United States v. Elizabeth Holmes and Ramesh Balwani

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I. WHY THIS CASE MADE THE LIST

A highly publicized and long-running multi-agency action against the former Chief Executive Officer and the former Chief Operating Officer of Theranos Inc. resulted in criminal convictions last year against both executives for their roles in deceiving investors, doctors, and patients about the Company's failed diagnostic tests. While this case is not premised upon violations of the Federal Food, Drug, and Cosmetic Act (FDCA)—and might even be considered by some industry observers to be ancient history at this point—the case is nevertheless important, and not only because the individuals at the helm were held personally and criminally accountable for their conduct. The case remains relevant because it has attracted the attention of lawmakers, and regulators are pointing to the underlying facts as a cautionary tale to promote a change in the regulatory landscape surrounding diagnostics.

II. SUMMARY OF THE CASE

Former Chief Executive Officer (CEO) of Theranos Inc. (Theranos or the Company), Elizabeth Holmes, and former President and Chief Operating Officer (COO), Ramesh "Sunny" Balwani, were indicted in June 2018 for defrauding investors, doctors, and patients by lying about the performance of the Company's blood testing technology and about the Company's financial condition, key business dealings, and future prospects.[1] Charges were brought by the U.S. Department of Justice (DOJ) in the Northern District of California based on an investigation conducted by the Federal Bureau of Investigation (FBI), U.S. Food and Drug Administration (FDA), and the U.S. Postal Inspection Service (USPIS). Each defendant was charged with two counts of conspiracy to commit wire fraud, in violation of 18 U.S.C. § 1349, and nine counts of wire fraud, in violation of 18 U.S.C. § 1343.

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[1] The original indictment was superseded on July 14, 2020, and the second indictment was superseded on July 28, 2020. The summary below discusses the allegations that were made in the operative indictment dated July 28, 2020. *See* Third Superseding Indictment, United States v. Elizabeth Holmes & Ramesh "Sunny" Balwani, No. 5:18-CR-0258-EJD, Doc. No. 469 (N.D. Cal., July 28, 2020).

In essence, the defendants were charged with making false statements in advertisements and using other methods to persuade doctors and patients to use the Company's tests, even though they were aware that the tests were not capable of providing accurate and reliable results. For example, the executives claimed (or directed the Company to claim) that Theranos could quickly and accurately run a combination of tests at once from a single blood sample comprised of a few drops of blood collected from a fingerstick. Defendants made these representations despite their personal knowledge that the technology was not capable of consistently producing accurate and reliable results for certain blood tests, including tests for calcium, cholesterol, gonorrhea, glucose, HbA1c, HIV, testosterone, and TSH. To induce individuals to purchase the tests, the advertisements also falsely claimed that the Theranos tests were cheaper than blood tests from conventional laboratories.

The defendants were also alleged to have made numerous material misrepresentations to potential investors (though direct communications, marketing materials, media statements, financial statements, etc.) about the Company's business relationships with Walgreens and the U.S. Department of Defense (DoD), the regulatory status of the analyzer and tests, and the quality of the tests. The executives claimed that the TSPU (Theranos' proprietary analyzer) was capable of performing the full range of clinical tests using fingerstick samples while producing better results and at a faster speed than conventional methods. In reality, the TSPU performed a limited number of tests, was slower than some competing analyzers, and could not compete in terms of throughput or simultaneous testing against larger, conventional machines. The indictment alleges that the defendants were aware of the accuracy, reliability, and performance limitations of the analyzer when they touted the technology's performance.

In addition to misrepresenting the technology's performance capabilities, the indictment alleges that the executives misrepresented to investors the Company's revenue potential and made a number of false representations, including that 1) its business partnership with Walgreens was expanding when, in fact, the rollout was stalled due to Walgreens' concern with the performance of the technology; 2) the Company had a profitable relationship with the DoD when, in fact, the revenue from military contracts was limited; 3) the DoD had deployed the technology to the battlefield, when in fact, it had not; 4) the Company had conducted certain tests on patient samples using the Company's proprietary technology, when in fact, the patient samples were tested using other commercially available analyzers; 5) the Company's proprietary technology had been validated by several pharmaceutical companies and research institutions, when in fact, it had not; 6) patient samples were being run using the Company's proprietary technology during certain demonstrations to investors, when in fact, the demonstration was faked; and 7) FDA clearance or approval of the proprietary analyzer and tests was not required but that Theranos was planning to make a submission to the FDA voluntarily because FDA clearance or approval was considered the "gold standard" in the industry. In reality, the indictment alleges that the executives knew that FDA was requiring Theranos to make a submission.

The case against Holmes and Balwani was bifurcated into separate trials for each defendant. The trial against Holmes commenced in September 2021. After a fifteen-week trial, the jury found Holmes guilty of conspiracy to commit wire fraud against the Company's investors and three counts of wire fraud related to the scheme to

defraud investors.[2] Holmes was acquitted of the patient-related fraud conspiracy count and the three counts of fraud against individual patients. The jury could not reach a unanimous verdict with respect to three individual investor fraud counts against Holmes. An additional count of wire fraud relating to a Theranos patient had been dismissed during trial. On November 18, 2022, Holmes was sentenced to over eleven years (135 months) in federal prison and was ordered to surrender to begin serving her sentence on April 27, 2023.[3]

Balwani's trial commenced in March 2022, and he was convicted in July 2022 on all counts of investor and patient fraud.[4] In December 2022, Balwani was sentenced to almost thirteen years (155 months) in federal prison for his role in perpetuating the fraud.[5] A hearing on the amount of restitution that each defendant will owe is still pending. Both defendants have appealed their convictions.[6]

Aside from the criminal action, the individual defendants and the Company have suffered additional fallout from their actions. Holmes and Theranos previously settled a civil complaint by the U.S. Securities and Exchange Commission (SEC) related to the fraud whereby Holmes agreed to pay a $500,000 penalty, return 18.9 million shares of Theranos, relinquish her voting control in the Company, and be barred from serving as an officer or director of a publicly owned company for ten years.[7] (Balwani's SEC case was stayed pending resolution of the criminal case.[8]) In addition, Theranos settled consumer law violation claims made by the Arizona Attorney General alleging that the Company made false, deceptive, misleading, and unfair claims to consumers regarding the tests.[9] Walgreens and Safeway ended their business relationships with Theranos, and Walgreens sued the Company, which resulted in a settlement for an

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2 Final Verdict Form, United States v. Holmes, Case No. 5:18-CR-00258-EJD, Doc. No. 1235 (N.D. Cal. Jan. 3, 2022).

3 Order on Sentencing, United States v. Holmes, Doc. 1712 (Jan. 10. 2023).

4 Final Verdict Form, United States v. Balwani, Doc. 1507 (July 7, 2022).

5 Order on Sentencing, United States v. Balwani, Doc. 1730 (Feb. 16, 2023).

6 Holmes Notice of Appeal, United States v. Holmes, Doc. 1670 (Dec. 2, 2022); Balwani Notice of Appeal, United States v. Balwani, Doc. 1705 (Dec. 21, 2022).

7 Press Release, U.S. Sec. & Exchange Comm'n, Theranos, CEO Holmes, and Former President Balwani Charged with Massive Fraud (Mar. 14, 2018), https://www.sec.gov/news/press-release/2018-41.

8 Order Staying and Administratively Closing Action, Sec. & Exchange Comm'n v. Ramesh Sunny Balwani, Case No. 5:18-CV-01603-EJD (N.D. Cal. June 30, 2021).

9 Press Release, Az. Att'y General, AG Brnovich Obtains $4.65 Million for Arizonans Who Purchased Theranos Blood Tests (Apr. 18, 2017), https://www.azag.gov/press-releases/ag-brnovich-obtains-465-million-arizonans-who-purchased-theranos-blood-tests; Ken Alltucker, *Theranos Reaches $4.65 Million Fraud Settlement with Arizona*, AZCENTRAL (Apr. 18, 2017), https://www.azcentral.com/story/money/business/health/2017/04/18/theranos-reaches-465-million-settlement-arizona-blood-testing/100582618/.

undisclosed amount.[10] In the face of these and other legal actions, the Company eventually closed its labs, laid off its employees, and dissolved.[11]

III. CMS AND FDA CONCERNS ABOUT THE TESTS

The indictment did not include any charges under the Federal Food, Drug, and Cosmetic Act (FDCA), nor were any charges brought alleging any violations of the Clinical Laboratory Improvement Amendments (CLIA). The government nevertheless was permitted to introduce some evidence related to the Company's failure to comply with these laws and related regulations. The Company had received reports from the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the California Department of Public Health (CDPH) detailing their respective observations from regulatory inspections. When ruling against Holmes' motion to exclude such evidence, the court explained that the evidence was probative of Holmes' state of mind, intent, and knowledge. In particular, the court found that:

> the evidence has a tendency to show Holmes' state of mind regarding Theranos' interactions with the regulatory agencies, the extent to which Holmes knew or should have known that Theranos was failing to meet certain federal regulations, and whether Holmes intended to mislead investors regarding the accuracy and reliability of Theranos' technology.[12]

Consequently, the jury was instructed that it could consider evidence of regulatory violations in light of the specific elements that must be proved in connection with the counts charged in the indictment.[13]

The evidence of regulatory violations presented to the jury included a redacted report from CMS outlining deficiencies it observed during a recertification and survey of Theranos' Newark, California laboratory in September 2015. The report pointed out multiple deficiencies, including failure to ensure acceptable quality control (QC) for the proprietary system prior to reporting patient test results, failure to institute a quality assessment (QA) procedure to identify and correct problems when the system failed to meet precision requirements, and failure to establish a QA procedure to identify and correct problems with the QC program. The report listed several examples where large percentages of QC samples reported values that called into question the ability of the system to produce accurate results.

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[10] *Walgreens Officially Breaks-Up with Theranos*, FDANEWS (June 17, 2016), https://www.fdanews.com/articles/10158-walgreens-officially-breaks-up-with-theranos; Christopher Weaver, John Carreyrou & Michael Siconolfi, *Walgreen Sues Theranos, Seeks $140 Million in Damages*, WALL ST. J. (Nov. 8, 2016), https://www.wsj.com/articles/walgreens-seeks-to-recover-140-million-investment-from-theranos-1478642410; Emily Wasserman, *Safeway Severs Ties with Theranos as $350M Deal Collapses*, FIERCE BIOTECH (Nov. 11, 2015), https://www.fiercebiotech.com/medical-devices/safeway-severs-ties-theranos-as-350m-deal-collapses.

[11] *Theranos Calls It Quits*, FDANEWS (Sept. 6, 2018), https://www.fdanews.com/articles/188300-theranos-calls-it-quits; *Embattled Blood-Testing Firm Theranos to Dissolve: WSJ*, REUTERS (Sept. 4, 2018), https://www.reuters.com/article/us-theranos-bankruptcy/embattled-blood-testing-firm-theranos-to-dissolve-wsj-idUSKCN1LL077.

[12] Order re Motions in Limine at 13, United States v. Holmes, Doc. 798 (May 22, 2021).

[13] Final Jury Instructions at 33, United States v. Holmes, Doc. 1206 (Dec. 9, 2021).

CMS sent a letter to Theranos dated January 25, 2016 informing the company that following the November 20, 2015 survey of the laboratory, CMS determined that 1) the facility was not in compliance with all of the Conditions required for certification in the CLIA program; and 2) that based on the condition-level requirement at 42 C.F.R. § 493.1215, Hematology, the laboratory's deficient practices posed "immediate jeopardy to patient health and safety."[14] As a result, immediate corrective action was necessary because the non-compliance "has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."[15] The letter notified Theranos that the Company had ten calendar days in which to provide a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy had been removed. Theranos submitted a response to this letter on February 12, 2016, but CMS concluded that the submission did not demonstrate that the laboratory had come into compliance and abated the immediate jeopardy. After some additional back and forth between Theranos and the agency, CMS revoked Theranos' CLIA certificates, imposed a civil money penalty, and levied other sanctions on the Company.[16] Theranos appealed the revocation but subsequently reached a global settlement agreement with CMS, whereby CMS withdrew the revocation of the CLIA certificates and reduced the civil monetary penalty, and Theranos agreed not to operate a clinical laboratory for two years.[17] Evidence pertaining to the settlement with CMS was excluded from the trial.[18]

FDA also inspected the Newark facility in August and September 2015, and it issued a Form FDA-483 inspectional observation report outlining nine observations of objectionable conditions.[19] Of note, the Company was cited for shipping an uncleared medical device in interstate commerce. According to the 483 report, FDA identified the Company's capillary tube nanotainer (a blood specimen collection device) as a Class II medical device, but the Company had identified it as a Class I exempt medical device. FDA also uncovered several systemic issues and cited the Company for failing to: have adequate procedures for evaluating complaints, evaluate and document complaints, document corrective and preventive action (CAPA) activities, document software validation activities, evaluate potential suppliers, maintain adequate records of acceptable suppliers, establish procedures for device history records, and perform quality audits.

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[14] Letter from CMS to Theranos dated Jan. 25, 2016, Trial Exh. 4621a.

[15] *Id.*

[16] Letter from Ctrs. for Medicare & Medicaid Servs. to Sunil Dhawan, Director, Elizabeth Holmes, Owner & Ramesh Balwani, Owner, Theranos (July 7, 2016), https://www.wsj.com/public/resources/documents/r_Theranos_Inc_CMS_07-07-2016_Letter.pdf.

[17] Settlement Agreement, Exhibit 29 to Declaration of Amy Mason Saharia in Support of Ms. Holmes' Motions in Limine and Daubert Motions to Exclude Expert Testimony, United States v. Holmes, Doc. 583-3 (Nov. 20, 2020); *Theranos Reaches Resolution with Centers for Medicare & Medicaid Services*, BUSINESS WIRE (Apr. 17, 2017), https://www.businesswire.com/news/home/20170417005931/en/CORRECTING-and-REPLACING-Theranos-Reaches-Resolution-with-Centers-for-Medicare-Medicaid-Services.

[18] Order re Motions in Limine at 16, United States v. Balwani, Doc. 1326 (Feb. 28, 2022).

[19] U.S. FOOD & DRUG ADMIN., THERANOS INC. (NEWARK) FORM FDA-483 (Sept. 16, 2015), https://www.fda.gov/files/about%20fda/published/Theranos--Inc.--Newark--CA-483-Issued-09-16-2015.pdf.

FDA contemporaneously inspected the Company's Palo Alto facility and issued a separate Form FDA-483 inspectional observation report outlining five observations of objectionable conduct.[20] FDA found that the Company's design validation did not ensure that the device conformed to defined user needs and intended uses, the design was not validated under actual or simulated use conditions, the Company failed to adequately document design input requirements and design risk analysis, and designated individuals did not review and approve important regulatory documents (such as a hazard analysis) prior to issuance.

IV. IMPACT OF FAULTY TESTS ON PATIENTS

In response to the CMS investigation observational findings, the Company performed a patient impact assessment, which concluded that the laboratory performed poorly and exhibited abrupt shifts in quality control target means. Since the Company could not discern the magnitude of the bias on patient results, the laboratory concluded that there was a "possible patient impact for every test reported" from the proprietary instruments.[21] The laboratory consequently "voided" all patient test results reported from these instruments, but according to the Company's lab director at the time, Theranos did not communicate that it had voided the results to all the affected patients.[22]

The government also provided specific examples of patients who had received inaccurate test results. For example, one patient testified that she received test results from Theranos that falsely indicated that she had HIV antibodies, causing her emotional distress.[23] Another patient testified that he received test results from Theranos that falsely indicated that he could have aggressive prostate cancer. After two of the three fingerstick tests he received from Theranos showed high prostate-specific antigen (PSA) levels, the patient took a fourth test taken venously by another company, which showed that his PSA levels were normal.[24] Another patient testified that a Theranos test falsely showed that she had experienced a sudden drop in hCG hormones, which would suggest a miscarriage. This was particularly concerning to the patient since she had previously had three miscarriages. Because the results were inconsistent with other clinical findings, her practitioner ordered another hormone test from another company, which revealed that the Theranos test was inaccurate. The patient eventually gave birth to a healthy baby.[25]

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[20] U.S. FOOD & DRUG ADMIN., THERNANOS INC. (PALTO ALTO) FORM FDA-483 (Sept. 16, 2015), https://www.fda.gov/media/94721/download.

[21] Patient Impact Assessment, Trial Exh. 4943.

[22] Dorothy Atkins, *Ex-Theranos Lab Chief Doubted Holmes' Implausible Takes*, LAW360 (Nov. 9, 2021), https://www.law360.com/articles/1439134/ex-theranos-lab-chief-doubted-holmes-implausible-takes.

[23] Dorothy Atkins, *Theranos Patient Got Incorrect HIV Test Result, Jury Told*, LAW360 (Nov. 17, 2021), https://www.law360.com/articles/1441334/theranos-patient-got-incorrect-hiv-test-result-jury-told.

[24] Dorothy Atkins, *Fortune Writer Claims Holmes Duped Him as DOJ Wraps Case*, LAW 360 (Nov. 18, 2021), https://www.law360.com/articles/1441736/fortune-writer-claims-holmes-duped-him-as-doj-wraps-case.

[25] Dorothy Atkins, *Theranos Test Wrongly Suggested Miscarriage, Jury Hears*, LAW360 (Sept. 21, 2021), https://www.law360.com/articles/1423718.

The government argued that the evidence of patient harm justified enhanced sentences for the defendants, but the court disagreed. Since Holmes was acquitted from the patient-related fraud, the judge declined to enhance her sentence to account for the harm to patients that may have resulted from her false statements.[26] The court also declined to enhance Balwani's sentence to account for patient harm. One factor in this decision was the fact that the "vast majority" of the samples that Theranos tested in its labs were run using other FDA-approved technology, not Theranos' platform, and that no evidence was offered to suggest that the FDA-approved devices had produced inaccurate results. With respect to patients who were tested using the Theranos technology, the court found that it was a "close question" whether Balwani consciously disregarded the risk of death or serious bodily injury to these patients, since Balwani tended to defer to the judgment of Theranos scientists. Although the evidence was consistent with a finding that Balwani "was aware of inaccuracies and intended to deprive patients of the benefit of their bargain," the court found that on balance, the evidence did not weigh in favor of imposing an enhancement to Balwani's sentence on these grounds.[27]

V. IMPLICATIONS ON REGULATORY LANDSCAPE

The criminal case against the former Theranos executives was not an FDA or CMS case, but rather it was a wire fraud and conspiracy case that was focused largely on misrepresentations about the performance of the tests that defrauded investors and patients. In many aspects, the allegations made here were likely simpler for a jury to understand than any allegations of regulatory misconduct that could have been made with the same set of facts. Evidence of regulatory violations was presented to demonstrate that the defendants had knowledge that the tests were plagued with difficulties yet continued to make false statements to secure business advantage. The regulatory status of Theranos' tests would have added a layer of complexity to the government's case, however, had the government sought a cause of action under the FDCA. Ultimately, the strategy paid off, since the prosecutors in this case succeeded in securing guilty verdicts and lengthy criminal sentences, making an example of high-profile executives and holding them personally accountable for their actions.

Although the potential for patient harm did not factor into the court's sentencing decisions, it was clearly a factor in the government's motivation to prosecute this case. According to an FDA press release about the case:

> The conduct alleged in these charges erodes public trust in the safety and effectiveness of medical products, including diagnostics. The FDA would like to extend our thanks to our federal law enforcement partners for sending a strong message to Theranos executives and others that these types of actions will not be tolerated.[28]

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[26] Order on Sentencing, United States v. Holmes, Doc. 1712 (Jan. 10, 2023).

[27] Order on Sentencing, United States v. Balwani, Doc. 1730 (Feb. 16, 2023).

[28] Press Release, U.S. Food & Drug Admin., Theranos Founder and Former Chief Operating Officer Charged in Alleged Wire Fraud Schemes (June 15, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/june-15-2018-theranos-founder-and-former-chief-operating-officer-charged-alleged-wire-fraud-schemes.

When Balwani was prosecuted, FDA put out a similar statement warning that FDA "will vigilantly investigate and bring to justice individuals and companies responsible for putting the public health at risk."[29]

The timing of this case is noteworthy because the regulatory regime governing laboratory developed tests (LDTs) has been under scrutiny in recent years, particularly in light of the increasing complexity of some LDTs as well as the quality of some LDTs that were developed in response to the COVID-19 pandemic. FDA has historically maintained that it has regulatory authority over LDTs (which are in vitro diagnostic (IVD) tests that are designed, manufactured, and used within a single laboratory) but that it had decided to exercise enforcement discretion and not require most LDTs to undergo premarket review or be subject to other regulatory requirements. In contrast, FDA has to date focused its regulatory oversight on commercial IVD tests pursuant to its authority to regulate medical devices and biological products under the FDCA. FDA regulates the safety and effectiveness of IVDs through a variety of premarket and postmarket controls, including requiring premarket submissions to allow FDA to assess the analytical and clinical validity as well as the quality of the design and manufacture of the test.[30] Clinical laboratories are regulated by CMS pursuant to its authority under CLIA, which requires laboratories to establish certain performance characteristics to assure analytical validity for use of the test system in the laboratory's environment.[31]

Lawmakers, regulators, and other stakeholders have pointed to this case as evidence for the need for additional regulatory oversight over laboratories.[32] For example, The Pew Charitable Trusts sent a letter to Xavier Becerra, the Secretary of the Department of Health and Human Services (HHS), in April 2021 advocating, among other things, for legislation to "update FDA's regulatory oversight of diagnostic tests and to provide regulatory certainty."[33] The letter acknowledged that Theranos "was not representative of the broader laboratory industry" but noted that the company had an incentive to offer its tests under the LDT framework in order to avoid FDA's premarket requirements. Pew argued that the example highlights "the risks associated with CLIA, which does not require premarket review even for high-risk tests," cautioning that "patients may be exposed to unreliable tests for years before regulators learn of any potential issues." Pew is advocating for Congress to enact the Verifying Accurate, Leading-edge IVCT Development (VALID Act) in order to close the "loophole" that Theranos' leaders exploited to avoid independent review of their devices.[34]

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[29] Press Release, U.S. Food & Drug Admin., Theranos Chief Operating Officer Ramesh "Sunny" Balwani Found Guilty of Conspiracy, Wire Fraud (July 27, 2022), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/theranos-chief-operating-officer-ramesh-sunny-balwani-found-guilty-conspiracy-wire-fraud.

[30] *See* FDA REGULATION OF LABORATORY-DEVELOPED TESTS (LDTS), CONG. RSCH. SERV.: IN FOCUS (Dec. 7, 2022), https://crsreports.congress.gov/product/pdf/IF/IF11389.

[31] 42 C.F.R. Part 493.

[32] *The Theranos Saga: A Wake-Up Call for the Lab-Developed Test Market*, MED. DEVICE NETWORK (Jan. 25, 2022), https://www.medicaldevice-network.com/features/theranos-ldt-regulation/.

[33] Letter from Liz Richardson, Project Director, Pew Charitable Trusts to The Hon. Xavier Becerra, Secretary, U.S. Dep't of Health & Human Svcs. (Apr. 28, 2021), https://www.pewtrusts.org/-/media/assets/2021/04/pew-urges-reversal-of-federal-policies-limiting-diagnostic-test-oversight.pdf

[34] Liz Richardson, *The Theranos Problem Congress Must Still Solve—Patients Need Protection*, THE PEW CHARITABLE TRUSTS: TRUST MAGAZINE (May 27, 2022),

The VALID Act would create a new regulatory pathway for in vitro clinical tests (ICVTs), which would regulate both LDTs and commercial IVD kits under a risk-based framework. Variations of this bill have been introduced in Congress during the past few years. Last year, the bill was included as a rider in an amendment to a Senate FDA user fee bill, the Food and Drug Administration Safety and Landmark Advancements (FDASLA), which had been approved by the Senate Health, Education, Labor, and Pensions (HELP) Committee but was not voted on by the Senate. VALID was ultimately not included as a rider in the Food and Drug Omnibus Reform Act (FDORA), which passed at the end of 2022 and authorized a number of FDA programs and initiatives that were considered by Congress during user fee negotiations.[35]

VALID was recently re-introduced in the U.S. House of Representatives by Reps. Larry Bucshon (R-Ind.) and Diana DeGette (D-Col.).[36] According to a press release by Rep. Bucshon, the legislation "comes in the wake of several high-profile scandals—including companies such as Theranos—that have led to increased demand among public health officials for greater oversight of diagnostic tests being used to screen patients in the United States."[37] Rep. DeGette has actively followed the Theranos testing scandal as part of her role as Energy and Commerce Committee Oversight and Investigations Subcommittee Ranking Member. Along with other Committee leaders, DeGette had previously sent letters to the Company as well as to FDA and CMS requesting information about the situation.[38]

FDA Commissioner Robert Califf has testified before Congress in favor of the VALID Act.[39] In the absence of legislation, FDA officials have indicated that the agency would consider administrative action, which could include rulemaking, to impose additional requirements on LDTs.[40]

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https://www.pewtrusts.org/en/trust/archive/spring-2022/the-theranos-problem-congress-must-still-solve-patients-need-protection.

[35] David Lim, *VALID Act Left Out of Year-End Omnibus*, POLITICO PRO (Dec. 20, 2022), https://subscriber.politicopro.com/article/2022/12/valid-act-left-out-of-year-end-omnibus-00074748;

[36] Verifying Accurate Leading-edge IVCT Development Act of 2023 or the "VALID Act of 2023", H.R. 2369, 118th Cong. (2023).

[37] Press Release, Larry Bucshon, M.D., Lawmakers Move to Reform Diagnostic Testing in United States (Mar. 29, 2023), https://bucshon.house.gov/news/documentsingle.aspx?DocumentID=4402.

[38] Press Release, Energy & Com. Comm. Democrats, Democratic Committee Leaders Request Information from FDA and CMS on Theranos' Inaccurate Blood Tests (July 26, 2016), https://democrats-energycommerce.house.gov/newsroom/press-releases/democratic-committee-leaders-request-information-from-fda-and-cms-on.

[39] *See, e.g.*, *Hearing on the Federal Response to COVID-19 Before the H. Comm. on Energy and Commerce Subcommittees on Health and Oversight & Investigations*, 118th Cong. (Feb. 8, 2023), https://energycommerce.house.gov/events/joint-oversight-and-investigations-subcommittee-and-health-subcommittee-hearing-titled-the-federal-response-to-covid-19-1 (statement of Dr. Robert Califf, Commissioner of Food and Drugs, U.S. Food and Drug Administration).

[40] Nick Paul Taylor, *FDA Moving Ahead with Rulemaking on Lab Developed Tests Without Waiting for Congress: BioWorld*, MEDTECH DIVE (Mar. 2, 2023), https://www.medtechdive.com/news/fda-rulemaking-lab-developed-tests-hillebrenner/643972/.