




# Legislating in the time of a pandemic: window of opportunity or invitation for recklessness?

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## INTRODUCTION

The delay in providing widespread diagnostic testing has significantly exacerbated the extent and consequences of the COVID-19 epidemic in the USA.<sup>1</sup> Even when tests were available, a notable proportion were reported to give inaccurate results.<sup>2</sup> In response to these failures, two bills were immediately introduced in Congress to revise the Food and Drug Administration (FDA) approval process for diagnostic tests. The bipartisan Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2020, which had been under development in earlier versions for several years, was quickly updated with more expansive language on emergency use and introduced in both the House and Senate on March 5, 2020.<sup>3</sup> Senator Rand Paul introduced his Verified

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1 Shawn Boburg et al., *Inside the Coronavirus Testing Failure: Alarm and Dismay Among the Scientists Who Sought to Help*, WASH. POST, <https://www.washingtonpost.com/investigations/2020/04/03/coronavirus-cdc-test-kits-public-health-labs/?arc404=true> (accessed Apr. 3, 2020).

2 Christopher Weaver, *Questions About Accuracy of Coronavirus Tests Sow Worry*, WALL STREET J., <https://www.wsj.com/articles/questions-about-accuracy-of-coronavirus-tests-sow-worry-11585836001> (accessed Apr. 2, 2020).

3 Verifying Accurate Leading-edge IVCT Development Act of 2020, H.R. 6102, 116th Cong. (2020) (companion bill S.3404) [hereinafter VALID Act].

Innovative Testing in American Laboratories (VITAL) Act of 2020 in the Senate on March 17.<sup>4</sup>

These bills attempt to leverage the current crisis to enact fundamental reforms of diagnostics regulation. To be sure, the regulatory system for diagnostics in the USA is problematic, with inconsistent regulatory pathways and important gaps and weaknesses, and has been the subject of multiple but unsuccessful reform efforts over the past decade (see Part I ‘*infra*’). The history of public health legislation, including key statutory authority of both the FDA and the Environmental Protection Agency (EPA), shows many statutes were enacted during the ‘windows of opportunity’ opened by a crisis or disaster to fix a long-standing or under-appreciated problem (see Part II ‘*infra*’). However, legislating during or just after a disaster can also result in overreactions or precipitous policy changes that are not sufficiently thought through (see Part III ‘*infra*’). Given these dynamics, and the situation at hand, we explore whether the current pandemic is an appropriate ‘window of opportunity’ or an ‘invitation for recklessness’ for major legislative changes to diagnostics regulation.

### THE DIAGNOSTICS REGULATORY ‘PROBLEM’

Diagnostic tests play a critical role in both medicine and public health, ranging from routine cholesterol testing to complex genomic analyses.<sup>5</sup> By diagnosing individuals, healthcare providers and patients can make informed decisions about treatment options. In public health practice, testing and screening can enable officials to identify, track, and efficiently intervene on disease in populations. This importance of diagnostics to medicine and public health raise several competing concerns and values. Safe and effective diagnostics must have a threshold level of accuracy and validity to provide useful information to patients and officials, as misleading test results may cause them to forgo beneficial interventions or undergo unnecessary and potentially harmful ones.<sup>6</sup> Ensuring these goals generally involves applying two standards, (i) analytical validity, referring to how accurately and precisely a diagnostic measures its intended analyte and (ii) clinical validity, describing how well a diagnostic can characterize or predict a patient’s health status.<sup>7</sup> Yet, applying high standards to diagnostics, especially should clinical validity call for complex clinical trials, may delay access to valuable diagnostics and undercut potentially beneficial innovation.

Balancing these interests has become more challenging with the emergence of molecular diagnostics technologies, which test for various ‘-omics’ such as genomics or microbiomics. Such testing enables new diagnostics possibilities such as predicting the risk and severity of a patient developing a condition or how an individual might respond to an intervention. These innovations rely on tools such as algorithms and reference databases to measure and interpret their analyte, which pose more complicated analyt-

4 Verified Innovative Testing in American Laboratories Act of 2020, S. 3512, 116th Cong. (2020) [hereinafter VITAL Act].

5 See generally Cara S. Kosack, Anne-Laure Page & Paul R. Klatser, *A Guide to Aid the Selection of Diagnostic Tests*, 95 BULL. WORLD HEALTH ORG. 639 (2017).

6 Euan A. Ashley, *Towards Precision Medicine*, 17 NATURE REV. GENETICS 507, 516–17 (2016).

7 SECRETARY’S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY, U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES 96–98, [https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS\\_oversight\\_report.pdf](https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_oversight_report.pdf) (accessed Apr. 2014).

ical and clinical validity questions than more routine tests.<sup>8</sup> Databases, algorithms, and medical understanding of how genomic (or other -omics) variants relate to an individual's health constantly evolve, complicating efforts to determine when a diagnostic is valid 'enough' and raising the possibility of decaying validity over time.

The current regulatory landscape struggles to comprehensively manage these concerns for molecular diagnostics, treating diagnostics differently based primarily on whether the test is sold as a kit or offered in-house by a laboratory, rather than based on risk. Since the 1970s, the FDA has applied its three-tiered, risk-based regulatory scheme for medical devices to products called in vitro diagnostics (IVDs).<sup>9</sup> These IVDs are testing kits which manufacturers produce to market and sell to clinical laboratories and physician offices. Low risk, routine tests receive little review, but the agency may require clinical studies to determine both analytical and clinical validity of more complex diagnostics before allowing them market entrance.

Clinical laboratories may also develop in-house diagnostics and offer them solely to patients receiving their services. Referred to as laboratory developed tests (LDTs), these diagnostics have traditionally not required FDA approval or clearance. The developing laboratories must be certified under the Clinical Laboratories Improvement Amendments (CLIA), which sets some standards for laboratory staff, equipment, and protocols.<sup>10</sup> However, CLIA standards for LDTs are less stringent and more limited in scope than FDA review of diagnostics as products, where CLIA review only evaluates the accuracy of diagnostics generally without assessing for clinical validity.<sup>11</sup>

Over the past three decades, the FDA has become increasingly concerned about complex diagnostics offered as LDTs without regulatory review of clinical validity. Since at least 1992, the agency has asserted that its authority over medical devices extends to LDTs as well as IVDs, claiming it has exercised enforcement discretion since the 1970s. The FDA has tried and failed to formalize standards for LDTs several times, most recently with a draft guidance proposed in 2014.<sup>12</sup> Stakeholders in laboratory medicine pushed back each time, protesting that stringent rules would undercut patient access to innovative diagnostics and arguing that LDTs constitute the practice of medicine rather than a product subject to FDA review.<sup>13</sup> IVD developers countered with regulatory fairness arguments, noting the current regime enables clinical laboratories to offer virtually the same diagnostic as their IVDs without costly and rigorous FDA review.

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8 Gail H. Javitt & Katherine Strong Carner, *Regulation of Next Generation Sequencing*, 42 Suppl. J.L. MED. & ETHICS 9, 10–11 (2014).

9 21 C.F.R. §§ 809, 862–64 (2020). See also U.S. Food & Drug Admin., *Overview of IVD Regulation*, <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation> (accessed Sep. 16, 2014).

10 42 C.F.R. § 493.1253 (2020).

11 See U.S. Ctrs. Medicare & Medicaid Servs., *What is CMS' Authority Regarding Laboratory Developed Tests (LDTs) and How Does It Differ from FDA's Authority*, (2013), [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA\\_FAQs.pdf](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/LDT-and-CLIA_FAQs.pdf).

12 U.S. Food & Drug Admin., *Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* (2014), <https://www.fda.gov/media/89841/download>.

13 See e.g., Paul D. Clement & Laurence H. Tribe, Am. Clinical Laboratory Ass'n, *Laboratory Testing Services, As the Practice of Medicine, Cannot Be Regulated as Medical Devices*, <https://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf> (accessed Jan. 6, 2015).

In the mid-2010s, several legislative proposals were floated to resolve these regulatory issues.<sup>14</sup> One particular proposal, beginning with an effort by the Diagnostic Test Working Group and evolving into the VALID Act, aimed to strike compromises by incorporating all diagnostics (including LDTs) into products called in vitro clinical tests (IVCTs) subject to relatively flexible FDA review. This bill has gained the most support to date both within and outside of Congress and, under Commissioner Gottlieb, the FDA also supported some form of the compromise identified by the VALID Act.<sup>15</sup> Over a several year period, multiple successive drafts of the planned legislation were circulated to stakeholders and then revised based on the feedback. In March 2019, one expert observer wrote that ‘the VALID Act enjoys bipartisan and bicameral support and, after years of discussion between Congress, FDA, labs, patients, and other interested stakeholders, seems poised to be enacted before the end of the current Congress.’<sup>16</sup> By January 2020, the legislation was ready to be introduced in the following few weeks once the impeachment issue was resolved.<sup>17</sup>

Then COVID-19 hit. The slow rollout of diagnostics for the SARS-CoV-2 virus in the US inhibited public health surveillance and delayed critical decision-making. The FDA has been widely accused of contributing to the stalled response,<sup>18</sup> though criticism has focused on emergency rules and responses rather than the everyday oversight of IVDs versus LDTs. During a federally declared public health emergency, the Secretary of Health and Human Services (HHS) can empower the FDA to expedite regulatory review of products through temporary emergency use authorizations (EUAs).<sup>19</sup> However, emergency rules create a rare scenario where LDTs are, at least in effect, more directly subject to FDA review,<sup>20</sup> as inaccurate or invalid tests could interfere with public health decisions. Since EUAs typically require a threshold level of ‘evidence of effectiveness,’<sup>21</sup> many clinical laboratories lack the resources to obtain a timely EUA during an emergency.

During the COVID-19 pandemic, HHS Secretary Azar declared a public health emergency in late January 2020, then triggered the FDA’s EUA powers on February 4, 2020.<sup>22</sup> On the same day, FDA granted an EUA to the diagnostic developed by

14 Turna Ray, *Amid Competing LDT Regulatory Proposals, Common Ground but Key Disagreements for Congress to Consider*, GENOMEWEB, <https://www.genomeweb.com/molecular-diagnostics/amid-competing-ldt-regulatory-proposals-common-ground-key-disagreements> (accessed Sep. 28, 2015).

15 U.S. Food & Drug Admin., *FDA’s Views on the Diagnostic Accuracy and Innovation Act (DAIA)*, <http://www.fdalawblog.net/wp-content/uploads/2018/08/FDA-LDT-Draft-Leg.pdf> (accessed Aug. 3, 2018).

16 Aaron L. Josephson, *Device Modernization Series: In Vitro Clinical Tests*, <https://www.mintz.com/insights-center/viewpoints/2146/2019-03-device-modernization-series-vitro-clinical-tests> (accessed Mar. 7, 2019).

17 Personal communication from Ralph Hall, Jan. 16, 2020.

18 Editorial, *The Epic Failure of Coronavirus Testing in America*, NY TIMES, <https://www.nytimes.com/2020/03/19/opinion/coronavirus-testing.html> (accessed Mar. 19, 2020).

21 U.S.C. § 360bbb–3 (2020).

20 See, e.g., Michael Mezher, *FDA Sends Three Letters Over Unapproved Zika Diagnostics*, RAPS, <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/3/fda-sends-three-letters-over-unapproved-zika-diagnostics> (accessed Mar. 14, 2016). Even while some laboratory stakeholders question the FDA’s authority over LDTs during a public health emergency, no reports have emerged of LDTs for COVID-19 offered without an EUA during the early weeks of the pandemic.

21 U.S. Food & Drug Admin., *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* 7–8 (2017), <https://www.fda.gov/media/97321/download>.

22 85 Fed. Reg. 7316 (Feb. 7, 2020).

the Centers for Disease Control and Prevention (CDC). Unfortunately, the CDC tests were found to lack validity and several weeks passed before a revised EUA could be granted. The largest private diagnostics developers did not receive EUAs until mid-March 2020,<sup>23</sup> due in part to requirements for evidence of effectiveness. As the severity of the pandemic and political scrutiny increased, the FDA relaxed its EUA requirements for diagnostics several times. These efforts included permitting some CLIA-certified laboratories to validate and use LDTs prior to communicating with the FDA.<sup>24</sup> However, the early enforcement decisions and lack of early engagement with industry had already discouraged many clinical laboratories from developing or seeking authorization for LDTs,<sup>25</sup> and the delayed availability of testing during the initial weeks of the pandemic significantly exacerbated the spread of the virus in the USA.

### WINDOW OF OPPORTUNITY?

The US legislative process for any given issue is characterized by static inertia interrupted by an occasional ‘policy window’ opened by external changes or events that suddenly catapult a specific issue to the forefront of Congressional attention.<sup>26</sup> The US Congress is confronted by thousands of potential issues it could and should address and, even without political polarization and partisan gridlock, it is impossible for Congress to legislate on every item meriting attention. For most issues, statutory change is not possible without some type of crisis or dramatic event to create a window of opportunity by triggering Congressional attention, and even that attention might be fleeting. As such, advocates of change need to strike quickly.<sup>27</sup>

The history of public health and safety legislation in the USA is characterized by this dynamic of ‘punctuated equilibrium’<sup>28</sup>— long periods of static intransience interrupted by brief flurries of rapid change, often instigated by some crisis or tragedy. Indeed, virtually every major change in the legislative authority of public health regulatory agencies such as the FDA and EPA was enacted in response to public health tragedies or crises due at least in part to regulatory failures or omissions.

Peter Barton Hutt, former Chief Counsel at the FDA, observed that ‘sensational product disasters and the major publicity that attends them . . . have accounted for many

23 U.S. Food & Drug Admin., *Emergency Use Authorization*, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev> (accessed Mar. 31, 2020).

24 U.S. Food & Drug Admin., *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency: Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*, <https://www.fda.gov/media/135659/download> (accessed Mar. 30, 2020).

25 Michael D. Shear et al., *The Lost Month: How Failure to Test Blinded the U.S. to Covid-19*, NY TIMES, <https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html?action=click&module=Spotlight&pgtype=Homepage> (accessed Mar. 28, 2020).

26 JOHN W. KINGDON, *AGENDAS, ALTERNATIVES AND PUBLIC POLICIES* 173–88 (1984).

27 Kingdon quoted an unnamed interest group analyst for this analogy: “People who are trying to advocate change are like surfers waiting for the big wave. You get out there, you have to be ready to go, you have to be ready to paddle. If you are not ready to paddle when the big wave comes along, you are not going to ride it in.” *Id.* at 173.

28 See generally PUNCTUATED EQUILIBRIUM AND THE DYNAMICS OF US ENVIRONMENTAL POLICY (Robert Repetto ed., 2006).

of our most important food and drug laws.<sup>29</sup> Examples include: first, the Food and Drugs Act of 1906<sup>30</sup> was enacted in response to the publication of Upton Sinclair's book 'The Jungle,' an instant best-seller about the horrific conditions in meat processing plants, triggering public outrage about the safety of foods and patent drugs.<sup>31</sup> The book caused meat sales to fall by over half within a few weeks of publication, and provoked industry, scientific organizations, and politicians to quickly scramble to enact the 1906 law that created the initial statutory authority for today's FDA.<sup>32</sup> Second, The Federal Food, Drug and Cosmetic Act of 1938,<sup>33</sup> which among other things required premarket safety evidence of pharmaceuticals, was quickly enacted after a cough medicine (elixir of sulfanilamide) containing the toxin diethylene glycol (antifreeze), to improve taste, killed 107 people (mostly children).<sup>34</sup> Third, the Kefauver-Harris Drug Amendments drug approval amendments of 1962,<sup>35</sup> which put the burden of proof on a drug manufacturer to demonstrate both safety and efficacy before marketing a drug, was enacted in the wake of the thalidomide tragedy causing children to be born with malformed limbs.<sup>36</sup> Long-pending changes to the statute were ultimately 'put into play' by the thalidomide tragedy.<sup>37</sup> Fourth, The Medical Device Amendments of 1976,<sup>38</sup> which first gave FDA premarket authority over medical devices, closed a long-recognized gap in the FDA's regulatory authority, but it took Congressional hearings in 1975 that documented thousands of women injured from the Dalkon Shield intrauterine device to finally push Congress to act.<sup>39</sup>

As Hutt observed from these and other examples, 'it is readily apparent that the legislation that has often been most important in establishing national policy on food and drug regulation has been created in the aftermath of a major product disaster.'<sup>40</sup>

A similar pattern of major legislative enactments in response to major disasters exists for much of the EPA's main authorizing legislation. The modern environmental era was precipitated by a series of triggering events in the late 1960s—including the Torrey Canyon oil spill, Ohio's Cuyahoga River catching fire, and the original Earth Day celebration in 1970—that 'radically changed the environment surrounding pollution control regulation' and led to the promulgation of the first wave of major environmental

29 Peter Barton Hutt, *The Transformation of United States Food and Drug Law*, 60 J. ASS'N FOOD & DRUG OFFICIALS 1, 24 (Sept. 1996).

30 Pub. L. No. 59-384, 34 Stat. 768 (1906).

31 Philip J. Hiltz, *The FDA at Work: Cutting-Edge Science Promoting Public Health*, FDA CONSUMER MAGAZINE, Jan./Feb. 2006, [https://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2006/106\\_fda\\_work.html](https://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/2006/106_fda_work.html).

32 *Id.*

33 Pub. L. No. 75-717, 52 Stat. 1040 (1938).

34 Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAGAZINE, Jan.-Feb. 2006, <https://www.fda.gov/about-fda/histories-product-regulation/promoting-safe-effective-drugs-100-years>.

35 Pub. L. No. 87-781, 76 Stat. 780 (1962).

36 Meadows, *supra* note 34.

37 *Id.*

38 Pub. L. No. 94-295, 90 Stat. 539 (1976).

39 Carol Rados, *Medical Device and Radiological Health Regulations Come of Age*, FDA CONSUMER MAGAZINE, Jan./Feb. 2006, <https://www.fda.gov/about-fda/histories-product-regulation/medical-device-radiological-health-regulations-come-age>.

40 Hutt, *supra* note 29, at 25.

statutes including the National Environmental Policy Act (1970), the Clean Air Act (1970), and the Clean Water Act (1972).<sup>41</sup>

Since this initial burst of legislation, subsequent environmental statutes have often resulted from an environmental tragedy or disaster,<sup>42</sup> which has been described as the ‘catastrophic model of risk regulation.’<sup>43</sup> Examples include: first, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980,<sup>44</sup> known more generally as Superfund, was precipitated by the highly publicized Love Canal hazardous waste controversy.<sup>45</sup> Second, the Emergency Planning and Community Right to Know Act of 1986<sup>46</sup> was catalyzed by the tragic Bhopal industrial explosion in India in December 1984 that killed over 3000 people.<sup>47</sup> Third, the 1989 Exxon Valdez oil spill resulted in the Oil Pollution Control Act of 1990, breaking a decade-long stalemate in Congress on addressing the risk of oil tanker spills.<sup>48</sup>

For both the FDA and EPA then, the primary regulatory statutes were promulgated after high-profile tragedies that sparked intense and immediate public, media, and Congressional concern. In some cases, the underlying problem was well-known to legislators, and extensive vetting of different ideas through Congressional hearings and stakeholder engagement had already occurred, with the precipitating tragedy providing the ‘final straw’ that pushed the legislative solution over the finish line. An example is the 1938 FDA amendments, where ‘[m]uch of the costly work of building coalitions behind legislation had already been accomplished.’<sup>49</sup> Other disasters such as Love Canal catalyzed new statutes that were less developed and vetted, and perhaps resulted in regulatory overkill.<sup>50</sup> Another observation is that after a crisis, the representatives introducing corrective bills tend to have more extreme positions than the authors of bills enacted during non-crisis periods, which tilts legislation adopted in response to tragedies to be more sweeping and path-breaking than legislation adopted in less urgent times.<sup>51</sup>

The COVID-19 pandemic has created such a policy window for reforming US diagnostics regulation, a debate which had been sputtering for several years but had

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41 Evan Ringquist, *Environmental Protection Regulation*, in REGULATION AND CONSUMER PROTECTION: POLITICS, BUREAUCRACY AND ECONOMICS 143, 150 (Kenneth J. Meier, E. Thomas Garman & Lael Kaiser, eds., 1998, 3d ed.).

42 An exception is the Deepwater Horizon tragedy, which did not result in any legislative response, notwithstanding substantial pressure for such change. See Jaime Eagan, *Never Waste a Good Crisis: Deepwater Horizon and a Call for Congressional Action* (2011), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2514675](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2514675).

43 Eric R. Pogue, *The Catastrophic Model of Risk Regulation and the Regulatory Legacy of Three Mile Island and Love Canal*, 15 PENN. ST. ENVTL. L. REV. 463, 465 (2007).

44 Pub. L. No. 96–510, 94 Stat. 2767 (1980).

45 Pogue, *supra* note 43, at 475.

46 Pub. L. No. 99–499, 100 Stat. 1728 (1986).

47 Steven J. Christiansen & Stephen H. Urquhart, *The Emergency Planning and Community Right to Know Act of 1986: Analysis and Update*, 6 BYU J. PUB. L. 235 (1992).

48 Pub. L. No. 101–380, 101 Stat. 484 (1990). See Matthew E. Kahn, *Environmental Disasters as Risk Regulation Catalysts? The Role of Bhopal, Chernobyl, Exxon Valdez, Love Canal, and Three Mile Island in Shaping U.S. Environmental Law*, 35 J. RISK & UNCERTAINTY 17, 18 (2007).

49 Daniel Carpenter and Gisela Sin, *Policy Tragedy and the Emergence of Regulation: The Food, Drug, and Cosmetic Act of 1938*, 21 STUD. AM. POL. DEV. 149, 177 (2007).

50 Pogue, *supra* note 43, at 483.

51 Kahn, *supra* note 48, at 36.

been unable to get across ‘the finishing line.’ The crisis here was foreseeable yet largely underrepresented in the diagnostics debate, which instead has centered on regulation for non-emergencies, while recent epidemics have seen the CDC successfully develop and deploy testing. Now, the pandemic and the weak US testing response has created a window of opportunity to discuss diagnostics regulation generally, prompting two bills to be floated.

The VITAL Act identifies FDA overregulation of diagnostics, especially LDTs, as the key issue which precipitated the poor COVID-19 testing rollout.<sup>52</sup> This proposal would leverage lawmaker attention to use improved laboratory quality standards, rather than FDA, to oversee LDTs and embolden clinical laboratories to develop diagnostics for any potential future need.<sup>53</sup> The VALID Act would instead advance a robust new regulatory regime for the FDA to manage all diagnostics as IVCTs, building on positions with bipartisan support such as risk-based premarket review of IVCTs and some form of optional management-based regulation for test developers.<sup>54</sup> The VALID Act contains a freshly added special standard for declared public health emergencies, allowing test developers to use their self-validated diagnostics while still seeking emergency authorization from FDA.<sup>55</sup> These provisions for emergencies could appeal to lawmaker interest in addressing the testing issues observed during the pandemic to catalyze more fundamental regulatory reform for diagnostics even during non-emergencies.

#### INVITATION FOR RECKLESSNESS?

Though crises can throw open policy windows, legislating during a disaster also creates an invitation to recklessly establish, modify, or disrupt regulatory regimes. Emergency decision-making typically bypasses procedural norms around holding hearings, engaging with stakeholders, and justifying the purpose of decisions through written reports.<sup>56</sup> Substantively, emergency policymaking may result in regulatory norms or programs poorly calibrated to the longer-term and complex set of stakeholder interests and policy concerns at play. Specifically in food and drug crisis decision-making, Peter Barton Hutt comments ‘[a]s is often true under those conditions, the legislation has been shaped as much by public emotion as rational policy design.’<sup>57</sup> Accordingly, legislatures tend to underregulate a problem before a crisis occurs, but often overregulate after disaster strikes.<sup>58</sup> This overcompensation can result in miscalibrated trade-offs between complicated sets of

52 Office of Sen. Rand Paul, *Dr. Rand Paul Introduces VITAL Act to Speed Availability of Testing in Health Emergencies*, <https://www.paul.senate.gov/news/dr-rand-paul-introduces-vital-act-speed-availability-testing-health-emergencies> (accessed Mar. 18, 2020).

53 VITAL Act, *supra* note 4, at § 2(c).

54 VALID Act, *supra* note 3, at § 3 (proposing “Sec. 587B. Premarket review.” and “Sec. 587D. Technology certification.”). See generally Cary Coglianese & David Lazer, *Management-Based Regulation: Prescribing Private Management to Achieve Public Goals*, 37 L. & SOC. REV. 691 (2003).

55 *Id.* § 3 (proposing “Sec. 587A(5) Emergency use.”). The FDA’s strategy during the pandemic ultimately began to take this type of approach. See U.S. Food & Drug Admin., *supra* note 24.

56 Abbe R. Gluck, Anne Joseph O’Connell & Rosa Po, *Unorthodox Lawmaking, Unorthodox Rulemaking*, 115 COLOM. L. REV. 1789, 1807–11 (2015).

57 Hutt, *supra* note 29, at 25.

58 Pogue, *supra* note 43, at 477, 483.



interests and values, potentially limiting the effectiveness or efficiency of subsequent regulation.

The tendency toward short-term thinking and possibility of limited legislative history or analysis in emergency policymaking can make implementation, interpretation, and adjudication challenging for regulators and courts, especially in the years following the conclusion of the crisis.<sup>59</sup> The emergence of the 510(k) pathway for medical device clearance provides one such example, where the FDA found statutory provisions calling for ‘performance standards’ for medium-risk devices too onerous and largely abandoned them in favor of ‘substantial equivalence’ reviews.<sup>60</sup> Decreased participation in crisis decision-making can also jeopardize the long-term legitimacy of norms or programs established during emergencies. Legislating during a crisis grants stakeholders a shorter window to provide comments or feedback on proposed norms and, depending on how the crisis impacts them, stakeholders may have less capacity to comment at all.

Lawmaking in the wake of the terrorist attacks of September 11, 2001 offers a cautionary tale for making broad oversight changes during or immediately after a crisis. In particular, the USA PATRIOT Act was enacted barely 6 weeks following the attacks.<sup>61</sup> The statute established a multifaceted regulatory regime for counterterrorism with sweeping new surveillance powers, the added crime of ‘domestic terrorism’ to enforce, and targeted restrictions for immigrants. Numerous civil society and political entities retrospectively criticized these measures over civil liberties and privacy concerns, drawing on constitutional norms and policy arguments on limited effectiveness and discriminatory outcomes.<sup>62</sup> Ultimately, the criminal regulatory system set up appeared grounded in emotion and crisis overreaction as much as, or more than, sound policy and legal analysis,<sup>63</sup> and may have unnecessarily and disparately infringed on rights without effectively promoting national security.

The Patriot Act illustration offers another related lesson, that emergency decision-making can prompt an abrupt and durable shift in regulatory goals, values, and motivations. Immediately prior to 9/11, the Federal Trade Commission (FTC) and other stakeholders had been promoting the adoption of enforceable data protection rules to promote privacy at the dawn of the internet age.<sup>64</sup> However, Zuboff illustrates how the crisis-driven urgency, combined with the politically damaging perception that the USA

59 See Gluck et al., *supra* note 56, at 1807–11; Hutt, *supra* note 29, at 25.

60 INST. OF MED., PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS: BALANCING PATIENT SAFETY AND INNOVATION: WORKSHOP REPORT 6, 9 (2010), <https://www.nap.edu/read/12960/chapter/1>; Walter G. Johnson, *A Balancing Act: Safety, Innovation, and Resources in the Implementation of Medical Device Legislation*, 12 J. SCI. POL’Y & GOVERNANCE, no. 1, 2018, at 4–6.

61 Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Pub. L. No. 107–56, 115 Stat. 272 (2001).

62 See, e.g., Natsu Taylor Saito, *Whose Liberty? Whose Security? The USA PATRIOT Act in the Context of COINTELPRO and the Unlawful Repression of Political Dissent*, 81 OR. L. REV. 1051, 1059–60, 1111–1128 (2002).

63 See Beryl A. Howell, *Seven Weeks: The Making of the USA PATRIOT Act*, 72 GEO. WASH. L. REV. 1145, 1205–07 (2004).

64 See ROBERT PITOFSKY ET AL., FED. TRADE COMM’N, PRIVACY ONLINE: FAIR INFORMATION PRACTICES IN THE ELECTRONIC MARKETPLACE: A REPORT TO CONGRESS, <https://www.ftc.gov/sites/default/files/documents/reports/privacy-online-fair-information-practices-electronic-marketplace-federal-trade-commission-report/privacy2000text.pdf> (accessed May 1, 2020).

was unable to forecast the 9/11 attack, resulted in rapid legislative moves to bolster surveillance and data-sharing by both public and private entities.<sup>65</sup> Proposed privacy plans were scrapped in an instant, casting aside the growing normative support for data protection rules immediately prior to the crisis. This shift in values and goals affected not only lawmakers but also regulators at the FTC, who backed away from broader data protection activities and advocacy to support narrower and more acceptable data security initiatives.<sup>66</sup> The conversation around promoting digital privacy protections then fell dormant for over a decade.

In the case of diagnostics regulation, a similar swing in values could occur with the pandemic, modulating not only emergency rules but also more general regulatory norms for after the crisis. The diagnostics debate has long been balanced on the fulcrums of safety versus innovation, consumer protection versus patient access, and overregulation of LDTs versus regulatory fairness between IVDs and LDTs. However, the public health costs of a slow COVID-19 testing rollout fused with widespread frustration over the FDA's stunted approach toward LDTs could result in an abrupt and ill-considered realignment of how policymakers weigh these competing values.

#### CONCLUSION: GRABBING THE OPPORTUNITY, PRUDENTLY

Rahm Emanuel once said '[y]ou never want a serious crisis to go to waste.'<sup>67</sup> Of course, not all crises are equal, and the policy window opened by the COVID-19 pandemic could be distinguished from previous examples like 9/11 along several dimensions. While the 9/11 attacks suddenly created an acute crisis and called attention primarily to counterterrorism, this pandemic has scaled up into an emergency enduring for months and requires legislative attention on everything from economic policy to medical equipment production.<sup>68</sup> The acute demands on lawmakers from various policy domains during the months-long pandemic have no doubt contributed to Congress's decision not to legislate immediately on diagnostics regulation. Still, there will be a need for Congress to address diagnostics, sooner or later, as a result of the perceived COVID-19 diagnostic testing problems.

The current COVID-19 crisis creates a double-edged sword between opportunity and opportunism. Synthesizing lessons described above from prior legislative activities during emergencies suggests several criteria for evaluating whether public health reforms during a pandemic will likely lead to a measured, legitimate regulatory regime. These criteria include satisfying procedural norms, diverse stakeholder engagement, rigorous policy analysis, and consistency with pre-crisis values and balances of complex, competing interests.

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65 SHOSHANA ZUBOFF, *THE AGE OF SURVEILLANCE CAPITALISM: THE FIGHT FOR A HUMAN FUTURE AT THE NEW FRONTIER OF POWER* 106–10 (2019).

66 *Id.*

67 Quoted in Eagan, *supra* note 42, at 17.

68 See Catie Edmondson, *5 Key Things in the \$2 Trillion Coronavirus Stimulus Package*, NY TIMES, <https://www.nytimes.com/2020/03/25/us/politics/whats-in-coronavirus-stimulus-bill.html> (accessed Mar. 25, 2020).

On one hand, the VITAL Act excavates a deregulatory approach to LDT oversight which some stakeholders advanced in 2015 without gaining significant traction.<sup>69</sup> The draft would reprioritize innovation, patient access, and easing burdens on clinical laboratories as the preeminent values for diagnostics oversight,<sup>70</sup> in emergencies and non-emergencies alike. In capitalizing on frustrations with the FDA and the slow testing rollout during the pandemic, this legislative option could downgrade safety and performance in the hierarchy of values for all diagnostics regulation moving forward. It has not gone through the stakeholder vetting, Congressional hearings, and thoughtful deliberation that have characterized successful legislative enactments in the wake of previous crises.

On the other hand, the VALID Act would create different standards for diagnostics in ordinary and emergency settings, though recent justifications for the bill have also focused on flexibility, innovation, and access. Upon releasing the updated draft VALID Act in early March 2020, its sponsors promoted the proposal based on the flexible emergency norms the bill would create.<sup>71</sup> Here, the need and support for a ‘fix’ to the emergency diagnostics authority problem is being leveraged to create a comprehensive regulatory scheme for non-emergency oversight of diagnostics. The VALID Act and its earlier versions have gone through several years of deliberation and refinement, taking into account the views of the relevant stakeholders and the FDA, and building bipartisan support in both the Senate and the House. Moreover, the VALID Act addresses the well-recognized double-track problem with the current regulatory system that has not been fixed due to legislative inertia and a crowded Congressional agenda.

The VALID Act has already been the subject of extensive policy analysis, broad stakeholder engagement, and lawmaking procedures and would keep intact a balance between various competing values and interests for diagnostics regulation struck prior to the pandemic. Using the window of opportunity created by COVID-19, with the demonstrated urgency to reform emergency norms, to enact the comprehensive reform of diagnostics regulation provided by the VALID Act would therefore exemplify the type of crisis-based lawmaking that has been successful in the past to create much of our public health legislation.

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69 See Ass’n for Molecular Pathology, *Proposal for Modernization of CLIA Regulations for Laboratory Developed Testing Procedures (LDPs)*, <https://www.amp.org/advocacy/advocacy-resources/laboratory-developed-testing-procedures-ldps/clia-modernization/> (accessed Aug. 4, 2015).

70 See Office of Sen. Rand Paul, *supra* note 52.

71 Office of Rep. Larry Bucshon, *Lawmakers Introduce Legislation to Expand Nation’s Diagnostic Testing Capabilities*, <https://bucshon.house.gov/news/documentsingle.aspx?DocumentID=3841> (accessed Mar. 5, 2020) (The “legislation would... overhaul how the FDA reviews and approves diagnostics... [giving] laboratories greater flexibility to respond to public health emergencies while continuing to keep patients safe.”).