have a financial incentive to cut corners on quality to be honest brokers. Congress needs to look at solutions to systemic gaps in the FDA's ability to conduct oversight of foreign manufacturers. The FDA considers all approved generics to be equivalent, but data shows us this is not the case. This is why testing drugs for quality is so, so important.

In our hearing in March, ChinaRx author, Rosemary Gibson testified about the Department of War's testing of generic drugs. What they have found so far is shocking. Of 13 medicines tested, 15 percent were found to have serious manufacturing defects, including containing toxins and carcinogens, and not dissolving properly. These stories of bad quality drugs coming from Communist China and India aren't isolated incidents. The problem is systemic.

The Federal Government needs to do everything we can to make the drugs that Americans and seniors rely on here in America and bring manufacturing back here. Put simply, a country that cannot provide itself—cannot provide for itself cannot, protect itself, and it cannot remain safe, strong, and prosperous in the long run. America is too great a country to be as vulnerable as we are on this matter.

When American manufacturing is not an option, we must turn to our affiliate or to our allied nations with proven testing standards, not adversaries and bad actors who cut corners at the expense of American lives. I hope that in today's hearing we can draw attention to the people and their family members who have been affected by these poor quality foreign drugs.

We have a great witness panel here today who are advocates for transparency and patient safety and can speak to these longstanding quality issues with foreign generics. Now, I would like to turn it over to Ranking Member Gillibrand for her opening statement.

OPENING STATEMENT OF SENATOR KIRSTEN E. GILLIBRAND, RANKING MEMBER

Senator GILLIBRAND. Thank you, Chairman Scott. Thank you for calling today's hearing. Welcome to all our witnesses. I am very grateful to meet you and excited to hear your testimony. I am looking forward to continuing this conversation on how we can improve the quality and reliability of our generic drug supply chain. As we have heard from our previous hearings, these supply chains are vulnerable to disruption.

With decreased domestic manufacturing, we are putting ourselves in an increasingly perilous position. Underlying market factors in the United States have led to a race to the bottom where incentives for manufacturers are solely based on cost, not quality.

While almost all generic drugs that Americans take are safe, Congress must empower the FDA to conduct rigorous oversight to make sure foreign manufacturers comply with our safety standards.

Congress must also work with industry to move away from costs being the only factors in purchasing. We must incentivize manufacturers and purchasers to consider quality when they are sourcing active pharmaceutical ingredients and final dose foreign medicines. We must expand testing of these drugs and ingredients too.

There have been many recommendations made before this Committee on how to ensure the drugs that enter the U.S. market are high quality. This includes legislation, like our bipartisan CLEAR LABELS Act, or proposals to expand supply chain mapping.

I am thrilled that there is so much bipartisan excitement around strengthening our generic pharmaceutical supply, and I look forward to working with Chairman Scott and other members of this Committee to solve these evergreen problems. Thank you.

The CHAIRMAN. I want to thank Ranking Member Gillibrand for her bipartisan support of efforts to change our drug supply chain in this country. Our witness panel has firsthand experience in their personal and professional lives with the low quality genetics that are harming everyday Americans.

I would like to thank them for being here today to discuss their experiences and how we can stop substandard foreign drugs from entering the U.S. market. Lisa Salberg is the founder of HCMA and has spent decades advocating for patients with her rare heart condition. She knows firsthand what is at stake when drug quality fails. Living with a transplanted heart, she depends on her medication to survive.

When she was switched to a substandard generic that was ineffective, it nearly cost her her life. Thankfully she was able to figure it out—figure out it was the medication causing her decline in health before it was too late.

Now she is an advocate, a strong advocate for drug quality and transparency. I want to thank you for being here today, and please tell your story.

STATEMENT OF LISA SALBERG, FOUNDER AND CEO, HYPERTROPHIC CARDIOMYOPATHY ASSOCIATION, DENVILLE, NEW JERSEY

Ms. SALBERG. Thank you, Chairman Scott, and Ranking Member Gillibrand, and distinguished members of the Committee for this opportunity to address you today. My name is Lisa Salberg, and I literally come to you with my heart in my hands. This is my literal physical heart that has been explanted.

I bet that is a first. I am asking for your help to protect lives of patients like me who depend on generic medication every day. We think we are saving money, but we may be adding to the financial health burden of our Nation in ways yet unmeasured.

I was born and raised in Rockaway Township, New Jersey, and I was diagnosed in middle school in 1980 with hypertrophic cardiomyopathy, a genetic heart muscle disease that runs in my family and through generations. It has claimed many lives far too soon, including my sister.

My personal medical history includes two pacemakers, five implantable defibrillators, and a lifetime of cardiac medication. I had a stroke in 1990. I am partially blind in one eye. I have had progressive heart failure, and then in 2017, I got a transplant. It

was on Groundhog's Day that I received a donor heart from a woman named Brandy, and we are a beautiful match.

We are perfect together. She has helped me regain nearly perfect health—health I am fighting now to protect. In 1995, after I lost my sister, I founded the Hypotrophic Cardiomyopathy Association, a non-profit that has served over 20,000 families worldwide, and HCMA has developed 62 centers of excellence across the Nation's most prestigious academic and health communities in the country.

We have aided in drug discovery, advanced diagnostics, and we have connected over half a million patients with the right doctors. I have published over 20 peer-reviewed journal articles, I have written three books. I am not a physician. I am a patient advocate. I am here because the system is failing people like me.

My first experience with generic drugs, we will talk about in just a second. What I thought was a personal anomaly has revealed itself to be a systematic failure with life-threatening consequences for patients nationwide. My experience isn't unique. It is a pattern.

First time was 1996. I was taking beta blockers to manage my heart rate. A generic beta blocker replaced my name brand, and after two doses, my heartrate wasn't coming down. I went back to the brand name and thought this was a me thing. Years later, my dear friend, Dr. Harry Lever from the Cleveland Clinic had heard a news report and said, Lisa, we need to talk.

I think I know why we are having these problems with our patients having erratic responses to their blood pressures. Guess what? It wasn't a me thing. It is a ″we″ thing. In 2017, I get my transplant. I am going to be prescribed tacrolimus, brand name PROGRAF. It is to prevent rejection.

My insurance was not covering a name brand, forcing me to generics and some tricky territory. Tacrolimus is managed by monitoring your levels. If you go too high, you burn out your kidneys and other things. If you got too low, you risk rejection. My target is 6.5 to 7.5.

I remained on one manufacturer as best I could, but shortages, and eventually that one was taken off the market. Knowing the variables, I take my very fragile veins through a lot of draws for blood and a lot of expense in that as well, and sometimes I have to get more than one blood draw a month to make sure my levels are okay.

Sometimes it was coming in too high, 9.9. You shake when it goes too high. When it came in at 3.9 and it is too low and I am open to rejection, there are no symptoms. You are just open to rejection. Now I pay $120 a month per dose of my name brand PROGRAF because I can't trust generics.

My life literally depends upon it. Across the HCMA network and beyond, patients report to me daily emergency room visits, missed work, deteriorating health. We do the work, and we find that they have changed their manufacturer of a drug and let's go back to the other one and see how you are feeling. There is no accountability, no transparency, and no recourse for patients in these situations.

We should mention that 85 percent of our generic drugs come into this country through three different providers or purchasers. What do we do to fix it? Well, I am going to urge all of you to pursue concrete codified reforms, not voluntary guidelines, to mod-

ernize our generic drug system, and to hold purchasers and manufacturers and decisionmakers accountable.

The base of all this is Hatch-Waxman. We got to go back and fix it. We need to make sure that ANDAs not only require meeting bio equivalents, but dissolution rates. That has been the problem in all of my drugs, the dissolution rate is wrong. We need to inspect every batch of medication brought into the United States before it hits anybody's system.

We cannot send red labeled drugs out to patients. We need to use independent laboratory testing—the red, yellow, green that you guys have heard a lot about over these past few meetings. The system works and we should be doing this more transparently. I would hope that the FDA would publicly manage a website where all those test results could be made public.

Anything red goes back to the manufacturer or destroyed at their expense, and we do not allow anybody to take red medication. We need to get the FDA control to refuse low-quality drugs from entering the United States and hold bad actors accountable the first time, not after decades.

I support bipartisan legislation like the Transparency and Quality Pharmaceutical Act that may be coming from McCormick and DeLauro. I will let my friends explain that one. I applaud you on the clear label act. However, I think we need to pair it with payer level reform so patients can actually take action on the information on the label rather than just being stuck in the lowest formulary.

Good actors should—if they get green scores, good actors shouldn't be burdened with extra reviews. Poor quality manufacturers must be held responsible for the financial burden, the product, the destruction, and the liability for downstream health expenses caused by their drugs.

Last, I will state that I agree with Drs. Kellermann and Schulman in their recent New England Journal article when they said, ″the FDA should stop claiming that all generic drugs sold in the United States are equally safe and effective. It cannot verify that without product testing.″ Thank you very much for the time, and I am happy to take any questions.

The CHAIRMAN. Now, I will recognize Ranking Member Gillibrand for the next witness.

Senator GILLIBRAND. Thank you, Mr. Chairman. I want to introduce our next witness, Dr. Adam Clark-Joseph. Dr. Clark-Joseph is a Chief Analytics Officer and Co-Founder of Valisure, a technology company working to address a critical gap in the pharmaceutical supply chain through independent quality assurance.

Dr. Clark-Joseph was driven to founding Valisure by his personal experience with significant complications arising from batch variability in his anticonvulsant medication. Dr. Clark-Joseph utilizes his expertise as a digital chemist to employ big data and machine learning for enhancing transparency in the pharmaceutical supply chain. You may begin.

STATEMENT OF ADAM CLARK-JOSEPH, PHD, CHIEF ANALYTICS OFFICER AND CO-FOUNDER, VALISURE, NEW HAVEN, CONNECTICUT

Dr. CLARK-JOSEPH. Ranking Member Gillibrand, Chairman Scott, members of the Committee, thank you for the honor of speaking before you today.

I have taken medicine for depression for most of my adult life. I first encountered a bad batch of medicine when I was 25. After a refill, I suddenly fell ill, and after my doctor identified the problem, he told me that sometimes you just get a bad batch.

At twenty-seven, it happened again, and I became ill for months. Then at twenty-nine, after yet another incident, I used my chemistry background and some equipment in my home to test my pills myself, and I discovered that they were massively underdosed, so that was the last straw for me.

I reached out to my longtime friend and scientist, David Light, and together we founded Valisure, America's first laboratory dedicated to independently testing and certifying on-market drug products.

We started Valisure to address drug quality problems, but we didn't initially realize the full scope and severity of these problems. Within a few years, our findings led to recalls of more than 25 million pharmacy products worth over nine billion. We began testing the blockbuster drug Zantac because my infant daughter had just been prescribed the liquid form. Our discovery of the drug's instability sparked its global withdrawal.

Our later work drove rolling recalls of sunscreens and hand sanitizers, as well as dozens of national recalls of multiple drugs due to the presence of various carcinogenic contaminants. Why is this shocking problem of low-quality drugs in America so under-recognized? Bluntly, it is because for 40 years, the former FDA drug leadership has claimed to everyone that all approved drugs are equivalent in quality.

This demonstrably false narrative created a market that competes only on price, which incentivizes cost-cutting, overseas manufacturing, and products being made just good enough to minimize regulatory scrutiny, all in the near complete absence of independent testing.

When you buy a car, do you just want the cheapest one in its class that claims to be legal to drive on the road? Of course not, yet this is essentially how we are forced to buy drugs in America. Recently, the New England Journal of Medicine published an article, which Ms. Salberg referenced, titled, ″Substandard Generic Drugs, Threats to Patient Safety and National Security.″

Its very first recommendation was that the FDA should stop claiming that all generic drugs sold in the United States are equally safe and effective. Once we acknowledge that not all generics were created equal, we can end the race to the bottom and begin fostering a race to the top.

The FDA currently has a ″closer to zero″ program for contaminants like lead in baby food. Clearly, the same should apply to medications. If one manufacturer's product contains far lower contaminant levels than another's, then all else being equal, shouldn't we prefer the objectively cleaner product, even if neither are so bad

that they break the law? In pursuit of exactly this end, the military, via the Uniformed Services University, began a project with Valisure a few years ago to independently test essential medicines and assign quality risk scores to classify suppliers as red, yellow, or green.

By translating complex chemistry into these simple red, yellow, green quality risk designations, procurement decisions can easily favor objectively higher quality manufacturers and avoid lower quality ones. Incidentally, tacrolimus, which you just heard about from Ms. Salberg, is on the military's essential medicines list, and we found generics that rated red because the pills dissolved too quickly.

Notably, the FDA received so many complaints that after 11 years, it completed a clinical study and concluded a lack of bioequivalence to the brand. Our independent chemical testing effectively reached the same conclusion in weeks rather than years and identified the root cause mechanism.

More broadly, testing across 25 drugs and 359 suppliers has already shown that 72 percent of suppliers scored green, while 15 percent scored red. There was no correlation between price and quality. Also, on average, higher contaminant levels were found in certain drugs manufactured in India and China than in the same drugs made in the U.S. Simply buying green and avoiding red could be transformational for incentivizing quality and American made medicine.

It could also save billions of dollars and thousands of lives. This is not just a theoretical concept. Kaiser Permanente, which like both the military and the VA, represents several percent of the U.S. pharmaceutical market, already requires independent testing of certain generic drugs that it procures, and has been doing so for years. We know this works, and it works at scale.

Representatives Rich McCormick and Rosa DeLauro will be introducing the Bipartisan Transparency and Quality in Pharmaceuticals Act to incorporate the USU's chemical quality metrics and also independently derived manufacturing location metrics into military drug procurement. They are also working to include this bill in the NDAA and provide funding in the Fiscal Year 2027 Defense Appropriations Bill.

We respectfully ask that this Committee support this legislation. It is our one singular recommendation, because after over a decade of researching the problem, we strongly believe that this is the most impactful solution available. Thank you again for your engagement on this critical issue and for allowing me to share my story.

The CHAIRMAN. Thank you. Now I would like to introduce Dr. Suzanne de la Monte, Vice Chair of Pathology and Laboratory Medicine at Brown University's Albert Medical School. She has conducted extensive research on exposure to contaminants in food and medicine, and potential health implications for patients.

Her work helps us understand the real biological consequences of what happens when Americans unknowingly consume drugs with manufacturing defects, toxins, and carcinogens. Thank you for being here. Please begin your testimony.

STATEMENT OF SUZANNE DE LA MONTE, MD, MPH, PROFESSOR AND VICE CHAIR OF PATHOLOGY AND LABORATORY MEDICINE, ALPERT MEDICAL SCHOOL OF BROWN UNIVERSITY, PROVIDENCE, RHODE ISLAND

Dr. DE LA MONTE. Chairman Scott, Ranking Member Gillibrand, and committee members, thank you for this opportunity to participate in these hearings on drugs safety, supply chains, and risk to aging Americans. I am a physician scientist who studies mechanisms of aging related chronic diseases, particularly those that damage the brain and cause insulin resistance like diabetes, obesity, and dementia.

My educational and academic backgrounds have equipped me to conduct such research, understand their societal impact, and experimentally demonstrate how the toxins' exposures cause chronic disease states that are currently epidemic and particularly afflict seniors. In contrast to messaging designed to pin these problems on genes, in fact, the decade over decade increases in chronic disease rates mirror the effects of exposures rather than aging genetics per se.

What could possibly be the culprit? Convergent factors including several of the testimoneys highlighting significant quality concerns about generic medications manufactured in foreign countries drew my attention to this Committee. Prior to that, I had already begun to investigate the potential cause of several insulin resistant diseases in a person I will refer to as Sam.

Sam was previously healthy, gainfully employed, and productive. His only medical problem was hypertension. However, after taking two years of a prescribed generic antihypertensive medication, Sam developed type 2 diabetes, obesity, muscle weakness, and metabolic problems.

His symptoms worsened, his cell status progressively deteriorated, rendering him chronically ill and virtually incapable of caring for himself or his disabled child. Deep dives into Sam's new unexpected complex illnesses led to evidence that he had been chronically exposed to toxic levels of nitrosamines present in his prescribed antihypertensive medication.

My expertise includes research in non-cancer causes of toxic effects of nitrosamines. We know that chronic low dose exposures can cause insulin resistant diseases, diabetes, obesity, dementia. Sam's blood work, and eventually records released from the pharmacy, confirmed that his nitrosamine exposures had occurred via contaminated lots of his medication.

Sam's now debilitating chronic disease state mirrors what we have observed in experimental models and in humans exposed to nitrosamines from various sources, including dietary and medicinal. How many people were exposed and developed these serious side effects, we don't know.

Unfortunately, despite an FDA recall early in 2025, contaminated lots of the index medicine continue to be sold in the United States. Sam, unaware of the recall, took the medication as prescribed.

Nitrosamine contamination of drugs is an old story in pharmaceutical industry, but the problem is managed or eliminated by

standardized clean manufacturing protocols, extensive monitoring, end product testing, and quality control. Nitrosamine contamination is just one example of how lax regulatory oversight in generic drug manufacturing can have devastating effects on health. Problems concerning unsafe drug manufacturing disproportionately impact seniors in part because they are victims of polypharmacy.

More than 40 percent of Americans who are over 65 take five prescribed medications a day, and between 10 percent and 20 percent take 10 or more per day. Healthcare providers often prescribe additional drugs to combat the side effects of the targeted therapeutics.

However, side effects from those drugs add even more prescriptions. Matters are worsened by many non-prescription generic medications used by seniors. More drugs mean increased risk for adverse events like toxin contamination exposure. Growing concerns about generic drugs originating in foreign countries, particularly China and India, and that were widely sold at attractive, possibly unrealistically low prices in the United States stem from unacceptable manufacturing conditions and lax oversight on quality, safety, and efficacy.

These problems threaten the health and welfare of consumers, particularly seniors. Circling back to our extreme reliance on cheaper, but concerning quality generics, the year over year soaring prevalence rates of chronic diseases, including diabetes and dementia, parallel the rate shifts in overseas, poorly regulated generic drug manufacturing, coupled with polypharmacy.

Sadly, this cascade is driven by financial gains yet makes no sense to spend lavish amounts of money on so many medicines that make so many seniors sicker and sicker with chronic diseases. Thank you.

The CHAIRMAN. Thank you for your testimony. Next, we have Dinesh Thakur, he is a public health advocate who put everything on the line as a whistleblower against Indian manufacturer Ranbaxy, exposing systemic violations of FDA manufacturing standards that resulted in a $500 million settlement with the DOJ.

Now he advocates for drug quality, stronger FDA oversight, and holding foreign manufacturers accountable who cut corners at the expense of American patients. He is a proud Floridian. Thank you for being here. Please begin your testimony.

STATEMENT OF DINESH THAKUR, PUBLIC HEALTH ACTIVIST, ST. PETERSBURG, FLORIDA

Mr. THAKUR. Thank you. Chairman Scott, Ranking Member Gillibrand, and distinguished members of this Committee, I thank you for convening this hearing on this topic that impacts all of us.

My background and training is documented in my statement. I was a whistleblower in the prosecution of a generic drug company by the U.S. DOJ in May 2013, where that Indian company pled guilty to seven counts of criminal felony and agreed to pay half a billion dollars in fines to the U.S. Government.

While I have presented my analysis and made substantive recommendations in my written statement, which I have submitted to this Committee, I beg your indulgence now. Let me provide you a few concrete examples of the issues that I referenced in my state-

ment. We intentionally picked these examples that are not technical. I have a whole stack of these investigation reports here which I am more than happy to hand it over to the Committee today.

Let me give an example of a company called IPCA Laboratories, an Indian generic manufacturer that makes and sells metoprolol tartrate and furosemide beta blocker, and a diuretic in our market here in the United States. Let me walk through the chronology of how we have held this company to account for its fraudulent behavior over the last 16 years.

In 2014, based on an inspection report on Form 483, USFDA Inspectors Peter Baker and Joanne King, this is what they said, the company was manipulating test results so that they could pass the inspections by playing with instruments in their controls. Backdating results. The report says integration parameters are manipulated in order to achieve passing results. Raw data files have been manipulated, deleted from the system. In October 2014, USFDA Inspectors Peter Baker and Dipesh Shah had similar observations in their inspection reports.

They spoke about attempts to hide results from review, overwriting raw data files, original reports—results not being reported, and partially shredding documents. The USFDA went back to do followup inspections five years later, in August 2019. Inspectors Arsen Karapetyan and Patrick Upadhyay said in their report, which I have a copy here, it says that a cascade of failures in your quality control responsibilities, missing raw data. Repeat analysis by preparing fresh samples when the original testing failed.

The USFDA conducted another inspection in 2023, led by Investigators Rajiv Srivastava and Kellia Hicks and they said in their report, which I have a copy here, the company invalidated outer specification results without a scientific valid cause. The investigation kept open for 10 months without justification.

The USFDA conducted another inspection last year, led by Investigator Salim Akhter. It said in his report here, for the U.S. market, the facilities are not cleaned properly to minimize contamination and fail to provide scientific data. In fact, in January 2016, the USFDA Director of Manufacturing Quality, Thomas Cosgrove had this to say about this company. Your firm routinely retested samples without justification. We observed systematic manipulation of data, backdating test data, manipulating parameters to obtain passing results, and here is the punchline.

In 2017, in August, the USFDA Office of Criminal investigation closed the investigation of this firm. In late 2022, the USFDA inspectors for—you know, so this is one example. Another example is a drug called cisplatin. This is a drugs that is used to treat cancer. We had a shortage of this drug in this country back in 2022, and this company, the company that made this drug, was a single source for us based in India.

The warning letter issued to this particular company by the Director of Manufacturing Quality at the USFDA, Francis Goodwin, said in his warning letter, I have investigated and observed plastic bags filled with torn and discarded original GMP documents. An analyst destroyed GMP records by pouring acetic acid in the trash

bin containing analytical balance slips. He wrote, 20 batch records allowed changes to be made in manual entries.

The point I am trying to make here, Chairman Scott and Ranking Member Gillibrand, imagine if this behavior was observed and documented in a financial services firm. The records demonstrating illegal behavior were destroyed by pouring acidic acid into waste bins. Would we accept that? The fact that, you know—would we let and draw and go by paying a fine and not holding Mr. Lay and Mr. Skilling accountable?

This is what we are doing right now. Then we hear from my panelists here that we continue to have bad quality drugs in the country. This is the time for you to call up the USFDA Office of Criminal Investigation and ask them very pointedly why these investigations have been closed. I thank you for your time.

The CHAIRMAN. I want to than each of you. We will start with questions. We will start with Senator Tuberville.

Senator TUBERVILLE. Thank you, Mr. Chairman, for holding this hearing. Today we are not discussing a new issue. As we all know, America has lost power in the generic drug and pharmaceutical ingredient market. We are relying on China for several drugs, and it goes deeper than a trade issue. It is a national security issue. This is not a partisan issue with talking points.

There is real life patient harm and oversight that has fallen short. We just heard an excellent testimony from Ms. Salberg here about her past and her problems, and we thank her for being here today. I want to start with Dr. de La Monte. Can you tell me how often unannounced inspections happen in foreign pharmaceutical facilities?

Dr. DE LA MONTE. I can't tell you how often, but I know they are infrequent, and they are often tipped. There is no way to actually hold them truly accountable for what is going on.

Senator TUBERVILLE. Thank you. Mr. Thakur, can you paint a really good picture for us of a lab in India, and especially you, you know, worked in them, about what you see when you go in there, what they are trying to hide and not trying to hide? Can you paint good picture of everybody here for that?

Mr. THAKUR. Sure. I can speak to you from my own experience working in India. I had a misfortune of working in a company in India for 18 months. Typically what happened in those days was that the USFDA gave essentially a 2-month intimation saying that we are coming to inspect your facilities.

Now, that changed after Ranbaxy. The USFDA established an office in India and China, but they closed them down, and I don't know why. You have to ask them for that, but in that particular case, when the inspector comes in, the way that our regulations work, the GMP regulations work is we have an honor system.

What we do is we say, this is how you told us that you make the drug. When we come and inspect you, we want to make sure that we see that you follow what you have told us when you asked us for approving this drug.

This is what market authorization in this country really means. When we go there, we look over documentation. We look at the processes and it is very easy to game that if people are given ahead notice.

In my case, the greatest example that I knew about was that in 2005, when an inspector came in and asked for certain documents which were not available, the inspector was told, well, we will give it to you tomorrow morning, and overnight the company fabricated those documents, put them in a steam room to make them look like old documents. Now, is that acceptable to us?

Senator TUBERVILLE. No. Ms. Salberg, how can we have high-quality generic drugs? How do you think we can do that?

Ms. SALBERG. Simply inspect every batch that comes into the United States at the manufacturer or the purchaser's expense and send anything that is not the quality that is in the original ANDA right on back where it came from.

Senator TUBERVILLE. Dr. Joseph, I am intrigued with your ability to test your own drugs. Can you explain that?

Dr. CLARK-JOSEPH. Yes. Although my degree wasn't in chemistry, I studied quite a bit of chemistry in college, and I worked in my professor's laboratory one summer. Everybody has got to have a hobby. I am a little bit on the nerdy side.

Senator TUBERVILLE. You think?

Dr. CLARK-JOSEPH. Yes.

Senator GILLIBRAND. He is a football coach. Do not listen to him. He doesn't know what he doesn't know.

Dr. CLARK-JOSEPH. Yes, so I had a number of reagents, glassware, microbalances and so on, and I had been playing around with similar sorts of—you know, I took lots of supplements. I tried breaking those down into their component pieces and so on, so I had done similar tasks before and, yes, the stars aligned in this case.

Senator TUBERVILLE. Yes. You brought up one point there when we are talking about generic drugs. We have tens of billions of dollars spent in this country every year on supplements that are on the counter that don't have—that are not prescription drugs and there is no telling what is in these things, and you know, they look pretty in the bottles and most of us in here take a supplement or whatever. You got any thoughts on that Mr. Thakur?

Mr. THAKUR. Regulation for medicine actually is fairly extensive. Regulation of supplements is significantly below standards for us in terms of regulation of what really happens.

The example that Senator Scott spoke about, the deaths from eye drops, these were over the counter eye drops and should trusted, that when we go to CVS and Walgreens and actually buy these, that, you know, they are supposed to work the way that they are intended. We see issues of contamination of bacteria that, you know, people lost sight.

We had deaths, you know, in those cases. That is an egregious example, but the regulation of supplements is significantly smaller, lower, compared to the regulation for medicine.

Senator TUBERVILLE. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Ranking Member Gillibrand.

Senator GILLIBRAND. Thank you, Mr. Chairman. Dr. Clark-Joseph and Mr. Thakur, independent testing for international manufacturing, the global nature of generic drug supply chain means that 40 percent of finished dose products sold in the U.S. are produced abroad.

When inspecting international facilities, the FDA routinely gives foreign manufacturers up to 12 weeks advance notice, which is a lot. This allows bad actors 3 months to falsify data, sanitize facilities, cover up noncompliance. The FDA also does not routinely perform independent random testing of generic drugs already on the market. Compounding this issue when a foreign facility fails an audit, the FDA may waive enforcement to prevent shortages despite the quality of the generic drug.

This creates a race to the bottom market incentive where purchasers have no financial incentive to care about drug quality or reliability. Dr. Clark-Joseph, could independent third party testing of generic drugs change the financial incentives to prioritize quality among companies operating in the U.S.? Is it possible to scale enough testing to make an impact?

Dr. CLARK-JOSEPH. Yes, absolutely, to both questions. The first point as to, could it change financial incentives, I believe that procurement reform of precisely the type included in Representative McCormick and DeLauro's Transparency and Quality in Pharmaceuticals Act would. Introducing quality metrics and independently derived drug manufacturing metrics into the military drug procurement would, in addition to the direct effects, have ripple effects throughout the private sector.

Senator GILLIBRAND. Are you saying start with just the military's acquisition, seven percent, and then you think doing that, testing that, making that the highest quality would then create more incentives for the rest of the thirty-three percent?

Dr. CLARK-JOSEPH. Absolutely, because once there is a kind of gold standard for examining quality, one set by the Government, ideally codified into law, that will both create a precedent that these other large group purchasers can follow without fear of being a pioneer.

Though kudos to Kaiser for their pioneering work in that manner. Perhaps more importantly, this will create at least the specter of potential liability either in a legal sense or liability to their patients who might become aware of things and force decisionmakers at the purchasing level to take quality into account.

Senator GILLIBRAND. Create a certification standard so it can be certified, inspected type thing.

Dr. CLARK-JOSEPH. That would be wonderful.

Senator GILLIBRAND. Dr. Thakur—or Dinesh Thakur.

Mr. THAKUR. I think that clearly there is a cost involved in testing everything that comes into the country. What we need to understand is what is the consequence of not doing that because we really don't have good data as to what is a consequence of poor quality medicine in terms of hospitalization, in terms of adverse events. We just don't track that kind of information.

In order to justify what is needed to create a testing program, you always look back and say, well, we have gotten over this far by doing this. Mostly when patients go to their pharmacist and say, my medicine isn't working, they are usually told that it is a psychosomatic thing. It is all in your head because the drug looks different. Here is the challenge.

The challenge is that there is no liability for purchases today. They can determine what goes in the formulary. Like, for example,

most formularies essentially have manufacturers, two or three manufacturers, and usually they are located overseas.

As a patient, if I go to my CVS and say, look, if my formulation is yellow or red, I really don't have the ability to influence that because the purchasing decision is made by the formulary at that point in time.

Creating a liability at the procurement level that I was talking about, that I think at least will change the equation a little bit and incentivize buyers to be able to look at quality as well. Right now, every negotiation is about price. It is not about quality at all.

Senator GILLIBRAND. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Ranking Member. Ms. Salberg, how did you figure out your drug wasn't working?

Ms. SALBERG. My drug didn't work in a number of different ways, at different points. The beta blocker, my heart rate didn't come down. The tacrolimus, I found in the morning when I had my coffee, and my hand was shaking. That is a telltale sign of being high dosed on tacrolimus.

This one over here is the one that sent it below normal, 3.9 and opened me for rejection. This has no symptoms. You just are open to rejection. You have to do a lot of blood testing and I have been through a lot of IVs and a lot of blood draws in my life. I don't have good veins. At certain points, they are going to have to literally start pumping my fingers for blood to test my levels.

They have had to do that in the past when you couldn't get access to a vein. I have challenged veins that I have to pay somebody to poke to go test the drugs again. Sometimes it is twice a month to make sure my levels are proper. Now that I am on name brand, I am down to my monthly to every other month blood tests.

The CHAIRMAN. You have insurance, I guess.

Ms. SALBERG. I do have insurance.

The CHAIRMAN. If your generic doesn't work, do you have to pay the higher co-pay because of the brand, even though it doesn't work?

Ms. SALBERG. Yep.

The CHAIRMAN. Even though you proved it doesn't work?

Ms. SALBERG. Yep.

The CHAIRMAN. That surprised you, didn't it?

Ms. SALBERG. It's—I am sorry?

The CHAIRMAN. Doesn't that surprise you?

Ms. SALBERG. Oh, it shocks me, but I am a patient advocate, and I have watched how the health insurance companies put us in a really bad position, especially those with chronic illness.

The CHAIRMAN. Yeah, that doesn't make sense. Dr. Clark-Joseph, so the argument that some buyers have is they say, oh, it is going to cost more money. Have you ever done an analysis that, because when you end up back in the hospital or your condition is not treated, it actually costs more money? Have you ever done an analysis that says that is not actually—even if it costs a little bit more for the, you know, American drug, it's still worth it?

Dr. CLARK-JOSEPH. Yes, absolutely. I am actually, both I and my co-founder, David Light, are co-authors on a recent working paper on precisely this issue. We estimated the cost from adverse events associated with low quality drugs.

I am very happy to followup with detailed calculations and so on. We found a number that we feel is very conservative of about $18 billion per year and the actual cost of testing every batch would be a tiny fraction of that.

Generic drugs in the United States, although we do pay significantly more than the rest of the world for our branded drugs, we pay something like 33 percent less on average for our generic drugs. We found in our experience with Kaiser and others that testing and certifying every batch would add about one to three percent to the cost.

We could still pay more than 30 percent less than the rest of the world and have a fully certified generic drug supply that would be of high quality.

The CHAIRMAN. Dr. de La Monte, you talked about a drug that was recalled?

Dr. DE LA MONTE. Yes, the drug was recalled by the FDA, and yet it remained on the market, and, you know, one of the pharmacies——

The CHAIRMAN. If I have a—if my car is recalled, right, I get a letter sent, right, and they tell me I have to go in and get something done, so that is not the way the FDA works?

Dr. DE LA MONTE. Not that I am aware. First of all, the physicians who prescribe the drug are usually unaware that something has been recalled. The company, you know, one of the—I don't want to name pharmacies, but specific pharmacies, they should know that a drug has been recalled and not sell it to the clients. It seems irresponsible to just get away with it and not—and to enable disease to go forward.

Again, it is clearly a pricing issue, or they had it shelved and they want to sell it. It is a big problem because I think lack of awareness on the client, the physician, and the people who are purchasing it just don't seem to be aware. Hospitals may also be involved in this. They just buy stuff up in large amounts, again, price driven.

The CHAIRMAN. What kind of contaminants are found in medicines, and what kind of risk do they pose to patients?

Dr. DE LA MONTE. Well certainly nitrosamines are one of the big ones, and the reason I really pay a lot of attention to that is because they are linked to chronic diseases which are currently pandemic in the world. You know, we have—just taking low dose nitrosamine causes diabetes, obesity, fatty liver disease, and dementia.

You can just name the gang of four that is causing trouble in the United States and all the money we spend on trying to treat these people. Unfortunately, once you have these kinds of diseases that are drug induced, they are harder to treat. Now, I will give you a good example.

The 1960's and 70's, the rates of diabetes in people who were between 60 and 70 were far lower than they are today. The cost of treating them today is much higher. If you look at 60 to 70 year olds back then to those now, the rate is so much higher, and yet our medicine is supposedly better. What happened?

The CHAIRMAN. Mr. Thakur, so when you were a whistleblower, did the FDA say thank you? Thank God that you are here. You

know, why won't you come in and show us how we are going to improve this, and then can you brag about all the changes they have made?

Mr. THAKUR. I wish it was true. I am sorry it wasn't.

The CHAIRMAN. Oh, it is not true?

[Laughter.]

Mr. THAKUR. I did offer to meet with the FDA. Unfortunately, that never came to pass.

The CHAIRMAN. They didn't—they don't care.

Mr. THAKUR. I am sure they must have a good reason for that. I can't comment why, I mean, they wouldn't want to meet with somebody like me. I had something to offer.

The CHAIRMAN. Ms. Salberg, what do you hear from—do you have any stories of other patients that have gotten bad quality drugs or ineffective drugs?

Ms. SALBERG. Many. Dr. Lever and I meet up on a podcast every couple of weeks, and we were talking about generic drug quality. About five days later, a young man from—who was at that time living up in—by Buffalo, New York, and he called and said, I am taking myself to the hospital right now.

I am like, what is going on, hon? He is like a 28-year-old guy. He said, my beta blocker is not working. My heart rate, I feel like I am going to die. I got to go to the hospitals. I am, like, go, go get it checked out. Then he got stabilized, looked at the meds, changed the generic.

He went back to his old drug, and he was fine again. That was just like a regular old Tuesday afternoon in the office with somebody calling saying they have got a problem. I have a board member who is on thyroid medication, and she had a battle trying to keep her thyroid levels even on generics and gave that up decades ago for name brand only because thyroid medications are very specific. I have had many people hospitalized, and Dr. Lever at the Cleveland Clinic was constantly dealing with this.

Not only with beta blockers, but the problems back in about 2017, or 1916, 1917, 1918, with tacrolimus. We were losing transplant patients, and nobody could figure out why. Why are they dying? They have been stable for 10 years and then all of a sudden they are in rejection. It is because they got inert drugs.

You know how much it costs to put a heart in a person? It is about a million bucks, and this is like five bucks. Why are we not supporting the amazing work that we are doing with this high expense, high output procedure with a five dollar drug?

The CHAIRMAN. Dr. Clark-Joseph, why aren't we testing? I mean, the FDA—I think the Department of War is starting to test now, right?

Dr. CLARK-JOSEPH. That is correct.

The CHAIRMAN. Why isn't the FDA doing that? I mean, it seems pretty simple.

Dr. CLARK-JOSEPH. Well, the FDA is mostly set up from a process perspective in their inspection and examination capacities and that is certainly an important part of the equation. Making sure that the production facilities and production lines are as they are supposed to be is important.

However, as we have seen, it doesn't catch everything. We, Valisure, are very much mission aligned with the FDA, but have a complementary set of expertise and capabilities. I don't have a full explanation beyond that of why the FDA has not gone this route. We look forward to any productive collaboration we can have with them going forward.

The CHAIRMAN. Are there examples that you know of in the private sector where, in contrast to Federal Government, where with drugs they purchase based on quality first, then price?

Dr. CLARK-JOSEPH. I know we have been running a program with Kaiser for a number of years now, wherein in order for manufacturers to enter their bidding process for their next year's procurement, the manufacturers need to first get their medications tested and then if they are selected, agree to ongoing certification. Kaiser is therefore a private-sector example—they are still asking manufacturers to compete on price but filtering down to the ones who are highest quality and then letting them compete on the price.

The CHAIRMAN. Dr. de La Monte, the FDA relies heavily on self-attested manufacturing data to meet manufacturing standards. Do you feel comfortable that if somebody has an economic incentive to cut costs and the FDA just relies on their stuff, does that make any sense to you?

Dr. DE LA MONTE. The economic incentives are unacceptable. We have to go for quality and patient care and outcomes. We are in a healthcare profession to make people well, not worry—I mean, the small amount of money that is cited for additional testing and third-party qualification, seems like we should be willing to pay that amount. You can't get everything for nothing, so, right.

The CHAIRMAN. Senator Gillibrand.

Senator GILLIBRAND. Thank you. Dr. de La Monte and Ms. Salzberg—or Salberg—in both of your testimoneys, you discuss the long term impacts that low quality medication has on the health of patients. However, many consumers do not have the background or expertise to discern whether a medication is safe or not. This could potentially lead to mistrust with all generic drugs.

Ms. Salberg, as a patient advocate, how should policymakers promote the need for oversight and increasing transparency, while avoiding panic that could lead patients to stop treatment or delay care if they are financially unable to pay for brand name drugs?

Ms. SALBERG. Thank you for that question. I think, number one, we have to be honest. We have to tell the American people the honest truth, and we can start today by having the FDA update their website, because it tells you generics are the same. That is a lie. We can't lie to the American people.

We have to tell them the truth. The good news is 70-plus percent of generic drugs are great quality, and they work very well. We should lean into enforcing good actors to be prominent. We should also tell people if they are taking a medication that they have taken for a chronic illness for a long period of time, and they notice they are feeling different, to immediately communicate with their physician.

Senator GILLIBRAND. Make that a red flag. Do you have a—have you worked with the AARP to get them to notice that on their website, so like as a trusted source of information?

Ms. SALBERG. The HCMA is much smaller than the AARP, and they have not listened to my advice thus far, so maybe this might change that, and I hope that they would do that. I would just really love if you guys could get the FDA to actually tell the truth on their website. That would be helpful.

Senator GILLIBRAND. We will work on that. Dr. de La Monte, can you expand on the potential public health consequences if patients lose confidence in FDA approved medicines and begin avoiding or discontinuing medically necessary therapies based on incomplete or misunderstood information? How should we increase doctor and patient education on this issue?

Dr. DE LA MONTE. First, I think there is a relatively low awareness in general among physicians about side effects that are specifically due to the drugs. That is a big problem in medical education where we just assume that the drug will work. We think because it was FDA approved, it is FDA approved to buy the generics, and I think that is a misunderstanding.

Second, I like the idea of third party testing and then having a validation of color codes, so they know this has been third-party tested. I actually contacted a supplement company that I use, and I said, by the way, how do I know this is not poison? They actually showed me all their third party testing and validation.

I said oh, so it is out there, and you could actually tell people. I like the idea of having a website, but there is so much on the web, so you need to have a way for—I mean, right now, people are using AI for medicine. I mean you may just dial it in, whatever it is. You would think that some of those complications of a specific generic from company X is problematic and shouldn't be prescribed.

I mean eventually we have to drill down to physicians and health care workers telling people that we are going to keep to the safe ones. I think that is the way to go. There are safe ones, people are not dying every second, but they have these complications.

I think because they are not dying every second, we just keep dismissing the ones that are bad. We need to come up with the good group and tell people that there in fact are bad groups.

Senator GILLIBRAND. Yes, agreed. It would be great to have a clearinghouse of information on an FDA-approved website to actually track production and manufacturers that have bad track record.

Dr. DE LA MONTE. I agree.

Senator GILLIBRAND. I would think. Dr. Clark-Joseph, Valisure is a leader in independent chemical testing for carcinogens and toxic impurities in generic drug manufacturing, filling a critical transparency gap in the global pharmaceutical supply chain. You have partnered with the Department of Defense on pharmaceutical quality assurance assessment studies to chemically test and score generic medications.

How has this collaboration informed your ability to scale, standardize for a model for large purchasers, and how can we use it to reward safe manufacturers? Along with that, when various pharmacy chains offer their own generics, do they have better quality assurance because they themselves become brand names like CVS or Walgreens?

Dr. CLARK-JOSEPH. Let me go in reverse order. With respect to large pharmacies such as, as you mentioned, CVS or Walgreens having their own brand, my impression is that they are still sourcing them and procuring them in exactly the same way, and that they do not yet have any additional internal or independent quality verification or certification built in.

As to our project with the Uniformed Services University for the military, it has led to fleshing out an operational version of this red, yellow, green scoring system, which has been guided by an expert review panel, and we have further put in the details to do this. We have gotten an excellent snapshot of the quality risk profile of the extant manufacturers, of the top essential medicines, which also overlap with high use medicines in general.

That said, we also know through our work with Kaiser Permanente, that this absolutely can be done at scale. The kind of snapshots that we have been generating for the Uniformed Services University, ideally would both be updated on a regular basis because manufacturers can change their procedures if things turn over, and also perhaps pave the way for batch testing in kind of the Kaiser model nationwide.

Not to sound like a broken record but this is again why we are really, really excited and urge your support for the Transparency and Quality in Pharmaceuticals Act.

Senator GILLIBRAND. Yes. It makes sense because you could incentivize not only drug—pharmaceutical chains to do it. You could incentivize hospital networks to do like with Kaiser Permanente.

The DOD to do it. You can find the large purchasers or even group purchasing organizations to do it, to mandate that they have to have the high quality and testing done. Then they say we have been tested.

My assumption is if you create these large groups doing it, it will create a standard and then people will all be asking for that standard. It will also raise awareness that you can pay for a higher level quality of drug and that everyone should have that choice to pay for higher quality level of drug.

Dr. CLARK-JOSEPH. Absolutely. Yes, we really believe that beginning with military appropriation reform will start that ripple effect exactly as you described.

Senator GILLIBRAND. Then the elite hospital networks will be next. Then from there, I think the most successful pharmaceutical chains will be next. I mean, CVS is going to want to certify that their drugs and their medicines that they are putting on their label are tested.

Dr. CLARK-JOSEPH. Absolutely. One point—although, yes, there is some minimal additional cost to testing, it is important to note that we didn't find a correlation between price and quality in these drugs.

It is not like the greens are the most expensive ones. There is actually a paper by Kevin Schulman and someone else not too long ago that looked at the impact of the recalls of the angiotensin II receptor blockers (ARBs) that were recalled because they were contaminated with nitrosamines.

He compared the price and volumes for those to the angiotensin–converting enzyme inhibitors, the ACE drugs that serve a similar purpose but weren't recalled.

He found that despite the recalls of these objectively bad batches, the price of the ARBs did not increase relative to the control, and the volume, if anything, slightly increased.

Senator GILLIBRAND. Even if they did slightly, people would be happy to pay it. If you just look at a generic of Zyrtec and then you look at Zyrtec, the generic is—let's say it is a $10 dosage model. The generic might be $6. There is $4 in there you can play with. If it has to be $7 instead of $6. You are still offering a lower price, but you are guaranteeing the quality.

Dr. CLARK-JOSEPH. Absolutely.

Senator GILLIBRAND. There is a huge difference in price. If you are price sensitive, you are buying the generics generally. There is still room between the brand and versus the generic to add a little more value.

Dr. CLARK-JOSEPH. Absolutely, 100 percent.

Senator GILLIBRAND. Mr. Chairman, I have asked all my questions, and I have to go pick up my son. Thank you all. I have a child arriving at an airport. Thank you all for your testimony today. I am very grateful.

The CHAIRMAN. Thank you, Ranking Member Gillibrand. Dr. Clark-Joseph, have any insurance companies or anybody listened to you that you could save them money by—at all? Has anybody?

Dr. CLARK-JOSEPH. We have pitched it a number of times. That was earlier on in our trajectory. At the time, we didn't have well-established data. It was just, hey, it seems entirely rational that this would save you money in the long term.

We hope that with the accretion of more and more data that is, in some ways, becoming overwhelming, pointing to the actual economic health costs these things, that insurance companies and health systems will be much more interested.

The CHAIRMAN. Can you show me that Medicare would save money?

Dr. CLARK-JOSEPH. I would have to followup with you for detailed analysis, but I think it is overwhelmingly likely that Medicare would ultimately save a lot of money.

The CHAIRMAN. Well, whenever you are ready, I can organize a meeting for you with CMS to do that.

Dr. CLARK-JOSEPH. I would be delighted. Thank you.

The CHAIRMAN. Right now, you guys know the risks. How do you pick your drugs? Because you have got some pill bottles there, right? Does it say where you got it?

Ms. SALBERG. I brought these three because this is the one that was under dosing me. This is the ones that was overdosing me and this one came in the middle, but it is a generic and then I went to name brand, and I am not risking it anymore

The CHAIRMAN. You know where those all came from?

Ms. SALBERG. Where did they come from? No, I didn't know. This one is an interesting one. You will like this. It is Sandoz. I am from Jersey. They used to be down the street. I figured it was a local. It is made in India.

The CHAIRMAN. How did you find that out?

Ms. SALBERG. Because I have smart friends who help me research, and I am a patient advocate who has more resources.

The CHAIRMAN. It is not on the bottle, is it?

Ms. SALBERG. No, no, no. It is on the bottle——

The CHAIRMAN. Show that—your clothing all has country of origin——

Ms. SALBERG. My clothing does, my shoes do—everything, yes.

The CHAIRMAN. Yes, and that makes you feel good.

Ms. SALBERG. Yes. You don't know where it is coming from. You don't know who made it. There is another component here that I do want to bring up, and that is temperature. When these drugs are imported, we don't that they are temperature controlled, and we don't what the temp really is——

The CHAIRMAN. We know they are not.

Ms. SALBERG. What is that?

The CHAIRMAN. No, no, you know they are not temperature——

Ms. SALBERG. We know they are not temperature regulated, yes. They can get very hot. That is not safe.

The CHAIRMAN. Yes. How about the rest of you? If you know—I guess you know. Are you pretty good about everything you might, you or your family might take, or your friends?

Dr. CLARK-JOSEPH. I try——

The CHAIRMAN. It is an important friend to have.

Dr. CLARK-JOSEPH. I like to think so. I try very hard, but even I—sometimes it is just something I worry about and have very little control over. In spite of my connections with Valisure and so on, I am still ultimately forced to use basically the same pharmacies that everyone else is.

If the ones in town have made what strike me as poor purchasing decisions that month there's little I can do. I take duloxetine. It has been a lifesaver for me. There is a whole thing with drug specific nitrosamines in duloxetine. That has had me very worried.

The CHAIRMAN. Somebody else? Dr. de La Monte, do you know where your drugs come from?

Dr. DE LA MONTE. I wonder——

The CHAIRMAN. You should know this stuff, right? It is impossible, isn't it?

Dr. DE LA MONTE. It is really tough. The thing is, somebody has to have skin in the game to get this to work.

You know, I have asked people I know who are in the higher levels of making drugs whether they could actually make their own generics, or whether they would supervise the generics, because they are the source of the compound. They all claim it is impossible. I think it is they just want to push it aside and not do it.

The CHAIRMAN. They don't have to, so then why do it, right?

Dr. DE LA MONTE. Right. This is extra work. I think the push can come from consumers. If this concept were somehow popularized and made aware, you get a lot of pushback from people who are angry that this is what is happening.

You know, there are some people out there who are on TV and the like who might be interested in sharing the information and making people aware, and, you know, they are so good at drama.

You know, showing the outrageous component of what we are getting and realizing that, you know, things could be fixed. Sometimes you need a lot of pressure from people who are actually the victims, especially the senior citizens who have a lot of political clout.

The CHAIRMAN. It is how our Government is supposed to work, right?

Dr. DE LA MONTE. Well, it is supposed to, but if people don't know, if it is a secret. You know, if you are getting food that comes from wherever, you could at least read the label. Now you can read the labels, but medicines, we don't——

The CHAIRMAN. Senator Gillibrand and I have a bill, the CLEAR LABELS Act, so it will have country of origin for the ingredients of manufacturing, so that is a start. We are also working on mapping where all the ingredients come from.

I think—and you know, the Federal Government has got unbelievable buying power. I used to run the largest hospital company. I can tell you what—you know, I was only two percent of the healthcare dollar, but I could buy on volume so I could direct the market, right.

The Federal Government can do the same thing if they want to do it, but, you know, they will say, oh, gosh, it is going to cost us more money, or blah, blah, blah. It doesn't really matter. If you are dead, it doesn't help you much. We are going to get this done. Thank each of you for being here. I think this was a great hearing.

Problems with drug quality are affecting the American people, especially older Americans whose health relies on these medications. No American should have to wonder if the drug they are taking is safe or contains the medicine they need to stay healthy. I am going to continue to work with all my colleagues to support policies that bring safe and high quality drugs to patients.

I look forward to continuing to work with my members on this Committee. 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. I want to thank each of you for being here.

[Whereupon, at 4:39 p.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

Written Testimony of Lisa Salberg
Before the Committee on Aging
U.S. Senate

Poisoned Pills: The Human Cost of Dangerous Foreign Drugs

June 3, 2026

Lisa Salberg, CEO & Founder
Hypertrophic Cardiomyopathy Association

Ranking Chairman Rick Scott, Ranking Member Kirsten E. Gillibrand, and distinguished members of the Senate Committee on Aging:

Low-cost generic drugs could have cost me my donor heart.

My family history is shaped by cardiac disease. In 1953, my grandfather suffered a cardiac arrest at 42, on the evening of my father's high school graduation. A few years later, my great aunt passed from a stroke at 52. Later, my uncle was diagnosed with what was then called IHSS, now referred to as hypertrophic cardiomyopathy (HCM). Then my sister Lori was diagnosed with an atrial septal defect and HCM. Lori passed away in 1995 at 36 from sudden cardiac arrest. My turn came in 1980, when I was 12. I lived with the complications of my diagnosis until I required a heart transplant at 47.

I am Lisa Salberg, COE and Founder of the Hypertrophic Cardiomyopathy Association (HCMA) in 1996. I was born and raised in Morris County, NJ. I spent 18 years as a human resources manager and health plan administrator for a mid-sized company, until transitioning to patient advocacy in 2005. At that time, I gave up my day job in HR to build the HCMA into a highly functional patient advocacy organization serving more than 22,000 families globally. I proudly represent those with HCM and associated genetic heart muscle conditions. I am a published author of more than 25 peer-reviewed journal articles and 3 books. The HCMA has developed 62 HCMA Recognized Centers of Excellence in the United States. I am also a recognized leader in the global HCM ecosystem. My testimony today includes my lived experience, professional observations, and recommendations to make positive change.

In 1996, our families took my sister's children on a week-long vacation to Cape Cod, a trip they had missed the year before. On the way north, I stopped at my pharmacy to pick up my Corgard, a beta blocker. On the way to Cape Cod, I went to take the pill and realized that it looked different, and I immediately called my pharmacist. The pills were generic, not the name-brand medication I was accustomed to. The pharmacist assured me that generic drugs were equivalent to name-brand and that there should be no issues using them. However, after taking the generic medication, I noticed my heart rate was not decreasing, which was the reason for taking the drug in the first place. I tried another dose, and still

experienced no change.

I requested that my prescription be forwarded to a pharmacy in Cape Cod. At my own expense, I refilled the prescription there. I felt fine after taking just one dose of the name-brand medication. Since then, I have done my best to monitor the generic drug manufacturers and my symptoms, and when necessary, have opted to pay extra for the assurance of receiving the medication I was originally prescribed. Bad bata blockers impact my quality of life and my ability to function regularly.

Fast forward to 2012, when a dear friend and colleague at the Cleveland Clinic, Dr. Harry Lever, called me saying that he had just heard something on NPR about drug quality, and this might be the answer to the mystery of why some patients would go from stable to highly symptomatic in very short timeframes, contrary to the usual HCM disease progression, which is typically spread over decades. Together, we began to examine this problem more closely.

On February 2, 2017, a phone call changed my life for the better. A beautiful donor heart was available for me. Knowing that generic drug quality can vary greatly, and understanding that I had to remain stable on one brand of the anti-rejection medicine tacrolimus, to give myself the strongest chance for a long life with Brandy, my donor's name, and that of my current heart. Brandy needed to stay safe, and I am responsible for assuring the medicines I use to protect her are consistent. My insurance company did not permit me to take a name-brand drug, so I was financially forced to take generics. I was, and continue to be, conscious of the manufacturer and always remain with the same one. As it turns out, the generic I had chosen was problematic, with many complaints and FDA documentation indicating so. I was unable to get tacrolimus manufactured by Accord due to a shortage, so they switched my manufacturer to Sandoz. I did not know that this drug was now manufactured overseas, in this case, India. My experience convinced me to test my tacrolimus levels to ensure appropriate metabolization of the tacrolimus. When my blood work came back, it wasn't at a therapeutic level.

Here is a crash course on transplant medications. To avoid rejecting my heart, it is necessary to maintain stable tacrolimus levels. From the time of my transplant, my goal

level was between 6.5 and 7.5. To my surprise, the Sandoz caused my levels to drop to 3.9, below therapeutic and perilous, leaving me at risk of rejection of my precious donor heart. Then, while on my "trusted" or "steady" manufacturer, my levels started to rise up to 9.9, causing shaking and potential kidney damage. The only solution to ensure I had the highest quality medications possible required taking name-brand drugs at my own cost, since it is Tier 4 on the formulary. Generics would cost me $20 per month, while name brands cost $100 to $130 per month, depending on my plan. My current co-pay per dose is $120.00, increasing my monthly cost to $380.00 monthly for co-pays, deductibles, and out-of-pocket maximums. $4,560 annually, while my HSA maximum is $3300 annually.

Through my work as a patient advocate in the HCM space, I have the privilege of working with thousands of patients worldwide, many of whom take beta blockers, some of the most problematic medications. We have to teach patients and clinicians how to investigate generic drug labels. We provide an educational portal on our website for patients to check the FDA website for recent correspondence regarding problems with generic manufacturers. It is the only thing that we can do to help patients stay safe. This process is arduous, complicated, and difficult to understand for many Americans. For decades, people have been led to believe that generics are the same as name brands, rather than being taught the truth about Hatch-Waxman, the variability of generics, and how to report problems.

Generic drugs are not only confusing for patients to understand, but even clinical trial researchers are largely unaware of the variability. Three years ago I attended an annual meeting in Washington, DC, called the Cardiovascular Clinical Trialists (CVCT). I attended a session at the National Press Club with a group of lipid experts, the people who focus on coronary artery disease and lipid management; they were perplexed that the clinical trials and their real-world experience did not match. During this meeting, I asked whether they used generic or name-brand drugs for their real-world trials. Several speakers said that generics are the same as brand-name drugs. I reminded them that under Hatch-Waxman, generic drugs only need to be 80 to 125% of the label claim, and that there are no standardized dissolution rate measurements, which could be the difference they're seeing in clinical practice. Patients are not actually getting the drugs that were tested originally; they're getting a version of them. The room seemed stunned, then broke out into applause

at my question. If the clinical trialists did not know that generics aren't equal, how can a patient know?

We have a very important job ahead of us: maintaining high-quality generic drugs. We are aware that they are available, cost-saving, and life-saving. However, the current system does not allow patients to know what is in the drugs and how much we are taking. The government needs to provide oversight to ensure that everyone, regardless of their socioeconomic status or education level, can understand where their medications were compounded, manufactured, and bottled, and to provide clear distribution documentation to ensure truth and labeling.

Knowing where medications come from is important, but its value to the average consumer is limited. I support the Clear Labels Act's requirement for identifying API origins. Still, it will not necessarily keep consumers any safer, as the drug in question may be the only one available at the pharmacy or reimbursed by payers.

The Valisure lab company's work with the Department of Defense provides independent batch testing to ensure quality and clearly rates drugs into one of 3 categories:

- Green (meets the bioequivalence and dissolution with no added contaminants),
- Yellow (variation in bioequivalence or dissolution, possible contaminants),
- Red (does not meet bioequivalence or dissolution and may contain contaminants or toxins),

This ensures no unsafe drugs make it past the border and into the bodies of American consumers.

Looking at root causes and building a stronger, safer supply chain can be achieved at minimal expense and may yield overall savings for the US healthcare system.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments) amended the FD&C Act to, among other things, add section 505(j), establishing a statutory abbreviated approval pathway for generic drugs. In this process, the ANDA submission is tested to ensure it meets the FDA's bioequivalence. Bioequivalence is established if the (90%) confidence interval for the geometric mean ratio

(test product vs. reference product) for both (AUC) and (C_{max}) falls entirely within the limits of (80.00%) to (125.00%). It does not require that dissolution evaluation be part of the process.

Dissolution is important for health practitioners because, for drugs to be absorbed and have a physiological effect on the human body, they must be in solution. For solid preparations, such as tablets and suppositories, the dissolution rate affects how fast a drug is absorbed in the body.

It is also imperative that the drug quality be independently inspected to ensure that each batch maintains the same bioequivalence and dissolution rates as in the original submission.

In the US, 85% of generic drugs are purchased by the top 3 purchasing Groups.

- Red Oak Sourcing: A 50/50 joint venture between CVS Health and Cardinal Health. It handles the generic drug sourcing and supply chain negotiations for both parent companies, acting as one of the largest buyers by volume.
- WBAD (Walgreens Boots Alliance Development): A global procurement joint venture based in Switzerland. It handles sourcing for both generic and brand products for Walgreens, Boots, and Cencora (formerly AmerisourceBergen).
- ClarusOne Sourcing Services: A joint venture between Walmart and McKesson. It focuses heavily on aggregating the generic pharmaceutical procurement scale for both of these massive retail and wholesale companies.

The following changes are needed to the current law, policy, and practice.

1. Update Hatch-Waxman to require ANDAs to meet bioequivalency and dissolution requirements at the time of submission, and include new language requiring proof by independent batch evaluation upon receipt of products in the United States (or for distribution to US consumers).
2. Independent testing laboratories can be co-located with manufacturers' import locations managed by the purchasing groups. Where appropriate, testing protocols

will be established to assess drug quality and dissolution rates using the green-yellow-red scoring system, based on ANDA bioequivalence evaluations, dissolution rates, the absence of contaminants or toxins, and the identification of the country of origin for all APIs and manufacturing processes. The test result documentation should be publicly reported on a fully transparent website managed by the FDA. Daily reports are to be sent to the FDA, with updates on quality, and include a strong documentation trail to ensure that poor-quality drugs are removed from the country.

3. If the drugs score yellow or red after testing, a protocol for secondary testing will be established. If two labs agree on a "red" score, the drug is returned to the manufacturer or destroyed at their own expense. If it is yellow, additional protocols should be put in place to determine whether the drug distribution is appropriate.
4. In line with the goal of manufacturing more drugs in the United States, US manufacturers of generic drugs should receive the highest score for country of origin when API and manufacturing occur in the US.
5. Manufacturers outside the US must have annual independent inspections of their labs at their cost. Independent inspectors will be chosen at random by the FDA. This system incentivizes current low-performing manufacturers to improve their manufacturing processes and keeps Americans safe from poor-quality generic drugs.
6. Support and advance legislation supportive of common-sense steps to improve the quality and transparency of the generic drug supply. Representatives Rich McCormick (GA-6) and Rosa DeLauro (CT-03) are introducing the bipartisan Transparency and Quality in Pharmaceuticals Act to incorporate USU's chemical quality metrics and independently derived manufacturing-location metrics into military drug procurement. It is my understanding that they are working to include this bill in the NDAA and provide funding in the Defense Appropriations bill for Fiscal Year 2027.

Does Hatch-Waxman need to be revisited? Yes. We need to codify into law the inclusion of laboratory testing, ensure dissolution rates are included in ANDAs, and require systematic, independent laboratory review of all generic drugs entering the United States before distribution. Clear liability must be placed on the purchaser of the drug from the

manufacturer, to ensure that product liability lies with the purchaser. If a purchaser of generic drugs knowingly permits drugs that do not meet the ANDA, they will be liable for future health damages. Such policies incentivize independent laboratory review and ensure that all batches of generic drugs imported into the United States are safe.

As therapeutics have advanced in nearly all fields, targeted therapies will soon become tomorrow's generics. For example, Eliquis (apixaban) and Xarelto (rivaroxaban) are powerful anticoagulants used to reduce the risk of blood clots in patients with atrial fibrillation, which is present in 25% of the HCM population. When these drugs go generic, we cannot accept 80 to 125% of the original label; we must ensure a steady release of the drug over the dosage period. If we do not take these steps, the result will be avoidable strokes and bleeds. If the current market sweep data from Valisure indicates 70% of generics are "green," leaving 30% of generics at considerable risk, the cost of stroke management and recovery would devastate our already struggling health system. 8 million Americans are currently on blood thinners.

It is clear we need independent batch inspections, and that manufacturers that fail to meet the standards be suspended from distribution in the United States until they can prove they have produced two (or more) batches that meet established quality standards. Truth in labeling is essential. I support the Clear Label Act to ensure the derivation of active pharmaceutical ingredients (APIs) is available on labels and searchable online. We must do more to bring API generation onshore in the United States to ensure we have a safe and secure pipeline to meet our country's needs. Creating economic incentives to expand drug development and manufacturing in the USA should be a top priority for our governing bodies.

There are precise stages in the generic drug distribution cycle that begin with the premise that generic drug producers comply with Hatch-Waxman. The entry point to the consumer stream must be guided by legislative protection or regulatory language. There must also be liability consequences for each company that fails to comply, including being prohibited from distributing its medications in the United States. I recommend adding an independent review of each batch of drugs arriving from all manufacturers. When the purchasing agents in the United States acquire these drugs, they can choose with which US-based,

independent company to contract. Batches that fail would be reported to a central repository held by the FDA or other source, as deemed appropriate by the Senate committee. The record of failed batches would be made public, creating the opportunity for the manufacturer to provide commentary and correction plans transparently and to provide updated results once they meet quality standards. The purpose is not to vilify manufacturers, but to hold them responsible for continuous, standardized, high-quality production throughout the product life cycle. By adding this step, US drug purchasers will only have high-quality drugs available.

It is difficult to measure the damage done by inappropriately dosed medications with bad dissolution rates, and how much disease burden is impacted by physicians and patients believing that the patient is on guideline-directed therapy, yet somehow not responding. This brings me back to that moment at the CVCT meeting. When a room of clinical trialists had that “aha” moment that the study drug they tested is not the same as the generic the patient actually receives, and there is no way to know whether they are getting the proper dose at the proper time. We need to act quickly to ensure that does not happen any longer.

Citations

Biochemistry, Dissolution and Solubility Jue Xi Lu; Connor Tupper; Alejandra V. Gutierrez; John Murray. 9/12/22 https://www.ncbi.nlm.nih.gov/books/NBK431100/

Appendix 1: Patient Feedback on Generic Drugs

04/13/2026
12:46 PM

Hello Lisa,

I'm writing with my own testimony about my experience with generic drugs:

My name is Dawn Levitt. I was born with Hypertrophic Cardiomyopathy that required me to receive a heart transplant in January 2006 at the age of 38. I recovered very well and returned to full-time work in less than a year following my transplant. I received name brand Prograf as my primary anti-rejection medication following my transplant.

In 2012, I changed jobs and my new insurance refused to cover name-brand Prograf so I began taking generic Tacrolimus. During the summer of 2013, I began to experience shortness of breath on exertion and was diagnosed with asthma and given an inhaler that didn't help. By October of 2014, after two years of taking generic Tacrolimus, I was admitted to the hospital for severe shortness of breath and was then diagnosed with Transplant Coronary Artery Vasculopathy, (CAV). CAV is the leading cause of death for heart transplant recipients.

In June 2015, nearly ten years after I received my transplant, I had my first major episode of transplant rejection. It is unusual to experience rejection so long after a transplant. Over the next three years, I experienced episodes of chronic rejection, which led to a second heart transplant in October of 2018.

It was not until after I received my second heart transplant that I learned of recalls and warnings issued for the generic brands of tacrolimus that were given to me. It is my belief that the reduced efficacy of those generic drugs precipitated the CAV and rejection of my heart and caused me to undergo the pain and expense of a second heart transplant.
I believe that it is imperative for the U.S. to increase the oversight and quality testing of imported generic drugs to prevent unnecessary pain, suffering, and death.

Sincerely,
Dawn Levitt

Thank you for including our experiences on this topic. I find it to be so important to have access to brand name medications because generic brands are inconsistent in how they work and we can be feeling worse because of the amount of fillers in the medications. The doctors then have to try to figure out if we are getting worse or just not getting full good medication. Side effects are another issue that make me not want to take a generic medication. Cost should not be the only determinant in medications being denied by insurance.

Joel Brimmer

As a heart transplant recipient, I initially filled all of my anti-rejection medications through my transplant hospital's pharmacy; they were not generic. Since my transplant hospital is out of the state that I live in , It was costing me a tremendous amount of money due to the fact that my insurance did not want me to fill prescriptions in another state,which is only a 30-minute train ride for me. Once having to switch to generic drugs, I have had many ups and downs with my transplant drug levels. Currently, I can't get my tacrolimus to stabilize and I definitely think the sudden drop is due to inferior tacrolimus from generic companies that are made in other countries with very little oversight. I have fought very hard to live life and be healthy . Generic drugs are untrustworthy, and I really do feel that they jeopardize my heart transplant.

Lisa Vecchione

I have taken the brand Toprol for 20 years. Once my insurance no longer started covering the brand and following Dr. Lever's advice, I decided to do a trial of the authorized generic medication. At the time, it was made by Par Pharmaceuticals and the brand was made by Astra Zeneca.

As soon as I switched to the Par, and continuing for the whole month I took Par, I had chest pain. I switched back to the brand the next month, and have not had any more problems with symptoms, but my insurance company will not pay for brand medication. Even with a prior authorization, they cover very little.

I therefore pay out of pocket for the brand Toprol XL at a cost of approx $120/month. And the drug has been sold several times and at this point in time, an authorized generic is not

available. At one point you could only obtain the authorized generic by mail order from Eagle Pharmacy in Florida, but I am not even sure that is an option anymore. I just think it isn't manufactured.

There is not enough quality control on generics, especially those that are time-released like Toprol.

I have other occasions where the pravastatin I take gave me discomfort so I only take one specific brand. In fact, I try to stick with the same brands even of generics once I find one that I can tolerate well.

Cynthia Waldman
Los Angeles, CA

Poisoned Pills: The Human Cost of Dangerous Foreign Drugs

Hearing before the United States Senate Committee on Aging
June 3rd, 2026

Testimony of Adam Clark-Joseph, Co-Founder and Chief Analytics Officer, Valisure

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee, thank you for the honor of speaking before you today.

I have taken medicine for depression for most of my adult life. I first encountered a bad batch of medicine when I was 25; after a refill, I suddenly fell ill, and my doctor told me that sometimes you just get a bad batch. At 27, it happened again, and I became sick for months. Then at 29, after yet another incident, I used my chemistry background and some equipment in my home to test the pills myself. I found they were massively under-dosed.

That was the last straw. I reached out to my longtime friend, scientist David Light, and together we founded Valisure, America's first laboratory dedicated to independently testing and certifying on-market drug products.

We started Valisure to address drug quality problems, but we didn't initially realize the full scope and severity of those problems. Within a few years, our findings led to the recalls of more than 25 million pharmacy products,[1] worth over $9 billion.[2] We began testing the blockbuster drug Zantac when my infant daughter was prescribed the liquid form; our discovery of the drug's instability sparked its global withdrawal.[3] Our later work drove rolling recalls of sunscreens[4] and hand sanitizers,[5] as well as dozens of national recalls of multiple drugs[6] due to the presence of various carcinogenic contaminants.[7]

Why is the shocking problem of low-quality drugs in America so under-recognized? Bluntly, it's because for 40 years, the former FDA drug leadership has claimed to everyone that all approved drugs are equivalent in quality.[8] This demonstrably false narrative created a market

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[1] Felton, Ryan. "Why Is FDA Going After Lab That Found Benzene in Sunscreen?" *Consumer Reports*. March 31, 2022.
[2] Edney, Anna. "FDA Lags Behind Lab That Found Benzene in Dry Shampoos, Sunscreen" *Bloomberg News*. November 9, 2022.
[3] Thomas Katie. "Zantac Products Should Not Be Sold or Used, F.D.A. Warns, Citing Cancer Danger" *The New York Times*. April 1, 2020
[4] Byron, Ellen. "Sunscreen Recall: What to Know as J&J Recalls Some Neutrogena Sprays Over Benzene" *The Wall Street Journal*. July 16, 2021
[5] Ducharme, Jamie. "Scientists Are Finding Out Just How Toxic Your Stuff Is" *TIME Magazine*. May 9, 2024
[6] Edney, Anna. "L'Oreal Recalls Acne Treatment Effaclar Duo in US on Cancer-Linked Benzene" *Bloomberg News*. March 10, 2025
[7] Erman, Michael; Mishra, Manas. "Online pharmacy Valisure says tests show carcinogen in diabetes drug metformin" March 2, 2020
[8] Cenziper, Debbie; Rose, Megan; Roberts, Brandon; Hwang, Irena. "The Secret Gamble at the FDA That Exposed Americans to Risky Drugs" *ProPublica*. June 17, 2025

that competes only on price,[9] which incentivizes cost-cutting, overseas manufacturing,[10] and products made just good enough to minimize regulatory scrutiny, all in the nearly complete absence of independent testing.

When you buy a car, do you just want the cheapest one in its class that claims to be legal to drive on the road? Of course not—yet this is essentially how we are forced to buy drugs.

Recently, the New England Journal of Medicine published an article titled "Substandard Generic Drugs — Threats to Patient Safety and National Security."[11] Its very first recommendation was that "the FDA should stop claiming that all generic drugs sold in the United States are equally safe and effective." Once we acknowledge that not all generics are created equal,[12] we can end the race to the bottom and begin fostering a race to the top.

The FDA currently has a "closer to zero" program for contaminants like lead in baby food.[13] Clearly the same should apply to medications. If one manufacturer's product contains far lower contaminant levels than another's, then shouldn't we prefer the objectively cleaner and safer product, even if neither are so bad they break the law?

In pursuit of exactly this end, the Military, via the Uniformed Services University, began a project with Valisure a few years ago to independently test essential medicines and assign quality-risk scores to classify suppliers as "red," "yellow," or "green".[14,15] By translating complex chemistry into simple "red/yellow/green" quality-risk designations, procurement decisions could easily favor objectively higher-quality manufacturers and avoid lower-quality ones.[16]

Incidentally, tacrolimus, which you just heard about from Mrs. Salberg, is on the Military's essential medicines list, and we found "red"-rated generics because the pills dissolved too quickly. In fact, the FDA received so many complaints that, after 11 years, the FDA completed a clinical study concluding lack of bioequivalence to the brand. Our independent chemical testing effectively reached the same conclusion in weeks instead of years, and identified the root cause mechanism.[17]

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[9] Teasdale, Ben; Light, David; Schulman, Kevin. "Price and Quality in the Generic Pharmaceutical Market" *Circulation*. Volume 145, No. 16. April 18, 2022
[10] Gibson, Rosemary. China Rx: Exposing the Risks of America's Dependence on China for Medicine. Prometheus. Buffalo, New York. 2018
[11] Schulman, Kevin; Kellerman, Arthur. "Substandard Generic Drugs — Threats to Patient Safety and National Security" *The New England Journal of Medicine*. Volume 394, No. 17. March 18, 2026
[12] Noh, In Joon; Gray, John; et. al. "Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events" *Production and Operations Management*. February 6, 2025
[13] Food and Drug Administration. "Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods" January 6, 2025.
[14] Edney, Anna; Griffin, Riley. "Cheap Generic Drugs May Not Be Safe for US Troops" *Bloomberg News*. December 4, 2023
[15] Valisure. "VALISURE SIGNS AGREEMENT WITH DEPARTMENT OF DEFENSE TO INDEPENDENTLY TEST & QUALITY SCORE DRUGS" August 8, 2023
[16] Fletcher, Lisa; Nejman, Andrea; Aaron, Nathan. "Bad drugs could threaten US troops: Inside lab doing groundbreaking tests to address it" *The National News Desk*. May 18, 2026
[17] Cenziper, Debbie; Rose, Megan."After His Kidney Transplant, He Took Tacrolimus From an FDA-Investigated Factory" *ProPublica*. June 23, 2025

More broadly, testing across 25 drugs and 359 suppliers has already shown that 72% of suppliers scored "green," while 15% scored "red." There was no correlation between price and quality. Also, on average, higher contaminant levels were found in certain drugs manufactured in India and China than in the same drugs made in the US. Simply buying "green" and avoiding "red" could be transformational[18] for incentivizing quality and American-made medicine. It could also save billions of dollars and thousands of lives.[19]

Kaiser Permanente, which, like both the military and the VA, represents several percent of the US pharmaceutical market, already requires independent testing of certain generic drugs it procures.[20] We know this works at scale.

Representatives Rich McCormick (R-GA-07) and Rosa DeLauro (D-CT-03) will be introducing the bipartisan "Transparency and Quality in Pharmaceuticals Act" to incorporate USU's chemical quality metrics, and also *independently* derived manufacturing-location metrics, into Military drug procurement. We respectfully ask this Committee to support this legislation. It is our one, singular recommendation, because after over a decade of researching this problem, we strongly believe this is the most impactful solution available.

Thank you again for your engagement on this critical issue and for allowing me to share my story.

Attached to this testimony are the documents outlined below which reinforce many of the central themes and offer greater detail. One common concern that has been raised regarding efforts to reform drug procurement by avoiding lower quality manufacturers is that it could theoretically cause drug shortages and price hikes. This is a logically circular argument given that one of the primary reasons for drug shortages are quality problems, but this theoretical concern has been reviewed with real world data in the attached Circulation article titled "Price and Quality in the Generic Pharmaceutical Market." This paper found no evidence of volume or price differences when angiotensin receptor blocker drugs (e.g. valsartan, losartan, irbesartan) where recalled due to carcinogenic contamination and ostensibly cleaner versions remained on the market.

- "Substandard Generic Drugs — Threats to Patient Safety and National Security"
- Military Drug Quality Risk Scoring Project Summary
- "Price and Quality in the Generic Pharmaceutical Market"
- "Estimation of Economic and Public Health Burden of Low-Quality Generic Drugs for Chronic Disease and Potential Solutions"

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[18] Tony Sardella, Testimony to Senate Committee on Aging. "Bad Medicine: Closing Loopholes that Kill American Patients" October 8, 2025
[19] Suarez, Victor; et. al. "Estimation of Economic and Public Health Burden of Low-Quality Generic Drugs for Chronic Disease and Potential Solutions" *SSRN*. May 27, 2026
[20] Edney, Anna; Griffin, Riley. "Drug Safety Fears Spur Pentagon Plan to Test Widely Used Medicines" *Bloomberg News*. June 7, 2023 (See "The Kaiser Model")

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Substandard Generic Drugs — Threats to Patient Safety and National Security

Kevin Schulman, M.D.,[1,2] and Arthur L. Kellermann, M.D., M.P.H.[3]

Generic drugs account for more than 90% of prescriptions filled in the United States. The first paragraph on the home page of the Office of Generic Drugs at the Food and Drug Administration (FDA) asserts that "FDA-approved generic drugs have the same high quality, strength, purity and stability as brand-name drugs." On the strength of this assurance, America's doctors, pharmacists, and patients assume that every version of a generic drug is equally safe. But this proposition is now being seriously challenged.

Back in 1984, the Hatch–Waxman Act established an "abbreviated new drug approval" process for generic drugs. This new pathway led to a sharp drop in drug prices. Between 2009 and 2019, the availability of generic medicines saved U.S. patients $2.2 trillion, according to the FDA.

Over time, intense price competition drove most production of generic drugs and ingredients offshore to countries with low labor costs and lax regulatory controls. Once that shift occurred, relentless pressure to minimize costs led some manufacturers to compromise on quality. Rapid globalization also outstripped the FDA's capacity to monitor manufacturers. In 2022, the Government Accountability Office reported that 61% of foreign plants had not been inspected by the FDA in the preceding 5 years.[1]

When FDA inspectors finally reach these plants, some find glaring problems. In 2023, inspectors in India reported that Intas Pharmaceuticals employees had poured acid over quality-assessment documents to keep them from being reviewed. In 2025, an FDA report noted that employees at a Hetero Pharmaceuticals plant destroyed manufacturing documents and stored drug ingredients in an unregistered warehouse where inspectors found birds, lizards, and cats.

More than 60% of generic-drug shortages are attributable to quality concerns, according to the FDA. Shortages are most likely to happen when production is concentrated in a few plants and problems with quality are found at one of them. For example, the Intas Pharmaceuticals plant that failed its 2023 inspection was one of only two suppliers of cisplatin, a vital cancer drug, to the United States. The failure triggered a months-long shortage.

In another instance, a private-

sector laboratory detected high levels of nitrosamines (known carcinogens) in drugs made by several FDA-approved manufacturers, prompting recalls of metformin, angiotensin-receptor blockers, angiotensin-converting–enzyme inhibitors, prazosin, and ranitidine. More recently, independent tests of generic methylphenidate found nitrosamine levels above the FDA's safety threshold in 7 of 15 immediate-release products.[2]

Low-quality drugs can harm patients. Although there was not much interest in this issue when generic drugs were assumed to be high quality, cases of organ failure have been linked to poor-quality immunosuppressive drugs.[3] Recently, a team of U.S. and South Korean researchers with access to FDA data determined that significantly more serious adverse event reports were linked to generic drugs manufactured in India than to equivalent drugs manufactured in the United States.[4]

The fragility of America's global supply chains complicates FDA enforcement. In 2008, a total of 238 deaths in the United States were linked to adulterated Chinese heparin. When the FDA toughened its approach to quality assessment of foreign manufacturers, shortages of more than 200 medications followed. This crisis prompted the FDA to prioritize minimizing drug shortages over ensuring safety. In some instances, overseas companies were allowed to ship shortage drugs to the United States from plants the agency had banned from exporting drugs to the United States. Congress, doctors, and patients were not informed, according to *ProPublica*.

There is a better way to assure the safety of generic drugs. In 1994, the European Medicines Agency (EMA), for example, established a proactive approach involving risk-based surveillance in addition to systematic planned and ad hoc testing of generic drugs both on the market and during routine inspections of manufacturers (in contrast, the FDA does not routinely test generic-drug products themselves, either on the market or during quality inspections of manufacturing plants). EMA testing relies on a network of official medicines control laboratories (OMCLs) that operate in accordance with International Organization for Standardization (ISO) accreditation standards for testing and calibration laboratories. At any point in a drug's life cycle, an OMCL can pull samples for product testing. If they couldn't do so, an OMCL brochure asserts, "patients and users of medicines in Europe could be exposed more often to defective (e.g., contaminated) or falsified and illegal products."

Five actions could leverage market forces to ensure drug safety in the United States. The first is acknowledging the problem. The FDA should stop claiming that all generic drugs sold in the United States are equally safe and effective. It cannot verify this claim without product testing. Moreover, recent budget and personnel cuts may make the agency's oversight of generic-drug quality even more challenging.

Second, to compensate, the FDA can encourage testing of generic-drug quality by independent, ISO-accredited laboratories. Recently, a group of pharmaceutical experts developed a scoring system that translates test results and past regulatory data into a readily interpretable rating scale.[5] Data from an ongoing evaluation of essential medicines for the U.S. Department of Defense illustrate the value of this approach (see table). The FDA could use test results to prioritize its factory inspections and strengthen oversight.

Third, federal agencies, including the Centers for Medicare and Medicaid Services, could purchase drugs on the basis of best value rather than lowest cost. High-quality generic drugs are often available at prices similar to those of low-quality products. Consistent use of only high-quality generic medications could reduce costs by preventing complications and improving outcomes.

Fourth, quality scores could be made transparent to consumers. Kaiser Permanente does not buy certain generic medicines unless they are independently certified by a laboratory of its choice. If drug-quality information were widely available, patients, health systems, and pharmacies would reward high-quality suppliers with contracts and market share. Structurally, transparency would drive the market toward higher quality more quickly and definitively than episodic FDA plant inspections can do.

And fifth, the U.S. government should oversee an effort to rebuild America's capacity to manufacture generic drugs, combining investment in private manufacturing with incentives for purchasing U.S.-made products under the Medicare and Medicaid programs. Currently, the United States is vulnerable to an embargo of essential drugs or the materials required to make them. A recent evaluation for the Department of Health and Human Services found that 87% of sites that make active pharmaceutical ingredients (APIs) and 63% of sites that produce finished dosage forms were located

Quality and Safety Scores of 13 Essential Medicines.*

Medication	Green	Yellow	Red	Total	Primary Concern
Vancomycin	20	0	1	21	Arsenic
Tacrolimus	4	4	4	12	Fast dissolution
Potassium chloride	15	3	4	22	Lead, thallium
Pantoprazole	17	0	4	21	Fast dissolution
Metronidazole	19	0	2	21	Lead, arsenic, lithium
Metoprolol	11	5	2	18	Slow dissolution
Metformin	20	7	3	30	Dimethylformamide
Magnesium sulfate	7	0	0	7	None
Lisinopril	8	0	2	10	Arsenic
Calcium gluconate	4	0	2	6	Lead
Bupropion	17	4	5	26	Fast dissolution
Atorvastatin	11	3	5	19	Lead, arsenic, lithium
Ampicillin	13	1	1	15	Lead
Total no. of products (%)	166 (72.8)	27 (11.8)	35 (15.4)	228 (100)	—

* Shown are results of quality testing of 13 generic medications that are included in the U.S. Department of Defense drug formulary; the tested products were purchased from pharmaceutical wholesalers. The numbers shown are the number of products tested that were assigned to each color category. Overall scores are based on three safety measures (absence of carcinogens, toxic elements, and endotoxins) and two effectiveness measures (proper dosage and rate of dissolution). An expert review panel assigned a quality score (from 0 to 100) to each version of the 13 tested drugs, with a categorical rating of "red" (major quality concerns), "yellow" (quality concerns), or "green" (no quality concerns). Test results for samples rated as red were confirmed by independent analytic laboratories (https://www.valisure.com/valisure-newsroom/ahrmm24-dod-led-pharmaceutical-quality-assessment).[5]

overseas. In 2021, a private holding company bought the only U.S. manufacturing plant licensed for the production of amoxicillin out of bankruptcy. Bringing generics manufacturing back to the United States is in our national interest. Advanced pharmaceutical manufacturing, pioneered by the Medicines for All Institute in Virginia, produces high-quality APIs at lower cost than traditional factory methods. CivicaRx, a not-for-profit generics company, supplies member hospitals by paying high-quality manufacturers a sustainable price under long-term contracts. We believe that both approaches should be more widely embraced.

Most generic drugs are safe, but a troubling minority are not. Testing finished drugs, signing "green" manufacturers to long-term contracts, and sharing quality scores with the public would help realign market forces to improve safety. The United States already tests a wide range of consumer products. We should also test our generic drugs.

Disclosure forms provided by the authors are available at NEJM.org.

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This article was published on March 18, 2026, at NEJM.org.

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DOI: 10.1056/NEJMp2518256

Drug Quality Scoring (PhaSQ) Project Summary of First 25 Essential Medicines

Prepared by Valisure, June 1, 2026

Key Points / BLUF

Independent testing of 359 suppliers of 25 essential medicines found that most are low-risk / "green"-rated (72%) while a minority are high-risk / "red"-rated (15%). Quality appears to correlate with location, and there appears to be no correlation between quality and price. Incorporating drug quality scores into federal purchasing could be transformative for incentivizing quality and American-made medicines without increasing costs or causing shortages.

Background Summary

Public health and national security are threatened by record numbers of drug shortages that are primarily caused by manufacturer quality problems, ~80% of US drugs originating from China or India, and growing evidence of problems with generic drug quality and safety. Estimates suggest that the lowest quality 10% of generic drugs lead to over $18 billion in avoidable public health costs annually. In 2012, FDA identified that the root cause of drug supply problems is "the inability of the [generic drug] market to observe and reward quality." Recent analyses and Congressional hearings have reached the same conclusion. Currently, large health systems like Kaiser Permanente are leading the way in finding solutions and are already using data from this project for millions of patients.

This project aims to serve as a model for the nation by attaching drug quality risk scores to national drug codes (NDCs) used by all U.S. drug purchasers and payors. This is not intended to measure clinical effectiveness or FDA / regulatory compliance, but instead to create transparency to objective quality metrics to guide purchasing. Initial data suggests that quality metrics correlate with the location of manufacturing for final dosage forms (FDF), active pharmaceutical ingredients (API), and key starting materials (KSM), with highest quality in the USA and lowest in India and China.

Analytical Summary of First 25 Drugs

A combination of "safety" (carcinogens, toxic elements, endotoxins) and "effectiveness" (dosage, dissolution) analytical tests were performed on products from all available suppliers of the listed drugs purchased from various private-market wholesalers. Samples with results suspected of a "red" designation were secondary tested at a network of commercial and analytical laboratories. The primary and secondary data was reviewed by the Expert Review Panel, and they established a scoring framework to assign "red," "yellow," or "green" designations based on the JAPhA paper "Evidence-Based Quality Scores for Rating Drug Products and Their Utility in Health Systems" (the Panel members are all co-authors of this paper). Below are summary results from scoring the aggregate available 359 private-market suppliers of the initial 25 drugs (some overlap of suppliers exist between drugs, but each supplier of each drug is scored independently):

Drug	Green	Yellow	Red	Primary Reason for "Reds"
Metformin	17	8	6	Carcinogen: "DMF"
Lisinopril	8	0	2	Toxin: Arsenic
Potassium	15	3	4	Toxins: Lead, Thallium
Metoprolol	11	5	2	Slow Dissolution
Magnesium Sulfate	7	0	0	N/A
Tacrolimus	5	3	4	Fast Dissolution
Ampicillin	13	1	1	Toxin: Lead
Atorvastatin	11	3	5	Toxins: Lead, Arsenic, Lithium
Ca Gluconate	4	0	2	Toxin: Lead
Vancomycin	20	0	1	Toxin: Arsenic
Bupropion	17	4	5	Fast Dissolution
Metronidazole	19	0	2	Toxins: Lead, Arsenic, Lithium
Pantoprazole	17	0	4	Fast Dissolution

Drug	Green	Yellow	Red	Primary Reason for "Reds"
Dextrose	4	0	0	N/A
Norepinephrine	10	1	0	N/A
Atropine	8	1	0	N/A
Furosemide	17	7	3	Carcinogen: Nitrosamine, Slow Dissolution, Talc
Amlodipine	16	0	0	N/A
Duloxetine	1	2	5	Carcinogen: Nitrosamine, Fast Dissolution, Talc
Sodium Bicarbonate	5	0	2	Toxins: Arsenic, Particulates
Amiodarone	8	1	1	Fast Dissolution
Epinephrine	3	0	0	N/A
Sodium Phosphate	7	2	2	Toxins: Arsenic
Phenylephrine	10	1	3	Toxins: Arsenic
Trazodone	6	3	1	Fast Dissolution
TOTAL %	72%	13%	15%	

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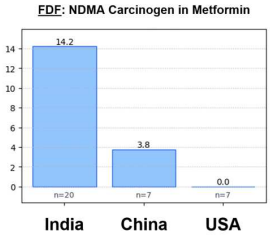
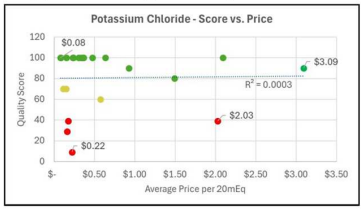
Manufacturing Location Correlates with Quality

To investigate any relationship between manufacturing location and quality metrics, researchers at Ohio State University have been collaborating with this project and merging the chemical quality data with their own data on manufacturing location. Key initial results from a detailed analysis on metformin data are summarized below:



No Correlation between Price & Quality

A comparison of Valisure's actual purchase price to the quality risk score for potassium chloride drugs was conducted and results shown below. In summary, there was no correlation between price and the quality risk scores – high quality drugs are available at low prices. This conclusion mirrors the results from 3 recent, peer-reviewed studies on the analysis of metformin, methylphenidate, and angiotensin receptor blockers, linked below.



Journal of the American Heart Association (2022): Price and Quality in the Generic Pharmaceutical Market

American Journal of Managed Care (2024): Safety vs Price in the Generic Drug Market: Metformin

Journal of the American Academy of Child & Adolescent Psychiatry (2025): The Price and Quality of Methylphenidate Products

Potential Utility Example

Based on the Military's 30mg lisinopril formulary, below is a model for potentially reforming purchasing of essential medicines according to "best value" practices instead of the current status quo of "lowest cost technically acceptable."

	Status Quo		"Best Value" Contracting				
Supplier	FDA-Approved	Price[c]	Quality Score →	Manufacturer Location[a] →	Independent Certification[b] →	Final Score	Price[c]
Labeler 1	Yes	$6.57	100	USA	Yes (+10)	110	$6.57
Labeler 2	Yes	$6.24	100	USA	No	100	$6.24
Labeler 3	Yes	$6.90	100	India (-30)	No	70	$6.90
Labeler 4	Yes	$6.37	100	India (-30)	No	70	$6.37
Labeler 5	Yes	$6.77	90	China (-61)	No	29	$6.77
Labeler 6	Yes	$19.71	39	Taiwan	No	39	$19.71
Labeler 7	Yes	$6.04	39	China (-61)	No	-22	$6.04
Labeler 8	Yes	$7.10	39	China (-61)	No	-22	$7.10

Example Based on Current Data and DoD formulary for 30mg lisinopril

← **Best value:** save money, improve quality, buy American

← Potentially most purchased currently

← Cheapest

[a] *Currently based on manufacturer headquarters location and public records*

[b] *Labeler generally engages in independent certification*

[c] *Pricing model centered on private market average for 100-count bottle*

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Circulation

PERSPECTIVE

Price and Quality in the Generic Pharmaceutical Market

Ben Teasdale, MPhil; David Light, BS; Kevin A. Schulman, MD

Branded medications dominated the prescription market in the 1980s, constituting 81% of fills in the United States. A majority lacked generic equivalents even after patent expiry. In 1984, the Hatch–Waxman Act eased the regulatory burdens of generic approval, radically changing the prescription landscape. Today, generic prescriptions account for 90% of new prescriptions and have saved patients an estimated $1.5 trillion.[1]

Although a significant economic advantage for consumers, generic medications are only a benefit to the extent that they provide the same quality product for patients as their branded counterparts. Currently, the market relies on Food and Drug Administration (FDA) review and inspections of manufacturers' quality management processes to assure drug quality. This approach has become increasingly strained during this period of rapid expansion of the generic market.

Concern about the quality of generics is a well-documented issue for cardiology. The sale of adulterated heparin in 2008 resulted in 149 deaths and many more severe adverse reactions, leading to large-scale recalls by Baxter. In 2010, the FDA determined that the majority of the 4 million nitroglycerin prescriptions dispensed the year before had not been approved for sale in the United States.

Recently, generic angiotensin II receptor blockers (ARBs) were found to contain carcinogenic N-nitrosamine impurities, which, beginning in 2018, led to a series of recalls of manufacturing lots of valsartan, losartan, and irbesartan. Unfortunately, concerns about manufacturing quality persist worldwide given the globalization of the supply chain. Health Canada led a new round of recalls in 2021 over elevated levels of mutagenic azido impurities in ARBs, and there were similar recalls in the United Kingdom and Europe.

The FDA estimated that 8000 people would have to be consistently exposed to the highest dose of contaminated valsartan for 4 years before any 1 person developed new cancer. The European Medicines Agency, taking a more conservative approach, estimated the ratio to be closer to 1 in 3000.[2] Since 2018, the FDA has reported recall of at least 12 million bottles of ARBs. Assuming each of these bottles was contaminated, this supply could have caused 31 to 83 cancers.

The cases of heparin, nitroglycerin, and ARBs represent the most publicized cases of quality control issues in the generic drug market. Fortunately, there is no indication that these events signal widespread concerns of substandard quality. Carcinogenic risk appears low relative to the known mortality benefits of these medications; however, these quality issues are preventable, and the truth is that we do not know how representative they are.

The generic medication market evolved to deliver low-cost products as its major focus. Despite the maturity of organizations within the supply chain, the issue of quality in the United States has been sidelined, delegated to the FDA alone, who focus their oversight on manufacturers. Beyond the manufacturer level, the distributors, wholesalers, retailers, and pharmacy benefit managers who profit off the sale of pharmaceuticals lack any corresponding accountability for the quality of the products they sell.

Manufacturers of generic drugs must demonstrate to the FDA that their products are bioequivalent to

Key Words: Food and Drug Administration ■ generic drugs ■ pharmaceutical industry ■ pharmaceutical economics ■ quality of health care

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For Sources of Funding and Disclosures, see page 1186.

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the brand medication, that they meet certain labeling requirements, and that the manufacturers have certain manufacturing capabilities and quality processes. Once multiple generic manufacturers gain FDA approval, variation in medication quality becomes invisible to purchasers throughout the supply chain, and manufacturers compete to gain market share solely by offering lower prices. Manufacturers thus respond to a market where price, not quality, is the only observable characteristic of a product. The FDA has shared this perspective, testifying in 2019 on the maturity of quality management systems, "The market currently has no visibility into manufacturing facilities' quality."[3]

One of the factors straining the ability of the FDA to keep up with quality oversight of generic products has been the rapid globalization of the supply chain during the last 2 decades. By 2020, 74% of establishments manufacturing active ingredients were located oversees.[4] The FDA, a US government agency, must now oversee a global market where it does not have direct jurisdiction. This results in bureaucratic barriers to performing effective site visits. For example, inspection of foreign facilities requires visa applications and prior announcements of inspection dates, allowing these facilities to better prepare for inspections. The FDA relies on self-reported quality data from manufacturers, even in environments where veracity of data has been questioned. Further, the FDA does not perform routine testing at the product level. Although the FDA does investigate products when it has suspicion, there is currently no systematic exploration of product quality that would raise this suspicion.

The role of the FDA has been further complicated by the COVID-19 pandemic. Since March 2020, the FDA has been forced to limit itself to only "mission-critical" inspections of foreign manufacturers, with 3 inspections reported in the last 9 months of 2020.[4] The FDA now faces a backlog of surveillance inspections, and it was projected that 43% of foreign facilities would not have been inspected in 5 years by the end of 2021.

In essence, we have a market focused on price, with quality assurance relegated to the FDA's review of an initial application, manufacturer-provided data, and increasingly difficult site inspections, all in the absence of systematic quality surveillance by the purchasers of medication.

An open question is whether the presence of quality issues is an inherent tradeoff in a market that provides access to low-cost medications. To test this question, we examined the impact of product recalls on price and volume for ARBs (which were impacted by recalls) and angiotensin-converting enzyme (ACE) inhibitors (which were not impacted by recalls) for the period between the first quarter of 2018 through the first quarter of 2021 using prescription data from the Medicaid State Medication Utilization Database.[5] Overall, we found that recalls did not impact unit price or access for ARBs compared with ACE inhibitors, with prices increasing more for ACE inhibitors than ARBs during this period (13% and 7%, respectively). Meanwhile, the rate of use of ARBs increased relative to ACE inhibitors, with fills for ARBs increasing 156% and fills for ACE inhibitors increasing 64%.

Overall, these data suggest that we do not have to sacrifice quality for low costs, because prices did not increase disproportionately after removing poor-quality products from this market. If this is the case, why should we tolerate a generic drug market that looks solely at price and not at quality, given the quality concerns we reviewed in the cardiology market?

It's easy to imagine a market where quality factors into purchasing decisions. Just because the generic market is regulated does not mean that the supply chain should defer all quality assessments to FDA inspections and data reported from manufacturers testing their own product. Quality could also be monitored and assured from periodic testing of products independently sampled at later stages of the medication supply chain. Consumers could be protected by providing a transparent medication quality score that wholesalers, distributors, retailers, and consumers could check when making purchase decisions.

Ultimately, the healthcare system needs a supply chain that is accountable to quality. Our analysis suggests that higher-quality products are already available for the same price, but we lack a reliable mechanism for identifying these products. If we prescribe an ARB to help treat a patient with heart failure, it's not a clinical or economic advantage to use a $0.50 pill of poor quality when a better alternative is already available.

ARTICLE INFORMATION

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Sources of Funding

None.

Disclosures

David Light is Chief Executive Officer, board member, and equity holder in Valisure, a pharmaceutical testing firm. Dr Schulman has received grants from the National Basketball Association, Inc; and personal fees from HealthQuest, Molley Rice, Frazier Healthcare Partners, ISMIE Mutual Insurance Company, and all unrelated to this article. In addition, Dr Schulman is a board member and shareholder for Grid Therapeutics; managing director and shareholder in Faculty Connection, LLC; on the board of advisors for and shareholder in Prealize; a board member and shareholder in Reserve Therapeutics (Pharmaceutical Services Company); passive investor in Altitude Ventures Inc. and Excelerate Health Ventures; senior associate editor for Health Services Research; President of the Business School Alliance for Health Management (uncompensated).

an advisory board member for CivicaRx (uncompensated); and a board member for Catalysis (uncompensated), outside of the submitted work. B. Teasdale reports no conflicts.

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Estimation of Economic and Public Health Burden of Low-Quality Generic Drugs for Chronic Disease and Potential Solutions

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Abstract:

Objective

Conservatively quantify the public health and economic damages of low-quality generic drugs on chronic disease management in the United States based on available studies, and review health system solutions to avoid low-quality and incentivize high-quality generics.

Data Sources

Generic drug quality is an evolving but sparse field of research; therefore, the expertise of 21 experts with experience in the field were relied upon to identify meaningful areas of existing research within chronic disease, where medication issues are expected to be most pronounced due to longevity and persistence of treatment. Four diseases (epilepsy, multiple sclerosis, atherosclerosis, and hypertension) were chosen by the group due to the relative abundance of informative studies and the diversity of the diseases. A chronological review of published health system solutions was also performed.

Data Synthesis / Results

Extrapolating from studies in these four chronic diseases and focusing on the most directly observable 10% low-quality generic drugs, we conservatively estimate the 2024 economic burden of this low-quality subset of generic drugs at $18.4 billion growing to $238 billion over the next 10 years if not addressed, largely due to many thousands of avoidable serious adverse events like disease relapse and hospitalizations. Potential solutions are discussed that may enable a market correction to avoid the low-quality generic drugs and incentivize continuous product improvement.

Conclusion and Relevance

This novel review represents the first broad population analysis of the substantial economic and public health impact from low-quality generic drugs and synthesizes modern approaches to addressing this largely underappreciated issue. Real-world approaches are reviewed where pharmacy practice can be modified to help ensure only the highest-quality generics are dispensed to patients to improve outcomes and reduce waste.

Introduction:

Generic drugs are a critical component of healthcare delivery in the U.S., saving billions of dollars for the American public by offering lower-cost alternatives to innovator drug products [1]. Generic drugs are FDA-approved through an abbreviated new drug application, where the FDA reviews data provided by manufacturers to demonstrate bioequivalence. The FDA does not routinely test the actual generic drug products before approval or once they are on the market [2]. Over the last several years, there has been growing concern surrounding the chemical quality of a subset of these generic drugs and

the possibility of "low-quality generics" being less effective for, and potentially harmful to, patients [3] [4] [5] [6].

Since the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, which created the generic drug industry, generic drugs grew from roughly 14% of all U.S. prescriptions to currently over 90%, [7] drug shortages in the U.S. have increased substantially over the last decade, with manufacturer quality problems being a major driver, [8] and roughly three drug recalls per day occur in the U.S., often related to carcinogenic impurities [9] or metrics of effectiveness [10].

While always a global industry, the manufacturing of these critical products and their ingredients has largely moved overseas, primarily to India and China [11] [12]. Since 2009, the Government Accountability Office has considered the FDA's oversight of medical products as "high risk" [13] with increased concern due to COVID-19 complications [14] and continued challenges [15], especially with foreign inspections [16], even years after the pandemic [17]. Furthermore, new research has shown that such foreign manufactured generic drugs appear to be associated with significantly more serious adverse events compared to domestically manufactured versions of the same drug [18]. Together, the global nature of the generic drug supply chain and the concerns over poor product and supply chain quality are increasingly being considered serious concerns to both public health and national security [19] [20] [21].

Many misconceptions exist about the regulation of drugs in the U.S. which may have historically led to an underappreciation of the scope and impact of low-quality generic products [22]. Physicians' misconceptions were illustrated in a national survey where 78% of respondents identified the role of the FDA was to "Remove a drug from market if unexpected risks are detected," [23] a function that the FDA lacks due to not possessing mandatory recall power over drug products (FDA can only recommend voluntary product recalls [24]). In the same survey, 40% of physician respondents believed "testing drugs" constituted a substantive function of the FDA. However, since the 1960s, the FDA largely abandoned analytical testing of drugs in favor of a facility inspection program to review manufacturer compliance with Good Manufacturing Practices (GMP) and relying on the manufacturers' self-reporting of their own analytical tests [25]. Currently, the FDA tests only a few dozen on-market drug products per year when they are flagged for specific cause [26]. Even when products were tested due to quality concerns, the FDA failed to identify some of the most significant chemical drug quality problems in recent years, including with ranitidine (Zantac), metformin, valsartan and losartan. It was only through independent testing by third parties that product contamination with potent carcinogens were identified leading to recalls and market withdrawals [25].

Generic drug quality problems are perpetuated and exacerbated by the structure of the supply chain serving the generic drug market that purchases only the lowest price products, with all product quality assumed to be equal given FDA oversight and review [27] [28]. In 2012, a senior FDA official co-authored a paper on drug shortages which concluded

"The fundamental problem we identify is the inability of the market to observe and reward quality [29]." Following the COVID-19 pandemic, the U.S. Administration for Strategic Preparedness and Response (ASPR) recommended in a 2022 report that the U.S. government should leverage its collective buying power to reform procurement protocols and revise purchasing models to increase emphasis on product quality and supply chain resilience, not simply lowest cost [30]. In a recent Senate Finance Committee hearing on drug shortages, Senator Mike Crapo summarized the expert witness testimonies by stating "Every one of you has made the point that one of the big problems here is that we don't compensate for quality, we compensate for price of product only" [31].

One issue omitted from this discussion, and from previous analyses of multi-billion-dollar failures in care delivery [32], is the clinical and economic harm from poor quality generic drugs. Given the lack of systematic assessment of product quality, it is difficult to quantify the downstream impact of low-quality products. However, recent research has begun to shed light on this issue. We review four case studies of the economic impact of low-quality generic drugs. Based on these studies, we begin to extrapolate the economic impact of low-quality generic drugs on the US healthcare system and their potential harm to patients.

Evidence Review:

We identified four disease categories that had extant literature on generic drug quality: epilepsy, multiple sclerosis (MS), atherosclerotic cardiovascular disease (ASCVD), and hypertension. For each of these conditions, we reviewed the available literature related to the economics of generic drug quality in the context of potential harm to public health.

For all these studies, the prevalence of poor-quality generic drugs in the market is unknown. However, reports exist in press and academic literature roughly estimating the prevalence of clearly identifiable, low-quality generic drugs at 10% [25] [33]. The Department of Defense has initiated a research program where all available generic drug products were procured, tested and quality risk scored. The results for the first thirteen essential medicines published in the New England Journal of Medicine found 15.4% of the 228 evaluated drug products received the lowest quality rating of a "red" [34]. For our analyses here, we make the conservative assumption of the lesser of the observed values of 10% objectively low-quality generics that can be focused on for our study. We also assume no disproportionately higher impact of the lowest quality 10% of generics for the overall additional burden from generics use and further assume that only this bottom 10% are most immediately addressable by corrective measures.

For epilepsy, there exists a particularly large body of epidemiological evidence supporting substantial economic and patient harm from low-quality generic drugs. Retrospective population studies have been conducted broadly on generic drug use in epilepsy [35] along with the use of specific generic drugs [36], on switching between brand to generics [37],

the switching between generic-to-generic manufacturer of the same drugs [38], and batch-to-batch variability in the same generic [39]. We were unable to identify any published studies on the chemical testing of different anti-epileptic drugs.

To enable an estimation on public health impact, the following approximate U.S. statistics were incorporated into the calculations outlined in Table 1: existence of 3,356,000 epileptic patients [40], 90% of which use medications [41] and 86% of which are generics [42]. Combined with the estimated rate of most identifiable, low-quality generics being 10% and a total additional cost burden for patients taking generics of $3,254 [37], the estimated annual economic burden of these 10% low-quality generics is $845 million, which is approximately 3.02% of the total economic burden of epilepsy [43]. Applying these assumptions to observed higher rates of healthcare utilization in generic epilepsy medication users versus brand users [35], the 10% low-quality generics lead to approximately 20,780 avoidable hospitalizations for epilepsy patients.

For MS, clear evidence exists demonstrating direct harm to a handful of individuals from their generic disease modifying therapies that were chemically tested to reveal evidence of low-quality in the form of subpotent dosage. Two studies by Okuda et al. examined patients who were switched as a result of directed treatment transitions by third-party administrators from brand to generic versions of either fingolimod or teriflunomide. The individuals described in these reports experienced incontrovertible evidence of a relapse of their otherwise well-controlled MS, and a high number of randomly selected samples of their generic medications were tested revealing dosage levels below the minimum regulatory standard of 90% content of the labelled ingredient in the majority of samples [44] [45]. Of the eight generic MS medications from eight different manufacturers tested across the two studies, three contained dosage levels below 90% and one was at risk of failure with an average dosage of 91% (standard deviation of 3%). Exposure to subpotent fingolimod was also associated with higher absolute lymphocyte counts, suggesting clear differences in the biological effect of the generic version. Furthermore, the resultant variable release of immune cells from lymphatic tissue may have placed patients with MS at greater risk for a relapse. Although these results suggest an approximate 38 – 50% prevalence of particularly low-quality generics in MS treatment, larger studies are needed to better understand a more exact estimate.

Relapse rates for MS can be difficult to quantify as the reporting of such events vary [46] and published studies reveal a broad range of annualized relapse rates with values of 5% [47] to 35-36% in individual studies [48] [49]. Conservatively assuming that 10% of generic disease modifying therapies for MS are of identifiably low quality, and approximately 44% of those induce a relapse due to subpotent dosage, then in combination with an approximate of 69% of MS patients using medications [50], and 90% of which are generic [7], the estimated relapse rate would be roughly 2.73%, or about 24,972 avoidable MS relapses annually. When further considering U.S. statistic on MS of 913,925 patients [51] and an average healthcare cost of an MS relapse to be $23,970 [52], then the estimated

conservative annual economic burden of these low-quality generics is $599 million, which is approximately 0.70% of the total economic burden of MS [53].

For ASCVD, there exists study of not only additional economic burden and poorer clinical outcomes with generic drug use versus brand, but furthermore different prevalence of these factors is observed for different generic manufacturers. A study by Liang et. al. investigates brand Lipitor versus generic atorvastatin use, the most prescribed statin and treatment for ASCVD, and finds that generics use is associated with higher healthcare costs and poorer clinical outcomes, specifically a significantly smaller reduction in LDL-cholesterol levels compared to brand-name drugs. These associations are more severe for standard generic manufacturers than for authorized generic manufacturers, which are licensed to replicate the proprietary formulation of the brand version [54]. Leveraging Liang et. al. study's conclusion of approximately $429 higher medical service costs for generic atorvastatin users and the U.S. statistics of 18,700,000 ASCVD patients, 47.8% taking the common statins of atorvastatin or rosuvastatin [55], 95% of which are generic (data from atorvastatin and assumed consistent for rosuvastatin) [54] together with assuming 10% identifiable, low-quality generics prevalence, then the estimated annual economic burden of these low-quality generics for treating ASCVD is $364 million or approximately 0.18% of the total economic burden of ASCVD in 2023 [56]. From a public health perspective, these 10% low-quality generics lead to approximately 200,403 avoidable outpatient visits for ASCVD patients.

For hypertension, striking examples exist of unambiguously low-quality generic versions of key medicines with the discovery of carcinogenic contaminants traced to manufacturing practices [57]. The FDA has estimated that the contamination in the angiotensin receptor blocker (ARB) valsartan may lead to one additional cancer case in 8000 exposed patients [58], and there is some epidemiological evidence of increased hepatic cancer risk from contaminated valsartan [59]. This serves as evidence of clear differences in manufacturing quality of generic drug products but is not quantified in our analysis of reduced clinical effectiveness of disease treatment and related adverse events. In hypertension drugs, there is evidence in other Western nations of higher rates of adverse events after multiple anti-hypertensive drugs went generic [60] [61], and higher rates of hospitalizations with the use of generic valsartan versus the brand [62]; however, no economic burden analyses are known to have been conducted nor direct testing of generic drugs for properties known to impact effectiveness.

Of use here are numerous studies in hypertension that have established a strong correlation of blood pressure to serious adverse events like stroke, cardiovascular disease, and heart attacks [63] [64], and furthermore the detrimental effect of high variability in blood pressure on these same outcomes [65]. There is clear evidence of variations in the manufacturing quality of hypertension medications. If the assumption is made that of the 10% of these generics that are identifiably the lowest quality have a similar rate as with MS (44%) of leading to the adverse clinical outcome of high variability in blood pressure which is correlated to a 0.500% higher rate of coronary heart disease,

0.046% higher rate of stroke and 0.056% higher rate of heart attack, then in combination with the U.S. statistics of a cost burden of $13,000, $35,000 [66] and $18,300 [67] per condition respectively, 119,900,000 hypertensive patients, 79% of which taking medications [68] that are 90% generic [7], the estimated annual economic burden of the 10% low-quality generics for treating hypertension is $344 million or approximately 0.16% of the total economic burden of hypertension in 2019 [68]. This is a similar value to that calculated for ASCVD where an estimate of total economic burden of generics was available. From an adverse event perspective, these calculations suggest that the 10% low-quality generics for the treatment of hypertension contribute to 2,111 heart attacks, 1,736 strokes, and 18,790 cases of coronary heart disease, all of which could be avoidable if these were replaced with high-quality generics.

National Impact:

To estimate the overall national burden of the estimated 10% low-quality generics that are most readily identifiable and potentially avoidable, a weighted average of the calculated effects across the four chronic diseases was used to produce an estimation on the impact broadly on chronic disease. This weighted average of 0.40% is applied to the estimated 2024 economic burden of total chronic disease in the U.S. of $4.54 trillion [69] [70], resulting in an estimate for the annual economic burden of these low-quality generics on chronic disease in the U.S. of approximately $18.4 billion. Assuming a 5.6% growth rate of healthcare costs [71] and a stable percentage of it being attributable to chronic disease, the cost of the roughly 10% lowest quality generic drugs in the U.S. over 10 years is approximately $238 billion. A summary of these calculations is provided in Table 1.

Poor quality generic drugs can have significant economic impact if they fail to provide the full therapeutic benefit of the product. This failure can have significant economic impact where treatment prevents hospitalizations or other clinical events. In a market where 90% of the products are generic products, a full economic analysis of the downstream impact of poor-quality products is difficult to estimate. Our analyses here, derived from specific studies across 4 disease classes, are likely conservative estimates of this clinical and economic impact.

Discussion:

There is increasingly clear evidence that serious problems exist in the pharmaceutical supply chain that harm public health. The evidence reviewed suggests avoiding the use of approximately 10% of generic drugs that are identifiably low-quality could lead to over $18 billion in annual savings and substantial improvement in public health and patient outcomes. However, it is also important to acknowledge that not all generics are poor-quality, nor should generics be abandoned in favor of branded medications. Instead, the intention is that by approximating the economic and public health costs of this subset of

low-quality drug products, the impetus to invest in solutions will accelerate and will ultimately bolster trust in generics overall, which appears to be eroding particularly with younger patients [72].

Addressing these quality issues can help create a market that rewards objectively higher-quality products and establishes an industry driven by continuous product improvement as opposed to manufacturing products just good enough to meet minimum standards, a particularly pervasive problem in drug manufacturing and regulated industries. Indeed, studies which have evaluated implementation of continuous improvement practices in manufacturing of medical devices [73] and pharmaceuticals [74] have concluded "continuous improvement can be problematic in the context of regulatory processes" and "a regulated environment can be a further barrier to CI [continuous improvement] deployment in an organization," respectively. Implementation of continuous improvement incentivized by health system purchasers recognizing and valuing quality could result in a generic drug industry that not only closes any gap between generic and brand quality, but could exceed it. In an evaluation of dimethylformamide carcinogen levels in valsartan drug products, the average of the generics showed a substantially higher level than the brand; however, of the seven companies tested, the consistently cleanest was a generic manufacturer, not the brand [75] [76]. Objective improvement in generic drug quality could eventually address not only the quality differences but also overcome any public negative perception or nocebo effect that may contribute to reduced outcomes [77].

This continuous improvement approach mirrors that taken by the Environmental Protection Agency (EPA) regarding toxins like the carcinogen benzene, which is a dangerous contaminant in the environment and has also been discovered at unacceptably high levels in a variety of drug products [78] [79]. The EPA, like the FDA, sets regulatory limits on benzene (e.g. 5 ppb in drinking water); however, uniquely, "EPA has set a goal of 0 ppb for benzene in drinking water … because benzene can cause leukemia" [80], a practice that can motivate industries to not only meet a regulatory requirement, but also strive to continuously reduce such a toxin for which epidemiological studies have concluded that "there is probably no safe level of exposure" [81]. Such a regulatory approach could bolster the effectiveness of solutions currently being attempted at a number of large health systems.

Health System Solutions:

Even without damages from low-quality generics well quantified, the clear problems with some generic manufacturers have led to increasing engagement to find solutions. Shortly after the passage of the Food and Drug Administration Safety and Innovation Act in 2012, the FDA started suggesting that quality metrics should be established to evaluate the suitability of drug manufacturers [82]. However, despite the efforts of multiple industry associations and FDA operated pilots [83] and workshops [84] for creating a 5-star Quality Management Maturity (QMM) rating system, neither a finalized scoring framework nor its

use in the supply chain has been achieved. In fact, shortly after the FDA announced pilots and workshops to accelerate progress on QMM development, many industry groups strongly opposed the QMM system and claimed manufacturers would likely not participate in the voluntary program [85] [86].

In theory, there are four primary definitions of "quality" that could be differentiated for drug products and their manufacturers: product (defined by its chemical attributes), resilience (defined by operational metrics), regulatory (defined by compliance information), and location (defined by the country where a product is manufactured). Table 2 evaluates the relative accessibility of the data and complexity of metrics inherent to these quality definitions. This comparison may help explain why QMM and other such systems which rely heavily on resilience and regulatory quality definitions that are often proprietary and hard to define, have been historically challenging to develop or implement; and why some health systems have recently chosen to rely on product quality to successfully establish solutions that are being actively utilized.

The first published example of a health system solution came from the Cleveland Clinic which maintains a "black list" of generic drug manufacturers that it does not buy from due to complaints by doctors that observed issues in their patients [87]. This approach is limited by the collection of anecdotal evidence from individual practitioners and its application may be too broad as it applies to all products from a manufacturer that may have multiple facilities and products with varying levels of quality; however, it was able to be implemented at the scale of a health system that services approximately 3 million individuals [88], enabling it to ostensibly avoid lower quality generics and preferentially purchase higher quality versions.

In recent years, large health systems have developed more sophisticated solutions that involve independently testing the chemical quality of generic drugs. University of Kentucky (UK) HealthCare, which provides 1.4 million outpatient visits annually [89], announced a drug testing program operated by their College of Pharmacy "to test UK HealthCare's incoming drugs for identity and quality in order to improve patient outcomes and to report adulterated drugs to the FDA [90]." This UK Healthcare process provides drug product specific data that is regularly updated by independent researchers; however, while both the Cleveland Clinic and UK HealthCare models potentially improve care for their own patients, they are challenging to scale to other systems – the former due to requiring high engagement from practitioners and the latter requiring the existence of, and high engagement from, internal analytical facilities.

Two of the largest health systems in the U.S. have started operating solutions involving independent chemical testing of generic drug products that have scalable application broadly in the national supply chain. In line with ASPR's recommendation to "reform procurement protocols" to increase emphasis on quality and not simply lowest cost [30], Kaiser Permanente, with 12.5 million individual members [91], has been employing a contracting program for certain generic drugs where manufacturers already selected for

being high quality are required as part of their supply contract to submit samples from each batch for independent testing and certification by an independent laboratory [92]. In addition to protecting its patients, Kaiser has effectively introduced into the marketplace a new contracting element that could be leveraged by any contracting entity or health system, as referenced by ASPR for government health systems like those of the Department of Defense (DoD) or Veterans Administration. Health system use of such quality requirements may also lead to voluntary adoption of independent certification programs by manufacturers [93] [94]. The visibility of such independent certifications may also lead to increased confidence in adopting and adhering to medications, especially new therapies like the COVID-19 vaccine that was independently tested in England through the European Union's network of independent laboratories [95]. Researchers found that "Trust in the vaccines ... are supported through testing which is independent of the manufacturers." [96]

The DoD is also piloting a nationally scalable model for independently testing and differentiating the quality of drug products for the benefit of the Military Health System, which serves approximately 9.5 million members [97] and is often viewed as a model to the nation in terms of representative population and geographic variation [98]. In a multi-year study, the DoD is systematically evaluating each available manufacturer for each of 42 essential medicines [99] and through a series of objective chemical tests evaluated by an Expert Review Panel and scored through the Panel's published scoring framework [100] [101], assigning a red, yellow, or green quality risk score to all applicable National Drug Codes (NDCs) [102] [103]. Although not as direct and batch-level as the Kaiser program, the data from the DoD model applies broadly to most, if not all, manufacturers' products for the evaluated drug molecules and offers a simple and actionable process for utilization: strive to procure, or contract for, "green" rated drug products while avoiding "red" rated products. The fact that such quality risk scores are attached to NDCs enables any health system, group purchasing organization, distributor, pharmacy, insurance provider, or benefits manager to utilize the data since all purchasers and payors of drugs in the U.S. use these NDCs [104]. Currently, data from the DoD drug quality risk scoring project is being used by pharmacy procurement professionals to optimize quality drug sourcing at major health systems.

If we accept that drug quality issues exist and that actionable transparency to independent quality metrics is a valuable solution, concerns have been raised that implementation of such solutions, including the proposal of FDA's QMM, could give rise to drug shortages [105]. Indeed, the U.S. Pharmacopeia (USP), a private organization whose manufacturer-developed and registered testing methods are enforced by FDA law [106], stated that independent testing, like that which identified carcinogenic contamination in Zantac(ranitidine) drug products, "can cause harm and may even be life threatening" in addition to "leading to drug shortages [107]." This argument is countered by the fact that drug quality issues are a leading cause of drug shortages; and the example is ironic since the initial independent testing conclusion of ranitidine being unstable and forming carcinogens [108] was validated by the original manufacturer [109] [110] and the FDA

withdrew ranitidine from the U.S. market due to its instability and potential to be life threatening [111]; however, this theoretical matter has been reviewed with real-world data. The rolling national recalls of angiotensin receptor blockers (ARBs) valsartan, losartan, and irbesartan were evaluated for any impact on volume and price of these drugs in comparison to the similar therapeutic class of drug, the Angiotensin-Converting Enzyme (ACE) inhibitors. An evaluation of Medicaid data for the period during the recalls and a few years after "found that recalls did not impact unit price or access for ARBs compared with ACE inhibitors [112]." Although already partially addressed, this conclusion touches on another theoretical concern with an increased focus on quality transparency: price increase.

Although a real-world scenario where a subset of objectively low-quality, contaminated drug products was removed from the market in favor of leaving higher-quality, uncontaminated drug products did not result in increased prices beyond expected market inflation; it may still be of concern that improving quality of generic drugs may increase their purchase price. The relationship of price versus quality was further examined in the drug metformin, a frontline medication for the treatment of type II diabetes [113] and the second most prescribed drug in the U.S. in 2022 [114], which experienced numerous recalls due to carcinogenic contamination [115] after the unacceptably high presence of a carcinogen was identified by independent testing [116]. Dozens of bottles of metformin were acquired both by a university health system and an independent laboratory, and tested for the presence of carcinogens and the mapping of price versus carcinogen levels had no significant correlation [117]. This implies that high quality generic drugs are available at low prices in the current market and that adjusting the market to favor quality suppliers should not increase price. Recent research has also found that health system buyers would voluntarily pay incrementally more for higher quality drugs, if quality ratings were available [118] [119].

Additionally, the relative cost in healthcare of generic drugs is generally very low, and any additional costs for independent quality assurance are also reportedly low. For example, the total cost of an average prescription of metformin in 2022 is $70.33 [120], whereas most drug suppliers sell 90 tablets of metformin for less than $5.00, with many lower than $2.00 [117], and the cost of independently testing and certifying such medications for health systems is reported as 1 - 3% of the drug cost (approximately $0.02 - $0.15 for a metformin prescription) [103]. Restated in relative terms, this implies that for the average prescription of metformin, the acquisition cost of the generic drug itself is roughly 5% of the cost to a health system and requiring independent, batch-level testing would potentially add 0.1%.

Limitations

This study focuses on select therapeutic categories and key studies within them that enable the novel exercise of broadly quantifying the most direct harm from the most

identifiable low-quality generics. This approach is limited as it only provides insight on chronic disease and does not account for potential harm beyond complications with the disease being managed (e.g., cancer caused by carcinogenic contamination of a medicine). Given recent findings that "chronic disease is an overlooked risk factor for cancer, as important as five major lifestyle factors combined," [121] the chronic disease population might have elevated susceptibility to developing cancer from carcinogenic contaminants than the average population, among potentially other increased vulnerabilities. Further analysis is warranted to evaluate acute care medications and any damage separate from the treated disease. These assumptions permeate through the disease categories and may lead to substantial underestimation in our analysis of economic burden for the most identifiable, low-quality generic drugs. This study also does not consider the potential implications of counterfeit medications, a separate issue to authentic low-quality generics discussed here, and a problem that appears to primarily affect online pharmacies operating illegally [122].

Another limitation of this study is that it only evaluates research where the null hypothesis of all medications are made with equal quality, is false. There exist many statements [123], FDA-animated cartoons [124], and studies [125] [126] [127] that present the view that generics are of equally high quality to each other and to the brand product. Studies that support this null hypothesis are generally well-received by academia, industry, and regulators, whereas studies that identify problems in medication quality are often met with academic [128] [129] and industry criticisms [107] [130], regulatory actions [131] [132], and legal actions [133] – a common occurrence when financially adverse findings are identified in a large industry [134]. Given such potentially strong biases to avoid research identifying drug quality problems, it would not appear reasonable to compare the body of research of true versus false null hypotheses. Furthermore, the highly fragmented nature of the American drug supply where many different manufacturers of variable quality are regularly switched at pharmacies can make it particularly challenging to detect the presence of low-quality generics or directly correlate specific low-quality findings to a particular clinical harm [135].

Conclusion

The presence of some objectively low-quality generic drugs in the U.S. is a substantial blind spot for healthcare that could be costing many billions of dollars per year in preventable healthcare costs and causing severe adverse effects, especially in the treatment of chronic disease. Meaningfully addressing this issue, as is currently being started at leading public and private health systems, is expected to add de minimis cost for a likely major benefit of protecting patients, reducing healthcare costs, and improving incentives for quality and domestic manufacturing.

Patient Population				Estimation of Generic Drug Impact			Quantitation of Low-Quality Generics Cost				% of Total Disease Burden	
Epilepsy Patients in U.S.	% of Patients Taking Medications	% Generic	Observed Rate of Low-Quality Generics	Calculated through epidemiology research -->			**Increase total cost for generic users compared to brand**	Additional Economic Burden caused by generic use	Value of 10% improvement in generic drugs being closer to brand		Total Economic Burden of Epilepsy	% of cost due to low-quality generics
3,356,000	90%	86%	10%				**$3,254**	$ 8,452,408,176	$ 845,240,818		$ 28,000,000,000	3.02%
ASCVD Patients in U.S.	% on statins	% Generic	Observed Rate of Low-Quality Generics	Calculated through epidemiology research -->			**Increase total cost for generic users compared to brand**	Additional Economic Burden caused by generic use	Value of 10% improvement in generic drugs being closer to brand		Total Economic Burden of ASCVD	% of cost due to low-quality generics
18,700,000	47.8%	95%	10%				**$429**	$ 3,642,926,430	$ 364,292,643		$ 199,200,000,000	0.18%
Multiple Sclerosis Patients in U.S.	% of Patients Taking Medications	% Generic	Observed Rate of Low-Quality Generics	**Estimated rate of relapse from low-quality generics**	Estimate relapses from low-quality generics (%)	Adverse Outcome	Estimate relapses from low-quality generics (#)	Cost of MS relapse	Annual cost of 10% low-quality generics		Total Economic Burden of MS	% of cost due to low-quality generics
913,925	69%	90%	10%	**44%**	2.73%	MS Relapse	24,972	$ 23,970	$ 598,580,918		$ 85,400,000,000	0.70%
Hypertension Patients in U.S.	% of Patients Taking Medications	% Generic	Observed Rate of Low-Quality Generics	Estimated rate of higher blood pressure variability from low-quality generics	**Additional Adverse Event Rate due to High Variability**	Adverse Outcome	Estimated adverse outcomes from low-quality generics	Cost of adverse outcome	Annual cost of 10% low-quality generics		Total Economic Burden of Hypertension	% of cost due to low-quality generics
119,900,000	79%	90%	10%	44%	**0.5000%**	Cardiovascular Disease	18,790	$ 13,000	$ 244,272,600			
					0.0462%	Stroke	1,736	$ 35,000	$ 60,767,507			
					0.0562%	Heart Attack	2,111	$ 18,300	$ 38,622,429			
								Total:	$ 343,662,536		$ 219,000,000,000	0.16%
Total Chronic Disease									**Annual cost of 10% identifiably low-quality generics**	**$18,360,534,398**	Total Economic Burden of Chronic Disease (2024 est)	Chronic Disease Weighted Average
											$4,536,000,000,000	0.40%

Table 1: The various cited disease statistics and outcomes calculations discussed in this analysis are collected in this table by disease and for total chronic disease. The key cited academic research primarily driving the overall model is highlighted in bold, as is the result of the cost burden estimation of low-quality generics on total chronic disease. [Image file shown here. A spreadsheet version available upon request.]

Table 2: An overview of the four primary definitions of "quality" that could be differentiated for drug products and their manufacturers. The relative difficulty of creating metrics and accessing data for such definitions is ranked "red" for highest difficulty, "yellow" for medium difficulty, and "green" for lowest difficulty.

	Product	**Resilience**	**Regulatory**	**Location**
Examples of metrics	Heavy metals content, levels of carcinogens, dosage, dissolution rate difference percentage from brand	Additional inventory, multiple sources of critical inputs (e.g. API), level of quality management maturity (QMM)	Warning letter count and severity, import alerts, recalls	On-shore, near-shore, TAA-compliant
Metrics Complexity	Scientific and unambiguous (e.g. high toxin is bad; undetected toxin is good)	Stakeholder alignment difficult on metrics and meaning	Scientific but ambiguous as to its meaning (e.g. what constitutes a "severe" letter?)	Simple and unambiguous (e.g. U.S. site is good; non-TAA compliant site is bad)
Accessibility of Data	Available in public domain with acquisition of proper licenses	Largely proprietary and reliant on manufacturer voluntary engagement	Partial public domain, FOIA often required but can be redacted, difficult to link facility to drug products	Partial public domain, particularly problematic for API, raw materials
Relative Value	Highest overall value. Direct correlation to recalls, shortages, health outcomes	High value for preventing drug shortages	High value to industry, and likely correlated to shortages	High value to government, and to domestic pharmaceutical manufacturing

Disclosures:
Funding: This work was supported by the United States Department of Defense (DoD), Defense Health Agency under grant number HU00012420017. The sponsor had no role in the study design, collection, analysis, and interpretation of data, the writing of the report, nor in the decision to submit the article for publication.

Victor Suarez declares advisory board memberships at ScienceWerx, BioBuzz, and US Biologic. Principal at Blu Zone Bioscience Supply Chain Solutions, LLC, a consulting firm assisting biotechnology and life science supply chain organizations. Participation in the DoD grant.

David Light and Adam Clark-Joseph declare employment and stock ownership in Valisure, an independent testing laboratory. Participation in the DoD grant.

Kevin Schulman declares grant from Stanford Clinical Excellence Research Center, expert testimony for Motley Rice, LLC, and advisory board membership for Civica Rx SAB (unpaid).

Darin Okuda declares grants or contracts from Alexion, Biogen, Novartis, and National Multiple Sclerosis Society. Consulting fees from Biogen, Cortechs.AI, EMD Serono, Genentech, Genzyme/Sanofi, Immunic Therapeutics, Moderna, Pfizer, Zenas BioPharma, and expert witness testimony. Royalties for intellectual property licensed by The Board of Regents of The University of Texas System. Advisory board membership at the MS Foundation.

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Memorandum to the United States Senate Regarding Nitrosamine Contamination, Foreign Pharmaceutical Manufacturing, and Protection of American Public Health

Prepared in the style of a public-health and scientific policy memorandum attributed to Professor Suzanne de la Monte, M.D., concerning pharmaceutical contamination risks, regulatory oversight, and patient safety.

To the Honorable Members of the United States Senate:

The pharmaceutical supply chain remains one of the most critical components of public health in the United States. American citizens reasonably expect that medications dispensed through licensed pharmacies have been manufactured, tested, distributed, and regulated under the highest standards of scientific integrity and safety.

Recent recalls involving nitrosamine contamination in cardiovascular and chronic-use medications have raised substantial concerns regarding the adequacy of foreign pharmaceutical manufacturing oversight, contamination monitoring systems, quality-control enforcement, and supply-chain traceability mechanisms.

Nitrosamines are widely recognized in toxicological literature as potentially genotoxic compounds associated with DNA injury, oxidative stress, mitochondrial dysfunction, inflammatory signaling, and carcinogenic potential under certain exposure conditions. While scientific investigation continues regarding the precise long-term effects of chronic nitrosamine exposure, existing evidence demonstrates the necessity for stronger safeguards and more rigorous regulatory oversight.

Many of the affected medications are prescribed daily to medically vulnerable individuals, including elderly Americans, patients with cardiovascular disease, and individuals requiring chronic long-term treatment. Citizens consuming these medications often do so for years while relying entirely upon manufacturers, pharmacies, distributors, and federal regulators to ensure product purity and safety.

Scientific and Public Health Concerns

Scientific literature continues evaluating whether chronic exposure to elevated nitrosamine impurities may contribute to broader systemic disease processes involving oxidative injury, inflammation, immune dysregulation, metabolic dysfunction, and degenerative cellular stress.

Research involving nitrosamine compounds has explored several biological mechanisms including:

- DNA adduct formation and genetic instability.
- Oxidative stress and mitochondrial injury.
- Cellular inflammatory activation.
- Epigenetic alterations affecting immune and metabolic pathways.
- Potential pancreatic beta-cell injury associated with glucose regulation.
- Immune-system dysregulation and autoimmune activation pathways.

Emerging scientific discussion has also considered whether chronic toxic exposures may contribute to autoimmune activation in genetically susceptible individuals. Certain autoimmune markers, including anti-RNP antibodies, are associated in medical literature with Mixed Connective Tissue Disease (MCTD) and related autoimmune overlap syndromes.

Although additional research remains necessary to establish direct causation between specific pharmaceutical exposures and individual disease outcomes, the broader public-health implications of contamination events warrant immediate Congressional attention.

Relevant Federal Laws, Acts, and Regulatory Authorities

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §301 et seq.
Authorizes the FDA to regulate drug safety, adulteration, manufacturing standards, misbranding, recalls, and interstate pharmaceutical distribution.

Drug Supply Chain Security Act (DSCSA)
Enacted under the Drug Quality and Security Act of 2013 to establish pharmaceutical traceability and verification systems designed to protect consumers from unsafe or compromised medications.

Current Good Manufacturing Practice (cGMP) Regulations – 21 CFR Parts 210 and 211
Establishes mandatory standards governing pharmaceutical manufacturing quality, contamination prevention, testing, production controls, and documentation.

FDA Safety and Innovation Act (FDASIA) of 2012
Expanded FDA authority regarding oversight of global pharmaceutical supply chains and inspections of foreign manufacturing facilities.

Public Health Service Act, 42 U.S.C. §201 et seq.
Provides federal authority and responsibility to protect the public from unsafe products, preventable disease risks, and threats to public health.

Consumer Protection and Public Safety Obligations
Manufacturers, distributors, pharmacies, and regulated entities maintain a duty to ensure medications distributed to American citizens are not adulterated, contaminated, or unsafe for intended use.

Policy Recommendations to the United States Senate

The Senate should consider comprehensive reforms designed to strengthen pharmaceutical safety protections for American citizens and reduce dependence upon foreign manufacturing systems with documented quality-control concerns.

Recommended actions include:

• Expansion of FDA funding and staffing for overseas manufacturing inspections.

• Increased frequency of unannounced inspections at foreign pharmaceutical facilities.

• Mandatory real-time contamination reporting requirements for manufacturers.

• National lot-level recall notification systems accessible directly to pharmacies and consumers.

• Strengthened penalties for knowingly distributing adulterated pharmaceutical products.

• Expanded domestic pharmaceutical manufacturing incentives to reduce dependence upon foreign supply chains.

• Increased support for independent toxicology, epidemiology, and long-term public-health research involving nitrosamine exposure.

• Greater transparency regarding FDA warning letters, contamination investigations, recalls, and manufacturing enforcement actions.

Public Trust and National Responsibility

The issue before Congress extends far beyond one manufacturer or one recalled medication. At its core, this matter concerns whether the United States possesses adequate safeguards to protect millions of citizens from preventable contamination failures within an increasingly globalized pharmaceutical supply chain.

Americans should never unknowingly bear the consequences of preventable contamination failures resulting from inadequate manufacturing controls, poor oversight systems, or insufficient regulatory enforcement.

Strengthening pharmaceutical oversight is not anti-industry. It is pro-patient, pro-science, pro-accountability, and fundamentally aligned with the responsibility of government to protect the health, dignity, and longevity of the American people.

The United States Senate possesses both the authority and responsibility to strengthen safeguards ensuring that medications distributed within this country meet the highest standards of purity, transparency, manufacturing integrity, and public accountability.

Respectfully Submitted,

Professor Suzanne de la Monte, M.D.
Public Health and Neuropathology Research Perspective
Brown University (referenced for contextual presentation purposes only)

Prepared for policy discussion concerning pharmaceutical contamination risks, nitrosamine exposure concerns, foreign drug manufacturing oversight, and protection of the health and longevity of American citizens.

Testimony of Dinesh S Thakur
Public Health Activist

Before the
US Senate Special Committee on Aging

Hearing titled
Poisoned Pills: The Human Cost of Dangerous Foreign Drugs

June 3rd, 2026

Chairman Scott, Ranking Member Gillibrand and distinguished members of the Committee, I thank you for convening this hearing on a topic which impacts each and every one of us and for giving me the opportunity to appear before you today. My name is Dinesh Thakur, I am here to offer my testimony on the effectiveness of regulatory structure, its function and its impact on our drug supply and quality.

I am a Chemical Engineer by training. I obtained my Bachelor's degree from Osmania University in India in 1990 and my Master's degree from the University of New Hampshire in 1992. I have graduate training in Computer Engineering from Syracuse University. I was trained in drug development and manufacturing at Bristol-Myers Squibb Company for ten years in the US. In 2003, I had an opportunity to go and work in India at one of the largest generic drug manufacturing companies that sold in the US market. During my tenure at Ranbaxy Laboratories, I discovered that the company was selling adulterated drugs to patients in the United States. I reported this to the US FDA in 2005 and worked closely with them for eight years assisting in their investigation and prosecution of this company. In May 2013, Ranbaxy pled guilty to seven counts of criminal felony and agreed to pay penalties of $500 million to the US DOJ[1]. I was the whistleblower in that case. Since 2013, I have invested much of time in advocating for drug regulatory reform in India; a country from which the United States buys substantial volumes of medicine. Most recently, I co-authored a book, The Truth Pill – The Myth of Drug Regulation in India in 2022[2].

The Committee has heard testimony from prior witnesses[3] about the importance of generic drugs to our country, especially to seniors aged 65 and older who take at least one prescription medication, and more than

[1] https://www.justice.gov/opa/pr/generic-drug-manufacturer-ranbaxy-pleads-guilty-and-agrees-pay-500-million-resolve-false
[2] https://www.amazon.in/TRUTH-PILL-Dinesh-Singh-Thakur/dp/9392099177/ref=sr_1_1?crid=10GD9CZ8HBPPB&keywords=The+Truth+Pill&qid=1706805750&sprefix=the+truth+pill%2Caps%2C228&sr=8-1
[3] https://www.brookings.edu/articles/marta-wosinskas-testimony-before-the-senate-special-committee-on-aging/

half take four or more prescriptions on a regular basis. It is important to reiterate that over 90% of retail or mail pharmacy prescriptions dispensed in the United States are generic drugs.

Recent reporting [4,5,6] in the news documents how little has changed in the manufacturing facilities located overseas in terms of complying with our standards for drug manufacture Code of Federal Regulations CFR 211, commonly known as Good Manufacturing Practices. Inspectors from the US FDA document in their inspection reports, consistent and repeated violations of these standards which I saw during my employment over two decades earlier in India. I have reviewed the recent GAO reports documenting challenges with the Foreign Inspections Program at the US FDA and their recommendations to improve it. While I am sympathetic to the hurdles faced by the US FDA in implementing this program (since inspecting these manufacturing facilities thousands of miles away from the United States in a foreign country and a different culture is very hard); I am also dismayed at how little has changed. Many of the issues raised by the US FDA in recent warning letters to Indian pharmaceutical manufacturing companies are substantially similar to the issues raised in the case against Ranbaxy. Little seems to have changed since I first turned whistleblower 20 years ago and that should worry us.

For example, a Warning Letter issued to the manufacturer of medicine used to treat Cancer[7] based in India in November 2023[8] makes the following observation: "*your firm continued this egregious pattern of altering and recording defect counts*". This is a recurring observation in many of the findings of the US FDA inspectors when inspecting Indian manufacturing facilities. Fifteen years ago, in 2009, the US FDA had made a similar observation in a Warning Letter to Ranbaxy[9]: "*Your investigation into an out-of-specification assay result discarded the initial result…. You replaced the out-of-specification result with (another) result …*". This fraudulent behavior seems to repeat consistently in these foreign manufacturing facilities which supply medicines to patients in the US. Two years ago, we saw the true impact of such violations of our GMP code resulting in real harm to patients with contaminated eye drops[10]. Whatever regulatory actions the US FDA has taken between 2009 and 2024 do not seem to have their intended deterrent effect, thereby subjecting patients in the US to grossly substandard medicines.

[4] https://www.propublica.org/article/fda-generic-drug-equivalents-tacrolimus
[5] https://www.propublica.org/article/fda-generic-drug-testing
[6] https://www.pbs.org/video/generic-drugs-1768158997/
[7] https://www.nbcnews.com/specials/cisplatin-shortage-cancer-drug-chemotherapy-us/index.html
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[10] https://www.bloomberg.com/news/features/2023-07-17/eyedrop-recall-2023-and-infections-were-result-of-lack-of-fda-regulation

The solution, in my opinion, is two-fold. The first is to strengthen the Foreign Inspection Programs on the lines suggested by the GAO in its recent report. The second is to start rethinking the American approach to foreign regulatory inspections. Let me expand on both these suggestions.

1. Strengthening the Foreign Inspection Program

There are two aspects of the Foreign Inspections Program that merit attention by this Committee. Its design and its staffing. In 2022, The Government Accountability Office[11], in its report to the US Congress on FDA's Foreign Inspection Program documented that the US FDA had not finalized the design of a pilot program as of September 2021 despite the US Congress' directive that the agency use $3.5 million of its fiscal 2021 appropriation to establish pilot programs to increase the agency's use of unannounced inspections and short-notice foreign inspections. The agency had suspended a similar program in 2015 in the aftermath of Ranbaxy pleading guilty and entering into a consent decree. This delay is concerning. In fact, in its report to the Congress in January 2025[12], the GAO found that the US FDA has not met its domestic and foreign inspection targets since fiscal year 2018. In July 2025, the US FDA informed the GAO that it was unable to provide an update on the recommendations made by the GAO in 2022 to address staffing at its foreign offices. The agency has not identified an appropriate annual target and communicated this information to Congress, as the GAO recommended in January 2015[13].

As far as challenges to staffing and retention are concerned, in my considered opinion, a model that assigns and stations inspectors to foreign offices is better than the alternative. The Covid pandemic showed us how ineffective the inspections program was when international travel was curtailed. The agency had offices in India as a pilot which were successful in uncovering fraud at manufacturing facilities in India in a substantial manner. As long as our drug supply is dependent on manufacturing facilities abroad, it is imperative that we have a reliable and sustained cadre of investigators who are able to respond quickly to enforcing our regulations and ensure a safe and effective drug supply for patients in the US. Congressional support to alleviate these concerns is sorely needed so that the US FDA can build and retain a trained and qualified investigator cadre in its foreign offices.

[11] https://www.gao.gov/products/gao-22-103611
[12] https://www.gao.gov/assets/gao-25-107571.pdf
[13] https://www.gao.gov/products/gao-15-183

In the absence of a fully staffed and functional inspectorate for conducting foreign inspections, it has been suggested that we can rely on other national regulators[14] (e.g., the MHRA, the EMA) who similarly source a large volumes of medicines for their respective countries and share the burden of inspections and compliance among such a group. While this is a good idea in principle, it does not adequately address the concerns of our drug supply for a variety of reasons. Two such reasons are as follows:

- Of the 60 inspection reports made publicly available by the EMA for Indian manufacturing facilities between 2009 and 2024, only 16 were registered with the US FDA. And none of these inspection reports cite violations for data integrity as has been consistently documented in Form 483 by US inspectors.

- Inspections often are focused on products made for a specific market in addition to reviewing the overall Quality Management Systems. If a particular formulation/strength is not sold in the US market, its manufacturing process is often not the subject of inspection by the US FDA inspectors. Likewise, a formulation/strength sold only in the US may not be the subject of an inspection by a PIC/s partner.

2. Rethinking the American approach towards regulating foreign manufacturing facilities

It has been over two decades since I turned a whistleblower in the Ranbaxy case, at which time it became clear that the US FDA's foreign inspection program had serious shortcomings - the fact that the GAO raised red flags about the program in 2022 and in 2025 is very worrisome. The solutions proposed by the GAO are going to take time to implement and even when implemented fully, there is no real guarantee of outcomes. It is high time to accept the fact that the American regulatory approach, which is largely an honors-based system toward foreign pharmaceutical facilities with very different corporate cultures is fundamentally flawed. In essence we are trying to force a square peg into a round hole. It is time to think out of the box.

With this as a backdrop, I have four recommendations for the Committee to consider:

A. **Criminal prosecution to introduce a deterrent effect:** First, is to investigate the US FDA's prosecution practices when its drug inspectors discover brazen criminality during foreign inspections. In the last two decades, in addition to Ranbaxy, I know of only one Indian pharmaceutical company being fined

[14] https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs4751/files/downloads/WorkingPapers/GW%20Reg%20Studies%20-%20Improving-Cooperation-FDA-EU%20-%20RLutter%20&%20DZorn.pdf

$50 million[15,16] for destroying critical quality related data - such data is at the heart of the GMP model of regulation adopted by the US to monitor quality manufacturing practices in the pharmaceutical industry. The US FDA has documented this behavior in multiple inspection findings (Form 483s and Warning Letters) indicating a frightening amount of data fraud. Destroying such data is the equivalent of a financial services company shredding all its paperwork related to its accounting practices. It always means there is a coverup.

Under Sarbanes-Oxley, the management of such a firm would be criminally prosecuted. There have been multiple such instances[17,18,19] reported in the media of mind-boggling data fraud that cross the threshold of criminality in foreign drug manufacturing facilities. In one instance, the media reported that an Indian manufacturing facility had a whole quality testing lab[20] that was off the books; where quality data was being cooked up. In another instance, when massive data fraud at a Clinical Research Organization (CRO)[20,21] in India (these generate data that the pharmaceutical manufacturers require for regulatory approvals) was revealed by a whistleblower (who was later jailed by the local government), the Europeans cancelled[22,23,24] the marketing authorization of over 700 generic drugs which were approved on the basis of data generated at that particular facility. The US FDA, to the best of my knowledge, took no action despite sending its inspectors to the facility[25]; only one Indian manufacturer withdrew its drug from the US market because the whistleblower had specifically alleged that the laboratory in question had fabricated data used in its approval. There are many such examples[26,27,28,29].

Congressional oversight demands that the US FDA ensure there are no shortage of drugs in the country. To address this mandate, the agency is flexible with its rules, especially for medically necessary drugs where the manufacturer has a history of violating our standards and also holds a

[15] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/indian-cancer-drug-manufacturer-pay-50-million-concealing-and-destroying-records-advance-fda
[16] https://www.bloomberg.com/news/features/2019-02-01/the-4-3-billion-deal-that-blew-up-over-shoddy-drug-production
[17] https://www.bloomberg.com/news/articles/2019-07-16/drugmaker-shredded-quality-documents-ahead-of-fda-inspection
[18] https://www.bloomberg.com/news/features/2019-01-31/culture-of-bending-rules-in-india-challenges-u-s-drug-agency
[19] https://www.bloomberg.com/news/articles/2023-05-31/us-finds-contaminated-drugs-further-lapses-in-india-pharma-factories-post-covid
[20] https://www.fiercepharma.com/regulatory/dr-reddy-s-blasted-warning-letter-for-hiding-existence-of-testing-lab-from-fda
[21] https://www.science.org/content/blog-post/india-s-gvk-accused-systematic-fraud
[22] https://www.fiercebiotech.com/r-d/india-s-gvk-biosciences-gets-harsh-accusations-from-ema-on-fake-generic-trials
[23] https://www.chemistryworld.com/news/eu-regulator-calls-for-generic-drug-suspensions-/8216.article
[24] https://www.raps.org/News-and-Articles/News-Articles/2015/1/EMA-Recommends-Suspending-Drugs-over-GVK-Data-Inte
[25] https://www.outsourcing-pharma.com/Article/2015/08/31/Europe-bans-drugs-tested-by-GVK-FDA-monitors-but-keeps-allowing-sales
[26] https://www.biospace.com/article/indian-cro-quality-questioned-as-quest-life-sciences-warned-by-who-for-hiv-trial-fraud-/
[27] https://www.fiercepharma.com/pharma-asia/india-s-alkem-to-respond-to-european-data-fraud-probe
[28] https://www.outsourcing-pharma.com/Article/2016/04/25/WHO-says-Semler-Research-manipulated-data-and-warns-repeat-studies-may-needed
[29] https://www.statnews.com/pharmalot/2016/04/25/fda-warn-clinical-trials-run-indian-company/

large market share. Propublica reported recently[30] that "*A secretive group inside the FDA exempted the medications from import bans, ostensibly to prevent drug shortages. With each pass, the agency dismissed warnings from its own inspectors about* dangerous breaches in drug quality on factory floors." Its analysis identified more than 600 complaints in the FDA's files about the exempted drugs at three factories, each flagging concerns in the months or years after the medications were excluded from import bans. The reports cite about 70 hospitalizations and nine deaths.

This undermines the deterrence of holding wrongdoers to account, and "enables" manufacturers to factor in cost of compliance if caught into the cost of doing business. Sadly, this approach over the last decade has provided a permission structure to the generic companies to operate with impunity.

Manufacturing quality issues are the leading cause of drug shortages; 56% in 2011[31], 62% between 2013 and 2017[32] and 46% in 2022[33].

To be clear, I am not advocating for a witch-hunt; not every GMP violation warrants a criminal prosecution; but brazen acts of data fabrication or destruction of records (of which they are plentiful examples) most certainly do in a US court. Perhaps foreign pharmaceutical companies would take the US FDA foreign inspection program more seriously if they knew it had teeth. Compliance data from over the last decade shows that it does not.

The European Union employs a model where a Qualified Person (QPPV)[34] needs to be the resident of the EU and be accountable for drug safety and is therefore amenable to prosecution if gross violations of EU laws are discovered. The Committee should consider such a model where an officer of the foreign manufacturing company needs to be a resident of the US and is therefore accountable for the quality of our drug supply and gross violations of the US regulatory code. I would request the Committee to summon data on criminal prosecutions from the US FDA specifically in relation to its foreign inspection program and make it public so that activists like me can review it for accountability.

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[30] https://www.propublica.org/article/fda-drug-safety-foreign-manufacturers-takeaways
[31] https://pubmed.ncbi.nlm.nih.gov/23337525/
[32] https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions
[33] https://web.archive.org/web/20240314230016/https:/accessiblemeds.org/sites/default/files/2024-02/access-2024-Jacqueline-Corrigan-Curay-presentation.pdf
[34] https://www.gov.uk/guidance/guidance-on-qualified-person-responsible-for-pharmacovigilance-qppv-including-pharmacovigilance-system-master-files-psmf

B. **Mandatory end-user testing:** Second, is to consider a legal mandate, as contemplated by the Department of Defense[35], to put in place a mandatory testing program for all drugs entering the United States from countries where past inspections have demonstrated a consistent pattern of data fraud and GMP violations. Such testing can be limited to random statistical sampling or potentially risky drugs with known manufacturing issues, such as injectables. Such testing should be conducted by the purchaser, be it the Pentagon or the Pharmacy Benefit Managers. Inclusion in the formulary should ensure that the batch is of consistent quality and bioequivalent as approved by the US FDA through the ANDA process.

Yes, this will cost money; but there is simply no alternative at this stage when public confidence in the foreign inspection program appears to be at an all-time low - the data generated by these testing programs will provide us with an independent source of data to assess how effective the US FDA's foreign inspections program is. At the moment, we have no independent source of data to continue to believe that all generic formulations can be interchangeably prescribed; rather we have enough evidence to the contrary[36,37,38,39,40]. Patients in the US cannot wait another decade for the US FDA to fix its foreign inspection program. Such testing can end when we restore the confidence that the Quality Assurance process works as designed and envisioned in CFR 211.

However, creating different grades of generic drugs, by labeling them as "Red", "Green" or "Yellow" in my opinion is counterproductive. For the last five decades, healthcare providers in the United States have relied on the assurance that once the US FDA approves a generic formulation, it can be used interchangeably with the innovator drug. Creating various grades of quality undermines the confidence in our regulator; the consequence of this approach will be to create confusion among patients who lack the power to select an appropriate substitute at the pharmacy because the formulary that decides which generic equivalents are available for them is not in their control. It's the PBMs that decide which formulations are available.

Likewise, including Country of Origin on the label is a good idea in principle from the point of view of transparency, but it does nothing to empower the patient whose choices are dictated by the PBM.

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[35] https://www.bloomberg.com/news/articles/2023-06-07/drug-safety-fears-spur-pentagon-plan-to-test-widely-used-meds
[36] https://www.statnews.com/2024/01/25/chemotherapy-asparaginase-cancer-drug-investigation/
[37] https://www.bloomberg.com/news/features/2023-07-17/eyedrop-recall-2023-and-infections-were-result-of-lack-of-fda-regulation?srnd=storythread-RYQRPADWX2PS01
[38] https://www.bloomberg.com/news/features/2023-08-01/abortion-pill-provider-buys-from-indian-manufacturer-with-bad-quality-record
[39] https://www.bloomberg.com/news/articles/2018-09-17/prices-soar-for-hospital-drugs-after-shortages-hit-study-finds
[40] https://www.bloomberg.com/news/articles/2023-06-15/quality-issues-grow-at-generic-drugmaker-causing-chemo-scarcity

C. **Incentivize manufacturers to make investments in quality management systems:**

Empirical data from the market confirms price pressure on the generic drug manufacturers from concentrated purchasing power of the Pharmacy Benefit Managers (PBMs) and Group Purchasing Organizations (GPOs). While most of the attention is focused on their opacity and coercive behavior on payers and providers, a less articulated issue is their impact on manufacturers. A 2023 study of the generic pharmaceutical industry[41] found that many top-selling generics cost pharmacies less than $1.50 for a 30-day supply. Another 2024 analysis[42] found year-over-year deflation in acquisition costs for generic solid oral dosage formulations as high as 25%. Analysis by United States Pharmacopeia[43] of drug shortages show that over 50% of sterile injectables and 66% of solid oral dosage forms in shortage were invoiced at the pharmacy for less than $5 and $3 respectively in 2024.

Leveraging threats of exclusion, PBMs demand higher and higher rebates from drug manufacturers in exchange for including their products in their restrictive formularies. They exert undue influence of Monopsony Power over purchasing decisions by conditioning preferential treatment on manufacturer rebates. They extract fees from drug manufacturers as a part of commercial rebate negotiations. In fact, the American Society of Hematology has strongly protested[44] the practice of switching patients to change medications for non-clinical reasons primarily driven by PBMs decisions to remove a particular drug from their formulary. Academic data from the USC Schaeffer Center showed that intense PBM and purchasing organization price compression drove generic injectable profits down so far that U.S. companies abandoned production in the US, leaving the entire U.S. healthcare system vulnerable to a single overseas factory shutting down[45].

Such coercive practices result in real harm to patients. For example, to what extent did extractive pricing contribute to the bankruptcy of Akorn Pharmaceuticals[46], which was already facing regulatory action for cGMP violations from the US FDA and which resulted in an acute shortage of albuterol sulfate inhalation solution for pediatric patients in the aftermath of the Covid-19 pandemic is not known because the operations of these purchasing organizations are not transparent.

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[41] https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf
[42] https://www.46brooklyn.com/news/46brooklyn-2024-midyear-drug-pricing-report
[43] https://www.usp.org/supply-chain/drug-shortages
[44] https://www.hematology.org/advocacy/testimony-and-correspondence/ash-comments-on-the-ftc-rfi-on-business-practices-of-pbms
[45] https://schaeffer.usc.edu/research/overpaying-for-prescription-drugs/
[46] https://www.contemporarypediatrics.com/view/what-you-need-to-know-about-the-albuterol-shortages

We cannot expect to sustain such pressure to cut costs for life saving medicine and at the same time expect supply chain resilience and uncompromising quality. Something has to give; and we see that it is compliance with our standards and therefore the quality of medicine for our patients.

This unique characteristics of demand planning, an unpredictable market, a fragmented supply chain for raw materials and rigorous regulatory compliance all create challenges for a business that is under constant cost pressure. Onshoring the manufacturing of these mature generic drugs, even with the introduction of new technology and process (e.g., continuous process manufacturing) will not alleviate these challenges. Only those products that have a high entry barrier (e.g., sterile injectables) are able to sustain reasonable price elasticity because of a large market share (e.g., carboplatin). IV fluids have been notoriously prone to drug shortages, but they are largely manufactured in the US. Ascribing the reason for shortages to overseas manufacturing and non-compliance alone is incorrect.

A policy recommendation on this issue is premature because no substantive research exists due to the opacity of the extractive nature of the PBMs and the GPOs. The Committee should consider asking the GAO or another appropriate organization to study this issue and make this data available for independent researchers as well.

D. **A bilateral solution:** Finally, there is simply no avoiding the politics of Indo-American diplomacy and its effect on the US FDA's approach to the Indian pharmaceutical industry. The Government of India is very protective of its pharmaceutical industry and bats for the industry on the international stage. When the Europeans cancelled the approvals of 700 drugs post the scandal at the aforementioned CRO in 2016, the Indian government responded by cancelling long pending trade talks with the European Union[47,48]. When the US DOJ prosecuted Ranbaxy in 2013, the highest levels of the Indian government responded by claiming that "vested interests"[49] were acting against the Indian pharmaceutical industry. I've personally been threatened by the Indian drug regulator[50] for criticizing its actions. I suspect the US FDA is alive to these pressures and is treading a fine line. The question for you is whether the health of US citizens should be held hostage to the domestic politics of a foreign country? It may be time to dramatically escalate this issue to a diplomatic level and negotiate a

[47] https://www.fiercepharma.com/regulatory/india-defers-eu-trade-talks-as-ban-on-gvk-tested-drugs-rankles
[48] https://www.outsourcing-pharma.com/Article/2015/08/06/Indian-government-suspends-EU-trade-talks-over-spat-with-GVK-Biosciences
[49] https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-sees-us-lobbies-behind-fda-ban-on-ranbaxy-drugs/articleshow/3600276.cms
[50] https://x.com/d_s_thakur/status/1581846234490208256?s=20

bilateral diplomatic agreement with the Indian government on the issue of drug regulation to force India to amend its domestic laws to improve the quality of domestic drug regulation - a convergence in regulatory standards in both countries and better domestic inspections by Indian drug inspectors of their own manufacturing facilities will reduce the burden on the US FDA to conduct inspections half the world away. The US spends billions of dollars buying drugs from India every year. As a customer and a strategic ally, the United States is in a strong position to demand that it receive quality drugs from Indian manufacturing facilities.

As a proud American of Indian origin, who has grown up and studied in India, I would like to see a strong and mutually beneficial relationship between India and the United States but this should be a relationship based on mutual respect, not one where the health of US citizens is threatened at the altar of politics.

Questions for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"POISONED PILLS: THE HUMAN COST OF DANGEROUS FOREIGN DRUGS"

JUNE 3, 2026

QUESTIONS FOR THE RECORD

Dr. Adam Clark-Joseph

Senator Raphael Warnock

Question:

Rural health providers in Georgia rely on generic drugs to treat patients, including older Americans. Due to financial vulnerability, rural providers have limited capacity to build a stockpile of drugs in preparation for supply shortages.

How can Congress ensure rural hospitals and clinics provide affordable and safe generic drugs to seniors in times of a drug shortage crisis?

Response:

Two of the leading causes of drug shortages are quality problems and supply-chain fragility. At a high level, incentivizing generic-drug quality and domestic manufacturing are vital steps to address the drug-shortage problem.

Representatives Rich McCormick and Rosa DeLauro are introducing the bipartisan Transparency and Quality in Pharmaceuticals Act ("TRaQ Pharma Act") to incorporate the Uniformed Services University's chemical quality metrics along with independently derived manufacturing location metrics into military drug procurement. (They are also working to include this bill in the NDAA and provide funding in the Fiscal Year 2027 Defense Appropriations Bill.) The reforms supported by this legislation would shift military pharmaceutical procurement away from a model in which suppliers compete only on cost, in favor of a model in which quality and manufacturing location also factor into purchasing decisions.

This reform to military drug procurement would have a meaningful direct effect to incentivize improved quality and American drug manufacturing, which would spill over and improve conditions for the non-military segment of the generic-drug market. In addition, these reforms, by establishing a "gold standard" of sorts for quality and demonstrating well-functioning procurement that considers quality, would introduce a specter of potential liability for private-sector purchasers vis-á-vis quality, and thereby exert an important indirect influence to further incentivize high-quality drug selection by the private sector. In our view, the reform of military drug-procurement is the best option available in the near term to address shortages throughout the nation, including in rural Georgia.

Question:

It is critical to ensure transparency into where and how medicines are manufactured 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:

Requiring country-of-origin labels, as in the Clear Labels Act, is an excellent first step towards the greater transparency so desperately needed in the American generic drug market. While transparency to patients is admirable and desirable, patients have little choice or say in the manufacturer from which their pharmacy or health system decides to purchase drugs.

The most important step is to make independent quality and place-of-manufacture information available to those large purchasers, and to incentivize them to use that information in making their purchasing decisions.

Military drug procurement reform, of the sort proposed in McCormick and DeLauro's TRaQ Pharma Act and NDAA amendment is the most readily available measure to start this process. Adopting analogous reforms to CMS generic drug procurement, though moderately more involved (as it would require updating aspects of their reimbursement system), would be the most impactful longer-term measure for improving drug quality and security nationwide, especially for seniors.

Question:

How can Congress enforce existing reporting requirements and ensure greater transparency overall?

Response:

A critical problem with existing reporting requirements in the U.S. is that most rely on manufacturers to self-report. This is, in essence, like relying on an honor system. We strongly believe that a shift towards independent assessment, both in the form of independent chemical quality testing of finished drug products, and in the form of independently derived location metrics, is vital to the development of a transparent, safe, and secure generic drug supply in the U.S.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"POISONED PILLS: THE HUMAN COST OF DANGEROUS FOREIGN DRUGS"

JUNE 3, 2026

QUESTIONS FOR THE RECORD

Dinesh Thakur

Senator Raphael Warnock

Question:

According to a Government Accountability Office report, there have been inspection workforce shortages at the Food and Drug Administration (FDA) since 2018. From November 2021 to June 2024, the vacancy rate of investigators who oversee drug manufacturers increased from 9 percent to 16 percent, leading to fewer safety inspections of generic drugs. The Trump administration also dismissed more than 3,500 FDA employees in April 2025, further exacerbating the FDA's inspection workforce capacity.

How can Congress help stabilize the FDA inspection workforce and improve oversight over foreign manufacturing of generic drugs?

Response:

In the report you reference in your question, the GAO identifies the root cause of this increase in the vacancy rate to be "frequency and conditions of travel, pay, insufficient training, heavy workload and issues of work-life balance".

Among these issues, pay and training are something that the Congress can have a direct oversight of. The cadre of inspectors, their training, their pay is within the remit of the Senate Committee on Health, Education, Labor and Pensions. This committee can directly influence these factors.

The issue in my opinion is different. I am reproducing the following from the GAO report:

According to FDA officials, pilot implementation in China was slowed by COVID-19-related travel restrictions, a new visa application process, and new Chinese laws related to espionage and national security. In addition, FDA officials said that increased resource needs for pilot inspections have affected the pace of implementation. Specifically, FDA determined that unannounced inspections in the pilot are to be conducted by two investigators for safety reasons (historically, the majority of inspections were conducted by solo investigators).[36]

As of May 2024, FDA had initiated 114 pilot inspections in India (94 of which were unannounced) and 28 in China (16 of which were unannounced), according to an FDA presentation on the pilot's status. FDA plans to continue pilot implementation through each phase until it has completed about 250 unannounced and about 250 preannounced inspections in total across both countries.

This assumes that we continue to send inspectors located in Rockville, MD to conduct inspections of manufacturing facilities located in India and China, where a large volume of our drug supply originates from.

An inspectorate model that depends on international travel is bound to fail in my opinion. I have conveyed this to the House Energy and Commerce Committee in my testimony two years ago. Expecting inspectors located in the US to travel reasonably frequently, and therefore be subjected to workload and work-life balance issues which are a direct consequence of being away from home for weeks or months is not sustainable. Further, it also hinders in hiring inspectorate staff whose responsibilities are to be away from home and family for months, despite being offered better pay.

The US FDA conducted a pilot in the aftermath of the Ranbaxy case where they had local inspectorate staff in Delhi and Mumbai, located within our Embassies. This pilot ended after a year, but we don't know why the US FDA did not pursue this model. In my opinion, hiring and locating inspectorate staff, like our diplomatic cadre in our embassies in these two countries which have hundreds of manufacturing facilities registered with the US FDA and supply our drugs is a more viable model. The agency has not stated publicly why they don't consider this model viable after they concluded their pilot, therefore I am at a loss to offer an explanation.

As far as the HHS Transformation by reducing the number of staff at the US FDA, the agency fact sheet said that the DOGE reductions "will not affect drug,

medical device, or food reviewers, nor will it impact inspectors.″ I do not have access to the most recent data on how many of the inspectorate staff were affected by these reductions; it is reasonable to assume that any reductions would have further exacerbated an already untenable situation among the foreign inspectorate staff and thereby directly impacting our ability to ensure the quality of our medicines supply.

At the next opportunity, I hope you would ask the Commissioner why the model of locating an inspectorate staff at our Embassies in India and China is not a workable one, given all the challenges identified in the GAO report.

Statements for the Record

Association for Accessible Medicines
Statement for the Record
Senate Select Committee on Aging Hearing
June 3, 2026

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee, the Association for Accessible Medicines (AAM) appreciates the opportunity to submit this statement for the record regarding the safety, quality, and reliability of the generic medicines used every day by older Americans and patients across the United States.

AAM represents the manufacturers of finished generic medicines, manufacturers of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic industry. AAM's mission is to expand patient access to high-quality, safe, and effective generic medicines through a forward-looking and sustainable regulatory and policy environment.

Generic Medicines Are Essential to Patient Access

Generic medicines are central to prescription drug access in the United States. While generics make up 90 percent of total prescriptions but only 12 percent of total drug spending[1], most of this is for "non-specialty" medicines, whereas the major cost challenge now lies in specialty medicines[2]. In 2024 alone, patients in the United States filled approximately 3.9 billion generic prescriptions.[3]

That reach is especially important for older Americans. Medicare beneficiaries and patients managing multiple chronic conditions often depend on a consistent supply of affordable medicines to control blood pressure, treat diabetes, prevent strokes, fight infections, manage cancer, and address other serious health needs. For these patients, generic medicines are not simply lower-cost alternatives; they are often the practical foundation of access to essential treatment.

Because these medicines are so widely used and relied upon, public confidence matters. Unsupported claims that suggest FDA-approved medicines are unsafe because of where they are manufactured can have real consequences. Patients may skip doses, delay therapy, may decide to purchase more expensive medicines that they might not be able to afford, or lose confidence in treatments their clinicians have prescribed. A serious discussion about drug quality should be grounded in science, FDA standards, and actual evidence, not assumptions based on geography.

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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] https://link.psgconsults.com/2024-spend-and-trend-report
[3] Op. Cit.

Quality is Built into the Manufacturing Process

AAM members are committed to maintaining the quality, safety, and effectiveness of the medicines they supply to U.S. patients. Pharmaceutical quality is not established at a single point in time or through a singular or final test. Rather, it is the result of a comprehensive system that begins with product development and continues through manufacturing, testing, distribution, and post-market monitoring.

Manufacturers rely on extensive quality systems to help ensure medicines consistently meet FDA's rigorous standards for safety, effectiveness, and quality. These systems include validated manufacturing processes, qualified suppliers, controlled facilities, trained personnel, laboratory testing, ongoing monitoring, and established procedures to investigate and correct potential issues. Importantly, these safeguards are designed not only to maintain product quality, but also to identify, investigate, and address problems quickly when they arise.

Like all complex manufacturing industries, pharmaceutical manufacturing is not immune from quality challenges. When issues occur, manufacturers are expected to work closely with FDA to investigate root causes, implement corrective actions, and protect patient safety and critical product supply. Continuous improvement, transparency with regulators, and investment in robust quality systems are essential components of pharmaceutical manufacturing.

This commitment is especially important in the generic sector because these medicines are used at enormous scale and account for the vast majority of prescriptions dispensed in the United States. Manufacturers recognize that maintaining patient and provider confidence depends on consistently delivering safe, effective, and high-quality medicines.

FDA Standards Apply to Medicines Regardless of Geography

The core point for this hearing is straightforward: medicines made for U.S. patients must meet FDA's requirements regardless of where they are manufactured. The relevant question is not whether a medicine is made in the United States, India, China, Europe, or another region. The relevant question is whether the product, facility, ingredients, process, controls, testing, and quality systems satisfy FDA's standards.

FDA's Current Good Manufacturing Practice regulations, or CGMPs, are designed to ensure that medicines have the identity, strength, quality, and purity that are required. These regulations govern the systems and controls manufacturers must use to produce medicines for the U.S. market. They apply to both domestic and foreign manufacturers.

It is therefore inaccurate to suggest that a medicine is less safe simply because it is made in, or contains active pharmaceutical ingredients from, a particular country. Country of origin is not a proxy for product quality. FDA oversight, CGMP compliance, facility

inspection history, application review, process validation, product testing, supplier qualification, and post-market surveillance are far more meaningful indicators.

A country-based narrative also obscures how modern pharmaceutical supply chains work. Medicines, including brand and generic products, often depend on global networks for raw materials, active ingredients, components, manufacturing capacity, packaging, and distribution. Attempting to reduce quality questions to a product's geography oversimplifies the supply chain and risks steering the policy debate away from the actual factors that protect patients.

FDA Inspection Data Speaks for Itself

FDA's own inspection data reinforces the need for a more careful discussion. In its FY2024 Report on the State of Pharmaceutical Quality, FDA reported that drug quality assurance inspections increased from 522 in FY2022, to 766 in FY2023, to 972 in FY2024. FDA also reported that more than 62 percent of drug quality assurance inspections in FY2024 were conducted at foreign sites, the highest share to date.[4]

FDA's foreign inspections increased substantially in India and China. In FY2024, FDA inspected 34 percent of sites in India and 28 percent of sites in China that were listed in FDA's Site Catalog, compared with 24 percent of U.S. sites[5]. These figures demonstrate that FDA oversight of foreign facilities is not theoretical. It is an active and significant part of FDA's pharmaceutical quality program.

The inspection outcomes also deserve attention. FDA reported that, globally, 93 percent of all sites in the CDER Site Catalog had received either a No Action Indicated or Voluntary Action Indicated classification as their most recent inspection classification. The comparable figures were 93 percent for China, 92 percent for the United States, and 87 percent for India.[6]

Those numbers do not mean FDA should ignore quality concerns. They do not mean every facility presents the same risk. And they do not mean there are no legitimate issues requiring enforcement or remediation. But they do show that the evidence does not support a narrative that drugs manufactured overseas are unsafe. FDA's own data point to a more complex reality, one in which quality must be evaluated through inspection findings, compliance history, product risk, and facility-specific facts.

Strong Oversight Should Be Risk-Based and Scientifically Grounded

AAM supports strong FDA oversight of domestic and foreign manufacturing facilities. FDA's oversight tools include pre-approval inspections, routine surveillance inspections, for-

[4] FDA, FY2024 Report on the State of Pharmaceutical Quality, September 2025.
[5] Op. Cit.
[6] Op. Cit.

cause inspections, product sampling and testing, import screening, application review, adverse event monitoring, and other post-market activities. These tools work best when they are used in a risk-based, science-driven manner.

FDA's risk-based inspection model allows the agency to focus resources where they are most needed. Facilities may be prioritized based on factors such as the type of products manufactured, the facility's compliance history, the complexity of manufacturing operations, the time since the last inspection, and the potential impact on patients. This approach is appropriate because not every facility or product presents the same level of risk.

AAM also supports efforts to strengthen the foreign inspection program, including increased unannounced foreign inspections. FDA has announced its intent to expand unannounced inspections at foreign facilities producing medicines and other medical products for U.S. patients, building on pilot efforts in India and China. To the extent this helps ensure comparable oversight of domestic and foreign facilities, it is a constructive step.

At the same time, inspection policy should be designed to improve oversight, not simply to create the appearance of toughness. Some inspections, including certain pre-approval inspections, may require advance coordination so FDA can observe relevant manufacturing activity, ensure key personnel and records are available, and conduct a complete review. For foreign inspections, logistical issues such as travel, visas, language access, local government coordination, and facility operations can affect the efficiency and completeness of an inspection. The goal should be effective oversight and comparable scrutiny across geographies.

Regulatory Findings Should Not Be Mischaracterized

Congress should also be careful not to conflate regulatory findings with evidence that a finished medicine is unsafe for patients. CGMP violations are serious and must be addressed. FDA should take appropriate action when a facility fails to meet its obligations. But a regulatory observation or compliance action does not automatically mean that every medicine made at that facility is contaminated, defective, or clinically unsafe.

FDA has a range of tools to address noncompliance, including warning letters, import alerts, product recalls, injunctions, seizures, and other enforcement actions. The agency can also work with manufacturers to require corrective actions, additional testing, third-party oversight, or other safeguards where appropriate.

This distinction matters because patients can be harmed both by poor quality and by loss of access. In some cases, blocking a product from the market without a clinically adequate alternative may worsen or cause a drug shortage. FDA must be able to weigh the specific

risks and benefits in the context of patient need, the available supply, the nature of the compliance concern, and any safeguards that can be imposed.

That risk-based discretion is particularly important for medicines used by older Americans. Shortages of sterile injectables, antibiotics, oncology medicines, cardiovascular drugs, and other essential medicines can have immediate consequences for patient care. A policy that appears strict in the abstract may be harmful in practice if it removes medically necessary products from the market without improving patient safety.

Drug Shortages and Drug Quality Must Be Considered Together

Drug quality policy cannot be separated from the economics of generic medicine production. Generic manufacturers often operate in highly competitive markets with thin margins, particularly for older, low-cost medicines. These markets produce enormous savings for patients and taxpayers, but they can also be vulnerable when costs rise, supply chains are disrupted, or manufacturers exit.

Policies that impose duplicative testing, stigmatize FDA-approved medicines, or create broad country-based restrictions without a product-specific safety basis can unintentionally reduce the number of suppliers serving the U.S. market. Reduced competition and fewer suppliers can increase the risk of shortages. And shortages, particularly for older and medically complex patients, are themselves a patient safety risk.

This does not mean quality standards should be weakened. They should not. Rather, it means Congress should pursue policies that strengthen quality oversight while preserving a sustainable supply of affordable medicines. The goal should be a resilient market with multiple reliable suppliers, strong FDA oversight, and a clear pathway for addressing quality problems without destabilizing access.

Adverse Event Data Alone Cannot Measure Product Quality

The Committee should also be cautious about using adverse event reports to compare products, manufacturers, or countries. AAM supports robust adverse event reporting. These reports help FDA and manufacturers identify potential safety signals that may warrant further review. But adverse event reports are not designed to function as a comparative product quality database.

FDA's Adverse Event Reporting System contains reports that may be incomplete, duplicative, influenced by publicity, or unrelated to the medicine itself. Manufacturers are required to submit adverse event reports even when they do not believe the medicine caused the event. Reports may involve underlying disease progression, other medicines taken at the same time, patient-specific risk factors, prescribing issues, medication errors, or unrelated health events.

For that reason, adverse event reports should be treated as signals for investigation, not proof of product defects. They cannot reliably establish incidence rates, determine causation, or support broad conclusions that one country's medicines are less safe than another's. FDA and manufacturers should continue to evaluate these reports carefully, but policymakers should avoid using raw adverse event counts in ways that may mislead patients.

Testing Should Complement FDA's Science-Based Oversight

A similar caution applies to broad, un-targeted third-party testing. AAM supports appropriate product testing, including FDA surveillance sampling, inspection-related sampling, targeted testing, and manufacturer testing conducted under validated methods and regulatory standards. Testing can be an important tool when it is scientifically sound and tied to a legitimate quality question.

But testing that is not risk-based, not conducted using validated methods, or not interpreted in the proper regulatory and clinical context can confuse rather than clarify. Isolated results may appear alarming to the public even when they do not reflect a meaningful patient risk. Poorly designed testing can produce false positives or false negatives. It can also divert attention and resources from actual quality signals that FDA and manufacturers are best positioned to evaluate.

Patients should not have to interpret fragmented testing claims on their own. They should be able to rely on FDA's scientific review, inspection program, product standards, and enforcement authorities. When legitimate quality issues arise, FDA has tools to investigate and act. Congress should strengthen that system, not replace it with parallel processes that may undermine confidence without improving safety.

A Balanced Approach is Needed to Strengthen Quality and Protect Access

AAM supports continuous improvement in pharmaceutical quality oversight. FDA should have the resources, staffing, data infrastructure, and authorities needed to oversee a global pharmaceutical supply chain effectively. Congress should support continued improvements to FDA's foreign inspection program, quality surveillance systems, laboratory capacity, import oversight, and ability to identify and respond to emerging risks.

Congress should also ensure that policy responses are targeted to actual risks. Broad assumptions about foreign manufacturing, country-based restrictions, or duplicative requirements that do not improve product quality could undermine patient access. For older Americans, the consequences of reduced access can be serious, particularly when the affected medicines are low-cost generics that have limited suppliers.

A better approach is to hold all manufacturers to the same high standards, domestic and foreign alike, while giving FDA the tools to identify, prioritize, and act on real quality

concerns. This approach protects patients without encouraging misplaced fear about FDA-approved medicines.

Conclusion

Older Americans depend on affordable, high-quality generic medicines every day. The Committee is right to focus on drug quality, but the discussion should be rooted in science, FDA standards, and evidence. A medicine is not less safe merely because it is manufactured abroad or contains ingredients from a foreign source. Quality depends on compliance with FDA requirements, robust manufacturing controls, validated processes, testing, inspection history, and ongoing oversight.

AAM and its member companies stand ready to continue to work to strengthen confidence in the U.S. drug supply, support effective oversight, and ensure that patients continue to have access to the medicines they need. The United States has one of the strongest pharmaceutical regulatory systems in the world, if not the strongest. Congress should build upon that foundation by supporting policies that improve quality, sustain competition, and protect patients from both unsafe products and avoidable shortages.

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Senate Aging Committee

May 28th, 2026

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

I am writing this letter to offer my support for the committee's evaluation of our vulnerability as a nation on an unreliable supply of safe and effective medications in the USA. I write in a personal capacity in my 46th year as an MD. I have held faculty positions as an endocrinologist at Mayo Clinic in Rochester Minnesota and for the last 25 years at UCLA with a focus on diabetes care. Diabetes is one of the most prevalent conditions in the USA, affecting more than 40 million people. Untreated diabetes may result in blindness, kidney failure, leg amputation and early death from heart disease or stroke. Fortunately, medications are available that greatly reduce these risks, but most people with diabetes must take as many as 7 medications daily to realize this benefit.

It was therefore good news when many of these medications became available in a more affordable generic form with the assurance from the FDA that generic medications available in the USA were equivalent as the original branded medications. Like most practicing physicians, I assured my patients that the generic form of these medications were safe and effective based on the role of the FDA in oversight of generic drug manufacturing.

It was therefore a shock when the heparin disaster occurred in 2007 with adulterated heparin imported from China resulting in multiple deaths. Given the high profile of that disaster, like many other MDs, I assumed that the FDA would assure that appropriate measures be promptly taken to address the oversight failure that led to this tragic circumstance. But alarmingly there have been a series of subsequent revelations that this assumption was mistaken. FDA lacks capacity for oversight of a sprawling global supply chain. Moreover, FDA's approach to drug quality, review of manufacturer quality documents without systematic testing of generic drugs themselves, leaves our patients vulnerable to poor quality generic medications.

This issue is increasingly being raised by patients. As an MD who daily prescribes lifelong medications for diabetes, high blood pressure and cholesterol lowering, I am unable to assure the patients of the quality of the products that they will pick up at the pharmacy. To their surprise, when questioned, I reluctantly admit that I have no insight into manufacturer quality, so I cannot even make a recommendation of which generic products they should request.

Patients with diabetes are at high risk for cancer. Over the last several years, I have been shocked by the discovery of carcinogens in many of the medications I prescribe and that my patients take. This includes metformin, ranitidine, angiotensin-converting enzyme (ACE) inhibitors and Angiotensin Receptor Blockers (ARBs). In most of these cases, high levels of carcinogens are the result of poor-quality manufacturing processes. Without routine quality testing, my patients were likely exposed to these products long before they were subject to recalls. As a result, my

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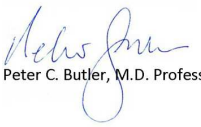
patients with diabetes, the patients most at risk for the development of cancer, have also been some of the most exposed to these poorly manufactured generic drug products.

Given that the heparin disaster occurred 20 years ago, it is long overdue that a solution be found to address the problem. I enthusiastically applaud the committee for taking up the issue. Patients tell me they would be pleased to pay more if needed if they could be assured that the generic medications they purchased were effective and safe. It is remarkable that we know more about the quality of products for sale at Amazon than we do about the medications that are essential for the treatment of diabetes. All Americans deserve an opportunity to look for a specific measure of assured quality when they pick up their medications at the pharmacy. Having transparency into generic drug quality will assure our patients that the generic drug market provides the value that deserve and demand.

Thank you for addressing this important issue,



Peter C. Butler, M.D. Professor of Medicine

TAXPAYERS PROTECTION ALLIANCE

June 1, 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

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

On behalf of millions of taxpayers and consumers across the country, the Taxpayers Protection Alliance (TPA) appreciates the opportunity to contribute to hearings to "examine the human cost of dangerous foreign drugs." TPA urges the committee against undermining the global drug supply chain, which supports America's healthcare system by delivering safe and effective medications to patients. Previous hearings and public comments have highlighted concerns about the use of internationally sourced active pharmaceutical ingredients (APIs), yet APIs have a commendable safety record—and continue to get safer. Promoting domestic API production is best achieved by regulatory reform, not imposing broad mandates or costly regulations on drug manufacturers. Heavy-handed government policies will reduce innovation, limit treatment options, and increase costs for patients and taxpayers.

A 2022 report commissioned by the Department of Health and Human Services (HHS) identified substantial regulatory hurdles that make domestic API manufacturing difficult and time-consuming. According to the report, permitting requirements and Food and Drug Administration (FDA) inspections mean that constructing a new manufacturing facility in the U.S. can take between five and seven years, while expanding an existing facility with an additional production line may require another three to five years.[1]

The lengthy FDA approval process for new medicines also imposes significant costs on patients and taxpayers. An in-depth analysis by the oncology news and information platform OncoDaily concludes, "Developing a new drug typically takes an average of 10 to 15 years, depending on various factors such as the type of drug and regulatory processes."[2] A recently-released TPA report titled "Blocking Breakthroughs: Delays and Denials at the FDA" finds that, even as the FDA has more taxpayer dollars and user fees at its disposal than ever before, rejections are becoming increasingly common. The 2025 rejection rate of nearly 30 percent was near decade highs.[3] Excessive delays and compliance costs contribute to higher healthcare spending, slow

[1] https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.
[2] https://oncodaily.com/drugs/ema-vs-fda-drug-development?utm.
[3] https://www.protectingtaxpayers.org/wp-content/uploads/2026/03/Blocking-Breakthroughs-Delays-and-Denials-at-the-FDA-v3.pdf.

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patient access to innovative treatments, and expand bureaucratic burdens that ultimately must be paid for by taxpayers.

To manage these runaway costs and regulatory hurdles, pharmaceutical manufacturers often rely on more efficient and cost-effective global supply chains to get critical medications to patients. Manufacturers should retain the flexibility to source APIs from international suppliers while passing resulting cost savings on to patients. In many cases, producers can manufacture high-quality APIs abroad at a scale and cost not economically feasible in the U.S. Rather than restricting access to global supply networks, policymakers should focus on reducing domestic regulatory barriers and supporting efforts that enhance supply chain resilience. Additional restrictions would reduce the availability of therapies while driving up prices for consumers.

As Americans continue to face rising drug costs, the committee has an opportunity to pursue practical reforms that expand access to critical medications. Cutting unnecessary red tape and improving regulatory efficiency would deliver meaningful benefits for patients, taxpayers, and the American healthcare system.

Sincerely,

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