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IMPROVING THE FDA: *LESSONS LEARNED FROM COVID-19 RAPID TESTS*

The Center for Growth and Opportunity at Utah State University

Improving the FDA: Lessons Learned from COVID-19 Rapid Tests

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Policy Paper

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Contents

Introduction 1

1 The early history of diagnostic testing regulation 2

2 The institutional logic of delay 4

3 Diagnostic testing regulation 6

4 COVID and rapid tests 8

5 Comparison with Germany 11

6 To reform the FDA, make it consider time 15

Introduction

Shortly before the Omicron wave of COVID-19 hit in December 2021, investigative journalists Lydia DePillis and Eric Umansky of ProPublica set out to understand why so few rapid tests were available in stores.[1] In a series of reports first published in November, they found a consistent story among those companies trying to bring tests to market in the United States. Getting approval from the Food and Drug Administration (FDA) was "an arbitrary, opaque process that meanders on, sometimes long after their products have been approved in other countries that prioritize accessibility and affordability over perfect accuracy."

DePillis and Umansky's articles uncovered an instance in which the FDA dragged its feet. This isn't unexpected. The agency has a long history of delaying decisions, especially when it comes to at-home diagnostic tests.

Delays have real costs. A group of researchers using an epidemiological-economic model found that 117,000 deaths would have been averted and GDP would have been $395 billion higher had rapid tests been available from June 1, 2020 to the end of 2020.[2]

To be sure, the long lines at testing centers and the empty shelves at the end of 2021 were not wholly the fault of a slow regulatory system. There was a sudden upsurge in demand for tests everywhere when the Omicron variant appeared. However, the United States faced a uniquely steep shortage of tests, made worse by a slow regulatory system.

The Germany experience with testing regulation offers a counterexample. Germany started with rules that were more lax compared to the relatively strict FDA.[3] When it became clear in the last months of 2020 that rapid at-home tests weren't as accurate as hoped, performance thresholds were ratcheted up by the German government. Eventually, a formal system of government approval was set up in March 2021 and tests conforming to the standard were then quickly approved. By the next month, Germany had 27 different tests available. At that time, the United States had only six tests on the market even though its rules had been in effect eight months earlier, beginning in July 2020.

The FDA does critically important work to ensure drugs and food are safe. But the agency needs to move quickly in times of emergency. Practices need to be reformed to minimize the costs and delays caused by inaction—especially for diagnostics.

Safety doesn't need to be sacrificed to get diagnostics to market, but only Congress has the authority to adjust the direction of the FDA. As such, this paper will explain why Congress should

- Amend the Emergency Use Authorization (EUA) process to consider the cost of time.
- Create clear reporting requirements on EUA approvals.
- Rethink the need for diagnostic usability trials.
- Refocus the standards for clinical trials for diagnostics.

1 Eric Umansky and Lydia DePillis. "Here's Why Rapid COVID Tests Are So Expensive and Hard to Find." ProPublica, November 4, 2021, https://www.propublica.org/article/heres-why-rapid-covid-tests-are-so-expensive-and-hard-to-find.

2 Andrew Atkeson, Michael Droste, Michael Mina, and James Stock, "Economic Benefits of COVID-19 Screening Tests," Working Paper, Working Paper Series (National Bureau of Economic Research, October 2020), https://doi.org/10.3386/w28031.

3 Aaron B. Wildavsky, *Searching for Safety.* New Brunswick: Transaction Books, 1988.

- Formalize rules for diagnostics.
- Mandate that the agency produce an official report on the costs of decision delays during COVID.

The following paper is divided into six sections. The first section reviews the agency's history with diagnostics. The second section reviews the economic logic behind delays. The third section reviews the legal underpinnings of diagnostic testing regulation through the story of 23andMe. In the fourth section, a more comprehensive history of COVID and rapid tests is presented. The fifth section compares the US regulatory experience with Germany. The sixth and final section explains why the above reforms should be undertaken.

There is no one singular reason why the US had slow approval times for rapid tests during the winter of 2021 into 2022. The causes are multiple and interconnected. As such, ensuring that delays don't happen in the future will require a number of reforms. Fundamentally, however, the FDA needs to consider time when it makes decisions.

1 The early history of diagnostic testing regulation

In vitro diagnostic (IVD) devices, commonly known as diagnostic tests, are categorized into one of two types. Laboratory-developed tests (LDTs) are the first major type of diagnostic. These tests are developed, validated, and conducted by an approved laboratory. In turn, laboratories are regulated under the program set up by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and operated by Centers for Medicare and Medicaid Services (CMS).

At-home COVID tests fall under a second type of diagnostic tests, commonly known as commercial kits.[4] Tests of this type are developed and distributed for a commercial purpose and sold over-the-counter. Rapid antigen and other at-home tests are thus legally defined as commercial tests.

The FDA exercises authority over both kinds of tests, but it has never completed the formal rulemaking process to root this authority.[5] For an agency that has completed countless rulemakings, the lack of a formal rule in diagnostic tests is notable.

The FDA's precautionary stance towards commercial tests stretches back to the moment when commercial tests were first launched. In 1971, Faraday Labs' Ova II pregnancy test hit the market, becoming the first direct-to-consumer diagnostic test.[6] But the test wasn't available for long because in December 1972, the FDA recalled the test, saying that the tests were "inaccurate, unreliable and prone to give false results." However, the agency still allowed the same tests to be processed in labs. With this move, the agency was claiming that the kit was only inaccurate

4 Amanda K. Sarata and Judith A. Johnson, "Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests," Report, UNT Digital Library (Library of Congress. Congressional Research Service., December 17, 2014), United States, https://digital.library.unt.edu/ark:/67531/metadc501872/.

5 For the remainder of this paper, the terms rapid tests, at-home tests, and COVID tests will all reference these at-home rapid tests, unless otherwise noted.

6 Shelby, Baird, "Don't Try This at Home: The FDA's Restrictive Regulation of Home Testing Devices," *Duke Law Journal* 67 (2017): 383–426, https://scholarship.law.duke.edu/dlj/vol67/iss2/3.

because it was in the hands of "laywomen," who were prone to misreading the results.[7] As later research would confirm, the fears raised at the time that users of home pregnancy tests "do not in general have sufficient training to detect malfunctions" never materialized.[8] Errors rates were about the same for labs as they were for the women taking the tests.

Faraday Labs first complied with the order and stopped making the test for commercial purposes, but then reversed course and took the FDA to court. Ultimately, the courts agreed with the company on a variety of claims. Importantly, the courts said that the FDA didn't have the authority to regulate diagnostics as the company had argued. The judge went further and explained, that "no pregnancy test, including those recognized by FDA as not only 'safe and effective,' but also considered by it as the most 'safe and effective' (a quality not required by the Act), is fully 100 percent reliable."[9]

In other words, the courts chided the agency for holding companies to impossibly high standards of reliability. Impossibly high standards would become a recurring theme.

In reaction to the ruling, Congress passed the Medical Device Amendments of 1976 (MDA), which gave the FDA the authority to regulate diagnostics. From then on, the FDA has had explicit power over medical devices, but it has been uneven in its application of that power. None of the changes made by Congress over the years have solved the internal demands for incredibly high standards.

The FDA first drew on its power to regulate diagnostic tests during the AIDS epidemic. In late 1987, "the FDA adopted a de facto blanket ban on immunodeficiency virus (HIV) home-testing kits."[10] A few years later in 1992, an HIV test kit that used a skin prick and mailer applied for premarket approval. After two more applications, the FDA pulled together an expert panel on the tests in 1994 to determine how to proceed. Following the suggestion of this panel, the agency delayed the decision on the pending applications and instead ran pilot programs. Then, two years later, in 1996, the first of these at-home tests gained approval—four years after the first application.[11]

Rapid HIV tests faced even longer delays. In 2002, what became the OraQuick rapid test was first given approval for use in labs.[12] Three years later, a commercial kit version of the quick HIV test was sent to the FDA for approval.[13] The application sat at the agency from 2005 until 2012 when it was finally given the go-ahead.[14] It took seven years for these tests to get approval.

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7 P.A. Entwistle, "Do-It-Yourself Pregnancy Tests: The Tip of the Iceberg?" *American Journal of Public Health* 66, no. 11 (1976): 1108–9, https://doi.org/10.2105/AJPH.66.11.1108-b.

8 Joan H. Robinson, "Bringing the Pregnancy Test Home from the Hospital." *Social Studies of Science* 46, no. 5 (2016): 649–74, http://www.jstor.org/stable/26107034.

9 Robinson, "Bringing the Pregnancy Test Home."

10 Steven Salbu, "HIV Home Testing and the FDA: The Case for Regulatory Restraint." *Hastings Law Journal* 46, no. 2 (1995): 403–57, https://repository.uchastings.edu/cgi/viewcontent.cgi?article=3178&context=hastings_law_journal.

11 Danielle R. Stevens, Caroline J. Vrana, Raviv E. Dlin, and Jeffrey E. Korte, "A Global Review of HIV Self-Testing: Themes and Implications," *AIDS and Behavior* 22, no. 2 (2017): 497–512. https://doi.org/10.1007/s10461-017-1707-8.

12 "Notice to Readers: Approval of a New Rapid Test for HIV Antibody," Centers for Disease Control and Prevention, November 7, 2002. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5146a5.htm.

13 Donald G. McNeil, "Rapid HIV Home Test Wins Federal Approval," *The New York Times*, July 3, 2012, https://www.nytimes.com/2012/07/04/health/oraquick-at-home-hiv-test-wins-fda-approval.html.

14 Roger Parloff, "The Quiet Scandal of the HIV Home Test Kit," *Fortune*, July 16, 2014, https://fortune.com/2012/07/09/the-quiet-scandal-of-the-hiv-home-test-kit/.

The indecision was deadly. According to the FDA's own research, the rapid HIV test was likely to prevent 4,000 new HIV infections in its first year of use, roughly 8 percent of the 50,000 new infections each year in the United States.[15] Had the test been available shortly after its development countless people would never have been infected or lost to HIV.

The arguments against at-home HIV tests in the 1990s and again in the 2000s echo the ones made against quick COVID tests. Concerned doctors and specialists in each of these instances claimed that home testing would be ineffective or unsafe due to consumer error. [16] Doctors Rochelle Walensky and A. David Paltiel, for example, warned in 2006 (just as OraQuick was being considered for market approval) that a poorly functioning home HIV test could undermine confidence in the reliability of HIV testing.[17] Later research found that a "diverse group of participants generally performed [self-testing] correctly with a few exceptions."[18] The worries were unfounded.

2 The institutional logic of delay

The FDA's reluctance to approve HIV test kits closely mirrors the agency's pattern with drug approvals as well. Indeed, there is a logic in delaying the decision to approve HIV tests as well as therapeutic drugs. The FDA is an agency that wants to reduce errors.

Approving a bad drug, which would be a Type I error, would likely result in the agency being summoned to stand before Congress and criticized on the front page of the New York Times. This is what happened with the heart drug Vioxx.[19] Eventually, Vioxx was pulled, but leadership at the agency faced hard questions in hearings before the House and Senate.

Failing to approve a good drug, a Type II error, is tougher for the public and policymakers to understand and grasp because it doesn't show up in headlines. As economist Alex Tabarrock explained it, "When the FDA fails to approve a good drug, people die, but the bodies are buried in an invisible graveyard."[20] Type II errors are also costly, but largely unseen.[21]

The FDA thus faces asymmetric costs. The institutional cost of a Type I error is much higher than the nearly non-existent institutional cost of a Type II error. These incentives tend to steer it away from Type I costs. High performance standards for drugs and diagnostics are one way that the agency reduces Type 1 costs. However, errors are also mitigated if the agency waits for better information to arrive. [22] This tendency to wait for better information occurred while HIV tests were being approved. It also occurred during the COVID pandemic.

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15 Roger Parloff, "The Quiet Scandal of the HIV Home Test Kit."

16 Salbu, "HIV Home Testing and the FDA"

17 Rochelle P. Walensky and A. David Paltiel, "Rapid HIV Testing at Home: Does It Solve a Problem or Create One?" *Annals of Internal Medicine* 145, no. 6 (2006): 459, https://doi.org/10.7326/0003-4819-145-6-200609190-00010.

18 Stevens, Vrana, Dlin, and Korte, "A Global Review of HIV Self-Testing."

19 Leonard V. Sacks, Hala H. Shamsuddin, Yuliya I. Yasinskaya, Khaled Bouri, Michael L. Lanthier, and Rachel E. Sherman, "Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000–2012," *JAMA* 311, no. 4 (2014): 378, https://doi.org/10.1001/jama.2013.282542.

20 Alex Tabarrock, "Why the FDA Has an Incentive to Delay the Introduction of New Drugs." FDAReview.org, Independent Institute, 2018. https://www.fdareview.org/issues/why-the-fda-has-an-incentive-to-delay-the-introduction-of-new-drugs/.

21 Leah Isakov, Andrew W. Lo, and Vahid Montazerhodjat, "Is the FDA Too Conservative or Too Aggressive?: A Bayesian Decision Analysis of Clinical Trial Design," *Journal of Econometrics* 211, no. 1 (2019): 117–36. https://doi.org/10.1016/j.jeconom.2018.12.009.

22 Daniel P. Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*, Princeton: Princeton University Press, 2010.

Despite not showing up in the newspapers or in a budget line, the costs of inaction can be substantial. Economist Sam Peltzman pioneered cost-benefit analysis of FDA actions in a pathbreaking 1973 paper that put some bounds on these errors.[23] Peltzman looked at drugs approved just before and after the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetics Act. These efficacy amendments (EA) aimed at curtailing ineffective drugs by mandating quality standards, but the added time under review imposed a weighty cost. As Peltzman wrote, "The main finding is that benefits forgone on effective new drugs exceed greatly the waste avoided on ineffective drugs. The estimated net impact is equivalent to a 5–10 percent tax on drug purchases."

Nearly half a century of research has confirmed and extended Peltzman's original conclusions. In one study from 1985, a one-year delay was estimated to cost some 37,000 to 76,000 lives over the course of a decade, depending on the drug.[24] A two-year delay doubled the calculation, meaning that between 74,000 and 152,000 lives were lost over a ten-year period. Then as now, the forgone benefits of having drugs come to market more quickly exceed the benefits of waiting.

The impact of the Prescription Drug User Fee Act (PDUFA) underscores the importance of getting medicines to market. This bill gave some drugs a quicker pathway to approval if the company paid a higher fee than is normal. The fees in turn promise an expedited service. As a result of this bill, wait times dropped and drugs got out into the market quicker.

By looking at the financial reports of a portfolio of drugs, researchers calculated the total amount of benefits and lives saved. PDUFA caused the private surplus of producers to increase by about $7 billion to $11 billion, while consumer welfare rose by $7 billion to $20 billion. In all, the combined social surplus was estimated to be between $14 billion and $31 billion. Critically, "the more rapid access of drugs on the market enabled by PDUFA saved the equivalent of 140,000 to 310,000 life years."[25] The PDUFA example shows life years are extended and consumers benefit when a product has quicker access to the market.

COVID rapid tests faced significant delays in getting approved and thus took time to get into the hands of consumers. The FDA set incredibly high standards and delayed its decisions on rapid tests, leading to fewer tests when the Omicron wave hit in late 2021. Had rapid tests been more widely available, consumers would have felt safer shopping, workers would have been able to return to work more quickly, and parents would have been comfortable sending their children back to school. Adding up all of these costs, a group of researchers using an epidemiological-economic model estimated the enormity of the FDA-imposed costs from delaying rapid test approvals. Over 117,000 deaths would have been averted and GDP would have been $395 billion higher had rapid tests been available from June 1, 2020 to the end of 2020.[26]

23 Sam Peltzman, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments." *Journal of Political Economy* 81, no. 5 (1973): 1049–91. http://www.jstor.org/stable/1830639.

24 Dale H. Gieringer, "The Safety and Efficacy of New Drug Approval," *Cato Journal* 5, no. 1 (1985): 177–201.

25 Tomas Philipson, Ernst R. Berndt, Adrian H.B. Gottschalk, and Eric Sun "Cost-Benefit Analysis of the FDA: The Case of the Prescription Drug User Fee Acts," *Journal of Public Economics* 92, no. 5–6 (2008): 1306–25. https://doi.org/10.1016/j.jpubeco.2007.09.010.

26 Atkeson et. al., "Economic Benefits of COVID-19 Screening Tests."

3 Diagnostic testing regulation

Although the FDA holds enormous authority over the diagnostics market, the agency has long refused to specify how it wields this power. This uncertainty, in turn, undermines the market. The FDA's handling of 23andMe, the ancestry and health testing company, is illustrative of the agency's approach to diagnostics.

When 23andMe first developed a genetic testing kit, the Bush administration was in its final years. As CEO Anne Wojciciki would later write, "Andrew von Eschenbach, then the FDA commissioner, indicated that the agency did not necessarily think our test was subject to regulation. We came away from those early discussions with the understanding that what we proposed did not require FDA premarket review."[27]

When President Obama took office, the FDA changed course on 23andMe, arguing tests now needed review. Soon, the agency opened up a line of communication with the company, and in 2013, after a five year back-and-forth between the two groups broke down, the agency sent the company a formal warning letter.

Sending a formal letter is one of the FDAs strongest actions. 23andMe would end up taking its product off the market for two years to get the regulatory issues cleared up. And it would be another two additional years for the genetic tests to be included with the ancestry tests.[28]

Wojciciki recounted what happened next when she started working to get premarket approval. "We learned from people with connections to the FDA that some officials felt very strongly that 23andMe should be reined in. We reached out to industry advisers who knew and understood the agency and had strong working relationships with some of its people. I wanted to start a conversation, but some folks did not even want to speak with us. The first time I emailed one adviser, she wrote back, 'I am not a fan of 23andMe.'"

The FDA was able to change course with 23andMe so quickly because it has wide discretion. In a move that happened again and again with the FDA, the agency started to work on rules for all LDTs beginning in 2007, but then never followed through on completing them.[29]

The tide seemed to be turning in June 2010, when the new FDA administration announced it would hold a public meeting to discuss the agency's regulatory authority over all LDTs. Officials began taking meetings with interested parties and went before Congress, but never followed up with the framework they promised.

In 2012 Congress gave the FDA a deadline to act on LDTs. Two years later in 2014, the agency officially notified Congress of its intent to regulate through draft guidance rather than issue an official regulation.[30] Unlike a regulation, a guidance cannot create a legally binding requirement, but the FDA uses them to help companies understand how the agency will make an approval.

27 Anne Wojcicki. "23andMe's CEO on the Struggle to Get over Regulatory Hurdles," *Harvard Business Review*, April 21, 2021. https://hbr.org/2020/09/23andmes-ceo-on-the-struggle-to-get-over-regulatory-hurdles.

28 Baird, "Don't Try This at Home."

29 Center for Devices and Radiological Health, "In Vitro Diagnostic Multivariate Index Assays - Draft Guidance," FDA, 2007, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/in-vitro-diagnostic-multivariate-index-assays-draft-guidance-industry-clinical-laboratories-and-fda.

30 "Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," Food and Drug Administration, 2014, https://www.fda.gov/media/89841/download.

Then, just after the 2016 election, the agency announced it would be delaying finalization of the draft guidance, kicking the decision to the incoming Trump administration.[31]

A few months later, the FDA released a discussion paper on diagnostic testing, said it would not be finalizing guidance, and then kicked the issue back to Congress to clarify.[32] No formal regulation or guidance have ever been adopted for diagnostic testing. Yet, the industry still follows the lead set by the draft guidance.

According to those guidelines, LDTs can be

1. Exempt from regulation entirely;
2. Only required to meet registration, notification, and adverse event reporting requirements; or
3. Required to meet registration, notification, and adverse event reporting requirements as well as premarket review and quality system regulation requirements.[33]

Instead of formal guidance, the FDA flexes its authority on diagnostic tests through warning letters. For example, four warning letters went out during the Zika crisis to two laboratories and two Texas hospitals for marketing "high-risk" unapproved diagnostics during Zika.[34] Additionally, just before the pandemic, Inova Genomics was sent a letter over their MediMap test, which predicts medication response.

An April 2019 letter explains the state of play before the public health emergency was announced in early 2020:

> FDA has not created a legal 'carve-out' for LDTs such that they are not required to comply with the requirements under the [Federal Food, Drug, and Cosmetics] Act that otherwise would apply. FDA has never established such an exemption. As a matter of practice, FDA, however, has exercised enforcement discretion for LDTs, which means that the FDA has generally not enforced the premarket review and other FDA legal requirements that do apply to LDTs. Although FDA has generally exercised enforcement discretion for LDTs, the agency always retains the discretion to take action when appropriate, such as when it is appropriate to address significant public health concerns.[35]

In the months leading up to the pandemic, the agency was quite explicit that it was taking a hands-off approach to diagnostic tests, but might still regulate tests if there was an emergency.

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31 Zachary Brennan, "FDA Delays Finalization of Lab-Developed Test Draft Guidance," Regulatory Affairs Professionals Society (RAPS), 2018, https://www.raps.org/regulatory-focus%e2%84%a2/news-articles/2016/11/fda-delays-finalization-of-lab-developed-test-draft-guidance.

32 "Regulation of Clinical Tests: In Vitro Diagnostic (IVD) Devices, Laboratory Developed Tests (LDTs), and Genetic Tests," Every CRS Report - EveryCRSReport.com, 2017, https://www.everycrsreport.com/files/20170411_R43438_73b86dc30fca1703aa59bfe65161c32b5b48a9ae.html.

33 "Regulation of Clinical Tests," Every CRS Report.

34 Michael Mezher, "FDA Sends Three Letters over Unapproved Zika Diagnostics," Regulatory Affairs Professionals Society (RAPS), 2016, https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/3/fda-sends-three-letters-over-unapproved-zika-diagnostics.

35 "Warning Letter: Inova Genomics Laboratory," FDA, 2019, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/inova-genomics-laboratory-577422-04042019.

In an odd quirk of the law, when the Secretary of the Department of Health and Human Services (HHS) declared a state of emergency on January 31, 2020, running tests actually became riskier for a lab. The move signaled to labs and hospitals that diagnostics tests would be carefully scrutinized by the FDA.

At the same time, the declaration of an emergency gave the FDA the ability to grant emergency use authorizations (EUAs) to fast-track vaccines, antivirals, and diagnostic tests. For vaccines and antivirals, the EUA process generally meant things went faster. For diagnostic tests, however, the EUA process meant companies needed an FDA approval letter where none was needed before. The process went slower, especially for any device previously assumed not subject to regulation or premarket approval.

Dr. Amesh Adalja, a senior scholar at the Johns Hopkins University Center for Health Security, was blunt about the impact, "Paradoxically, it increased regulations on diagnostics while it created an easier pathway for vaccines and antivirals."[36]

4 COVID and rapid tests

Rapid at-home COVID tests arrived into a world where they weren't trusted. A contingent of the academic medical community and the public health establishment maintained a skepticism about using at-home diagnostics for mass testing. Testing for pregnancy, HIV, Zika, and genetics had all faced similar headwinds. The market for rapid antigen tests suffered as a result.

Speaking to Roll Call in August 2020, Jennifer Nuzzo, an epidemiologist with the Johns Hopkins Center for Health Security, said that the idea of ubiquitous testing is "being pushed without really thinking through the operational consequences."[37] Continuing, she explained that, "You're potentially making consequential decisions on the individual level based on test results that are difficult to interpret."

Nuzzo wasn't alone. A letter penned by the editors of the *Journal of Clinical Microbiology* worried about "several potential challenges or problems with this strategy [of mass testing], including the limited availability of such tests, consequences of incorrect test results, difficulties with adherence to testing, and the questionable accuracy of such tests for detection of infectious people."[38]

Brett Giroir at the Department of Health and Human Services, echoed this belief. "You beat the virus by smart policies supplemented by strategic testing," he said on a call with reporters. "You do not beat the virus by shotgun testing everybody, all the time."[39]

The call, conducted on July 29, 2020, focused on the new FDA template for over-the-counter home tests to get an EUA. It was this template that effectively established the rules for tests to get approved by the FDA.[40]

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36 Chad Terhune, Dan Levine, Hyunjoo Jin, and Jane Lanhee Lee. "Special Report: How Korea Trounced US in Race to Test People for Coronavirus," Reuters, March 18, 2020. https://www.reuters.com/article/us-health-coronavirus-testing-specialrep/special-report-how-korea-trounced-u-s-in-race-to-test-people-for-coronavirus-idUSKBN2153BW.

37 Andrew Siddons, "Top Health Official Argues against More Widespread COVID-19 Testing." Roll Call, August 13, 2020. https://rollcall.com/2020/08/13/top-health-official-argues-against-widespread-covid-19-testing-approach/.

38 Matthew A. Pettengill and Alexander J. McAdam, "Can We Test Our Way out of the COVID-19 Pandemic?" *Journal of Clinical Microbiology* 58, no. 11 (2020), https://doi.org/10.1128/jcm.02225-20.

39 Siddons, "Top Health Official Argues against More Widespread COVID-19 Testing."

40 "Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use," FDA, https://www.fda.gov/media/140615/download.

Importantly, the template required rapid tests to be precise by establishing high performance standards. Sensitivity and specificity are the two basic testing performance metrics.[41] Sensitivity refers to the likelihood that the test will give a positive result when COVID is present, while specificity refers to how often the test will be negative when COVID is absent.[42] To borrow some common terms from statistics, a test with a high sensitivity has a low Type II error rate. There are few false negatives. In a similar way, a test with a high specificity has a low Type I error rate, and thus has few false positives.

The FDA required rapid tests to have a sensitivity higher than 90 percent and specificity higher than 99 percent. On the surface it would seem as though the US had comparable standards to Europeans, but in practice, it was much more stringent.

Determining if a rapid test has reached these marks comes by testing it against a more accurate lab test. The first step in this process is that a sample has to be diluted. Compared to their counterparts in Europe, US samples had to be diluted many more times. As Nikki Teran of the Institute for Progress explained, "This means, in theory, an antigen test in the US needs to be over 30,000 times more sensitive [than a test in the UK]." In other words, rapid test performance had to hit a much higher benchmark in the US compared to other countries.[43]

Another key difference between the US and our counterparts in Europe comes in the form of an additional human usability study. Separate from the clinical study establishing the accuracy of the tests, the FDA also requires that tests undergo a usability study to prove that the general public can use them. For rapid tests that were expected to be used at home, 100 participants needed to be recruited: "Fifty participants testing themselves and 50 participants testing another person (child or adult, depending on your intended use population)." [44]

The agency warned applicants away from trying to combine the two types of studies. "It may be possible to combine the Human Usability with the Clinical Evaluation; however, this study design does involve more risk as problems with the instructions for use could lead to a failed clinical study. FDA strongly recommends you discuss this option with FDA before design and execution."

It was a high bar and few were able to reach it at first. The first company to get approval through the EUA process was Abbott with its BinaxNOW kit in December 2020, four months after the FDA's template was released.[45] Abbott had a head start in some ways since BinaxNOW was adapted from a line of SARS testing kits that stretch back to 2003.[46]

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41 Adam Bonislawski, "Experts Weigh in on Europe's Embrace of Rapid Antigen Tests for COVID-19 While US Lagged," 360Dx, January 13, 2022, https://www.360dx.com/covid-19/experts-weigh-europes-embrace-rapid-antigen-tests-covid-19-while-us-lagged#.Yeor8VjMKqA.

42 "Guidance for Industry and FDA Staff: Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests," March 13, 2007, https://www.fda.gov/files/medical%20devices/published/Guidance-for-Industry-and-FDA-Staff---Statistical-Guidance-on-Reporting-Results-from-Studies-Evaluating-Diagnostic-Tests-%28PDF-Version%29.pdf.

43 Yuan-Po Tu, Jameel Iqbal, and Timothy O'Leary, "Sensitivity of ID NOW and RT–PCR for Detection of SARS-CoV-2 in an Ambulatory Population," ed. Goutham Narla, Mone Zaidi, and Ryan Phan, *ELife* 10 (April 20, 2021): e65726, https://doi.org/10.7554/eLife.65726.

44 FDA, "Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use."

45 "Abbott's BinaxNOW COVID-19 Rapid Test Receives FDA Emergency Use Authorization for First Virtually Guided, at-Home Rapid Test Using EMed's Digital Health Platform," Abbott MediaRoom, December 2020, https://abbott.mediaroom.com/2020-12-16-Abbotts-BinaxNOW-COVID-19-Rapid-Test-Receives-FDA-Emergency-Use-Authorization-for-First-Virtually-Guided-At-Home-Rapid-Test-Using-eMeds-Digital-Health-Platform.

46 "Abbott Labs Will Help Artus Market, Distribute PCR-Based SARS Test," GenomeWeb, May 15, 2003. https://www.genomeweb.com/archive/abbott-labs-will-help-artus-market-distribute-pcr-based-sars-test.

Not long after the template was released, the Department of Health and Human Services directed the FDA to clarify its role in premarket review. On August 19, 2020, the FDA adopted a new policy of not requiring premarket review for LDTs.[47] The late 2020 policy change also made it such that some tests didn't need emergency use authorization (EUA) letters. The change of course came from a legitimate read of the law, but it was a confusing policy nonetheless. As Gail Javitt, an attorney working in the industry, explained, "HHS said that FDA can't require premarket review of LDTs without notice-and-comment rulemaking, but it never said FDA didn't have jurisdiction over LDTs."[48]

Still the number of rapid home tests coming to market was a trickle. [49] By the end of February 2021, seven months after the template was released, only two tests had been approved. In March another four were approved, until June when another two were approved. As the next section more fully lays out, the pace was incredibly slow when compared to Germany. In January 2022, the US had 16 rapid tests in the market, while Germany had 38.

It took a formal congressional request to get the FDA to restate power over LDTs. On November 15, 2021, HHS Secretary Becerra officially restored the authority of the FDA to regulate all LDTs just as the Omicron wave was about to swell.[50]

With hindsight, it is clear one epidemiologist had been right. Back in November 2020, Dr. Michael Mina wrote in favor of shifting focus away from specific tests and towards a testing regimen's efficacy. As he and his colleagues explained, "The key question is not how well molecules can be detected in a single sample, but how effectively infections can be detected in a population by the repeated use of a given test as part of an overall testing strategy—the sensitivity of the testing regimen."[51] Diagnostics need to be calibrated as a part of a broader response that considers "how often it's used, to whom it's applied, when in the course of an infection it works, and whether its results are returned in time to prevent spread."[52]

Researchers and scientists trying to get the signoff for good rapid tests all echoed one chorus, that the agency was slow to respond and slow to approve tests. South Korea, the United Kingdom, and Germany all worked closely with their testing companies to develop and then approve tests.[53] But in the United States, tests were met with needless delays.

For example, Nanōmix out of Emeryville, California developed a rapid test with the help of a federal grant from the US Department Health and Human Services and submitted it to the FDA in February 2021.[54] In early June 2021, an FDA reviewer sent back a list of questions, giving

47 Turna Ray, "Labs Scramble after FDA Loosens Regulations on Some Tests," Modern Healthcare, August 31, 2020, https:/www.modernhealthcare.com/supply-chain/labs-scramble-after-fda-loosens-regulations-some-tests.

48 Ray, "Labs Scramble after FDA Loosens."

49 William Rinehart, "COVID Rapid Testing Regulations and Data," Google Docs, The Center for Growth and Opportunity, 2022, https://docs.google.com/spreadsheets/d/1dtE6CuWwVFzoftsY1dG73yssQ0tpc9Ro-dfrocFOnRw/edit#gid=554745818.

50 Eli Y. Adashi, Glenn Cohen, "SARS-CoV-2 Laboratory-Developed Tests Integrity Restored," *The Journal of the American Medical Association*, 327 no 13, https://jamanetwork.com/journals/jama/fullarticle/2789917.

51 Michael J. Mina, Roy Parker, and Daniel B. Larremore, "Rethinking COVID-19 Test Sensitivity — A Strategy for Containment," *New England Journal of Medicine* 383, no. 22 (2020), https://doi.org/10.1056/nejmp2025631.

52 Mina, Parker, and Larremore. "Rethinking COVID-19 Test Sensitivity."

53 Dennis Normile, "Coronavirus Cases Have Dropped Sharply in South Korea. What's The Secret to Its Success?" *Science*, March 17, 2020, https://www.science.org/content/article/coronavirus-cases-have-dropped-sharply-south-korea-whats-secret-its-success.

54 News February 10. "Nanōmix Seeks EUA for COVID-19 Antigen Test from FDA," *Medical Device Network* (blog), February 10, 2021. https://www.medicaldevice-network.com/news/nanomix-eua-antigen-test/.

Nanōmix a deadline of 48 hours to respond. [55] The company couldn't provide answers that quickly, so it was sent to the back of the line. The tests eventually got approved, but they were subjected to delays.

Roche also submitted an initial application in February 2021. [56] By the middle of the summer, however, the company was being told that the trials for the at-home test conducted in Europe wouldn't work for US approval. In contrast, the tests were approved in Germany in February 2021—before an official set of guidelines had even been adopted in that country.[57]

Another company, which preferred to remain unnamed in ProPublica reporting, withdrew its at-home test when it learned that trial data from India wouldn't work for FDA approval. Redoing the trials in the US would have cost millions, they explained.[58]

The decision-making apparatus at the FDA slowed, as it had with tests in the past. Still, it wasn't over the initial reviews of the tests. One FDA reviewer who quit over the indecision explained that he could easily sort through an application within a few days. A background in virology meant that he could evaluate the hundreds of pages easily and make a judgement. It was the layer of authority above him where applications would get stuck. Officials were paralyzed by indecision.[59]

"I could easily process dozens of them, but I ended up with one or two in my queue constantly. They would stay there forever," he said. Decisions about rapid tests would languish. They were neither rejected nor approved. So, the bottleneck didn't lie in the initial review, but in the middle management layer.[60]

Dr. Celine Gounder, a former advisory board member to the Biden administration, confirmed that the bottleneck wasn't in the reviews as such, but in the political layer of the administration. In a segment on Meet the Press, she explained, "The FDA under both the Trump and Biden administrations has really dragged its feet on authorizing these rapid antigen [tests] for the purpose of assessing 'are people contagious or not.'"[61] The agency was gripped with indecision.

5 Comparison with Germany

To understand US testing standards, it helps to compare them against those in Germany, a peer in medical innovation where rapid tests were more widely available and much cheaper. Germany's experience with rapid testing is important because it shows that another regulatory path is possible.

55 Umansky and DePillis, "Here's Why Rapid COVID Tests Are so Expensive and Hard to Find."

56 "Roche Announces the Filing for FDA Emergency Use Authorization for SARS-COV-2 Rapid Antigen Test, Allowing Healthcare Professionals to Make Fast Decisions at the Point of Care," Diagnostics, February 8, 2021. https://diagnostics.roche.com/us/en/news-listing/2021/roche-announces-the-filing-for-fda-emergency-use-authorization-for-sars--cov-2-rapid-antigen-test.html.

57 F. Hoffmann-La Roche Ltd, "Roche SARS-CoV-2 Rapid Antigen Test receives special approval for at-home patient self-testing using nasal swabs in Germany," GlobeNewswire News Room, February 26, 2021, https://www.globenewswire.com/news-release/2021/02/26/2183646/0/en/Roche-SARS-CoV-2-Rapid-Antigen-Test-receives-special-approval-for-at-home-patient-self-testing-using-nasal-swabs-in-Germany.html.

58 Umansky and DePillis, "Here's Why Rapid COVID Tests Are so Expensive and Hard to Find."

59 Umansky and DePillis, "Here's Why Rapid COVID Tests Are so Expensive and Hard to Find."

60 Umansky and DePillis, "Here's Why Rapid COVID Tests Are so Expensive and Hard to Find."

61 Francis Agustin, "FDA 'Dragged Its Feet' in Approving and Providing Rapid Tests, Former Biden Advisory Board Member Says," *Business Insider*, accessed October 24, 2022, https://www.businessinsider.com/former-biden-advisor-saus-fda-dragged-feet-covid-19-response-2022-1.

In 2010, in the Medical Devices Act, the German government clarified how diagnostic tests would be regulated going forward.[62] The law set rules for companies wanting to put a test out onto the market. While the German system of disclosures is more involved than others in the European Union (EU), the performance standards were deferred to those set by the EU in law. This meant that the country had a de facto open-door policy to diagnostic tests, which could only be ramped up if the German parliament changed direction or if the EU changed their performance standards.

So when the issue of approving rapid tests first came before the German government, it deferred to the EU, which was using standards set by the World Health Organization (WHO). These initial guidelines, which began in October 2020 and ran until December of that year, were significantly less stringent than Germany's current rules and far less involved than those of the United States.[63]

Philippe Etter, founder of medical regulatory consulting firm Medidee, told the trade publication 360Dx about what happened next. "You could clearly see European distributors going hunting in China for products and catching everything they could." Most often, they would simply ask Chinese rapid test manufacturers for standardized forms and then "forward [those documents] to the state. And away they would go. The regulatory burden and the risk for a distributor [in Europe] is not very high."[64]

As the winter 2020 COVID wave set in, tests that had been calibrated to the population of other countries, particularly Brazil where the virus was more widespread, began to be more widely used in Germany. Because the tests were designed to catch the virus in a place where it was prevalent, reports began to be circulated claiming that tests weren't doing well in Germany where the virus was less common. [65] In March 2021, alongside a new mass testing and reimbursement program, the government upped the standard for rapid tests.

All official tests had to pass a set of performance standards set by the Federal Institute for Drugs and Medical Devices (BfArM), the medical regulatory body in Germany, as well as the Paul Ehrlich Institute. Both of these organizations operate under the Federal Ministry of Health. Although the new rules began officially in March 2021, the government labs were working closely with labs and the medical industry, and had already approved at least three tests by the end of February.[66] Only results from these officially certified tests would clear a person to enter shops or restaurants, or get reimbursed by the new government scheme.

Meanwhile, all of the other tests that had been given approval were still valid until their agreements ended. The effect was a two-tiered system with official certified tests as well as more mass-marketed tests. The combination of both meant a relatively deep market and low prices.[67]

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62 "The Act on Medical Devices (Medical Devices Act)," Act Amending the Regulations Governing Medical Devices, 2010, https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/M/MPG_englisch.pdf.

63 "Mindestkriterien Für SARS-CoV-2 Antigentests Im Sinne Von § 1 Abs. 1 Satz 1 TestVO: Antigenschnelltests," Paul-Ehrlich-Institut, December 1, 2020, https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/mindestkriterien-sars-cov-2-antigentests.pdf?__blob=publicationFile&v=9;

64 Bonislawski, "Experts Weigh in on Europe's Embrace of Rapid Antigen Tests."

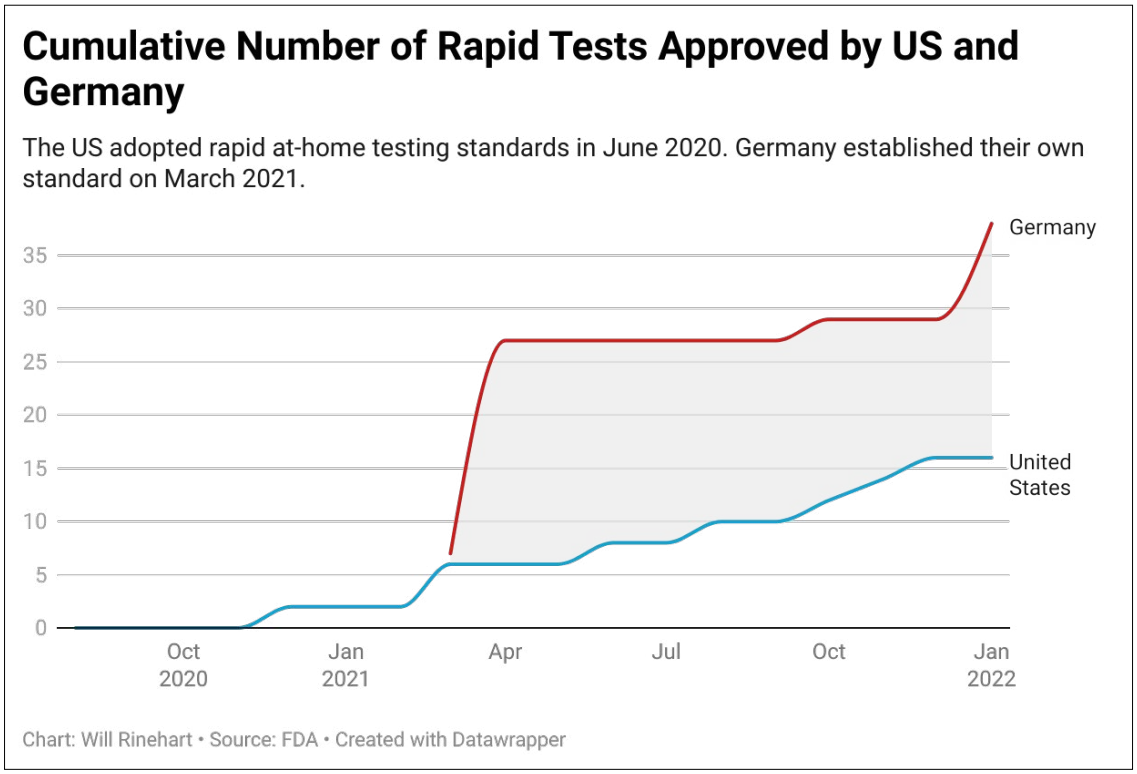
65 "SARS-CoV-2-TestSysTeMe," Paul-Ehrlich-Institut, February 25, 2021, https:/www.pei.de/DE/newsroom/dossier/coronavirus/testsysteme.html.

66 Abi Carter, "Germany Approves Rapid Corona Tests for Home Use: What You Need to Know," IamExpat, February 26, 2021, https://www.iamexpat.de/expat-info/german-expat-news/germany-approves-rapid-corona-tests-home-use-what-you-need-know.

67 Joshua Lerner, and Scott Stern, *Innovation Policy and the Economy*, Chicago, IL: National Bureau of Economic Research, 2008.

In quick succession, however, official rapid tests were approved in Germany.[68] The chart below tracks the number of official rapid COVID-19 tests approved over time in the United States and Germany. While Germany's approval process began later, in March 2021, the approvals racked up quickly in the first two months. By the end of that first month, Germany had seven tests approved, compared to six in the United States even though a standard had been set in late July 2020. By the end of the next month, April 2021, 27 tests were available in Germany with only six in the United States.

Figure 1. Cumulative Number of Rapid Tests Approved by the United States and Germany



The comparative growth trends between the two countries are indicative of their different approaches to tests. The German government created a niche for producers, official tests that got reimbursement. Medical providers rushed to fill the market, and German health regulators made quick decisions about the rapid tests.

More test manufacturers meant that Germany had a much deeper market when the Omicron wave hit last winter. In contrast, the FDA languished and chose to delay, approving a couple of tests every couple of months. This trickle of approvals limited the number of suppliers, which led to shortages long before the Omicron wave.[69]

68 "Minimum Criteria for Rapid SARS-CoV-2 Antigen Tests Pursuant to Section 1 Para 1 Sentence 1 TestVO (Statutory Test Regulation): Rapid Antigen Tests," Paul-Ehrlich-Institut, June 11, 2021, https://www.pei.de/SharedDocs/Downloads/EN/newsroom-en/dossiers/minimum-criteria-for-rapid-sars-cov2-antigen-tests.pdf?__blob=publicationFile&v=7.

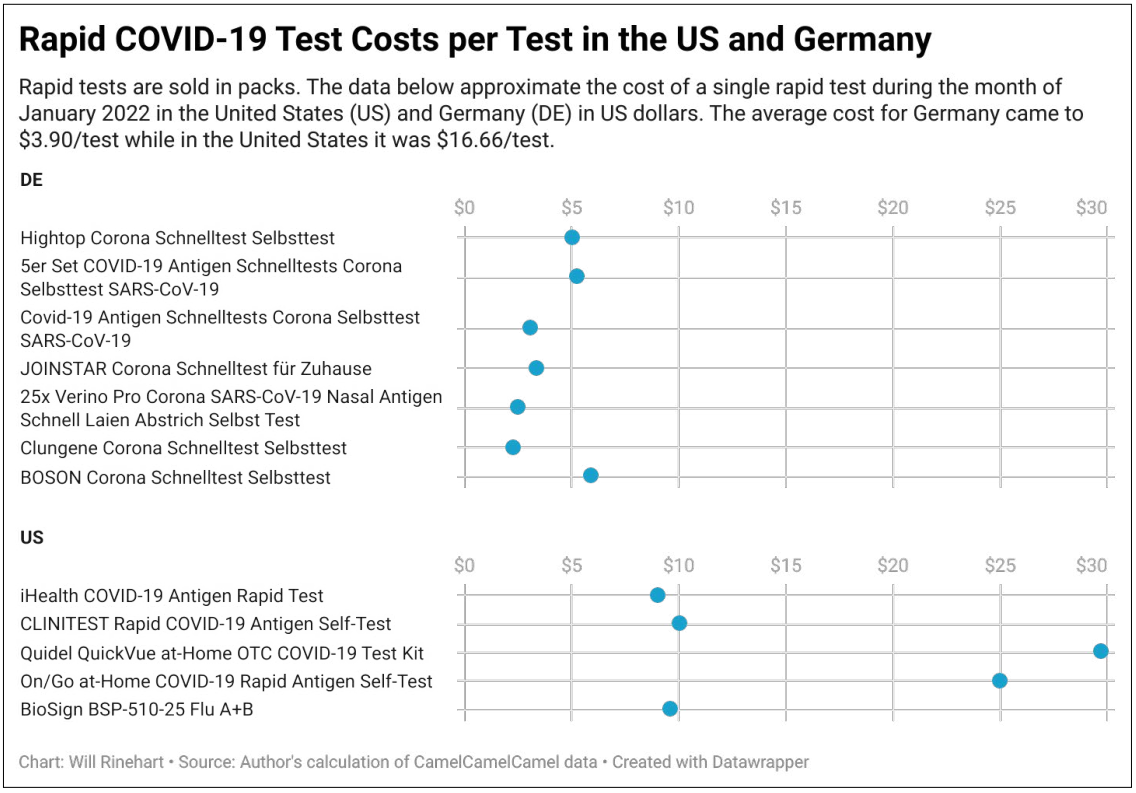
69 Carl O'Donnell, "Rapid COVID-19 Tests Increasingly Scarce, Pricey as Demand from Employers Jumps," Reuters, October 5, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/rapid-covid-19-tests-increasingly-scarce-pricey-demand-employers-jumps-2021-10-05/.

The United States could have had a growth curve more like Germany's. Internal reviewers and close watchers all think the US was capable of much higher approval rates. Indeed, the FDA scientist who vetted test applications mentioned above, told the reporters at ProPublica that, "They're neither denying the bad ones or approving the good ones."[70] Clearly, there was a rush of players to get to market, but they were stymied by the FDA. Because the agency constantly took time to assess, it effectively acted as a bottleneck in the approval process.

In his conversation with 360Dx, Etter was also clear that the US regulatory system is much slower to decide on approval than Germany: "The FDA has said, 'We don't want people using a product that will generate bad results.' So, they have been quite resistant to the propagation of products that could be misused." He ended by noting that the FDA's tough reputation probably kept some companies from even attempting to take their products through the process. [71]

If the FDA had the same throughput on approvals as the Germans did, rapid testing would be more widely available and less expensive.[72] Data from the Amazon tracking site CamelCamelCamel illustrates the price difference between countries. In the middle of the depths of the Omicron wave in January 2022, German prices per test came to just around $3.90, while US test prices were about $16.66. The table below helps to visualize the price differentials.

Figure 2. Rapid COVID-19 Costs per Test in the United States and Germany



70 Umansky and DePillis, "Here's Why Rapid COVID Tests Are so Expensive and Hard to Find."

71 Bonislawski, "Experts Weigh in on Europe's Embrace of Rapid Antigen Tests."

72 David Adler, "Inside Operation Warp Speed: A New Model for Industrial Policy," *American Affairs Journal*, May 20, 2021, https://americanaffairsjournal.org/2021/05/inside-operation-warp-speed-a-new-model-for-industrial-policy/.

Especially in a crisis, the FDA should be focused on expanding testing. We don't need perfect tests. We need lots of good tests.[73]

6 To reform the FDA, make it consider time

If policymakers wanted to deal with the problem of rapid testing quickly, should it arise again, Congress could craft a bill that allows for importation of rapid tests from selected countries. Senator Rand Paul has been advocating for a similar idea in his Accelerating New Pharmaceutical Competition Act, which would fast track FDA approval of medicines and devices that have met safety and efficacy standards in other developed nations.[74] Some of those provisions could be adapted to narrowly deal with the hang-ups in getting rapid tests approved here in the United States.

But this is just a Band-Aid on a much deeper institutional problem that needs to be addressed.

The FDA takes time to make a decision and has been generally slow in granting approvals for LDTs. These outputs are a logical consequence of the agency's incentives. As such, reforming the FDA will only happen if the incentives at the agency are slowly readjusted to consider the cost of inaction. The FDA does important work, but it needs to be reformed to ensure it doesn't needlessly delay decisions for tests that pose low risk.

First, the FDA should be transparent about its approval times for all of the EUA projects. While the agency reports on approvals, it doesn't publicly report on when applications came in in an easily accessed dashboard. Because the application date is uncertain, it is nearly impossible to track approval times. Mandated reporting requirements on the date of the application would mean Congress could keep tabs on the agency. This should apply for all projects going through the EUA process, which would necessitate changes in the law.[75]

Second, Congress should consider amending the EUA process. Section 4 of Public Law 108–276, where the EUA-enabling legislation resides, includes no directives on how decisions should be made at the FDA to grant an EUA. Including a provision within this part of the law that directs the FDA to consider the cost of time delays could be a solid first step to help push through tests.

Third, the process of approving diagnostic tests could be subject to a shot clock. PDUFA has a kind of shot clock, since it mandates the time period during which the agency has to act. The same kind of limitation could be adopted to EUAs to make sure that the FDA doesn't take too much time to decide. Amendments might limit the amount of time that the FDA could take to make a decision to 30 days. To ensure the time requirement had teeth, this would need to be coupled with a writ of mandamus, which would give test manufacturers the ability to take the agency to court.

Fourth, Congress should exempt diagnostics from needing usability tests. The United States is unique around the world in requiring such tests and yet the human performance of self-testing

73 Isaac Chotiner, "Paul Romer's Case for Nationwide Coronavirus Testing," *The New Yorker*, May 3, 2020, https://www.newyorker.com/news/q-and-a/paul-romer-on-how-to-survive-the-chaos-of-the-coronavirus.

74 "Dr. Rand Paul Creates Faster Path for Treatments with New FDA Legislation | Senator Rand Paul," accessed October 24, 2022, https://www.paul.senate.gov/news/dr-rand-paul-creates-faster-path-treatments-new-fda-legislation.

75 S.15 - 108th Congress (2003-2004): Project BioShield Act of 2004, S.15, 108th Cong. (2004), https://www.congress.gov/bill/108th-congress/senate-bill/15.

ranks high everywhere.[76] Besides, it has long been established that people do a good job of self-testing. In the case of HIV testing, one report on the use of tests found that a "diverse group of participants generally performed [self-testing] correctly with a few exceptions."[77]

Philippe Etter singled out usability studies as being a key difference between the US and others. "If you want to put a test on the market under an [FDA] EUA, you need to provide a human factors study showing that someone at home, an elderly person, whoever, can use it safely," he said. "In Europe, you can get by with a single page saying, 'Here are the instructions for use. We don't see any problem, bye-bye.'"

Fifth, Congress should be looking to reduce regulatory barriers that slow approval. In particular, a sticking point for many rapid tests was the requirement that all trials be conducted in the United States. The German experience with tests calibrated to Brazil seems to confirm the need for tests to be calibrated to the country.

At the same time, disallowing such tests means that regulators don't have the data to understand the efficacy of the rapid tests in practice. As Nikki Teran explained, "This creates a terrible Catch-22: The goal for emergency use of novel pathogen detection mechanisms should be to stop an outbreak, but manufacturers can't get the clinical data they need until one already happens."[78]

Furthermore, not *all* of the trials had to be conducted in the United States. The FDA could have allowed a company to have a plurality of tests conducted in the country and a small portion outside of it, in Canada or Mexico perhaps. Proper statistical weighting of tests conducted elsewhere could have supplemented US-based trials. Truth be told, it has taken some time for experts to come to general agreement on these methods. Still, this has only been accomplished through widespread use and data collection.

Sixth, the FDA needs to formalize its rules for at-home rapid tests. The lack of rules is important. In *Azar v. Allina*, a case involving health care providers, the Supreme Court ruled that informal guidance like a warning letter has little authority unless it is aligned with a notice-and-comment rulemaking.[79] In the event that an FDA action was ever challenged in court, a formal rule would be needed. The FDA should complete its rulemaking process, clarifying its regulatory stance with respect to diagnostic tests.[80]

At the same time, it is clear that the FDA is responsive when its reputation might be at stake. This offers an interesting opening for reform. Superficially, the agency conducts cost benefit analyses when they make their decisions.[81] But these studies don't often consider time delays as a kind of

76 Dylan A. Mistry, Jenny Y. Wang, Mika-Erik Moeser, Thomas Starkey, and Lennard Y. Lee, "A Systematic Review of the Sensitivity and Specificity of Lateral Flow Devices in the Detection of SARS-COV-2," *BMC Infectious Diseases* 21, no. 1 (2021), https://doi.org/10.1186/s12879-021-06528-3.

77 Stevens et. al., "A Global Review of HIV Self-Testing."

78 Nikki Teran, "Taking Emergency Use Authorization Seriously," Institute for Progress, January 27, 2022, https://progress.institute/taking-emergency-use-authorization-seriously/.

79 "Azar v. Allina Health Services," *SCOTUSblog*, accessed October 24, 2022, https://www.scotusblog.com/case-files/cases/azar-v-allina-health-services/.

80 "Diagnostics Reform Heats Back Up with Introduction of the Verifying Accurate Leading-Edge IVCT Development Act of 2021," Akin Gump Strauss Hauer & Feld LLP, 2021, https://www.akingump.com/en/news-insights/diagnostics-reform-heats-back-up-with-introduction-of-the-verifying-accurate-leading-edge-ivct-development-act-of-2021.html.

81 Center for Drug Evaluation and Research, "E9 Statistical Principles for Clinical Trials, US Food and Drug Administration, FDA, 1998, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e9-statistical-principles-clinical-trials.

cost. While it is a small part of the institution as a whole, expanding the ledger where costs are tallied has long been needed. Leaders in Congress should be looking for ways to ensure that time is included as a critical component of analysis in those areas where the agency conducts a cost benefit analysis.

As a final reform, Congress should direct the agency to take a year and produce a report on the cost of decisions during the COVID-19 pandemic. Testing isn't the only area where speedier decisions would have meant more saved lives. Vaccines were subject to delayed decisions as well. A full internal accounting of what happened during the early days of the pandemic would unearth pathways to reform.

While these changes won't completely solve indecision, they could go a long way to ensure future diagnostics make it into people's hands. Reform is needed, but this doesn't mean the agency needs to be dismantled. Rather, the agency just needs to move in a better direction.