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Reforms Needed to Modernize the US Food and Drug Administration's Oversight of Dietary Supplements, Cosmetics, and Diagnostic Tests

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Congress is in the process of reauthorizing the user fee programs that help fund operations of the US Food and Drug Administration (FDA), but legislators could not reach final agreement on 3 major provisions intended to modernize the agency's regulatory framework, advance innovation, and strengthen its ability to protect consumers. These provisions address the FDA's oversight of dietary supplements, cosmetics, and diagnostic tests for patients—and represent once-in-a-generation reforms developed through a largely bipartisan process.

All 3 industries are benefiting from technological advances that offer new opportunities to improve people's health, but also create new uncertainties and risks. For each of these industries, evidence indicates that products that slipped through a porous regulatory framework have put some individuals at risk. Industry participants have also expressed concerns about difficulties in advancing potentially beneficial new kinds of innovations under the FDA's existing regulatory authorities, which have not kept up with the market's current state.

The 3 provisions were years in the making. Aspects of each took shape while we individually served as FDA commissioner at 2 points over the last 20 years,[1] reflecting how long the FDA and many of its stakeholders have sought these new measures. Their absence from the final bill reauthorizing the FDA's user fee programs is a profound missed opportunity.

Congress could authorize these measures later this year when legislation to fund the federal government for the coming year is expected to pass. But that prospect is slim unless there is a strong bipartisan commitment to enact them.

Oversight of Dietary Supplements

About 80% of US consumers report using dietary supplements. Many of them help improve people's health, but some contain dangerous or unexpected ingredients or may be used in unsafe ways. Between 2004 and 2013, the FDA received more than 15 000 reports of health problems linked to dietary supplements, including nearly 4000 hospitalizations. A recent survey found that people overestimate the scope and strength of the FDA's regulation of supplements, mistakenly believing that the FDA reviews or tests products before they reach the market.[2] No such requirements currently exist; and manufacturers often do not disclose the ingredients of new products to regulators and consumers.

The provision to reform the FDA's oversight of dietary supplements would address this gap by giving the agency authority to require manufactures to list the ingredients that each product contains. Under the new provision, all manufacturers would be required to notify the FDA when a product is introduced or modified and to disclose the composition of ingredients and factors such as a product's intended dosage and serving size.

Oversight of Cosmetics

Most cosmetics are safe, but consumers currently have no reliable way to know what is in their products, to be alerted if a product has safety issues, or to be protected if a manufacturer fails to act to address clear safety problems. Calls for reforms have been made repeatedly when safety issues

have arisen, most recently in 2019, when asbestos was found in some cosmetics that were marketed under popular brands.[1]

The proposed legislative measures related to cosmetics would give the FDA authority to recall cosmetics found to contain ingredients likely to cause serious harm when companies refuse to initiate a voluntary recall. They would also require manufacturers to follow good manufacturing practices, disclose the ingredients, and attest that they have developed safety records for the products. Manufacturers of cosmetics would also be required to report serious adverse health events to the FDA.[3]

Oversight of Diagnostic Tests

Diagnostic tests used for screening blood and tissue samples hold the promise of increasingly accurate, early determination of a person's risk and health status through genetic, protein, and other markers—helping guide decisions leading to more effective treatment and fewer complications. But these products are regulated as medical devices, a framework that is increasingly outdated for modern diagnostic tests. The existing structure results in a bifurcated framework, in which the location where a test was developed, not what it purportedly does or its complexity, determines how the FDA regulates it. This configuration is not well suited to facilitating predictable and timely access to increasingly important innovations.

Today's diagnostic tests using genetic and other markers are evolving rapidly, as more sophisticated markers and richer data become available. But the FDA does not allow diagnostic tests already under its active oversight to be adapted quickly as the predictive value of genetic and other markers for disease risk evolves. The result is a cumbersome process for manufacturers of diagnostic tests to update their products based on the latest evidence and detection capabilities.

In contrast, test developers at laboratories in many academic medical centers have claimed that they are excluded from the FDA's regulatory framework and can introduce new tests or modify existing tests without seeking the FDA's permission; the FDA has stated in response that it is exercising enforcement discretion in not applying its framework. Instead, Medicare requires that these tests report data related to their accuracy. But Medicare generally reviews such data as part of its routine surveys, which occur every few years, and does not review a test's safety and effectiveness in its intended uses. This approach allows laboratory-developed tests to be updated rapidly, but does not provide a reliable assurance of consistent quality. A recent study reported that laboratory-developed tests offered for the same intended use as an FDA-approved companion diagnostic test had significant variability in their performance.[4]

This bifurcated approach is not aligned with what matters most to patients—assurance that the tests make use of the latest evidence, and that the results are consistent and reliable and will improve their care. Inaccurate test results and those based on out-of-date evidence can lead to misdiagnosis, inappropriate treatment decisions, and the spread of infectious disease.

The proposed FDA legislation creates a modern framework uniquely tailored to diagnostic tests and the rigor taken by the entities that develop them, including a new pathway to allow the FDA to take a laboratory- or company-based approach to regulation. The FDA would oversee the process used to develop and validate tests, rather than regulating only the tests themselves. Laboratories with good procedures for ensuring the reliability of their tests would, in many cases, be able to market new tests and iterations of existing platforms without undergoing the same premarket adjudications. At the same time, the new pathway would give the FDA clear authority to oversee tests and ensure that all tests meet certain common requirements for demonstrating that they reliably produce the molecular and genomic findings that they are intended to generate.

Many academic centers are understandably reluctant for their laboratory-developed tests to be subject to additional regulation. But institutions that demonstrate they are overseeing the safety and reliability of their laboratories would have a streamlined regulatory path not available today. The legislation would also grandfather in most of the existing laboratory-developed tests.

These 3 legislative provisions are not perfect. Both Democrats and Republicans have raised legitimate concerns, as have some stakeholders, but the relatively small issues that remain could be worked out through the Congressional committees that authorize the FDA. Congress should seize this opportunity to achieve long-awaited reforms that will modernize FDA's regulation, promote innovation, and provide US consumers greater assurance that the products they use are safe and reliable.

ARTICLE INFORMATION

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