Journal of Law, Medicine & Ethics (2025), **53**, 1, 168–170
doi:10.1017/jme.2025.56

CAMBRIDGE UNIVERSITY PRESS

Columns: Health Policy Portal

Certification Marks for Supporting Generic Drug Quality

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Abstract

Certification marks are a type of trademark used to show that a product or service meets specific standards or qualities set by an independent organization (not by the manufacturer or seller). Certification marks could enhance the quality perception and oversight of generic drugs. Despite the FDA's rigorous regulatory framework, skepticism about generic drug quality persists among patients and prescribers, partly due to the FDA's limited ability to inspect manufacturing facilities. Independent certification marks — similar to USDA Organic or Energy Star labels — could help communicate drug quality information more effectively to consumers, incentivize manufacturers to exceed baseline standards, and bolster trust in generics. Such a system could operate without legislative changes and offer a cost-effective supplement to existing FDA inspections, particularly given the challenges posed by an increasingly globalized drug supply chain and current FDA resource constraints.

Keywords: generic drug; FDA

About This Column

Aaron Kesselheim serves as the editor for Health Policy Portal. Dr. Kesselheim is the JLME editor-in-chief and director of the Program On Regulation, Therapeutics, And Law at Brigham and Women's Hospital/Harvard Medical School. This column features timely analyses and perspectives on issues at the intersection of medicine, law, and health policy that are directly relevant to patient care. If you would like to submit to this section of JLME, please contact Dr. Kesselheim at akesselheim@bwh.harvard.edu.

The US generic drug market is among the safest in the world due to stringent monitoring by the Food and Drug Administration (FDA) throughout the entire lifecycle and supply chain of a product. Still, both patients and prescribers exhibit generic drug skepticism based in part on the idea that generic drugs are lower quality products. This skepticism can reduce appropriate use of generic drugs and mitigate benefits such as their downward price pressure on equivalent products, increased adherence, and increased accessibility. The FDA, however, has stated that "many pharmaceutical manufactures have been slow to invest in [updated] quality management systems because the market currently has no visibility into manufacturing facilities' quality. This lack of transparency reinforces competition based solely on price and disincentivizes companies from making investments in upgrading their facilities and quality practices."[1]

The international drug supply chain challenges effective quality oversight by regulators like the FDA. While the FDA performed 16,100 domestic and 5,563 foreign inspections in fiscal years 2015–2019 (pre-pandemic), inspections decreased during the pandemic to only 8,391 domestic and 2,649 foreign inspections in fiscal years 2020–2024 (post-pandemic).[2] Over the last few decades, many drug manufacturers have moved their production facilities overseas to benefit from business advantages, such as lower labor costs. In 2019, only 28% of active pharmaceutical ingredient manufacturing facilities and 47% of finished dosage form manufacturing facilities supplying drugs in the US market were located within the US.[3]

Additional FDA funding could help continue to ensure high quality manufacturing standards, though Congressional action substantially expanding the budget of the FDA seems unlikely in the current political climate. One way to leverage the private market to help supplement regulatory oversight of generic drug quality would be to introduce generic certification marks. These marks could indicate the existence of routine independent generic drug testing in addition to the FDA's inspections and could otherwise help clearly communicate generic drug manufacturing information to the public.

Certification Marks

Certification marks are a type of trademark used by organizations other than the owner of a product that identify the product as meeting particular quality or productions standards. Certification marks currently exist in food, supplements, and other consumer products. Examples include "USDA Organic" for food production, "Energy Star" for appliance efficiency, and "NSF International" for

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Cite this article: L. Lindgren, A.S. Kesselheim, & S.S. Tu. "Certification Marks for Supporting Generic Drug Quality," *Journal of Law, Medicine & Ethics*, **53**, 1 (2025): 168–170. https://doi.org/10.1017/jme.2025.56

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https://doi.org/10.1017/jme.2025.56 Published online by Cambridge University Press

assuring the quality of dietary supplements, vitamins, and food products.

One of the main benefits of certification marks is that they communicate product quality information, often using a simple logo that consumers can recognize. In turn, certification marks are also important for incentivizing high-quality production from manufacturers. Quality certification and disclosure drive consumers towards higher-quality products, allowing certified manufacturers to capture larger market shares.

Traditionally, in the generic market, consumers generally cannot ensure they receive a particular manufacturer's product because the generic market is built upon years of evidence that each FDA-approved product is clinically interchangeable with the original drug and each other. As a result, generic manufacturers are incentivized to make the products that meet the FDA's quality standards as cheaply as possible so that they can extract the greatest amount of revenue. Compliance with FDA Good Manufacturing Practices and submission to routine or scheduled inspections are part of that process, but there is no way for generic manufacturers to communicate details of these quality-supporting practices to patients, such as how recently their facilities had been inspected or the absence of any warning letters or other corrective actions. With the wide dispersion of generic drug manufacturing sites and the FDA's perennial challenges subjecting them to oversight, private certification marks could help support consumer confidence in generic drugs.

Supplementing the Current System

Implementing a system of independent testing and certification marks to communicate generic drug quality would not require legislative intervention. Third-party labeling is not reviewed or approved by the FDA. Additionally, generic drugs are usually inexpensive, making independent testing economically feasible, especially relative to their brand-name alternatives. Some testing is already performed by the FDA, but it is limited. Within the FDA, the Center for Drug Evaluation and Research (CDER) maintains a comprehensive quality-assurance testing program that ensures both generic and brand-name drugs are manufactured to levels set by the US Pharmacopeia (USP).[4] USP certification marks are available on dietary supplements and food products, but they are not used for drugs. Additionally, due to resource constraints, CDER must employ a targeted, risk-based approach in which they focus their resources on particular products.[5] And when potential issues arise, these findings are released in a report that may be difficult to understand or that many consumers may not know exists altogether.

By focusing on the less expensive generic products, independent testing would allow greater flexibility to target a wide range of drugs in an effort to minimize generic skepticism, and certification marks would make testing information more accessible and comprehensible to consumers. And while consumers often do not choose their own generic alternatives, with the choice among manufacturers instead occurring at the pharmacy level, certification marks can still influence choices upstream in the supply chain. Pharmacies are not immune from market competition and therefore similarly face incentives to carry drug products that consumers trust, maintaining the opportunity for certification marks to influence the generic market through quality disclosure.

Furthermore, while using a certification mark may initially impose additional costs on manufacturers, widespread adoption remains feasible. For example, "B Corp" certification marks hold corporations to additional social sustainability standards beyond those of a traditional shareholder-oriented company. Still, despite these additional obligations, the number of B Corporations is growing, as a B Corp mark helps establish an advantage over competitors.[6] Similarly, a certification mark for generic drug quality would serve as an important distinguishing factor among several manufacturers producing otherwise identical products such that it would be in a manufacturer's best interest to put their product through independent testing and quality controls before displaying the certification mark.

Conclusion

Generic drug skepticism harms the cost-saving potential and accessibility of generic alternatives. While the FDA inspections and oversight ensure a safe generic drug market in the US, information about manufacturer inspections is generally inaccessible for consumers, and the agency continues to face challenges threatening its ability to perform effective inspections. Independent testing is an economically feasible opportunity to supplement FDA inspections, and certification marks can be leveraged to clearly communicate drug quality information to consumers, creating additional quality incentives for manufacturers and providing further assurance for consumers on the quality of generic drugs.

Role of the Funder. The funder had no role in the design or conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Funding. This work was funded by Arnold Ventures and the Commonwealth Fund.

Disclosures. Dr. Kesselheim reports serving as an expert witness on behalf of a class of individual plaintiffs in a case against Gilead relating to a new formulation of tenofovir disoproxil, and on behalf of a class of state attorneys general and payors in a case against numerous generic drug manufacturers related to alleged price fixing. Dr. Tu reported consulting for purchasers of lenalidomide and abiraterone acetate-containing products outside the submitted work.

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https://doi.org/10.1017/jme.2025.56 Published online by Cambridge University Press

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