CENTER FOR Science IN THE Public Interest

Laboratory-Developed Tests Final Rule: Public Health Benefits Outweigh the Costs

On May 6, 2024, the Food and Drug Administration (FDA) released its final rule to phase out enforcement discretion over laboratory-developed tests (LDTs), meaning the agency plans to actively regulate these products.[1] The rule clarifies that LDTs are medical devices under the Medical Device Amendments of 1976 and directs LDT manufacturers to comply with oversight requirements in five stages over four years.[1] The proposed rule, released in October of 2023[2], received almost 7000 public comments[3] that resulted in the inclusion of many exemptions in the final rule. Notable exemptions to the rule include LDTs currently in use (grandfathering), those reviewed by New York's Clinical Laboratory Evaluation Program (CLEP), those developed for unmet patient care needs within health systems, and tests with minor modifications.[1]

How much will this cost?

Concern about cost and resource burden was one of the most common complaints in public comments to the docket. Based on FDA's economic analysis of the final rule—a standard part of such rulemakings—implementation is estimated to cost the clinical laboratory industry an average of **$1.37 billion annually for 20 years** (3 percent discount rate)**.**[4] These costs include administrative monies spent to comply with registration, quality assurance and other requirements. However, most of this cost is incurred from preparing premarket submissions.[3] In addition, industry would be responsible for $0.069 billion annually in transfers, primarily in the form of user fees, paid to FDA.[3] Costs are expected to level off four years after implementation of the rule begins.[3]

Is the cost worth it?

In CSPI's view, yes. While the estimated cost of the rule is significant, the expected benefits are much greater. In the FDA's economic analysis, the estimated public health benefits are **$4.34 billion annually over 20 years**.[3] Said another way, **for every $1 spent by industry to comply with LDT oversight, there would be about $3 in public health benefit**, on average. The benefits would begin accruing two years after implementation of the rule, immediately offsetting the costs of the rule, and continue to increase year over year.[3]

This valuation of benefits is almost certainly an underestimate. Benefits were calculated based on harm avoidance related to only three specific conditions: cancer, cardiovascular disease (specifically from optimization of risk-lowering drugs such as statins) and infections, primarily sexually transmitted infections.[3] The analysis does not calculate non-health benefits such as

money saved on unnecessary tests, cost-savings from litigation involving faulty tests, or the cost of the spread of communicable diseases.[3]

Annual cost/benefit summary, based on 20-year analysis[3]

Cost	Transfers	Benefit	Net Annual Benefit (=Benefit-Cost-Transfers)
$1.37 billion	$0.069 billion	$4.34 billion	**$2.9 billion**

Did FDA consider alternatives to this rule?

Yes. FDA described several alternatives such as shortening or lengthening the phaseout period or offering virtually no exemptions.[3] Of those considered, the final rule presented the best balance of public health benefits and costs.[3]

For more information, please contact the Center for Science in the Public Interest at policy@cspinet.org.

[1] 89 Fed Reg. 37286. Medical Devices; Laboratory Developed Tests
[2] 88 Fed Reg. 68006. Medical Devices; Laboratory Developed Tests
[3] Food and Drug Administration. *Medical Devices; Laboratory Developed Tests.* Regulations.gov. October 3, 2023. https://www.regulations.gov/document/FDA-2023-N-2177-0001. Accessed <September 4, 2024>.
[4] Food and Drug Administration. *Laboratory Developed Tests Final Rule Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis.*; 2024. https://www.fda.gov/media/178133/download?attachment. Accessed <August 27, 2024>.