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

Poisoned Pills: The Human Cost of Dangerous Foreign Drugs

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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