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**Submitted January 26, 2026**

**Abridged version to be read at the hearing**

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

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

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

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

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

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

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

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

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[3] e.g., https://www.bloomberg.com/news/newsletters/2025-01-08/generic-drug-poses-dangers-when-potency-falls-short-of-brand-name

[4] https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html

[5] e.g., https://www.propublica.org/article/fda-hides-drug-names-contaminated-factories

[6] e.g., https://wjla.com/features/i-team/the-deadly-consequences-of-americas-reliance-on-foreign-made-drugs-medication-prescriptions-health-fda-inpesctions-generics-medicine-united-states-pills-cough-syrup-eye-drops

[7] https://journals.sagepub.com/doi/10.1177/10591478251319691

[8] A recent RAND study found that, while the U.S. does pay more for branded drugs than the rest of the world, we pay substantially less than the rest of the world for our generic drugs.

[9] See, e.g., Almeter, Philip J., et al. "FDA approaches in monitoring drug quality, forces impacting the drug quality, and recent alternative strategies to assess quality in the US drug supply." *Journal of Pharmaceutical Innovation* 17.2 (2022): 269-282.

[10] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5252874

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

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

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

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

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

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

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

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

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

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

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

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

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

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[21] The FDA already has, at least, facility level compliance scores (e.g., Figure 4 on page 5 of this: https://www.fda.gov/media/135046/download?attachment); they may also have internal drug level quality scores. They do not release these scores at the level of facility or drug; only occasionally in aggregate.

[22] e.g., https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4120736 ; https://pubmed.ncbi.nlm.nih.gov/39574836/

[23] e.g., DiRx, Mark Cuban Cost Plus Drugs

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

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

[24] This helps to address the fact that personal liability for producing adulterated products is much more easily enforceable for domestic plant and quality managers than for foreign managers, another factor that tilts attention away from strict compliance and towards cost in foreign facilities.
[25] https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen
[26] https://www.finance.senate.gov/chairmans-news/crapo-wyden-introduce-bipartisan-pharmacy-benefit-manager-legislation