Testimony Before the United States Senate Special Committee on Aging for the 09/17/25 hearing titled:

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

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

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

Generic drug marketplace design

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

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

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

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

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

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

Negative consequences of this market design

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

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

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[1] Ball, G. P., Shah, R., & Wowak, K. D. (2018). Product competition, managerial discretion, and manufacturing recalls in the US pharmaceutical industry. *Journal of Operations Management*, *58*, 59-72.

[2] Noh, I. J., Gray, J., Ball, G., Wright, Z., & Park, H. (2025). Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Drug Adverse Events. *Production and Operations Management*, *34*(9), 2601-2617.

[3] Anand, G., Ball, G. P., Gray, J. V., & Mukherjee, U. K. (2025). Operations Management in the Pharmaceutical Industry. *Journal of Operations Management*, *71*(3), 302-313.

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

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

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

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

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

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

Recommendations to mitigate these negative consequences

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

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

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

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

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

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

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

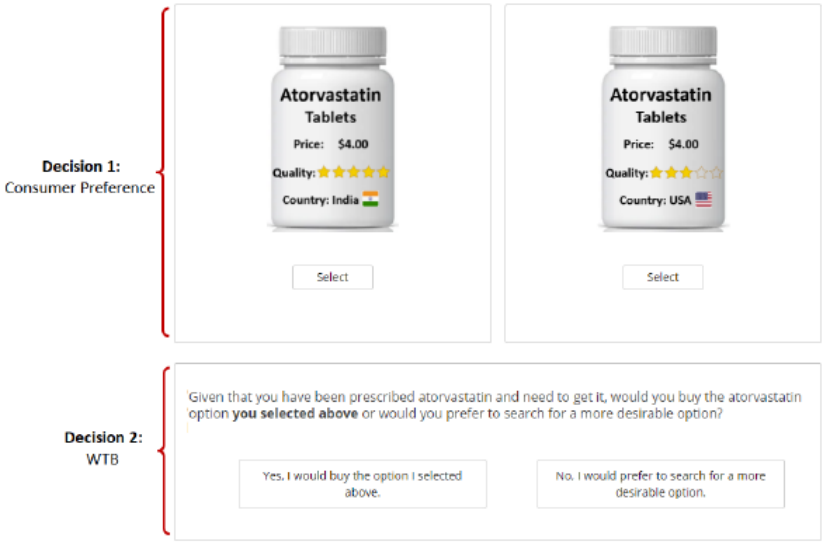

Figure 1 Screenshot with an Example of the CBC Task for Consumers.

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

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

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

[10] https://www.fda.gov/drugs/generic-drugs/overview-basics

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

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

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

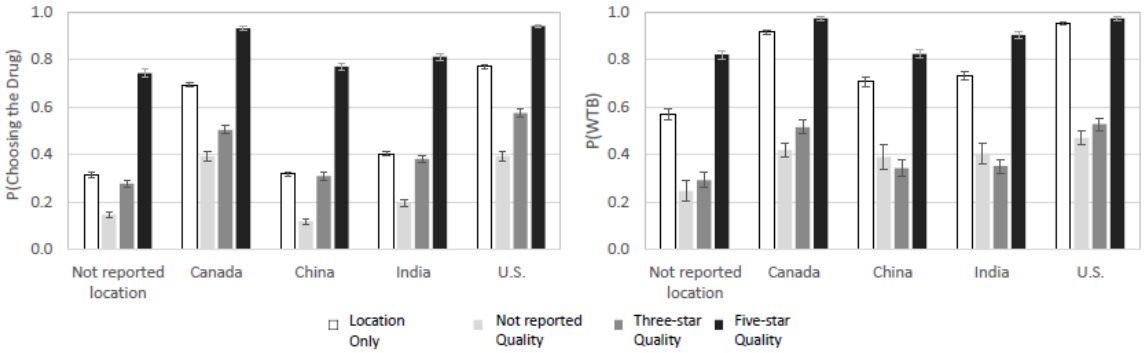

Figure 2 Margins plots including interactions with manufacturing location for Drug Preference (left) and WTB (right) for Consumers.

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

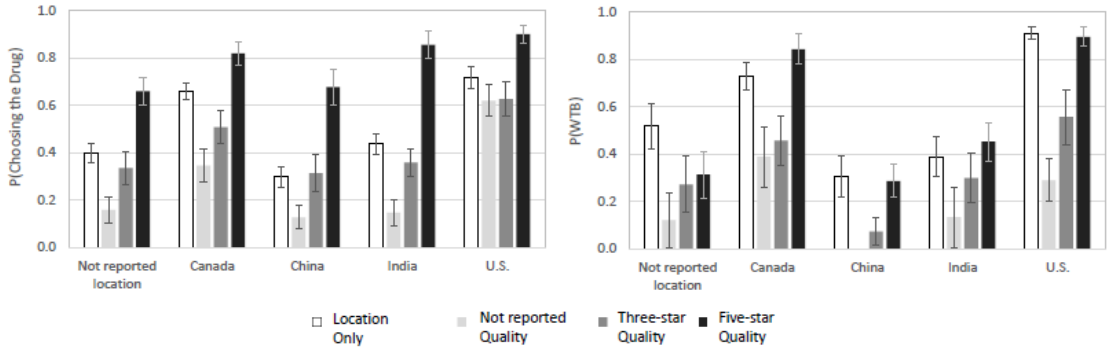

Figure 3 Margins plots including interactions with manufacturing location for Drug Preference (left) and WTB (right) for Pharmacists.

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

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

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

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

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

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

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

Summary

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

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

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

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