FREEDOM OF THE TEST

Alex Tabarrok[*]

Advancements in diagnostic tests and technologies hold the potential to usher in an era of personalized medicine, which could significantly extend and improve our health span. However, realizing this potential requires dismantling regulatory barriers, including certain FDA restrictions on speech, which currently impede the progress and accessibility of these innovations.

I. The Potential of Personalized Medicine 95
II. The Slow History of At-Home Tests 96
III. The FDA versus the First Amendment 99
IV. We Have a Right to Know 102

I. THE POTENTIAL OF PERSONALIZED MEDICINE

At-home testing—DNA testing, for example—is one of those personalized medicine advances that would have been unthinkable not too long ago. DNA tests can tell us about our ancestry, which diseases we may be especially prone to, and which drugs might work especially well or poorly for our body.

Personalized medicine can adjust medications not only to DNA which is unchanging but also to the dynamic response of RNA, proteins, and metabolites. Chen et al. describe how a patient was treated via a "personal omics profile (iPOP), an analysis that combines genomic, transcriptomic, proteomic, metabolomic, and

[*] Alex Tabarrok is Bartley J. Madden Chair in Economics at the Mercatus Center and Professor of Economics at George Mason University. I would like to thank Jane Bambauer, the editors, and referees for helpful comments. Parts of this paper draw from Alex Tabarrok, *Testing Freedom*, DISCOURSE (Jan 9, 2023), https://www.discoursemagazine.com/p/testing-freedom.

autoantibody profiles from a single individual over a 14-month period."[1] Studies like this point to a future in which we will be able to measure a disease or an infection and a body's response across many different variables in close to real-time. A personal omics profile could thus optimize healthcare strategies not just to a particular person but to a particular person at a particular time and place.

And we do have a history of making use of some aspects of personalized medicine in the United States. While the most advanced tests and devices are not yet integrated with the medical mainstream, pregnancy tests and AIDS tests have been common for years. The recent COVID pandemic also illustrated the value of real-time, at-home tests for viral antigens. Popular wearables like Fitbit are relatively simple medical devices that provide real-time measurements for things such as blood oxygen levels, skin temperature, and heart rate. Much more will be possible as sensors become cheaper, more refined, and more integrated with our bodies.

II. The Slow History of At-Home Tests

Personalized medicine, however, has advanced at a far slower rate than the underlying data and technology. U.S. Food and Drug Administration (FDA) regulation has slowed adoption and increased costs for tests and devices that inform patients about their own bodies. In fact, the FDA has a long-standing fear and antipathy towards personalized medical tests.

In 1972, the FDA confiscated thousands of home pregnancy tests, declaring that they were "drugs" meant to diagnose a "disease" and thus fell under the FDA's regulatory dominion. The case went to the U.S. District Court for the District of New Jersey, and Judge Vincent P. Biunno ruled that that the FDA had overstepped. "Pregnancy," he said, "is a normal physiological function of all mammals and cannot be considered a disease. . . . A test for pregnancy, then, is not a test for the diagnosis of disease. It is no more than a test for news."[2] As a result of Judge Biunno's ruling, home pregnancy tests are today easily available from pharmacies, grocery stores, and online shops without a prescription.[3]

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[1] Rui Chen et al., *Personal Omics Profiling Reveals Dynamic Molecular and Medical Phenotypes*, 148 Cell 1293, 1293 (2012).

[2] United States v. Article of Drug-Ova II, 414 F. Supp. 660, 664 (D.N.J. 1975).

[3] The FDA gained authority over all medical devices in 1976 and likely would have determined that home pregnancy tests were unlike any other previously marketed device. Thus, home pregnancy tests would have been treated as high-risk devices requiring pre-market approval and, if approved, requiring a prescription. Joan H. Robinson, *Bringing the Pregnancy Test Home from the*

These days, debates over home pregnancy tests from the 1970s seem anachronistic and paternalistic. Yet in 2023, during the debate over whether birth control pills should be sold over-the-counter (OTC), FDA scientists argued that women who bought the pill over-the-counter could not be trusted to take the pills on a regular basis.[4] (Oddly, women who got the pills with a doctor's prescription could so be trusted.) OTC birth control was approved in 2023, which means it took 50 years before birth control pills were allowed to be sold OTC.[5]

Indeed, the same paternalistic arguments appear again and again with every new testing technology. In the late 1980s, for example, the FDA simply declared that it would not approve at-home HIV tests, regardless of their safety or efficacy. As with pregnancy tests, the concern was that people could not be trusted with information about their own bodies. Testifying at an FDA hearing, Dr. Charles McCarthy of the National Institutes of Health argued that without professional oversight, "people who test positive or even falsely positive for HIV may react in hysterical or irrational ways, such as committing suicide, while those who test falsely negative may wrongly consider themselves 'resistant' to the deadly virus and continue high-risk behaviors."[6] While the first rapid at-home HIV test was developed and submitted to the FDA in 1987, it took 25 years before the FDA would approve these tests. (Now, you can easily buy such a test on Amazon.[7])

Hospital, 46 SOC. STUD. SCI. 649 (2016). As a result of Biunno's ruling, however, home pregnancy tests were grandfathered in as low-risk devices. The grandfathering in was not without cost, however, because to avoid expensive pre-market approval requirements any new home pregnancy tests must be "substantially equivalent" to older versions thus limiting the improvement that can be made.

[4] Pam Belluck, *F.D.A. Advisers Weigh Allowing First U.S. Over-the-Counter Birth Control Pill*, N.Y. TIMES (May 9, 2023).

[5] Opill was approved for over-the-counter sale in 2023. Norgestrel (progestin-only), the active ingredient in Opill, was approved for prescription use in 1973.

[6] Rebecca Kolberg, *A Public Policy Expert Charged Thursday Government Inaction on . . .*, UPI (Apr. 6, 1989), https://perma.cc/26DR-UNVU.

[7] Oraquick, *The OraQuick® In-Home HIV Test*, AMAZON.COM, https://perma.cc/P8UU-GHK4. Tests requiring mail in samples and telephone counseling had been allowed earlier. For a detailed timeline, see Shelby Baird, *Don't Try This at Home: The FDA's Restrictive Regulation of Home-Testing Devices*, 67 DUKE L.J. 383 (2017).

The FDA used the same paternalistic arguments to suppress genetic tests.[8] In 2010, the Director of the FDA's Center for Device and Radiological Health argued that direct-to-consumer genetic tests are risky because "a patient may make a decision that adversely affects their health, such as stopping or changing the dose of a medication or continuing an unhealthy lifestyle, without the intervention of a learned intermediary."[9] Since that time, the FDA has only grudgingly approved a small handful of the genetic tests, such as for being a carrier of Bloom syndrome, out of many more that could be useful to consumers.[10]

The most consequential failure of the FDA to allow consumers freedom of information was the delay in approving rapid antigen tests for COVID. Rapid antigen tests tell a consumer whether their body has enough virus to be infectious to others. When used widely, these tests can reduce the spread of COVID. Had these tests been available sooner, tens of thousands of lives might have been saved.[11] But these tests only became available in the United States as the pandemic was slowing because the FDA regarded them as too risky for consumers and did not prioritize their approval.[12]

Rapid antigen tests similar to those used for COVID could also be used to diagnose other viral diseases such as influenza. In addition to helping people decide when to stay home and prevent contagion, such tests could also allow for more accurate treatment and reduce the overuse of antibiotics. Nevertheless, even though these tests have long been technologically possible, there are no approved at-home flu tests in the United States.[13] In Germany, in contrast, rapid at-home combination COVID, flu, and RSV tests are readily available.[14]

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[8] *Id.* at 386.

[9] *Id.* at 405.

[10] *Id.* at 407.

[11] Andrew Atkeson et al., *Economic Benefits of COVID-19 Screening Tests* 3 (Nat'l Bureau of Econ. Rsch., Working Paper No. 28031, 2020), https://perma.cc/9Q2N-TWGE.

[12] Lydia DePillis & Eric Umansky, *Here's Why Rapid COVID Tests Are So Expensive and Hard to Find*, PROPUBLICA (Nov. 4, 2021), https://perma.cc/34YG-WDC2.

[13] Brittany Trang, *Why Doesn't the U.S. Have At-Home Flu Tests?*, STAT (Nov. 22, 2022), https://perma.cc/B65W-USSN. In an odd workaround, some clinicians now use flu-like symptoms and a negative COVID test as a test for flu! *See id.*

[14] Dorien Colman, *Hoest of Loopneus? Doe de Combitest*, DE STANDAARD (Dec. 22, 2022), https://perma.cc/BY2R-TK86.

III. THE FDA VERSUS THE FIRST AMENDMENT

The FDA and other agencies such as the Centers for Medicare & Medicaid Services (CMS) have a vital role in ensuring that tests are clinically accurate—tests should do what they say they do. Tests don't need to be perfect to be useful (think of thermometers, personality tests, and tire pressure gauges), but if a test advertises that it measures HDL cholesterol, it should do that within the tolerances its developer promises. The FDA and the CMS have the technical knowledge to ensure that tests work, and that's a skill that Americans value from these agencies.[15]

What Americans don't want is to be told "you can't handle the truth!" Yet when it came to at-home tests such as pregnancy tests, HIV tests, and genetic tests, that's exactly the reasoning the FDA used—and continues to use—to suppress information.

The FDA should ensure that tests are safe but "safety" means physical safety. The FDA may not declare a product unsafe because it might produce dangerous information. Patients have a right to know about their own bodies. Our antibodies, ourselves. The FDA has authority over drugs and devices but not over the practice of medicine or patients.

Judge Biunno had it right back in 1972 when he said that diagnostic tests produce "news." Test results, therefore, are a type of speech that fall under the First Amendment right to freedom of speech. The Supreme Court has repeatedly rejected restrictions on freedom of speech based on "a fear that people would make bad decisions if given truthful information."[16] In *Washington Legal Foundation v. Henney* (Henney then being FDA Commissioner), the court rejected FDA restrictions on the truthful promotion of off-label uses of a drug as "preposterous":

> The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity. . . . The government, however benign its motivations, simply cannot justify a

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[15] Competition, customer feedback, and learning tend to improve products over time but these processes are endogenous—they don't happen until customers experience the product, markets are established, and firms make profits that they can reinvest in product improvement. Similarly, the first tests on the market are often less accurate and convenient than later tests but subsequent tests are only better because the first tests were allowed on the market. Thus, in thinking about approval, the FDA should recognize not just current accuracy and quality, but the entire time-path brought about by the market process.

[16] Thompson v. W. States Med. Ctr., 535 U.S. 357, 374 (2002).

> restriction of truthful nonmisleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information.[17]

The question of whether consumers will respond "safely" to test results is no more relevant to the FDA's regulatory authority than the question of whether readers will respond safely to political news published in *The New York Times*. Thus, FDA restrictions on tests based on such fears are unconstitutional.[18] The FDA does not have the constitutional authority to regulate news.

The constitutionality of regulating information from truthful tests may come to a head as a result of recent FDA regulation of laboratory developed tests (LDTs). LDTs are tests developed, validated, and performed in-house by individual laboratories—they include blood tests, bacteriological and virological tests, complex molecule tests, genetic tests, and so forth. Although the FDA has claimed authority, until very recently LDTs have not been regulated by the FDA. During the COVID pandemic, however, the FDA asserted emergency authority and required that COVID tests be FDA pre-approved. The subsequent delay in approving tests harmed patients and slowed down the U.S. response to the crisis.[19] In April of 2024,

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[17] Washington Legal Found. v. Henney, 56 F. Supp. 2d 81, 85–86 (D.D.C. 1999).

[18] *Thompson*, 535 U.S. at 374–75; Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 773 (1976)):

> What is at issue is whether a State may completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients. Reserving other questions, we conclude that the answer to this one is in the negative.

See also Sorrell v. IMS Health Inc., 564 U.S. 552 (2011); Amarin Pharma, Inc. v. FDA, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

[19] Robert P. Baird, *What Went Wrong with Coronavirus Testing in the U.S.*, NEW YORKER (Mar. 16, 2020); Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 YALE L.J. 78, 99 (2020). In a remarkably prescient paper Clement and Tribe warned:

> The FDA approval process is protracted and not designed for the rapid clearance of tests. Many clinical laboratories track world trends regarding infectious diseases ranging from SARS to H1N1 and Avian Influenza. In these fast-moving, life-or-death situations, awaiting the development of manufactured test kits and the completion of FDA's clearance procedures could entail potentially catastrophic delays, with disastrous consequences for patient care.

however, the FDA formally asserted that LDTs are medical devices and thus are subject to FDA authority.[20] The claim that LDTs are medical devices is highly disputed[21] and is likely to come under new scrutiny given the overturning of *Chevron* deference.[22] The new FDA pre-approval regime slowed the development and widespread deployment of a test for bird flu, albeit with to-date fewer deadly consequences than the slowdown of COVID tests.[23]

The regulation of LDTs raises constitutional issues of free speech, especially the professional speech of physicians. LDTs provide crucial information, i.e. news, to physicians. The FDA could not forbid or regulate a physician's access to medical books or journals. How then can the FDA forbid or regulate a physician's access to the "book of life"? Again, the state may regulate the quality of a test, ensuring it accurately performs as intended within specified tolerances, but the test results are simply information or news. The FDA may not regulate the transmission or interpretation of the news produced by a test either from the lab to physicians or from physicians to patients.[24]

The regulation of AI diagnosticians will also raise issues of free speech. If AI is built into a device, will what it reports be regulated? What about if AI interprets the output of a device? If AI interprets the output of devices and tests and offers recommendations, is it any different than consulting a colleague?

PAUL D. CLEMENT & LAWRENCE H. TRIBE, AM. CLINICAL LAB. ASS'N, LABORATORY TESTING SERVICES, AS THE PRACTICE OF MEDICINE, CANNOT BE REGULATED AS MEDICAL DEVICES 18 (2015), https://perma.cc/D3JE-8A8R.

[20] News Release, FDA, FDA Takes Action Aimed at Helping to Ensure the Safety and Effectiveness of Laboratory Developed Tests (Apr. 29, 2024), https://perma.cc/LCW4-B8Y3.

[21] *See e.g.*, Letter from Jonathan Genzen, Chief Medical Officer, ARUP Laboratories, to the Division of Dockets Management, FDA (Nov. 28, 2023), https://perma.cc/N6VC-HZMB; Letter from Stacey Hughes, Exec. Vice President, Am. Hospital Ass'n, to Robert M. Califf, Comm'r, FDA (Dec. 1, 2023), https://perma.cc/U9R5-KLSP.

[22] Loper Bright Enters. v. Raimondo, 603 U.S. __ (2024).

[23] Amy Maxmen, *'We're Flying Blind': CDC Has 1M Bird Flu Tests Ready, but Experts See Repeat of Covid Missteps*, KFF HEALTH NEWS (June 20, 2024), https://perma.cc/WNY3-KNUP.

[24] Letter from Barbara Evans, U. of Fla. Coll. of L., to the Division of Dockets Management, FDA (Dec. 3, 2023), https://perma.cc/28TF-BGV6.

IV. We Have a Right to Know

New tests and devices will let us learn about the functioning of our own bodies and minds at an unprecedented level of detail. From better learning will come better treatments, and then better modifications and improvements. Personalized medicine will become personalized body and mind management. The future of personalized body and mind management, however, requires that the FDA be transformed from a paternalistic agency that tells consumers what they can and cannot know about their own bodies to a science-based adviser that helps people to learn about themselves for themselves.

Everyone has a right to learn what's going on in their own bodies—and the FDA has no remit to control the news, including news about how our bodies are functioning. The FDA cannot forbid Americans access to news based on concerns that people might make poor decisions if they know the truth. Data abundance must be coupled with free speech to help bring about a proactive and personalized health care system.