Health Law Outlook

The Health Law Forum ("HLF") is a student organization that connects Seton Hall Law students who are interested in health law with other students, faculty, health care organizations, and health law attorneys. HLF created Health Law Outlook to give its members an opportunity to research and write about health law and share their work outside of the classroom. Health Law Outlook also posts work that students prepared for classes or for other research and writing requirements.

Health Law Outlook encourages students to develop their knowledge of health law, practice research and writing skills, and develop interests in specific areas of health law.

Health Law Outlook is not a journal publication, and it does not engage in a student or external submissions process. Any student who chooses a health law topic and meets the deadlines with completed work product will have their work shared through this medium.

Health Law Forum is grateful to its E-Board, Faculty Advisors, students who share their work through Health Law Outlook, and all student members for their continuing dedication to HLF and the health law field.

ADDITIONAL WORKS available at:
https://scholarship.shu.edu/health-law-outlook/

HEALTH LAW FORUM

Willy Martinez

3L

Class of 2021

Throughout law school, Willy has primarily focuses his studies around food and drug law. In the last year, Willy has authored two articles that have been selected for law review publications.

His first article, ***Attack of the Clones: An Examination and Critique of FDA's Medical Device Regulatory Scheme***, is forthcoming in the next issue of the Tennessee Journal of Law & Policy.

His second article, ***How To Get Away With Immunity: FDA's Emergency Use Authorization Scheme and PREP Act Liability Protection in the Context of COVID-19***, is forthcoming in the next issue of the Loyola Consumer Law Review and has been listed on SSRN's Top Ten Download List.

In addition to his legal scholarship, Willy is involved with the Interscholastic Moot Court Board, the Appellate Advocacy Moot Court Board, and serves as a Research Assistant with the Office for Diversity, Equity, and Inclusion.

After graduation, Willy will be clerking at the Supreme Court of New Jersey.

A Cautionary Tale: Theranos, The LDT Loophole, and Implications on the COVID-19 Pandemic

William Chanes Martinez*

Introduction

> *"Oh! How beautiful are our Emperor's new clothes! What a magnificent train there is to the mantle, and how gracefully the scarf hangs. No one would admit these much-admired clothes could not be seen."*[1]

COVID-19 has thrusted the world into a global public health crisis not seen since the Spanish Flu Pandemic of 1918.[2] At the time of this writing, 85,229,481 positive cases have been reported, with 1,845,408 deaths, across all nations.[3] As the United States reached the grim milestone of 400,000 COVID-19 deaths, casualties continue to rise and have surpassed the World War II American fatality count.[4] On December 11, 2020, the U.S. Food and Drug Administration ("FDA") issued the first emergency use authorization ("EUA) for a vaccine for the prevention of COIVD-19.[5] Despite the arrival of the long-awaited COVID-19 vaccine, a vast majority of the American public will likely not be vaccinated until June 2021.[6] This is why the implementation of proactive, population-based testing strategies is essential to contain the pandemic as the United States begins vaccine distribution.[7]

On February 29, 2020, the FDA issued guidance[8] that authorized commercial, academic, and government labs to develop and use self-validated COVID-19 tests prior to

---

* J.D. Candidate 2021, Seton Hall University School of Law.

[1] Hans Christian Andersen, *The Emperor's New Clothes*, LIT2GO (2021), https://etc.usf.edu/lit2go/68/fairy-tales-and-other-traditional-stories/5637/the-emperors-new-clothes/.

[2] Claire Gillespie, *How Are the Spanish Flu and COVID-19 Alike? Here's What Doctors Say*, HEALTH (Nov. 17, 2020), https://www.health.com/condition/infectious-diseases/how-are-spanish-flu-and-covid-19-alike.

[3] COVID-19 Global Map, JOHNS HOPKINS CORONAVIRUS RESOURCE CENTER, https://coronavirus.jhu.edu/map.html (last visited Jan. 4, 2021).

[4] *Id.*

[5] Office of the Commissioner, *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

[6] Chas Danner & Matt Stieb, *What We Know About the U.S. COVID-19 Vaccine Distribution Plan*, INTELLIGENCER (Dec. 18, 2020), https://nymag.com/intelligencer/2020/12/what-we-know-about-u-s-covid-19-vaccine-distribution-plan.html.

[7] *See generally* Jeremy Veillard et al., *Testing, Testing, Testing: An essential strategy for public health, vaccine deployment and economic reactivation during COVID-19*, WORLD BANK (Dec. 17, 2020), https://blogs.worldbank.org/latinamerica/testing-testing-testing-essential-strategy-public-health-vaccine-deployment-and.

[8] Guidance documents are documents prepared for FDA staff, regulated industry, and the public that describe the agency's interpretation of or policy on a regulatory issue. See *Guidance Documents (Medical Devices and Radiation-Emitting Products)*, U.S. FOOD & DRUG ADMIN. (2019), https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products (last visited June 9, 2020). Guidance documents are not law and do not operate to bind FDA or the public. *Id.*

the agency's review of their EUA requests.[9] These types of COVID tests, known as laboratory developed tests (LDTs), are a specific types of *in vitro* diagnostics (IVDs) that do not require FDA approval before use on patient samples.[10] After such validation, the FDA required labs to notify the agency of their intent to submit an EUA request within 15 days.[11]

One company that took advantage of FDA's rules was a Boston-based startup – "Orig3n."[12] Early on in the pandemic, the Massachusetts Department of Public Health (MDP) selected Orig3n to develop a coronavirus test to be used at facilities across the Commonwealth, including North Hill Retirement Community—a nursing home located in suburban Boston.[13] Relying on the Orig3n test After having used the Orig3n test for months and receiving only one positive test, North Hill administrators were suddenly informed that 19 staff members tested positive for the virus at the same time.[14] MDP was called in to verify the results and discovered that all 19 results were false positives.[15] The Commonwealth launched an investigation and uncovered 383 false positives from the Orig3n tests, which had been used by more than 60 nursing homes in the state.[16]

Secretary Azar announced, that the FDA would not require premarket review of LDTs without notice-and-comment rulemaking on August 19, 2020 notwithstanding the fact that HHS and its general counsel, Robert Charrow, were aware of reports that many LDTs, like Orig3n's tests, falsely detecting the coronavirus.[17] HHS stated that its

---

[9] On February 4, 2020, Secretary of Health and Human Services (HHS) Alex Azar declared a public health emergency, invoking the agency's ability to issue Emergency Use Authorization (EUAs) for *in vitro* diagnostics medical devices (IVDs) designed to detect and/or diagnose COVID-19 pursuant to Section 564 of the Food, Drug, and Cosmetic Act (FDCA). *FDA issues guidance for expanded development of coronavirus diagnostic tests*, MODERN HEALTHCARE (2020), https://www.modernhealthcare.com/politics-policy/fda-issues-guidance-expanded-development-coronavirus-diagnostic-tests; *see also FDA Allows High-Complexity CLIA-Certified Labs to Perform Coronavirus Testing*, GENOMEWEB (Feb. 29, 2020), https://www.genomeweb.com/pcr/fda-allows-high-complexity-clia-certified-labs-perform-coronavirus-testing.

[10] *Laboratory Developed Tests*, U.S. FOOD & DRUG ADMIN. (2018), https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests (last visited Jan 3, 2021).

[11] MODERN HEALTHCARE, *supra* note 9.

[12] Kathleen McLaughlin, *HHS Relaxed Oversight of Problematic Covid-19 Tests Despite Being Told of Accuracy Concerns*, STAT (Nov. 2, 2020), https://www.statnews.com/2020/11/02/hhs-relaxed-oversight-of-problematic-covid19-tests-despite-being-told-of-accuracy-concerns/.

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*; *see also* Ryan Kath & Jim Haddadin, *Boston Lab Facing Penalties After COVID-19 Testing Errors*, 10BOSTON (Oct. 15, 2020), https://www.nbcboston.com/investigations/boston-lab-facing-penalties-after-covid-19-testing-errors/2212831/.

[17] McLaughlin, *supra* note 12; *see also* Assistant Secretary for Public Affairs (ASPA), *Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests*, DEPT. OF HEALTH AND HUMAN SERVICES, https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html (last updated Sep. 1, 2020); *see also* Jacqueline Howard, *Trump administration says FDA will no longer require premarket review of certain lab tests, including some Covid-19 tests*, CNN (Aug. 21, 2020), https://www.cnn.com/2020/08/21/health/covid-lab-developed-tests-fda-hhs-bn/index.html ("This means that makers of Covid-19 tests developed by certain individual laboratories -- such as Quest Diagnostics, LabCorp or those at academic medical

announcement was consistent with then- President Donald Trump's executive orders aimed at reducing administrative regulation.[18] While this announcement was made in the context of the COVID-19 pandemic, the agency's decision has direct implications for all LDTs, not just devices used to detect the coronavirus.[19]

There is little question that individuals will suffer harm as a result of the information they receive from the wildly inaccurate diagnostic tests currently on the market. The FDA acknowledges that the underreporting of inaccurate results from LDT diagnostic tests is "rampant," as expects labs are required to report on themselves.[20] As the Orig3n example shows, these companies are ill-suited to self-regulate. The FDA should not abdicate its role in protecting the public from faulty medical devices. As the death toll climbs in the United States and states race to distribute the vaccine, accurate testing is crucial to minimize the impact COVID-19. To achieve this, the FDA must be empowered to do its job and regulate all *in vitro* diagnostic tests, including LDTs.

This Essay proceeds in three parts. Part I provides a brief overview of the regulatory scheme for IVDs and FDA's attempts to regulate LDTs. Part II shines a light on Theranos—a Silicon Valley-based diagnostic testing company. Part III concludes by calling on the FDA to regulate LDTs and rebukes arguments that FDA lacks jurisdiction over LDTs.

I. Current Regulatory Scheme for *In Vitro* devices

a. Overview of In Vitro Device Regulation

In 1938, Congress passed the FDCA.[21] The Act gave FDA jurisdiction over medical devices but did not give the agency authority to review them for safety and effectiveness prior to market entry.[22] Accordingly, FDA relied heavily on post-market judicial remedies by bringing federal district court actions against device manufactures that had violated the FDCA's misbranding and adulteration provisions.[23]

After nearly 40 years of minimal medical device regulation, Congress granted FDA the authority to regulate the development, introduction, and marketing of medical

---

centers -- can distribute them without the need to first submit documentation for a premarket review process.").

[18] *Id.*

[19] *Id.*

[20] McLaughlin, *supra* note 12.

[21] PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 1193 (4th ed 2014).

[22] *Id.* at 1194.

[23] *Id.*: *see also* United States v. Article of Drug, 414 F. Supp. 660, 661 (D.N.J. 1975) (the FDA instituted an enforcement action against a pregnancy test kit sold for at home use. The agency claimed that this in vitro diagnostic test, consisting of vials of sodium hydroxide and hydrochloric acid, was a new drug under the provisions of the FDCA. A "new drug" is defined as: "[a]rticles' intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals are 'drugs,'" and, thus, require the manufacturer to file a new drug application with the agency to determine its safety and effectiveness. The district court rejected this argument, concluding that the definition did not apply to the testing kit "because its purpose is to indicate the existence or non-existence of pregnancy, which is not of itself a disease."); HUTT, *supra* note 21, at 1211.

devices through the enactment of the Medical Device Amendments of 1976 (MDA).[24] The MDA amended the FDCA's definition of "device" to include "in vitro reagent" to the list of articles categorized as devices.[25] The statute defines a "device" as:

> an instrument, apparatus, implement, machine, contrivance, implant, *in vitro reagent*, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . or intended to affect the structure or any function of the body . . ..[26] (emphasis added).

An *in vitro* diagnostic device is further defined as:

> reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. [27]

FDA organizes medical devices into three classes (e.g., Class I, II, III) based on the safety concerns associated with the device and the level of control needed to provide reasonable assurance of the device's safety and effectiveness.[28] With respect to pre-market regulation, Class I and Class II devices typically are "cleared" via FDA's 510(k) pre-market notification process.[29] That process requires the manufacturer to notify FDA of its intent to market a device that is "substantially equivalent" to another device that FDA already has cleared/approved for market.[30] Class III devices are subject to Pre-Market Approval (PMA)—the most stringent type of FDA device marketing application.[31] The

---

[24] Bruce R. Parker & Casey L. Bryant, *Arguments for and Against Potential FDA Regulation of Laboratory-Developed Tests and the Effect on Litigation*, 60 DRI FOR DEF. 65, 66 (2018); *see also* HUTT, *supra* note 21, at 1211.

[25] *See* HUTT, *supra* note 21, at 1211.

[26] 21 U.S.C. § 321(h)(2)–(3) (2020).

[27] 21 C.F.R. § 809.3(a) (2020).

[28] Class I devices are medical devices that present relatively few risks to human health or safety, thus subject to minimal oversight. Class II devices are medical devices for which "general controls alone are insufficient to ensure their safety and effectiveness." In addition to general controls, therefore, Class II devices are subject to special controls like, among other things, performance standards, pre-market data demands, post-market surveillance, special labelling requirements, and patient registries. Lastly, Class III medical devices are devices that present the highest potential risk to the public and, therefore, are subject to the most stringent regulatory controls. 21 U.S.C. § 360c(a)(1) (2020); *see* William C. Martinez, *Attack of the Clones: An Examination and Critique of FDA's Medical Device Regulatory Scheme*, 15 TENN. J. L. & POL'Y (forthcoming 2021) (manuscript at 12) (on file with author).

[29] Bonnie Scott, *Oversight Overhaul: Eliminating the Premarket Review of Medical Devices and Implementing a Provider-Centered Postmarket Surveillance Strategy*, 66 FOOD & DRUG L.J. 377, 379 (2011).

[30] STEVE KANOVSKY ET AL., *The Medical Device Approval Process, in* A PRACTICAL GUIDE TO FDA'S FOOD AND DRUG LAW AND REGULATION 227 (Kenneth R. Pina & Wayne L. Pines, eds., 6th ed. 2017).

[31] *Id.* at 235.

PMA process is intended to provide FDA "reasonable assurance" of the safety and effectiveness of these sorts of medical devices.[32]

To be approved or cleared, IVDs must demonstrate safety and effectiveness through analytical and clinical validation.[33] Analytical validation focuses on a test's ability to correctly and reliably measure a specific chemical compound, hormone, or genetic marker in a given sample.[34] Clinical validity refers to a test's accuracy in predicting the presence of, or risk for, a given condition.[35]

LDTs are IVDs that are "designed, manufactured and used within a single laboratory."[36] The FDA is clear that the FDCA definition of a device applies equally to IVDs manufactured by conventional device manufacturers, as well as those manufactured by laboratories.[37] Thus, the FDA has the regulatory authority to require pre-market approval, or 510(k) clearance, of LDTs.[38] However, since the implementation of the MDA, the agency has exercised enforcement discretion, meaning that the agency has decided not to enforce applicable provisions of the FDCA, as well as other FDA regulations, with respect to LDTs.[39]

b. Enforcement Discretion

Pursuant to the Section 702(a)(2) of the Administrative Procedure Act, "agency action . . . committed to agency discretion by law" is not subject to judicial review."[40] Thus, FDA enforcement discretion refers to the agency's authority not to enforce certain provisions of the FDCA.[41]

This much was clear in the Supreme Court's decision in *Heckler v. Chaney*, where Justice Rehnquist wrote for a majority that upheld the concept of agency discretion by rejecting a petition from death row inmates to compel FDA to enforce the "misbranding" provisions of the FDCA.[42] In *Heckler*, a state planned to execute a death row inmate by

---

[32] *See* HUTT, *supra* note 21, at 1211; *see also* Martinez, *supra* note 28, at 15 ("PMA applications typically include extensive clinical trial results, bench trials, laboratory studies, animal studies, and references to all standards relevant to a device's safety and efficacy.")

[33] *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)*, U.S. FOOD & DRUG ADMIN. 1, 7 (2014), https://www.fda.gov/media/89841/download [hereinafter LDT Draft Guidance]; *see also What Are In Vitro Diagnostic Tests, and How Are They Regulated?*, PEW CHARITABLE TRUSTS (May 14, 2019), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/05/what-are-in-vitro-diagnostic-tests-and-how-are-they-regulated. With respect to PMA application and IVDs, there are unique issues presented. To assure the consumer of safety and effectiveness, approval of an IVD PMA application focuses on the impact of the device's performance, and in particular on the impact of false positives and negatives results, on patient health. *See* HUTT, *supra* note 21, at 1244.

[34] PEW CHARITABLE TRUSTS, *supra* note 33.

[35] *Id.*

[36] *Laboratory Developed Tests*, *supra* note 10.

[37] LDT Draft Guidance, *supra* note 33, at 6.

[38] *Id.*; *see also* Parker, *supra* note 24, at 65.

[39] LDT Draft Guidance, *supra* note 33, at 6–7.

[40] 5 U.S.C. §701(a)(2) (2020).

[41] *See* John E. Meyer, *The Future of the FDA's Application of Enforcement Discretion on Laboratory Developed Tests*, 12 J. HEALTH & LIFE SCI. L. 43, 50 (2019).

[42] *See* Heckler v. Chaney, 470 U.S. 821, 823-24 (1985).

lethal injection with a drug that FDA had not been approved for such a purpose.[43] The FDA Commissioner rejected the inmates' the petition on the grounds that the agency lacked authority to interfere in a state's ability to carry out executions.[44] The FDA Commissioner stated further, "[w]ere FDA clearly to have jurisdiction in the area, . . . we believe we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters."[45]

The Court has recognized that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion."[46] As such, the FDA's decision not to take enforcement action is presumed immune from judicial review.[47] Because FDA refused to regulate LDTs in its discretion, LDTs are primarily regulated by the Centers for Medicare and Medicaid Services (CMS), pursuant to the Clinical Laboratory Improvement Amendments (CLIA), which empowers to regulate laboratories that develop LDTs.[48]

c. FDA's Recent Attempts to Regulate LDTs

In 2014, FDA issued a draft guidance document, explaining that the agency's "policy of general enforcement discretion towards LDTs [was] no longer appropriate."[49] The FDA contended that the CLIA regulations do not assure the safety and effectiveness of LDTs.[50] For example, FDA has serious concerns about the lack of clinical validity data of LDTs, which is not evaluated under CLIA, and has acknowledged this oversight may "potentially put patients at risk of missed or incorrect diagnosis, failure to administer appropriate treatment or administration of potentially harmful treatment with no benefit."[51] The FDA also was concerned with CLIA's review of analytical validation of LDTs.[52] While the FDA's review of analytical validation occurs prior to market entry, CLIA's review occurs after the device is already in diagnostic use.[53] Accordingly, "compliance with CLIA regulations alone does not adequately protect patient safety."[54] The FDA proposed a "risk-based approach" to regulate LDTs.[55] Under the proposal, almost every LDT would be subject to some level of premarket approval/clearance.[56] However, on

[43] *Id*. at 823.
[44] *Id.*
[45] *Id.* at 824-25.
[46] *See id.* at 831.
[47] *Id.*
[48] *See* Hutt, *supra* note 21, at 1244.
[49] LDT Draft Guidance, *supra* note 33, at 8.
[50] *Id.* at 9.
[51] *Id.* at 9.
[52] *Id.*
[53] LDT Draft Guidance., *supra* note 33, at 9.
[54] *Id.* at 8–9.
[55] *Id.* at 11.
[56] *Id.* at 11–14; *see also* Parker, *supra* note 24, at 65. While the proposal laid out some exceptions, many LDTs would be subject to the same risk-based classification systems to which all medical devices are subject under the FDCA. Class III LDTs would be subjected to the more stringent PMA process, Class II LDTs would be required to submit a 501(k) application, and Class I LDTs would be subject to FDA discretion for approval through the 501(k) pathway as well. *Id.*

November 18, 2016, the FDA changed course and, thus, left the matter to Congress and the incoming Trump Administration.[57]

II. The Fall from Grace – Elizabeth Holmes and Theranos

> *"I have done something, and we have done something, that has changed people's lives. . .. I would much rather live a life of purpose than one in which I might have other things but not that."* [58]

Elizabeth Holmes envisioned a way to perform multiple assays with a single, small blood sample and then wirelessly deliver the test results to a doctor.[59] Holmes's idea manifested itself in the founding of $9 billion dollar blood testing start-up Theranos.[60] Theranos's stated mission was to revolutionize medical laboratory testing through innovative methods—utilizing a blood test that could help detect dozens of medical conditions, from high cholesterol to cancer, based on a drop or two of blood drawn with a pinprick from your finger and collected in a device called the "nanotainer."[61] Holmes's contended that the blood-analysis device, which she named "Edison," would "quickly and accurately analyze blood samples collected in nanotainers."[62]

Holmes was herald as the next Steve Jobs—the founder of a company "promising a health care revolution."[63] Holmes subsequently raised $6 million in funding, on the condition that she would not disclose how her technology actually worked.[64] In 2013, Theranos announced a partnership with Walgreens and began to offer its blood tests to the public at Theranos "Wellness Centers" located inside Walgreens retail locations.[65] Because Theranos did not sell its Edison devices to Walgreens, FDA approval was not required prior to market entry.[66]

On October 16, 2015, the *Wall Street Journal* published an article alleging that Theranos was not what it seemed.[67] According to the *Journal*, the Edison device could

---

[57] Shiela Kaplan, *FDA puts off closing lab-test 'loophole,' leaving decision to Congress and Trump*, STAT NEWS (Nov. 18, 2016), https://www.statnews.com/2016/11/18/fda-lab-test-loophole/.
[58] Ken Auletta, *Blood, Simpler: One Woman's Drive to Revolutionize Medical Testing*, THE NEW YORKER (Dec. 8, 2014), https://www.newyorker.com/magazine/2014/12/15/blood-simpler (quoting Elizabeth Holmes, former CEO and Founder of Theranos).
[59] *Id.*
[60] Nick Stockton, *Everything You Need to Know About the Theranos Saga So Far*, WIRED (May 4, 2016), https://www.wired.com/2016/05/everything-need-know-theranos-saga-far/.
[61] *Id.; see also* Indictment ¶¶ 4, 5, United States of America v. Elizabeth A. Holmes and Ramesh "Sunny" Balwani, No. CR 18-00258 LHK NC, 2018 WL 3216817 (N.D. Cal. 2018).
[62] Stockton, *supra* note 60; *see also* Indictment ¶ 5, United States of America v. Elizabeth A. Holmes and Ramesh "Sunny" Balwani, No. CR 18-00258 LHK NC, 2018 WL 3216817 (N.D. Cal. 2018).
[63] Stockton, *supra* note 60.
[64] Nick Bilton, *How Elizabeth Holmes's House of Cards Came Tumbling Down*, VANITY FAIR (Sept. 6, 2016), https://www.vanityfair.com/news/2016/09/elizabeth-holmes-theranos-exclusive.
[65] *Theranos and Walgreens Expand Diagnostic Lab Testing to the Phoenix Metropolitan Area*, BUS. WIRE (Nov. 13, 2013), https://www.businesswire.com/news/home/20131113005513/en/Theranos-and-Walgreens-Expand-Diagnostic-Lab-Testing-to-the-Phoenix-Metropolitan-Area.
[66] Stockton, *supra* note 60.
[67] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, WALL STREET J. (Oct. 16, 2015), https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901; *see also* Stockton, *supra* note 60.

"not detect enough molecules in blood samples to provide accurate readouts."[68] On March 18, 2016, CMS warned Theranos that it was not in compliance with CLIA regulations.[69] CMS stated that Theranos's deficiency posed "immediate jeopardy to patient health and safety."[70] In the report, CMS found that Theranos continued to run important blood tests on 81 patients in a six-month period despite erratic results from quality-control checks meant to ensure the test's accuracy.[71] In an attempt to comply with CLIA regulations, Theranos issued "tens of thousands of corrected blood-test reports to doctors and patients, voiding some results and revising others."[72] Nonetheless, CMS revoked Theranos' CLIA operating license and banned Holmes from owning or operating a medical laboratory for at least two years.[73] These events culminated with the dissolution of Theranos and an eleven-count indictment—charging Holmes and Sunny Balwani, the company's President, with conspiracy to commit wire fraud and wire fraud. The indictment alleges that Holmes and Balwani misrepresented the revolutionary potential of the Edison and defrauded investors in the process.[74]

---

[68] Carreyrou, *supra* note 67; *see also* Stockton, *supra* note 60. Two weeks after the Wall Street Journal article was published, the FDA released reports calling Theranos' nanotainer an "uncleared medical device." Sara Ashley O'Brien, *FDA calls Theranos vial an "uncleared medical device"*, CNNMONEY (Oct. 27, 2015), https://money.cnn.com/2015/10/27/technology/theranos-fda-reports/index.html; *see also* Mary R. Hole et al., Theranos Form FDA-483 Report, (Sept. 16, 2015), at 1, https://www.fda.gov/media/94712/download. FDA's inspection report noted Theranos' "[nanotainer] blood specimen collection device . . . is a Class II medical device. . . you are currently identifying it as a Class I exempted medical device. . . you are currently shipping this uncleared medical device in interstate commerce." *Id.* Yet, FDA made no indication that it would regulate the Edison device.

[69] Rebecca Robbins, *Theranos CEO Elizabeth Holmes faces possible government ban*, STAT (Apr. 13, 2016), https://www.statnews.com/2016/04/13/theranos-elizabeth-holmes-ban/; *see* Letter from Centers for Medicare and Medicaid Services to Elizabeth Holmes et al., on Proposed Sanctions pursuant to the Clinical Laboratory Improvement Amendments of 1988 (March 18, 2016) (available at http://online.wsj.com/public/resources/documents/cms20160412.pdf).

[70] *Id.*

[71] John Carreyrou & Christopher Weaver, *Theranos Ran Tests Despite Quality Problems*, WALL STREET J. (Mar. 8, 2016), https://www.wsj.com/articles/theranos-ran-tests-despite-quality-problems-1457399479.

[72] John Carreyrou, *Theranos Voids Two Years of Edison Blood-Test Results*, WALL STREET J. (May 18, 2016), https://www.wsj.com/articles/theranos-voids-two-years-of-edison-blood-test-results-1463616976.

[73] Megan Thielking, *Theranos CEO banned from blood test industry for two years*, STAT (July 8, 2016), https://www.statnews.com/2016/07/08/theranos-elizabeth-holmes-banned/.

[74] *See* U.S. Attorney's Office for the Northern District of California, *Theranos Founder and Former Chief Operating Officer Charged In Alleged Wire Fraud Schemes*, U.S. DEPT. OF JUSTICE (June 15, 2018), https://www.justice.gov/usao-ndca/pr/theranos-founder-and-former-chief-operating-officer-charged-alleged-wire-fraud-schemes; *see also* Indictment ¶¶ 19-28, United States of America v. Elizabeth A. Holmes and Ramesh "Sunny" Balwani, No. CR 18-00258 LHK NC, 2018 WL 3216817 (N.D. Cal. 2018). Theranos exemplifies the need for the FDA to regulate LDTs prior to market entry. A false positive or false negative result can have significant impacts on patient health. For example, Ms. Ackert ordered a Theranos test to assess possible side effects related to her breast-cancer treatment. *See* Christopher Weaver, *Agony, Alarm and Anger for People Hurt by Theranos's Botched Blood Tests*, WALL STREET J. (Oct. 20, 2016), https://www.wsj.com/articles/the-patients-hurt-by-theranos-1476973026. Ms. Ackert's Theranos lab report indicated a high level of an estrogen hormone called estradiol, which was an indication of a possible rare adrenal tumor or an elevated risk of breast-cancer reoccurrence. Ms. Ackert's sister said, "she wasn't the same," after receiving the news. Ms. Ackert's oncologist ordered another test from a different testing company,

III. A Call to Action

When the FDA issued its 2014 guidance proposing a "risk-based" classification system for LDTs, Dr. Jeffrey Shuren, then-Director of FDA's Center for Devices and Radiological Health, testified before the U.S. House of Representatives Committee on Energy and Commerce to explain the risk of underregulated LDTs and undetected inaccurate test result.[75] The clinical laboratory industry pushed back. At the time, American Clinical Laboratory Association President Alan Mertz said, "the FDA lacks the statutory authority to regulate laboratory developed testing services and likens its attempt to define a lab test as a medical device to trying to fit a round peg into a square hole."[76] Many in the industry, and other legal scholars, contend that LDTs are a "service" provided by laboratories and not medical products subject to FDA jurisdiction.[77]

The MDA authorizes the FDA to regulate the marketing and sale of medical devices.[78] The MDA explicitly amended the FDCA include "in vitro regent" on the list of articles categorized as devices.[79] As defined above, LDTs fall squaring into the definition of in vitro devices because they are "intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease.[80] Under the *expressio unius* canon of statutory interpretation, the expression of items in a list excludes those items not listed.[81] The Supreme Court has noted that this canon applies where "circumstances supporting a sensible inference that the term

---

which reported that her estradiol level was "less than 2 picograms per millimeter, compared with 313.5 picograms in Theranos' test result. That was the level her doctors expected." *Id.*

[75] Dr. Shuren noted, "[A] false-positive test result that is not detected could lead to harm from unnecessary medical procedures, delay of necessary medical procedures, and emotional distress. A false-negative result that is not detected could lead to injury, and even death, from unchecked progression of disease, and could have serious public health ramifications from the preventable transmission of infectious disease." *Hearing on Examining the Regulation of Diagnostic Tests and Laboratory Operations Before the Subcomm. On Health and Comm. On Energy and Commerce*, 113th Cong. 3-4 (2014) (statement of Jeffrey Shuren, M.D., J.D., Director, Centers for Devices and Radiological Health, U.S. Food & Drug Admin.), https://docs.house.gov/meetings/IF/IF14/20151117/104127/HMTG-114-IF14-Wstate-ShurenJ-20151117.pdf.

[76] *ACLA in Comment Letter: FDA Lacks Statutory Authority in Ill-Advised Move to Regulate Laboratory Developed Tests (LDTs) As Devices*, AMERICAN CLINICAL LABORATORY ASSOCIATION (Feb. 2, 2015), https://www.acla.com/acla-in-comment-letter-fda-lacks-statutory-authority-in-ill-advised-move-to-regulate-laboratory-developed-tests-ldts-as-devices/.

[77] *Id.*; *see, e.g.*, Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's Covid-Testing Debacle*, 130 YALE L.J. FORUM 78, 80–81 (2020) ("Section 564 allows the FDA to grant EUAs only for medical *products*, which the statute defines as "drug[s], device[s], or biological product[s]. It grants no new powers for the FDA to regulate clinical laboratory *services*. . . . The FDA is charged with regulating the 'test itself' but not the 'learned expert[s]' who use the test to provide laboratory services and, historically, has displayed careful respect for the distinction.").

[78] Parker, *supra* note 24, at 65.

[79] *See* HUTT, *supra* note 21, at 1211.

[80] *Laboratory Developed Tests*, *supra* note 10.

[81] *See* Chevron U.S.A. v. Echazabal, 536 U.S. 73, 81 (2002); *see also* Brandon Willmore et al., *Can Trump Order the FDA to Approve a Treatment for Unscientific Reasons?*, LAWFARE (Oct. 28, 2020), https://www.lawfareblog.com/can-trump-order-fda-approve-treatment-unscientific-reasons.

left out must have been meant to be excluded."[82] Thus, the list articulated by Congress is clear—the FDA is empowered to regulate *in vitro* medical devices, regardless of where the device is developed. The FDA can and must regulate LDTs prior to market entry; arguments to the contrary lack merit.[83]

FDA has statutory jurisdiction over LDTs and attempts by the executive branch to circumvent FDA's regulatory oversight amounts to usurping Congress' legislative authority. While the FDCA authorizes the Secretary to promulgate regulations to enforce the statute, Congress also delegated such power to the FDA Commissioner.[84] Accordingly, Secretary Azar's August 19, 2020 announcement requiring FDA to undergo notice-and-comment rulemaking in order to regulate LDTs is troubling.[85] Along similar lines, on September 15, 2020, Secretary Azar announced barred the FDA from signing any new rules without his approval, thus, "[a]ny prior delegation of rulemaking authority, including the authority to sign or issue a rule or a proposed rule, [was] rescinded."[86]

HHS claims that it has taken these actions to remain consistent with then- President Donald Trump's executive orders aimed at reducing administrative regulation.[87] Article II directs the President to "take care that the laws be faithfully executed."[88] The President,

---

[82] *See Echazabal*, 536 U.S. at 81.

[83] Opponents will cite new legislation as grounds that FDA "might lack authority" to regulate LDTs. Evans, *supra* note 77, at 83. On March 5, 2020, Congress introduced the Verifying Accurate Leading-edge IVCT [*in vitro* clinical test] Development Act (VALID), which would clarify FDA's authority over LDTs.[83] *Id.* For example, in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000), the Supreme Court relied on the FDA's longstanding disavowal of regulatory authority over tobacco and pointed to subsequently enacted tobacco-specific legislation that stopped short of conferring authority to ban sale of the product, as Congress' intent to not confer on the agency the authority to regulate tobacco. Opponents may argue the same here, as the FDA has chosen not to regulate LDTs and the VALID Act is currently being considered in Congress. However, unlike with tobacco, the FDA has always maintained the position that the agency is empowered to regulate LDTs and has chosen to utilize its enforcement discretion. Moreover, the FDCA already authorizes the FDA the regulate *in vitro* devices and makes no distinction between LDTs or other IVDs. The VALID Act would further clarify this position. Relying on precedent, opponents' arguments that FDA lacks jurisdiction to regulate LDTs still fails.

[84] *See* 21 U.S.C. § 379d (2020) ("The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter."); 21 U.S.C. § 371 ("The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.").

[85] McLaughlin, *supra* note 12; *see also* Assistant Secretary for Public Affairs (ASPA), *Rescission of Guidances and Other Informal Issuances*, DEPT. OF HEALTH AND HUMAN SERVICES, https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html (last updated Sept. 1, 2020); *see also* Howard, *supra* note 17 and accompanying text.

[86] Sheila Kaplan, *In 'Power Grab,' Health Secretary Azar Asserts Authority Over F.D.A.*, N.Y. TIMES (Sept. 19, 2020), https://www.nytimes.com/2020/09/19/health/azar-hhs-fda.html.

[87] *Id.*

[88] U.S. CONST. art. II, § 1. *See also*, Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 635–38 (1952) (Jackson, J. concurring) (at one end of the spectrum, presidential authority is at its utmost when the President acts pursuant to express or implied statutory authority. At the other end, presidential authority is at "its lowest ebb" when the President contradicts Congress's will. Between these two extremes, there is a "zone of twilight" in which the President can act where Congress has been silent and where the President is relying "upon his own independent powers."). Secretary

acting through the Secretary, must ensure that laws are "faithfully executed," and not obstruct agencies from carrying out their Congressional mandates.[89]

Conclusion

The LDT loophole is not a loophole, but a crevasse in the law. There is nothing ambiguous about the FDCA – it authorizes the FDA to regulate all *in vitro* devices. As this Essay maintains, public health officials and patients need access to accurate diagnostic testing in order to combat the COVID-19 pandemic. As the Orig3n and Theranos examples show, the lack of FDA regulation over LDTs can lead to absurd and dangerous results. While opponents to FDA regulation of LDTs argue that the agency lacks jurisdiction, the plain meaning of the statute undermines that claim. No group, be it the President, his agents, or private interests, should inhibit the FDA from doing its job—ensuring the safety and effectiveness of medical devices.

Azar's actions, with influence from President Trump, appear to conflict with the FDA's governing statue, placing these actions in Jackson's "lowest ebb" category.

[89] Nonetheless, proponents of the Secretary and the President's actions might argue, under the unitary executive theory, that once Congress grants an agency decision-making discretion, the President can direct the agency's outcome. *See* Michele Estrin Gilman, *The President as Scientist-in-Chief*, 45 WILLAMETTE L. REV. 565, 585 (2009). This author argues that administrative agencies, like the FDA, are agents of Congress, despite being considered part of the executive branch. Once Congress delegates power to an agency, the President serves as "a managerial agent for the legislature rather than an independent source of domestic policy." *Id.*; *see also* Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 MICH. L. REV. 193, 202–203 (1981). Following the unspoken assumption in *Massachusetts v. EPA*, 549 U.S. 497 (2006), the FDA is a scientific agency and must be protected from political interference. *See* Gilman, *supra* note 89, at 596; *see also* Jody Freeman & Adrian Vermeule, Massachusetts v. EPA*: From Politics to Expertise*, 2007 SUP. CT. REV. 51, 52 (2007) ("Expertise-forcing is the attempt by courts to ensure that agencies exercise expert judgment free from outside political pressures, even or especially political pressures emanating from the White House or political appointees in the agencies.").

Recommended Citation for this Post:

Willy Martinez, *A Cautionary Tale: Theranos, The LDT Loophole, and Implications on the COVID-19 Pandemic*, HEALTH LAW OUTLOOK (Mar. 16, 2021), https://scholarship.shu.edu/health-law-outlook/.

HEALTH LAW FORUM