

## Notes

# **DON'T TRY THIS AT HOME: THE FDA'S RESTRICTIVE REGULATION OF HOME-TESTING DEVICES**

SHELBY BAIRD<sup>†</sup>

### ABSTRACT

*Over the past forty years, the Food and Drug Administration (FDA) has successfully restricted consumers' access to home-testing applications based on the notion that it should protect individuals from their own reactions to test results. In the 1970s, the FDA briefly denied women access to home pregnancy tests that were identical to those used in laboratories. In the late 1980s and early 1990s, it relied on concerns about consumer responses to HIV status results to justify a categorical ban on applications for HIV home-testing technology. More recently, it placed burdensome restrictions on direct-to-consumer (DTC) genetic testing companies, such as 23andMe, based on fears that consumers would make irrational medical decisions after receiving genetic variant results.*

*Although the FDA has the statutory authority to ensure the “safety and effectiveness” of medical devices, it has expansively interpreted the term “safety” to encompass considerations of how consumers might use test results provided by purely informative devices. This Note argues that courts should not give the FDA deference on its broad interpretation of “safety” in restricting home-testing devices. It documents the evolution of the expertise-based rationale for judicial deference, noting that courts typically provide scientific agencies, including the FDA, “super deference” because of the complicated nature of their work. Ultimately, courts should not defer to the FDA’s interpretation of “safety” because it did not use its scientific expertise*

---

Copyright © 2017 Shelby Baird.

<sup>†</sup> Duke University School of Law, J.D. expected 2018; Yale University, B.A. 2014. Thank you to Dr. Nita Farahany for helping me formulate a topic and thesis, Jane Bahnson for leading me to valuable resources, Professor Rebecca Rich and the Scholarly Writing Workshop for providing me with valuable feedback on my first few drafts of this Note, Amelia DeGory and Stephen Tagert for commenting on later drafts, the editors of the *Duke Law Journal* for their hard work and excellent edits, and my family for their support and encouragement.

*when it considered how consumers might react to HIV home-testing and DTC genetic testing results. Further, the FDA should not have the authority to make decisions based on its view of “safety” because it should not have the power to make value judgments for consumers about whether they should seek their personal medical information.*

## INTRODUCTION

For most of 2013, American consumers had unprecedented access to information about their genetics. For ninety-nine dollars, anyone could purchase 23andMe’s direct-to-consumer (DTC) genetic testing kit, send in a saliva sample, and receive over two hundred individualized health reports on certain nonmedical traits, such as ancestry,<sup>1</sup> and information on DNA variants linked to higher risks for diseases, such as type 2 diabetes and Alzheimer’s.<sup>2</sup>

The Food and Drug Administration (FDA) eliminated this access when it issued a strongly worded Warning Letter to 23andMe on November 23, 2013.<sup>3</sup> The FDA ordered the company to “immediately discontinue marketing” its testing services until it received marketing authorization for its health reports, which the FDA characterized as “medical device uses” requiring premarket approval.<sup>4</sup> The FDA justified this restriction by noting that some of the intended uses for the kits were “particularly concerning.”<sup>5</sup> For instance, it said that “serious concerns are raised if test results are not adequately understood by patients.”<sup>6</sup> Further, it stated that consumers could overreact to test results by undergoing unnecessary treatments or could rely on the information to self-manage their own treatments through

---

1. Robert Hof, *Seven Months After FDA Slapdown, 23andMe Returns with New Health Report Submission*, FORBES (June 20, 2014, 12:04 PM), <http://www.forbes.com/sites/roberthof/2014/06/20/seven-months-after-fda-slapdown-23andme-returns-with-new-health-report-submission/#3af1662277d6> [<https://perma.cc/U8NH-EZQC>].

2. Robert C. Green & Nita A. Farahany, *The FDA Is Overcautious on Consumer Genomics*, 505 NATURE 286, 286 (2014).

3. Letter from Alberto Gutierrez, Dir., Office of In Vitro Diagnostics & Radiological Health, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to Anne Wojcicki, CEO, 23andMe, Inc. (Nov. 22, 2013), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm> [<https://perma.cc/9GRR-8WCT>] [hereinafter Warning Letter to 23andMe].

4. In making this determination, the FDA cited its authority under section 201(h) of the Federal Food, Drug & Cosmetic Act to require premarket approval for devices “intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease,” or “intended to affect the structure or function of the body.” *Id.*

5. *Id.*

6. *Id.*

dose changes or the abandonment of certain therapies.<sup>7</sup> The FDA also noted that 23andMe had not assured the agency that it had “analytically or clinically validated” the tests for their intended uses.<sup>8</sup> Demonstration of analytical validity requires the manufacturer to show that the test accurately detects the presence or absence of a particular genetic variant, whereas clinical validity requires that the genetic variant is actually related to the “presence, absence, or risk of a specific disease.”<sup>9</sup> As this Note will discuss, what the FDA required of 23andMe went beyond the definition of clinical validity; instead, the FDA wanted assurances that consumers could make sound medical decisions with the information given to them by the test.<sup>10</sup> In light of the concerns for consumer reactions and the tests’ validity, the FDA’s letter notified 23andMe that it needed to seek premarket approval as a Class III device,<sup>11</sup> which receives the FDA’s highest level of scrutiny.<sup>12</sup>

After 23andMe spent four years cooperating with the FDA’s lengthy evaluation process, the FDA only recently approved ten of 23andMe’s health reports for genes linked to disease risk.<sup>13</sup> The FDA

---

7. *Id.*

8. *Id.*

9. *How Can Consumers Be Sure a Genetic Test Is Valid and Useful?*, NIH U.S. NAT’L LIBRARY MED. (Oct. 3, 2017), <https://ghr.nlm.nih.gov/primer/testing/validtest> [<https://perma.cc/VR6G-MYKF>].

10. *See Paternalism vs. Empowerment: The FDA & 23andMe Conflict*, DUKE SCI. & SOC’Y, <https://scienceandsociety.duke.edu/paternalism-vs-empowerment-the-fda-23andme-conflict> [<https://perma.cc/UY2J-ZA8K>] [hereinafter *Paternalism vs. Empowerment*] (arguing that the FDA wrongly considered consumer reactions as clinical validity concerns); *infra* Part II.C. An explanation of the difference as it affects 23andMe states:

[T]he FDA fails to acknowledge a distinction between providing information and providing opportunities to act upon information. The difference is between the need for a “device” to be analytically valid and clinically valid (or both). 23andMe provides genetic information to individuals; any health and medical decisions people make based on that information are entirely separate from the services directly provided . . . 23andMe clearly advertised its product as being “for informational use only.” It in no way produces, markets, or distributes a device used by individuals in acting upon their medical decisions. A concern with the “clinical validity” of genetic information is . . . a concern with our general understanding of genetics and health. Clinical validity should be addressed in discussions regarding the technologies individuals use to act on their genetic information, not in discussing information access.

*Paternalism vs. Empowerment, supra.*

11. Warning Letter to 23andMe, *supra* note 3.

12. Stephanie P. Fekete, *Litigating Medical Device Premarket Classification Decisions for Small Businesses: Have the Courts Given the FDA Too Much Deference? The Case for Taking the Focus Off of Efficacy*, 65 CATH. U. L. REV. 605, 611–12 (2015).

13. The FDA approved tests for gene variants “associated with an increased risk for developing . . . the following [ten] diseases or conditions”: Parkinson’s disease, late-onset Alzheimer’s disease, celiac disease, alpha-1 antitrypsin deficiency, early-onset primary dystonia, factor XI deficiency, Gaucher disease type 1, glucose-6-phosphate dehydrogenase deficiency,

granted the approval after 23andMe submitted several studies to demonstrate analytical and clinical validity.<sup>14</sup> The FDA also announced that, even though it is creating new criteria for evaluating genetic health risk (GHR) tests, it will continue to consider “clinical relevance” in its evaluation and will refuse market authorization for genetic tests that “function as diagnostic tests” and could be used for treatment decisions.<sup>15</sup> Although the authorization of these ten tests represents a step forward for improved access to DTC genetic testing, the FDA’s continued focus on clinical validity, as well as its refusal to approve any diagnostic tests, indicates that the FDA is still regulating these services based on its concerns over actions that consumers might take *after* they receive test results.

The FDA’s central rationale for regulating DTC genetic testing—its trepidation about potential reactions to results—is alarming because the agency is unlawfully restricting consumers’ access to their personal medical information based on concerns about how individuals might respond to the very test results that they sought out. The FDA certainly has the statutory authority to promulgate regulations to ensure the “safety and effectiveness” of medical devices before they are marketed,<sup>16</sup> but the FDA’s interpretation of safety greatly expands its power. By interpreting the term “safety” to encompass considerations of how consumers *might use* the information to make medical decisions—which are separate from the device’s purpose of giving an accurate test result—the FDA affords itself broader discretion to regulate medical devices.<sup>17</sup>

The 23andMe story is indicative of a larger trend within the FDA: the agency has limited consumer access to personal medical information based on concerns that consumers will have negative reactions and make poor clinical decisions after receiving test results.

---

hereditary hemochromatosis, and hereditary thrombophilia. *FDA Allows Marketing of First Direct-to-Consumer Tests That Provide Genetic Risk Information for Certain Conditions*, U.S. FOOD & DRUG ADMIN. (Apr. 6, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm> [<https://perma.cc/FA29-E6BV>] [hereinafter 23andMe Approval Announcement].

14. *Id.* For further discussion of these studies, see *infra* notes 155–59 and accompanying text.

15. 23andMe Approval Announcement, *supra* note 13. For further discussion of these changes, see *infra* notes 160–66 and accompanying text.

16. See 21 U.S.C. § 360c(a)(1)(A)(ii) (2012) (requiring that the FDA evaluate all medical devices to “provide reasonable assurance of the safety and effectiveness of the device”).

17. See *Paternalism vs. Empowerment*, *supra* note 10 (explaining that “any health and medical decisions people make based on that information are entirely separate from the services directly provided”). For further discussion, see *supra* note 10 and accompanying text.

For example, in 1972, the FDA seized several thousand Ova II home pregnancy tests, which had only been on the market for one year.<sup>18</sup> The FDA justified this seizure with questions about the product's reliability in the hands of laywomen<sup>19</sup> even though the test was “identical” to those used by laboratories and “purported to be reasonably accurate” when used by consumers.<sup>20</sup> Then, in 1988, in the midst of the HIV/AIDS crisis, the FDA refused to consider device approval applications for home HIV blood-test kits.<sup>21</sup> This ban barred manufacturers from demonstrating that their home-testing kits were safe and effective.<sup>22</sup> The FDA's decision to limit applications to diagnostic tests performed in clinical settings has been widely regarded as a reaction to concerns that individuals would make rash decisions if they did not receive counseling about their HIV test results.<sup>23</sup>

These three cases illustrate a recurring theme: when the FDA evaluates a device that gives consumers greater power to discover important personal medical information through home-testing, the agency restricts the device's use under the guise of public safety and relies on concerns about potential negative reactions to justify those restrictions. This Note analyzes whether the FDA's statutory authority to ensure the safety of medical devices empowers the FDA to consider how consumers might use information obtained from an effective and nonharmful test, which does not make claims about clinical application. Although there are several different frameworks for analyzing agencies' interpretations of their own authority, the Supreme Court's jurisprudence on judicial deference shows that agency expertise is a

---

18. Richard D. Lyons, *Pregnancy Tests Held Unreliable*, N.Y. TIMES (Dec. 13, 1972), <http://www.nytimes.com/1972/12/13/archives/pregnancy-tests-held-unreliable-doityourself-detection-kits-are.html> [<https://perma.cc/Q2ZQ-S5F8>].

19. *Id.* (stating that the FDA seized the tests because it thought they were “inaccurate, unreliable and prone to give false results”).

20. Joan H. Robinson, *Bringing the Pregnancy Test Home from the Hospital*, 46 SOC. STUD. SCI. 649, 657 (2016).

21. Steven R. Salbu, *HIV Home Testing and the FDA: The Case for Regulatory Restraint*, 46 HASTINGS L.J. 403, 407 (1995).

22. *Id.* at 452–53.

23. *See id.* at 453 (arguing that the ban on home-testing device applications “implied that the FDA's foremost concern regarding HIV home-testing products was not primary safety and effectiveness,” but were instead, “considered unacceptable in principle” because of “social considerations”); Roger Parloff, *The Quiet Scandal of the HIV Home Test Kit*, FORTUNE (July 9, 2012), <http://fortune.com/2012/07/09/the-quiet-scandal-of-the-hiv-home-test-kit> [<https://perma.cc/2FRB-6RMH>] (explaining that the FDA enacted a ban on applications for HIV home tests “[o]ut of concern that some people might respond emotionally and irrationally” to the information provided by the tests).

central justification for deferring to an interpretation.<sup>24</sup> Additionally, courts typically provide scientific agencies, including the FDA, “super deference” because of the complicated nature of their work.<sup>25</sup>

This Note argues that courts should not give the FDA deference on its expansive interpretation of “safety” in restricting home-testing applications because the FDA did not use its expertise as a scientific agency when it considered how consumers might react to HIV home-testing and DTC genetic testing results. Further, this Note argues that, as a policy matter, the FDA should not have the authority to make decisions based on this view of “safety” because it should not make value judgments for consumers about whether they should seek their own personal medical information. The FDA should not be able to restrict individual access by effectively deciding that consumers cannot weigh the potential risks and benefits of seeking these test results, particularly when consumers can easily find all of the relevant information for doing so.

Part I explains the history of the FDA’s statutory authority to regulate medical devices and demonstrates that Congress granted the FDA the authority to make scientific inquiries into whether devices directly cause physical harm to consumers. Part II describes three cases in which the FDA has expanded the meaning of “safety” to restrict access to devices that provide consumers with personal medical information. Part III first shows that the FDA’s interpretation of “safety” is outside the scope of the statutory provision’s clear meaning. Then, it documents the evolution of the expertise-based rationale for judicial deference and argues that courts should not defer to the FDA’s interpretation of “safety” because the FDA did not use its scientific expertise in the relevant considerations. Finally, this Note argues that, as a policy matter, the FDA should not have the ability to restrict access

---

24. See generally Ronald J. Krotoszynski, Jr., *Why Deference?: Implied Delegations, Agency Expertise, and the Misplaced Legacy of Skidmore*, 54 ADMIN. L. REV. 735 (2002) (arguing that the expertise rationale for deference has the strongest justification for judicial deference); Paul Chaffin, Note, *Expertise and Immigration Administration: When Does Chevron Apply to BIA Interpretations of the INA?*, 69 N.Y.U. ANN. SURV. AM. L. 503, 525–31 (2014) (providing an overview of how agency expertise is central to the Supreme Court’s doctrine on judicial deference to agency statutory interpretation).

25. See Emily Hammond Mezell, *Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science*, 109 MICH. L. REV. 733, 734 (2011) (explaining that this view is “encapsulated in the principle that courts ought to be at their ‘most deferential’ when reviewing an agency’s scientific determinations” (quoting *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983))).

to devices giving personal medical information based on a paternalistic view of public safety.

## I. THE HISTORY OF THE FDA'S AUTHORITY TO REGULATE MEDICAL DEVICES

This Part provides a brief overview of the legislation granting the FDA the authority to regulate medical devices. The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) initially gave the FDA the ability to regulate medical devices.<sup>26</sup> The passage of the Medical Device Amendments of 1976 (MDA) then broadened the FDA's regulatory power to include ensuring that medical devices are safe and effective.<sup>27</sup> Taken together, the legislative history and language of these statutes demonstrates that the FDA's responsibility to ensure medical device safety is limited to scientific inquiries into whether devices directly cause physical harm to consumers.<sup>28</sup>

### A. Federal Food, Drug, and Cosmetic Act of 1938

Prior to the passage of the FDCA, the FDA did not have jurisdiction over medical devices.<sup>29</sup> Through the FDCA, Congress expanded the FDA's authority by giving the agency the ability to regulate medical devices.<sup>30</sup> The FDCA defined "medical device" as "an instrument, apparatus . . . [or] contrivance . . . including any component, part, or accessory . . . intended for use in the diagnosis . . . , cure, mitigation, treatment or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals."<sup>31</sup> Yet the FDA's power to regulate these

---

26. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–392 (2012)).

27. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 513, 90 Stat. 540, 540–46 (codified as amended at 21 U.S.C. § 360c).

28. This Part focuses on these two statutes because, for the purposes of this Note, they involve the most significant congressional changes to the FDA's authority over medical devices. The FDCA was the first statute to give the FDA the authority to regulate medical devices, and the MDA amended the statute to include considerations of safety and effectiveness—the operative language analyzed in this Note. *See infra* Parts I.A and I.B.

29. The Pure Food and Drug Act of 1906 only gave the FDA limited authority to regulate foods, drugs, and cosmetics. Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938); Peter Barton Hutt, Esq., *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L.J. 99, 100–01 (1989).

30. *Id.* at 102.

31. Federal Food, Drug, and Cosmetic Act § 201(h) (codified as amended at 21 U.S.C. § 321(h)).

devices was limited, as the agency could only take regulatory action against adulterated or misbranded medical devices after they were introduced into interstate commerce.<sup>32</sup>

### B. *Medical Device Amendments of 1976*

Soon after the FDA gained jurisdiction over adulterated or misbranded devices, a proliferation of fraudulent devices flooded the market.<sup>33</sup> Although the FDA brought successful postmarket actions against some of these products, keeping up with these devices strained its resources, and many lawmakers wanted to give the FDA broader authority to regulate medical devices more effectively.<sup>34</sup> Starting in the 1950s, Congress considered several changes to the FDCA that would expand the FDA's power to assure the safety and effectiveness of new medical devices.<sup>35</sup>

The major motivation for legislation expanding the FDA's jurisdiction was the growing public and governmental consensus that the FDA should protect consumers from physically dangerous and fraudulent devices.<sup>36</sup> For example, President Lyndon B. Johnson advocated for increased FDA regulatory authority over medical devices in his February 1967 consumer message.<sup>37</sup> To bolster his argument, President Johnson mainly focused on examples of medical

---

32. *Id.* § 304 (codified as amended at 21 U.S.C. § 334). A device was deemed to be “adulterated” if it consisted of a filthy substance, had been prepared in unsanitary conditions, was composed of “any poisonous or deleterious substance which may render the contents injurious to health,” or if it differed from the quality stated in its labeling. *Id.* § 501 (codified as amended at 21 U.S.C. § 351). A device was deemed to be “misbranded” if its “labeling [was] false or misleading in any particular”; if it did not have a label containing certain information about the business, quantity of contents, and directions for use and warnings against misuse; or if it was “dangerous to health” when used according to the label. *Id.* § 502 (codified as amended at 21 U.S.C. § 352).

33. Hutt, *supra* note 29, at 105.

34. *See id.* at 104–05 (noting that the FDCA gave the FDA the authority to take “regulatory action against the adulteration or misbranding of medical devices” and describing the FDA's response to the increase in fraudulent devices on the market after the passage of the FDCA).

35. *See id.* at 105–08 (chronicling congressional and executive efforts to expand the FDA's authority).

36. *See* Gary E. Gamerman, Note, *Intended Use and Medical Devices: Distinguishing Nonmedical “Devices” from Medical “Devices” Under 21 U.S.C. § 321(h)*, 61 GEO. WASH. L. REV. 806, 820 (1993) (“The Medical Device Amendments of 1976 . . . passed only after many preventable tragedies outraged the public and Congress.”).

37. Special Message to the Congress To Protect the American Consumer (Feb. 16, 1967), in 1 PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES: LYNDON B. JOHNSON 196, 201 (1968).

devices that caused direct physical harm to consumers.<sup>38</sup> Although the 1967 legislation did not pass, these arguments regarding physical safety were raised once more during the passage of the MDA. Both the House and Senate legislative reports also fixated on examples of unsafe devices that could cause consumers direct, physical harm.<sup>39</sup>

The legislative reports demonstrate that Congress additionally wanted to give the FDA the authority to regulate “quack” or “fraudulent” devices.<sup>40</sup> The description of the problems associated with these devices indicates that Congress wanted to regulate these products primarily because they were ineffective, rather than physically harmful and unsafe. For instance, the Senate report described a diagnostic service “based upon the theory that any ailment [could] be diagnosed by measuring [emanations] from a dried blood spot on sterile paper,” when, in fact, an investigation of these claims found that it was completely ineffective—it was “incapable of distinguishing the blood of animals or birds from that of man, or that of the living from the dead.”<sup>41</sup> Thus, the issue with these devices was not that they posed a safety hazard, but rather, were fraudulent because they made false diagnostic or therapeutic claims. Regulation of such devices now falls under the FDA’s duty to ensure the “effectiveness” of medical devices.<sup>42</sup>

---

38. In particular, President Johnson cited “[d]efective nails and screws for bone repair [that] required repeated operations to correct the damage,” “artificial eyes” that caused “serious infection[s],” and x-ray machines that “emitted excessive doses of radiation.” *Id.*

39. In the House report, the section entitled “Background and Need for Legislation” pointed to the following examples as justification for giving the FDA premarket regulatory authority over certain medical devices: the Dalkon Shield intrauterine device, which was highly unsuccessful and linked to sixteen deaths and twenty-five miscarriages by 1975; “[s]ignificant defects in cardiac pacemakers [that] have necessitated 34 voluntary recalls of pacemakers, involving 23,000 units, since 1972”; and intraocular lenses that seriously impaired eleven patients and caused the removal of the eye of five patients. H.R. REP. NO. 94-853, at 8 (1976). Further, the House cited the findings of the Cooper Committee, which was convened by the Secretary of Health, Education, and Welfare in 1969 to evaluate alternatives for FDA device regulation. *Id.* at 9. The committee found in its extensive literature review that “10,000 injuries directly related to medical devices over a ten year period, of which 751 had proved fatal.” *Id.* The Senate report focused on similar issues in its section “History of Regulation of Medical Devices and Need for Legislation.” S. REP. NO. 94-33, at 2–7 (1975). For instance, after noting that the need for the legislation was shown “by the history of several cases against unsafe devices undertaken by the FDA,” the report gave the example of weight loss devices that “aggravate[d] muscular, gastrointestinal, and other disorders.” *Id.* at 6.

40. H.R. REP. NO. 94-853, at 6, 7 (1976); S. REP. NO. 94-33, at 2–7 (1975).

41. S. REP. NO. 94-33, at 4, 5.

42. 21 U.S.C. § 360c(a)(1)(A)(ii) (2012) (requiring that the FDA evaluate all medical devices to “provide reasonable assurance of the safety and effectiveness of the device”).

Another concern motivating the legislation was “congressional and industry frustration with judicial manipulation of the FDCA allowing FDA to denominate as drugs many articles that were plainly devices.”<sup>43</sup> Both the House and Senate reports on the MDA cited two court decisions in which the FDA successfully expanded its jurisdiction by blurring the line between drugs and devices.<sup>44</sup> Accordingly, the MDA’s impetus was not only to expand the FDA’s jurisdiction over medical devices, but to also create clearer boundaries for the agency’s regulatory authority.

The MDA significantly expanded the FDA’s regulatory authority over medical devices by creating a premarket approval process for new medical devices.<sup>45</sup> The MDA required that the FDA evaluate all medical devices to “provide reasonable assurance of the safety and effectiveness of the device,” and then classify them based on the level of risk that they present to consumers.<sup>46</sup> The statute states that for the purpose of classifying the devices, the “safety and effectiveness of a device are to be determined—(A) with respect to the persons for whose use the device is represented or intended, (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probable benefit to health

---

43. Gamerman, *supra* note 36, at 820–21.

44. H. R. REP. NO. 94-853, at 8–9; S. REP. NO. 94-33, at 6 (pointing to the decisions in *Amp, Inc. v. Gardner*, 389 F.2d 825 (2d Cir. 1968) and *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784 (1969) where courts held, respectively, that a nylon suture and an antibiotic sensitivity disc were drugs instead of devices). “As a result of these decisions FDA classified as drugs soft contact lenses, a pregnancy kit, and intrauterine contraceptive devices which contain drugs or trace metals.” *Id.*

45. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 540, 552–59 (codified as amended at 21 U.S.C. § 360e (2012)).

46. *Id.* § 2 (codified as amended at 21 U.S.C. § 360c). There are three applicable classes. Class I devices are considered low risk and are “subject to general controls.” Fekete, *supra* note 12, at 610. General controls include: “adulterated and misbranded device prevention, registration of producers of devices . . . , and general provisions respecting control of devices intended for human use.” *Id.* at 611. Class II devices are considered moderate risk. They are “subject to special controls when general controls are not enough ‘to provide reasonable assurance of [the device’s] safety and effectiveness.’” *Id.* (quoting 21 C.F.R. § 860.3(c)(2) (2017)). “Special controls include ‘performance standards, postmarket surveillance, patient registries . . . guidelines . . . recommendations, and other appropriate actions that the [FDA] deems necessary.’” *Id.* Class III devices are high-risk and “are subject to general controls as well as premarket approval.” *Id.* The premarket approval process requires the manufacturer to provide the FDA copious amounts of information about the device, including “clinical studies and information as to the device’s efficacy and safety.” *Id.* at 611–12.

from the use of the device against *any probable risk of injury or illness from such use.*<sup>47</sup>

These instructions for device classification suggest two things. First, the inclusion of this language within the statute indicates that Congress intended to set boundaries for the FDA's determination of the safety and effectiveness of a device, which suggests that Congress did not want to give the FDA absolute discretion over what constitutes valid safety and effectiveness considerations. Second, the use of the language "injury or illness from such use" in section C suggests that Congress only wanted the FDA to consider a device's potential for direct, physical harm when determining safety; "injury or illness" connotes a tangible, physical impairment and "from such use" implies that the device directly caused the harm.<sup>48</sup>

The statute also requires the FDA to use a specific device classification process: the FDA classifies a device after it receives a recommendation from a classification panel that has evaluated the device.<sup>49</sup> The panel is comprised of "persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices . . . and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices."<sup>50</sup> Further, the Secretary of Health and Human Services' appointments to the panels must "consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions."<sup>51</sup> This description suggests that individuals should have the scientific expertise to evaluate whether the device will physically harm consumers and if it will be effective in its claims.<sup>52</sup>

Congress also expanded the medical device definition to include not only devices that diagnose diseases, but also those that diagnose "conditions."<sup>53</sup> Further, the MDA requires registration of device

---

47. Medical Device Amendments § 2(a)(2), 90 Stat. at 541 (codified as amended at 21 U.S.C. § 360c(a)(2)) (emphasis added).

48. For further discussion of Congress's intent to limit safety considerations to a device's potential for causing direct, physical harm to consumers, see *infra* Part III.A.

49. Medical Device Amendments § 2 (codified as amended at 21 U.S.C. § 360c(b)(2)).

50. *Id.*

51. *Id.*

52. For a discussion of the FDA's failure to utilize its scientific expertise in evaluating the safety of HIV home-testing and DTC genetic testing devices, see *infra* Part III.B.2.

53. Medical Device Amendments § 2(a)(2). This addition was likely in response to *United States v. OVA II*, 535 F.2d 1248 (3d Cir. 1976), in which the FDA unsuccessfully argued that it had

establishments,<sup>54</sup> authorizes good manufacturing practice regulations,<sup>55</sup> and provides the FDA with the authority to ban a device that “presents substantial deception or an unreasonable and substantial risk of illness or injury.”<sup>56</sup>

Although the final law “greatly strengthened the FDA’s authority to regulate medical devices,” Congress also wrote the MDA with the purpose of creating regulations that are “carefully tailored to the type of device involved.”<sup>57</sup> Consequently, the classifying scheme and its reliance on independent advisory panels limited the FDA’s authority by requiring that it “place all medical devices into one of three regulatory classes based on the level of regulatory oversight actually needed to provide reasonable assurances of safety or efficacy.”<sup>58</sup>

Moreover, several statements made during the House debates over the MDA suggest that at least some members of Congress were concerned about the FDA extending its jurisdiction over medical devices beyond the powers proposed in the legislation.<sup>59</sup> In his comments on the House’s consideration of the conference report on the Senate’s bill, Representative Paul G. Rogers assured the body that the legislation was “carefully designed so that the least regulation necessary to assure safety and effectiveness will be applied to devices.”<sup>60</sup> In a previous House debate over the MDA, Representative Mark Hannaford stated that although he had “become increasingly

---

the authority to regulate a home pregnancy test kit as a drug. For a discussion of the *OVA II* decision, see *infra* Part II.A.

54. Medical Device Amendments § 4 (codified as amended at 21 U.S.C. § 360); see Hutt, *supra* note 29, at 113 (describing the major changes instituted by the MDA). Under these provisions, device manufacturers must register with the FDA, as well as abide by several administrative provisions regarding registration.

55. Medical Device Amendments § 2 (codified as amended at 21 U.S.C. § 360j); see Hutt, *supra* note 29, at 112–13 (describing the major changes instituted by the MDA).

56. Medical Device Amendments § 2 (codified as amended at 21 U.S.C. § 360f); see Hutt, *supra* note 29, at 112–13 (describing the major changes instituted by the MDA).

57. Hutt, *supra* note 29, at 113.

58. Gamberman, *supra* note 36, at 821.

59. See *id.* at 821–22 (“Congress voiced the fear that FDA, like most agencies, relentlessly would extend its jurisdiction and power beyond the newly expanded parameters.”).

60. 122 CONG. REC. 13,778 (1976) (statement of Rep. Rogers). In a previous discussion of the bill, Rep. Rogers made similar comments about Congress’s intent to narrowly tailor the FDA’s authority:

What we have done is write a bill specific enough so that we just do not turn over to a bureaucracy and allow them to write whatever and however they want . . . . We have been specific because we believe the Congress should write the law specifically. The committee does not intend to allow regulatory agencies to do anything they want to.

*Id.* at 5851.

concerned over the phenomenon of law by regulation during [his] term in Congress . . . . [The MDA bill] is a clear expression . . . permitting the FDA to implement the law, not write it.”<sup>61</sup> Though these representatives do not speak for Congress as a whole, their statements indicate that several members of Congress raised the issue of limited FDA jurisdiction.

Taken together, the legislative history of the MDA demonstrates that Congress wanted to limit the FDA’s authority to regulate medical devices according to their safety and effectiveness even as it expanded the FDA’s jurisdiction over these devices. Further, the statutory language suggests that considerations of safety and effectiveness should be limited to scientific inquiries based on the direct, physical harm that a device might pose to a consumer. Interpreting the statutory language as permitting the FDA to consider potential indirect, nonphysical harms undervalues the legislative context of the MDA and the statutory limitations that Congress placed on the FDA. If Congress wanted to give the FDA the discretion to consider those types of harms, it would have passed legislation with broader language that did not restrict the FDA’s processes for determining the classification, safety, and effectiveness of devices. Thus, the FDA only has the statutory authority to consider direct, physical harms to consumers in determining whether a device is safe.

## II. INSTANCES OF FDA PATERNALISM IN EVALUATING THE SAFETY OF MEDICAL DEVICES

On several occasions over the last forty years, the FDA has interpreted its statutory authority to regulate the safety and effectiveness of medical devices to include considerations of how consumers might react to the information provided by certain home-testing products. The FDA’s attempted seizure of Ova II pregnancy tests, its ban on HIV home-test approval applications, and its intense scrutiny of DTC genetic testing demonstrate that the agency has repeatedly limited access to personal information based on concerns that are beyond the scope of its authority to consider the safety of new medical devices under the MDA. This Part provides an overview of the FDA’s regulatory actions on these three medical devices and analyzes the agency’s motivations for restricting consumer access to the information that the devices provide.

---

61. *Id.* at 5850 (statement of Rep. Hannaford).

A. *Pregnancy Tests in the 1970s—Ova II*

In 1971, Faraday Laboratories began marketing home pregnancy test kits;<sup>62</sup> advertisements in women's magazines for the tests carried the slogan, "When you want to be the first to know."<sup>63</sup> The kit was available without a prescription<sup>64</sup> and was "marketed with literature indicating its use for the purpose of performing, in the home, a 'preliminary screening test'" for pregnancy.<sup>65</sup> It contained "two glass vials and two bottles of solutions."<sup>66</sup> To complete the test, the user would mix a urine sample with the two solutions in two separate vials, combining different numbers of solution drops, in different time sequences, in each vial.<sup>67</sup> Women could tell whether they were pregnant based on "the presence or absence of distinct visual differences in the darkness" of the two vials.<sup>68</sup> The test was identical to those used in laboratories and "it purported to be reasonably accurate in the determination of pregnancy even when used by laypeople."<sup>69</sup> Some heralded the tests as an important advancement in the women's health movement, as they gave women greater control over and access to important medical information.<sup>70</sup>

Consumer access to the Ova II testing kit was short lived—on December 12, 1972, the FDA announced that it was recalling the product because it believed that the kits were "inaccurate, unreliable and prone to give false results."<sup>71</sup> Although the "reliability or safety" of the tests were not questioned when they were being used by laboratories, the FDA thought the kit was "unreliable" in the hands of laywomen.<sup>72</sup>

A representative from Faraday countered that the company's tests showed that the tests were "accurate and [reliable] when used as

---

62. Robinson, *supra* note 20, at 654.

63. Lyons, *supra* note 18.

64. *Id.*

65. United States v. Article of Drug . . . Ova II (*Ova II*), 414 F. Supp. 660, 622 (D.N.J. 1975), *aff'd*, 535 F.2d 1248 (3d Cir. 1976).

66. *Id.* at 662–63. The two solutions were hydrochloric acid (HCl) and sodium hydroxide (NaOH). *Id.* at 663.

67. *Id.* at 663.

68. *Id.* "Distinct differences of color" meant "not pregnant" while "essentially similar color and saturation indicate[d] pregnancy." *Id.*

69. Robinson, *supra* note 20, at 654.

70. *See id.* at 658 (noting that some medical professionals expressed their support for home pregnancy tests "with language of knowledge, information, confidentiality, control, and choices").

71. Lyons, *supra* note 18 (quoting the FDA's statement).

72. Robinson, *supra* note 20, at 657.

directed.”<sup>73</sup> The company initially agreed to recall the kits, but questioned the FDA’s authority to recall the product because it was not a drug.<sup>74</sup> At this point, the MDA was not yet in effect and the FDA only had postmarket regulatory authority over adulterated or misbranded devices that were related to disease or affected the structure or function of the body.<sup>75</sup>

In 1974, Faraday stopped complying with the FDA’s recall<sup>76</sup> and filed suit in federal court in the District of New Jersey against the FDA.<sup>77</sup> The court did not decide whether *Ova II* was “safe and effective,” but rather considered whether the FDA had the authority to regulate the testing kit as a drug under the statutory language.<sup>78</sup> The court granted Faraday’s motion for summary judgment<sup>79</sup> because “[t]he condition of pregnancy . . . is a normal physiological function of all mammals and cannot be considered a disease of itself.”<sup>80</sup> Further, the judge noted that “no pregnancy test . . . is fully 100% reliable, and even if they were 100% reliable would disclose no more than that pregnancy exists or does not exist.”<sup>81</sup> Accordingly, all pregnancy-related ailments or diseases cannot be considered in conjunction with the pregnancy test kits because those conditions “have other symptoms” and “must be separately diagnosed.”<sup>82</sup>

The court in *Ova II* also clarified some distinctions about the consideration of medical devices. First, the court signaled that the FDA cannot hold a manufacturer to an impossible standard of reliability by noting that “no pregnancy test, including those recognized by FDA as not only ‘safe and effective’ but also considered by it as the most ‘safe

---

73. Lyons, *supra* note 18.

74. *Id.*

75. See Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 304, 52 Stat. 1040, 1044 (1938) (codified as amended at 21 U.S.C. § 321(h)). Prior to the MDA, devices were defined as “instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.” *Id.* § 201(h). The FDA likely thought that it could successfully characterize the testing kits as a drug because the Supreme Court had recently ruled that the Bacto-Unidisk, which was a testing disc for the effectiveness of various antibiotics in treating an infection, was a “drug” under the FDCA. See *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 785 (1969).

76. Robinson, *supra* note 20, at 656.

77. *Ova II*, 414 F. Supp. 660 (D.N.J. 1975), *aff’d*, 535 F.2d 1248 (3d Cir. 1976).

78. *Id.* at 662.

79. *Id.* at 667.

80. *Id.* at 664.

81. *Id.*

82. *Id.*

and effective' (a quality not required by the Act), is fully 100% reliable."<sup>83</sup> Given that these kits used the same mechanisms as those used in laboratory tests, it is unclear why Ova II would have been dangerous for lay use if "error rates were simply disclosed with the device."<sup>84</sup> Further, the court correctly narrowed the scope of its inquiry into Ova II: it would only consider the conditions for which the test is indicated and not make determinations based on scenarios in which women might use the pregnancy test result to make decisions about separate pregnancy-related or other medical issues.<sup>85</sup> This distinction is important because the court likely recognized that many of the FDA's concerns over the testing kits were related to issues outside of the scope of the test's limited use.

Ultimately, the court's determination that the FDA could not impose premarket regulations on Ova II because it did not fit under the definition of a drug became moot after Congress passed the MDA, expanding the FDA's premarket authority to include medical devices that diagnose "conditions."<sup>86</sup> But the motivations underlying the FDA's actions in its attempt to regulate Ova II have not changed. In this instance, the FDA was likely trying to expand its jurisdiction over medical devices—which at the time only encompassed adulterated and misbranded products—because of its concerns for the welfare of women when using home pregnancy tests. Although there is little direct evidence about the FDA's motivations behind its recall of Ova II,<sup>87</sup> the circumstantial evidence outlined above suggests that the FDA wanted to restrict women's access to this information and keep these identical pregnancy tests in the hands of laboratories.

### B. HIV Home-Testing

The FDA's attempts to limit access to information based on the notion that the agency needed to protect consumers from their own

---

83. *Id.*

84. Robinson, *supra* note 20, at 657.

85. See *Ova II*, 414 F. Supp. at 664 ("[Pregnancy-related ailments] must be separately diagnosed. Neither Ova II nor any other pregnancy test attempts to do so. . . . [H]ere, the fact that there may be ailments or diseases related to pregnancy or associated with it is not an element that may be considered.")

86. For a description of the expansion of the device definition under the MDA, see *supra* notes 53–61 and accompanying text.

87. The FDA's website does not contain any information or documents regarding this seizure. Further, neither the Clerk's Office for the United States District Court for the District of New Jersey nor the National Archives could produce a copy of the *Ova II* case record. Thus, the only resources I was able to find regarding this case are those provided in this Section.

potentially negative reactions did not end with Ova II. During the HIV/AIDS crisis in the late 1980s, the FDA took a hard stance against HIV home-testing, in large part because of its concern that consumers would not be able to handle test results constructively.

Although the FDA was considering premarket approval applications for home HIV tests in 1986 and 1987,<sup>88</sup> it halted this development in March 1988 and decided to limit applications to blood collection kits that were “intended for professional use only.”<sup>89</sup> The FDA made this ban official in a guidance published in the Federal Register in February 1989.<sup>90</sup> This move effectively banned consideration of any applications for HIV home-test kits, as one of the criteria for applications was that they must be “labeled and marketed for professional use only within a health care environment (e.g., hospitals, medical clinics, doctor’s offices, sexually transmitted disease clinics, HIV–1 counseling and testing centers, and mental health clinics[]).”<sup>91</sup> Thus, manufacturers of HIV home-testing kits were not allowed to demonstrate that their products were safe and effective because the FDA would not consider their applications for premarket approval.<sup>92</sup>

Although the FDA had several issues with home HIV tests,<sup>93</sup> its notice for a public meeting on the subject in February 1989 indicates that it was concerned about consumers’ ability to understand and react safely to test results. The FDA set up a public forum to discuss its ban and the two types of home-testing kits: “blood collection kits,” which instructed consumers to send their blood samples to the testing company, and “[k]its for [c]ollection and [h]ome [t]esting of [b]lood for [e]vidence of HIV–1 [i]nfection,” which allowed consumers to test their own specimens.<sup>94</sup> Regarding blood collection kits, the FDA noted

---

88. Salbu, *supra* note 21, at 407.

89. Blood Collection Kits Labeled for Human Immunodeficiency Virus Type 1 (HIV-1) Antibody Testing; Home Kits Designed to Detect HIV-1 Antibody; Open Meeting, 54 Fed. Reg. 7279, 7280 (Feb. 17, 1989) [hereinafter HIV Testing Meeting].

90. *Id.*

91. *Id.*

92. Salbu, *supra* note 21, at 452–53.

93. The FDA made arguments for banning home HIV tests other than its concerns about consumer reactions. For instance, one FDA spokesperson explained that “refusal to consider applications of HIV home tests was based on several concerns, including the potentially improper drawing of blood samples, the possibility of blood samples being held for long periods of time, and the potential for blood samples to be affected by temperature changes during in-mail transit.” Salbu, *supra* note 21, at 407.

94. HIV Testing Meeting, *supra* note 89, at 7280–81.

that medical experts believed that HIV testing should include counseling for test results and solicited comments “regarding the ability to provide effective pre- and post-test counseling in a setting outside the health care environment.”<sup>95</sup> For combination collection and testing kits, the FDA invited comments as to “whether laypersons can adequately interpret the test results, and whether that interpretation in the absence of a medical professional is appropriate.”<sup>96</sup> Although the FDA listed other issues for the public meeting,<sup>97</sup> its concern for laypersons’ ability to understand and respond to their own results without professional oversight suggests that its ban on HIV home-test applications was informed, at least in part, by the view that consumers needed to be protected from receiving this information outside of a clinical setting.

Testimony from the FDA’s open meeting on this issue also demonstrates that the agency relied on concerns about consumer reactions instead of scientific data about the safety and effectiveness of HIV home-testing kits. The FDA revealed that at least seventeen companies indicated that they were interested in marketing HIV home-testing kits, which would require individuals to send blood or saliva samples for testing.<sup>98</sup> The FDA acknowledged the existence of technology that allowed a person to do the entire test at home even though no company had yet developed the test.<sup>99</sup> The expert opinions presented at the meeting were mixed.<sup>100</sup> The Vice President of the Hudson Institute—a public policy think tank that conducted some HIV/AIDS research<sup>101</sup>—urged the FDA to consider the home tests

---

95. *Id.* at 7281.

96. *Id.*

97. For blood collection kits, the FDA also asked for comments on the “[c]ollection and shipping of blood samples by laypersons,” the “[r]eturn of test results directly to the person from whom the sample was collected,” and the “[a]vailability of blood collection systems.” *Id.* at 7280–81. For combination collecting and testing kits, the agency asked for comments on “whether the kits should be made available OTC, [and] whether laypersons can reliably and safely perform the test.” *Id.* at 7281.

98. Rebecca Kolberg, *A Public Policy Expert Charged Thursday Government Inaction on . . .*, UNITED PRESS INT’L (Apr. 6, 1989), <http://www.upi.com/Archives/1989/04/06/A-public-policy-expert-charged-Thursday-government-inaction-on/3140607838400> [<https://perma.cc/26DR-UNVU>].

99. *Id.*

100. *Id.*

101. See Philip M. Boffey, *Research Group Says AIDS Cases May Be Twice the U.S. Estimate*, N.Y. TIMES (Aug. 20, 1988), <http://www.nytimes.com/1988/08/20/us/research-group-says-aids-cases-may-be-twice-the-us-estimate.html> [<https://perma.cc/XBT9-XVX7>] (discussing the Hudson Institute’s research). In fact, in 1988, the Hudson Institute estimated that President Reagan’s

immediately, arguing that “[t]o continue to prohibit it (home AIDS testing) is to condemn some Americans to death as [a] result of inadvertent transmission of HIV.”<sup>102</sup> On the other hand, a representative from the National Institutes of Health (NIH) argued that the tests could cause “all types of heartache,” as “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.”<sup>103</sup> The Deputy Director of the federal Center for Disease Controls’ AIDS program expressed concern about the effectiveness of the companies’ telephone counseling.<sup>104</sup>

Despite the Hudson Institute’s urging for greater access to this technology, the FDA did not relax its guidelines for HIV-testing applications until several years later.<sup>105</sup> Although the testimony from opponents of home-testing did not represent the FDA’s official position, the focus on shielding consumers from important medical information and the FDA’s refusal to reconsider its restrictions suggest that these concerns prevailed over considerations of the device’s scientific, analytical validity.<sup>106</sup> There is also evidence that the FDA was pressured by a powerful political coalition—including groups such as the American Medical Association and the Centers for Disease Control and Prevention, several members of Congress, and gay rights activists—that opposed home-testing applications because “they might be inaccurate or increase the risk of suicide.”<sup>107</sup> The FDA’s decision to take a strong, prophylactic measure against this technology by refusing

---

AIDS commission was underestimating the total number of Americans infected with AIDS, as well as the number of infected heterosexuals. *Id.*

102. Kolberg, *supra* note 98.

103. *Id.*

104. *Id.*

105. Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV-1 and/or HIV-2) Antibody Testing; Revisions to Previous Guidance, 60 Fed. Reg. 10,087 (Feb. 23, 1995) [hereinafter Revisions to Previous Guidance].

106. This Note does not analyze whether the FDA’s assumption that HIV test results have a high likelihood of eliciting negative reactions was correct, but rather demonstrates that the FDA relied on this consideration when it banned HIV home-testing applications. Further, this Note argues in Part III.B.2 that restricting access to this information interferes with the consumer’s autonomy to weigh the potential risks and benefits of seeking personal health information like HIV status—regardless of potential reactions.

107. Alexi A. Wright & Ingrid T. Katz, *Home Testing for HIV*, 354 NEW ENG. J. MED. 437, 438 (2006). It appears that the fear of harmful reactions was prevalent in these arguments, as “AIDS activists reinforced the latter point by distributing copies of the obituary of a man who had jumped off the Golden Gate Bridge after learning that he was HIV-positive.” *Id.*

to consider premarket applications for these devices makes it apparent that the FDA gave substantial weight to the notion that it needed to protect consumers from their own medical information.<sup>108</sup> In fact, the FDA openly acknowledged its concerns throughout the public comment process, and the director of the FDA's Center for Biologics Evaluation and Research admitted during the public meeting that the agency "took a conservative view" of its considerations of HIV home-testing kits.<sup>109</sup>

In April of 1990, the FDA hinted that it might begin considering applications for home-testing kits, but then reaffirmed the 1989 guidance limiting applications to tests for "professional use."<sup>110</sup> In 1994, three companies that had previously sought premarket approval for home tests sent new applications to the FDA, requesting that the agency reconsider the ban.<sup>111</sup> The FDA convened an advisory panel to consider the issue "[i]n light of scientific and technological developments and the changing nature of the HIV epidemic."<sup>112</sup> This time, the majority of the advisory committee members "believed that the potential benefits of over-the-counter (OTC) home specimen collection kits outweighed the potential risks."<sup>113</sup> Afterward, the FDA issued a guidance in February 1995 that lifted the ban on applications for home-specimen-collection testing kits.<sup>114</sup> Although the ban reversal was a victory for device manufacturers, the FDA still placed several burdensome guidelines on the approval of these devices. For instance, applications had to show that test results would be given to consumers by "persons appropriately trained in HIV notification and counseling" and that consumers with positive results would receive counseling that referred them to "medical and social support services" in their community.<sup>115</sup>

Although the FDA cited "scientific and technological developments and the changing nature of the HIV epidemic" as

---

108. For a discussion of the specific provisions of the FDA's ban on HIV home-test applications, see *supra* notes 89–91 and accompanying text.

109. Kolberg, *supra* note 98.

110. Blood Collection Kits Labeled for Human Immunodeficiency Virus (HIV-1) Antibody Testing; Availability of Letter for Interested Persons, 55 Fed. Reg. 30,982, 30,982 (July 30, 1990).

111. Salbu, *supra* note 21, at 411.

112. Revisions to Previous Guidance, *supra* note 105, at 10,087.

113. *Id.*

114. *Id.*

115. *Id.* at 10,088

reasons for reconsidering its ban on specimen-collection kits,<sup>116</sup> few developments had occurred during the previous five years.<sup>117</sup> The importance of diagnostic tools in the fight against HIV had not changed—the scientific community knew when the ban was imposed that “avoidance of new infection [was] the only method” available for curbing the number of HIV-related deaths.<sup>118</sup> Additionally, although the companies interested in marketing this product continued to develop HIV-testing technology during the ban, they were repeatedly denied the ability to show that the tests were safe and effective.<sup>119</sup> In fact, the former president of a company that sought approval for an HIV home-testing kit testified that when his company presented their product for final approval in 1994, they used “essentially the same data” they took to the FDA in 1987—the year they first applied for premarket approval.<sup>120</sup>

Thus, the FDA’s blanket ban on both types of home-testing products from 1988 to 1994 was not primarily based on scientific data on the safety and effectiveness of these devices.<sup>121</sup> Rather, the products were “considered unacceptable in principle” because the FDA was concerned about the potential ramifications of consumers having access to this information.<sup>122</sup> The application process could have given companies—who had the technology for home-testing kits years before applications were accepted—the chance to show that concerns about consumer reactions were not supported by scientific studies.<sup>123</sup> Instead, the manufacturers were denied this opportunity until the FDA decided that it would consider their data for approval. In fact, the FDA did not lift its ban on applications for combination home collection and testing kits (or “rapid home” tests) until *seventeen years* later in 2005.<sup>124</sup> Although at least one company submitted an application for approval

---

116. *Id.* at 10,087.

117. Salbu, *supra* note 21, at 452.

118. *Id.*

119. *Id.* at 452–53.

120. FDA BLOOD PRODS. ADVISORY COMM., TESTIMONY OF ELLIOTT J. MILLENSON, FORMER PRESIDENT & CEO, J&J/DIRECT ACCESS DIAGNOSTICS (2006), [http://www.fda.gov/ohrms/dockets/ac/06/slides/2006-4206OPH2\\_2b.htm](http://www.fda.gov/ohrms/dockets/ac/06/slides/2006-4206OPH2_2b.htm) [<https://perma.cc/SLE2-L6NB>].

121. Salbu, *supra* note 21, at 453.

122. *Id.*

123. See Parloff, *supra* note 23 (suggesting that the FDA could have allowed research to determine if the “apprehensions surrounding home testing were empirically justified”).

124. *Id.*

of a rapid home test in 1987, the FDA did not approve the first rapid home HIV test until *twenty-five years later* in 2012.<sup>125</sup>

### C. Direct-to-Consumer Genetic Testing

Around the same time that the FDA loosened restrictions on HIV rapid tests, it began to increase its enforcement efforts against another form of medical information: DTC genetic tests. Companies started to offer DTC genetic testing services in 2007.<sup>126</sup> In May 2010, the FDA started regulating these devices.<sup>127</sup> After Pathway Genomics announced that it was partnering with Walgreens to sell its home-testing kit in over 6,000 stores throughout the United States,<sup>128</sup> the FDA sent the company an Untitled Letter.<sup>129</sup> In the letter, the FDA noted that the company's kit "intended to report customary and personal genetic health disposition results for more than 70 health conditions" for the purpose of creating a "health regime to live a healthier, longer life."<sup>130</sup> Further, the FDA noted that the kit "appear[ed] to meet the definition of a device" under the FDCA, but the company did not have preclearance or approval for it.<sup>131</sup> As a result, Walgreens eventually cancelled the plan, and Pathway returned to selling the test online, but only giving results to physicians.<sup>132</sup>

The FDA then ramped up its surveillance of DTC genetic testing companies. A month after the Pathway letter, the FDA sent Untitled Letters to five additional companies, following the same line of

---

125. *Id.*

126. Green & Farahany, *supra* note 2, at 286.

127. Kayte Spector-Bagdady & Elizabeth Pike, *Consuming Genomics: Regulation Direct-to-Consumer Genetic and Genomic Information*, 92 NEB. L. REV. 677, 705 (2014).

128. *Id.*

129. The FDA uses two types of letters to notify companies of violations: Warning and Untitled Letters. Warning Letters alert the company of "violations that may lead to enforcement action." *Id.* at 704. Untitled Letters are used for "less significant violations." *Id.*

130. Letter from James Woods, Deputy Dir. of Patient Safety & Product Quality, Office of In Vitro Diagnostic Device Evaluation & Safety, Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., to James Plante, Founder & CEO, Pathway Genomics Corp. (May 10, 2010), <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM211875.pdf> [<https://perma.cc/X5BG-PWRP>]. Pathway Genomics' health claims do not affect this Note's subsequent analysis of the FDA's authority to regulate these types of tests based on concerns about consumer reactions. The decisions that consumers make in response to the tests—including those regarding their "health regime"—are secondary to the device's purpose to provide information. For a discussion of how consumer reactions are separate from the device's purpose, see *infra* notes 245–49 and accompanying text.

131. *Id.*

132. Spector-Bagdady & Pike, *supra* note 127, at 706.

reasoning.<sup>133</sup> In July of 2010, Jeffrey Shuren, the Director of the FDA's Center for Device and Radiological Health provided congressional testimony about the agency's decision to intervene in DTC genetic testing.<sup>134</sup> His testimony indicates that the FDA had several concerns about consumers receiving this type of information: "Marketing genetic tests directly to consumers can increase the risk of a test 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."<sup>135</sup> Shuren also noted that the six DTC companies that the FDA contacted had not "submitted information on the analytical or clinical validity of their tests to FDA for clearance or approval."<sup>136</sup> These statements show the FDA's initial regulation of DTC genetic testing was motivated in part by concerns about its clinical validity.<sup>137</sup> The FDA "sent similar letters to 15 other firms marketing DTC genetic tests" in July 2010<sup>138</sup> and three final Untitled Letters in May 2011.<sup>139</sup>

In March 2011, the FDA convened a meeting of the Molecular and Clinical Genetics Panel to "discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims."<sup>140</sup> It seems that the panel was concerned with guarding the public from what it considered potentially harmful information, as the participants considered the benefits and risks of making these services available without physician supervision. The report noted that the panelists had different opinions as to whether the "risks outweigh the benefits of offering this category of tests DTC."<sup>141</sup> Further, the participants "generally agreed" that they should

---

133. *Id.*

134. *Direct-to-Consumer Genetic Testing & the Consequences to the Public Health: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 111th Cong. 79 (2010) (statement of Jeffrey Shuren, M.D., Dir., Ctr. for Devices & Radiological Health, Food & Drug Admin., U.S. Dep't of Health & Human Services).

135. *Id.*

136. *Id.*

137. For an explanation of the FDA's expansive definition of clinical validity in the 23andMe context, see *supra* note 10 and accompanying text.

138. *Id.*

139. Spector-Bagdady & Pike, *supra* note 127, at 710.

140. DEP'T OF HEALTH & HUMAN SERV., SUMMARY OF THE MOLECULAR & CLINICAL GENETICS PANEL MEETING (Mar. 8-9, 2011), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM246907.pdf> [<https://perma.cc/H5CG-MZUX>].

141. *Id.*

recommend that certain types of genetic tests only be offered upon prescription.<sup>142</sup> In considering potential “mitigations against incorrect, misinterpreted, miscommunicated, or misunderstood test results” for tests offered without live counseling sessions, panel members had the following suggestions: first, providing patient training and education; second, utilizing a “knowledge test prior to providing the DTC clinical genetic test to assess whether the consumer understands the meaning or consequences of test results”; and third, requiring that companies provide “qualified genetic counselors” to consumers.<sup>143</sup> These considerations by the panel confirm that the FDA premised a substantial part of its concern over DTC genetic testing on its notion that it had a duty to protect consumers from receiving this information on their own, lest consumers react negatively without professional help.

Although 23andMe was going through the process of gaining premarket clearance for its health-related tests in 2012, the FDA sent a strongly worded Warning Letter to the company in November 2013, effectively withdrawing its applications.<sup>144</sup> The FDA ordered the company to “immediately discontinue marketing” the services and seek premarket approval as a Class III device.<sup>145</sup> The 23andMe Warning Letter used concerns about consumer reactions to test results to rationalize the regulation, rather than legitimate safety considerations about direct, physical harm.<sup>146</sup> The FDA found that some of the kits’ uses were “particularly concerning,” and cited the possibility that consumers could use their testing results to self-manage their medical conditions or discontinue therapies, as well as overreact and undergo radical, unnecessary treatments.<sup>147</sup> The FDA also noted that 23andMe needed to provide assurance that it had “analytically”

---

142. The report said that the following categories should be prescription only: “pre-symptomatic tests with high predictor for a disease, with potentially severe consequences, and pharmacogenetic tests.” *Id.*

143. *Id.*

144. Warning Letter to 23andMe, *supra* note 3.

145. *Id.*

146. For a discussion of the FDA’s concerns outlined in the 23andMe Warning Letter, see *supra* notes 5–8 and accompanying text.

147. Warning Letter to 23andMe, *supra* note 3. The Warning Letter explained that “patients relying on such tests may begin to self-manage their treatments through dose changes or even abandon certain therapies . . . .” Further, it noted that consumers who receive a false positive result for the gene for breast or ovarian cancer could “undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions.” *Id.*

and “clinically validated” the tests for their intended uses.<sup>148</sup> The FDA’s persistent reliance on consumer responses as a rationale for regulating DTC genetic testing devices demonstrates that it includes these considerations in its evaluation of clinical validity.

Despite the FDA’s approval of some DTC genetic tests, it continues to impose severe restrictions on consumers’ access to their genetic information based on concerns about consumer reactions to results. In 2015, approximately eighteen months after the 23andMe Warning Letter, the FDA approved the company’s carrier test for Bloom syndrome.<sup>149</sup> The process for seeking this approval was quite burdensome. In addition to studies focused on ensuring analytical validity, 23andMe performed two studies demonstrating clinical validity: one “usability study,” which indicated that “consumers could understand the test instructions and collect an adequate saliva sample,” and one user study “to show the test instructions and results were easy to follow and understand” for a diverse set of participants.<sup>150</sup>

The FDA also announced that it was classifying DTC carrier screening tests as Class II devices, which do not require premarket review.<sup>151</sup> 23andMe received approval for thirty-six carrier tests, including cystic fibrosis, later that year.<sup>152</sup> The FDA likely granted carrier screenings a regulatory carve out because it believed that consumers are unlikely to react negatively to results; carrier screenings do not implicate “the acute anxiety of personal disease risk” because the primary concern is whether the person might pass along the gene to children.<sup>153</sup>

---

148. *Id.* For an explanation of analytical and clinical validity, see *supra* note 10 and accompanying text.

149. *FDA Permits Marking of First Direct-To-Consumer Genetic Carrier Test for Bloom Syndrome*, U.S. FOOD & DRUG ADMIN. (Feb. 19, 2015), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm435003.htm> [<https://perma.cc/6JCA-VWT3>]. “Individuals born with Bloom Syndrome experience stunted growth, rarely reaching five feet in height and are very light-sensitive and predisposed to cancer such that life expectancy is in the 20s.” David Kroll, *FDA Approves 23andMe Gene Carrier Test*, FORBES (Feb. 19, 2015), <http://www.forbes.com/sites/davidkroll/2015/02/19/fda-okays-23andmes-direct-to-consumer-gene-carrier-testing-starting-with-bloom-syndrome/#152661d83791> [<https://perma.cc/9J3C-AC38>].

150. *Id.*

151. *Id.*

152. Erika Check Hayden, *Out of Regulatory Limbo, 23andMe Resumes Some Health Tests and Hopes to Offer More*, NATURE (Oct. 27, 2015), <http://www.nature.com/news/out-of-regulatory-limbo-23andme-resumes-some-health-tests-and-hopes-to-offer-more-1.18641> [<https://perma.cc/8P5T-DVX3>].

153. Kroll, *supra* note 149.

On April 6, 2017, the FDA announced that after nearly four years of consideration, it approved ten of 23andMe's genetic tests for diseases or conditions.<sup>154</sup> The agency acknowledged that these tests are the first DTC genetic tests approved by the FDA that "provide information on an individual's genetic predisposition to certain medical diseases or conditions, which may help to make decisions about lifestyle choices or to inform discussions with a health care professional."<sup>155</sup> Further, the FDA noted that it reviewed data for the tests through the *de novo* premarket review pathway, which it described as "a regulatory pathway for novel, low-to-moderate-risk devices that are not substantially equivalent to an already legally marketed device."<sup>156</sup>

Although this announcement seems like a significant accomplishment for 23andMe, the FDA's consideration of the clinical validity of these tests demonstrates that the agency is still regulating DTC genetic tests in light of concerns about potential consumer actions taken in response to test results. The FDA noted that 23andMe's tests were only approved after the company demonstrated their analytical and clinical validity.<sup>157</sup> In regards to clinical validity, the FDA required that "the results of all DTC tests used for medical purposes be communicated in a way that consumers can understand and use."<sup>158</sup> Although the FDA stated that the genetic information might help consumers make "lifestyle choices," it also noted that results "should not be used for diagnosis or to inform treatment decisions."<sup>159</sup>

Further, the FDA indicated in the approval announcement that it is reconsidering its evaluation process for genetic health risk (GHR) tests. The FDA noted that it is "establishing criteria, called special controls, which clarify the agency's expectations in assuring the tests' accuracy, reliability and clinical relevance."<sup>160</sup> These special controls would supplement general controls required by FDA regulations, and would "provide reasonable assurance of safety and effectiveness for these and similar GHR tests."<sup>161</sup> The FDA also vaguely alluded to

---

154. 23andMe Approval Announcement, *supra* note 13.

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.* Accordingly, 23andMe conducted a user study showing that "people using the tests understood more than 90 percent of the information presented in the reports." *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

making the approval process easier in the future: the agency noted that it “intend[ed] to exempt additional 23andMe GHR tests from the FDA’s premarket review, and GHR tests from other makers may be exempt after submitting their first premarket notification.”<sup>162</sup> Although the FDA did not give any further details on this potential exemption, it appears that this regulatory pathway would only apply to tests that have already been analytically and clinically verified, as the FDA also stated that the proposed exemption would “allow other, similar tests to enter the market as quickly as possible and in the least burdensome way, after a one-time FDA review.”<sup>163</sup>

Although the approval announcements for the carrier genes and GHR tests seem like victories for consumer access to DTC genetic testing, they do not signify a major shift in the FDA’s regulatory approach for these devices because the agency has demonstrated that it is still concerned about the clinical decisions that consumers might make after receiving genetic test results. In fact, the FDA noted in the GHR tests announcement that the newly proposed “special controls” for assuring safety and effectiveness will include agency expectations for “clinical relevance.”<sup>164</sup> This appears to encompass the same considerations as the FDA’s expansive formulation of clinical validity for DTC genetic testing—which includes considerations of consumer responses to test results—because “relevance” connotes test result usage for clinical decisionmaking.

The FDA also stated in the GHR tests announcement that the recent authorization and “any future, related exemption” for GHR tests excluded “tests that function as diagnostic tests.”<sup>165</sup> The FDA explained that these tests are “often used as the sole basis for major treatment decisions, such as a genetic test for BRCA, for which a positive result may lead to prophylactic (preventative) surgical removal of breasts or ovaries.”<sup>166</sup> Unsurprisingly then, along with the thirty-six carrier tests authorized in 2015, the FDA has only approved ten out of the company’s original 240 health condition tests after nearly four years of FDA consideration.<sup>167</sup> Thus, despite its recent

---

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

167. See Amy Maxmen, *23andMe Given Green Light To Sell DNA Tests for 10 Diseases*, NATURE (Apr. 6, 2017), <https://www.nature.com/news/23andme-given-green-light-to-sell-dna-tests-for-10-diseases-1.21802> [<https://perma.cc/UFE9-J7UB>].

authorizations for ten disease risk tests, the FDA's approval process and exclusion of genetic tests that could provide consumers important medical information indicates that it is still concerned about how consumers will use test results.

The current approval regime for DTC genetic testing reflects the continuation of the FDA's expansive interpretation of its duty to ensure the safety of devices under the MDA. The FDA's swift, strict regulation of DTC genetic testing and its characterizations of these services indicate that it has broadened its inquiries into these devices to include concerns about what consumers will do with results. The FDA appears to fear that consumers are not only unable to understand genetic testing results, but are also at risk of drastically changing their physician-guided treatment plans or undergoing unnecessary and dangerous procedures.

Regulatory restrictions that require DTC genetic testing companies to demonstrate the FDA's broad definition of clinical validity go beyond the scope of Congress's intent to limit the FDA's consideration of "safety" to the relevant scientific evidence of whether a device might cause physical harm.<sup>168</sup> Certainly, the FDA may consider the tests' accuracy in detecting genetic traits, but this inquiry does not encompass considerations of how consumers will react to certain results.<sup>169</sup> Accordingly, the FDA's rationale for setting burdensome restrictions on DTC genetic testing services is identical to its motivations for the seizure of the Ova II pregnancy tests and the ban on HIV home-testing kit applications—in all three instances, the FDA restricted individual access to personal medical information based on concerns about how people would respond to such information.

### III. CONSIDERATIONS OF CONSUMER REACTIONS ARE OUTSIDE THE SCOPE OF THE FDA'S STATUTORY AUTHORITY AND EXPERTISE

The FDA's actions regarding the Ova II pregnancy tests, HIV home-testing kits, and DTC genetic testing kits demonstrate that the FDA has repeatedly justified restrictions on access to personal medical information out of concern for how consumers might react to such

---

168. For a discussion of the FDA's statutory authority to consider the "safety" of medical devices under the MDA, see *infra* Part III.A.

169. See *Paternalism vs. Empowerment*, *supra* note 10 and accompanying text.

knowledge. Because the FDA was not constrained by the language of “safety and effectiveness” under the MDA when it recalled the Ova II pregnancy tests, this Part focuses on and analyzes the FDA’s restrictions on HIV home-testing kits and DTC genetic testing.

The FDA’s consideration of the actions consumers might take after receiving test results greatly expands its authority to evaluate the safety of medical devices. This expansion is untenable for two reasons. First, the FDA lacks the authority to consider these types of potential harms because the meaning of “safety” in the MDA is clear—it only includes considerations of scientific evidence that the device directly causes physical harm to consumers.<sup>170</sup> Second, the courts should not defer to the FDA’s broad interpretation of “safety,” which includes potential nondirect, nonphysical harms. The FDA is not entitled to deference in these cases because it did not use its expertise when it took regulatory action; even though the FDA is a scientific agency, its safety concerns for these devices were not supported by scientific inquiries. Further, as a policy matter, the FDA should not have the power to make value judgments for consumers about whether they can handle receiving information about their own bodies.

A. *The Term “Safety” Is Limited to Scientific Inquiries into the Potential for Direct, Physical Harm to Consumers*

Whether a statutory provision has a clear meaning can be part of a court’s deference analysis.<sup>171</sup> The statutory language, structure of the MDA, and legislative history demonstrate that the meaning of “safety” is clear—Congress intended to limit the FDA’s consideration of safety to scientific inquiries about a device’s potential to cause direct physical harm to consumers.<sup>172</sup>

First, Congress’s inclusion of instructions for determining safety and effectiveness indicates that it intended to limit the FDA’s discretion in considering these two requirements for medical devices.<sup>173</sup>

---

170. For a discussion of how the legislative history and language of the MDA demonstrates Congress’s intent to limit the FDA’s safety considerations, see *supra* Part I.B.

171. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). Under the first step of the *Chevron* test, the court determines “whether Congress has directly spoken to the precise question at issue.” If congressional intent is clear, the agency must follow this expressed intent. *Id.*

172. For a discussion of the language, structure, and legislative history of the MDA, see *supra* Part I.B.

173. For a discussion of the MDA’s instructions for determining safety and effectiveness, see *supra* notes 46–47 and accompanying text.

The language “risk of injury or illness from use” further suggests that Congress only wanted the FDA to investigate devices’ potential for directly causing physical harm in its safety determinations.<sup>174</sup> Second, the MDA’s structural limitations for the FDA’s consideration of “safety and effectiveness” demonstrate that the agency is limited to conducting scientific inquiries; the agency must consider recommendations from classification panels which, the statute suggests, are comprised of individuals who have the scientific expertise to evaluate the “safety and effectiveness” of devices.<sup>175</sup>

Finally, the historical record shows that the then-growing need for FDA regulation of physically dangerous and fraudulent products motivated Congress to expand the FDA’s jurisdiction to include an investigation into the “safety and effectiveness” of medical devices.<sup>176</sup> Both the House and Senate reports on the bill extensively cited unsafe devices that directly caused physical harm to consumers.<sup>177</sup> The descriptions within these reports indicate that the “safety” prong of the FDA’s mandate was meant to give the agency the authority to protect consumers from these dangers. Further, the “effectiveness” prong was intended to help the FDA weed out fraudulent or quack devices making false diagnostic or therapeutic promises.<sup>178</sup> Additionally, Congress’s concern over the FDA’s attempts to expand its jurisdiction over devices, highlighted in both legislative reports, suggests that Congress wanted to create boundaries for the agency’s regulatory authority.<sup>179</sup> In fact, two members of Congress echoed this concern and praised the MDA because it sufficiently tailored the FDA’s jurisdiction over devices.<sup>180</sup> Although these statements cannot definitively speak for Congress’s intent, they suggest that Congress considered the issue of limiting the FDA’s authority.

---

174. For a discussion of the statutory provision that sets standards for the FDA’s determination of safety and effectiveness, see *supra* note 47 and accompanying text.

175. For a discussion of this statutory provisions regarding requirements for classification panels, see *supra* notes 50–51 and accompanying text.

176. For a discussion of the political impetuses for the MDA, see *supra* notes 36–39 and accompanying text.

177. For a discussion of the House and Senate reports, see *supra* note 39 and accompanying text.

178. For a discussion of Congress wanting to give the FDA authority to regulate fraudulent devices, see *supra* notes 40–42 and accompanying text.

179. For a discussion of the congressional concerns about the FDA’s attempts to expand its jurisdiction, see *supra* notes 43–44 and accompanying text.

180. For a discussion of these statements made in favor of limiting the FDA’s jurisdiction during the passage of the MDA, see *supra* notes 59–61 and accompanying text.

Taken together, these aspects of the language and passage of the MDA indicate that Congress wanted to limit the FDA's authority to determine a device's safety to scientific inquiries into a device's potential to directly cause physical harm to consumers. Thus, the FDA does not have the authority to consider or evaluate nonscientific concerns about nonphysical harms that do not directly result from the utilization of a device.

Despite this statutory limitation, these considerations guided the FDA's decisions to ban HIV-testing-kit device applications and restrict DTC genetic testing. In both instances, the FDA considered whether consumers would react negatively to the test results and subsequently make poor medical or life decisions.<sup>181</sup> Using these concerns to determine the safety of a device is impermissible because negative reactions do not constitute direct physical harm. Furthermore, any actions that a consumer takes after learning this information are completely separate from the test results and, accordingly, do not relate directly to the device.<sup>182</sup> The tests have served their purpose once the consumer receives the test results;<sup>183</sup> the HIV-testing kits and DTC genetic tests do not provide clinical claims about what consumers should or should not do with the information.

Some might argue that the FDA has the authority to consider negative reactions because the information could cause some consumers psychological distress, which could lead to physical harm. Although such a reaction might be related to the results, this argument improperly combines the device's purpose—to give information and nothing more—with the consumer's own decisions about how to respond.<sup>184</sup> Further, allowing the FDA to consider how test results might affect consumers effectively shifts the regulatory focus away from the safety of the device itself to allowing the FDA to act as a

---

181. For a discussion of the FDA's regulatory actions against HIV home-testing kits and DTC genetic testing services premised on concerns about consumer reactions to test results, see *supra* Parts II.B and II.C.

182. See *Paternalism vs. Empowerment*, *supra* note 10 (noting that “23andMe provides genetic information to individuals; any health and medical decisions people make based on that information are entirely separate from the services directly provided, and most (if not all) significant clinical decisions made on behalf of such information must be made utilizing additional technologies under physician consultation” and that “[i]nformation is information, and nothing more”).

183. See *id.*

184. See *id.*

gatekeeper for disseminating personal information.<sup>185</sup> Accordingly, the FDA exceeded its statutory authority when it considered these potential reactions in determining the safety of the HIV-testing kits and DTC genetic testing services.

*B. The FDA's Interpretation Is Not Entitled to Deference Because the Agency Did Not Use and Should Not Have the Relevant Expertise To Make These Considerations*

Even if the meaning of “safety” were ambiguous, the courts should not defer to the FDA’s broad interpretation of this term. While courts use several tests to determine the appropriate level of judicial deference for agency statutory interpretation,<sup>186</sup> a central theme of the Supreme Court’s deference jurisprudence is that agencies are entitled to their interpretation because they possess superior expertise.<sup>187</sup> This Section will provide an overview of the expertise-based rationale for judicial deference as a framework for analyzing the FDA’s regulation of the HIV and DTC genetic testing applications. This Note argues that although the FDA normally receives deference because of the scientific nature of its work, courts should not defer to its expansive interpretation of “safety” for medical devices because it did not use its scientific expertise when it took regulatory action. Further, the FDA should not have the relevant expertise and power to evaluate devices based on consumer reactions to test results because the agency should not make value judgments about whether consumers are capable of seeking and dealing with their own medical information.

1. *The Expertise-Based Rationale for Judicial Deference.* Though courts use several frameworks to analyze agency interpretations and actions, the Supreme Court has not given much guidance for determining the appropriate level of deference given to informal FDA

---

185. *See id.* (“Preventing people from accessing genetic tests . . . calls into question the FDA’s authority to limit the dissemination of information. In order to justify such a limitation, we would have to strip individuals of their autonomous capacities and challenge the scope of First Amendment rights to information.”).

186. *See generally* Kristin E. Hickman & Matthew D. Krueger, *In Search of the Modern Skidmore Standard*, 107 COLUM. L. REV. 1235, 1239–50 (2007) (providing a general overview of the three major deference tests: *Skidmore*, *Chevron*, and *Mead*).

187. The following section draws heavily from the works of Chaffin and Krotoszynski. *See generally* Krotoszynski, *supra* note 24 (arguing that the expertise rationale for deference has the strongest justification for judicial deference); Chaffin, *supra* note 24 (providing an overview of how agency expertise is central to the Supreme Court’s doctrine on judicial deference to agency statutory interpretation).

documents,<sup>188</sup> which the agency utilized in its actions regarding HIV-testing kits and DTC genetic testing. At least once, the Supreme Court has declined to extend *Chevron* deference to one kind of informal guidance from the FDA, but there is no clear standard among lower courts for review of informal guidances generally.<sup>189</sup> Although there is little clarity on this issue, the FDA's safety determinations can be evaluated in light of a central theme in the Supreme Court's deference jurisprudence: agency expertise is highly valued and crucial to justifying judicial deference.<sup>190</sup>

Agency expertise was the Supreme Court's traditional rationale for granting deference to agency interpretations.<sup>191</sup> In an early deference case, *Skidmore v. Swift & Co.*,<sup>192</sup> the Court established a standard for deference that was premised on a theory of agency expertise.<sup>193</sup> In explaining its rationale, the opinion noted that "the [agency's] policies are made in pursuance of official duty, based upon more specialized experience and broader investigations and information than is likely to come to a judge in a particular case."<sup>194</sup>

Even after Congress created guidance for judicial deference in the Administrative Procedure Act (APA),<sup>195</sup> two years after *Skidmore*,

---

188. K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507, 533 (2011).

189. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Court held that one type of informal guidance was not entitled to *Chevron* deference. "[B]ut courts have noted that *Wyeth's* rationale" was probably motivated by other factors unrelated to the policy's informal status. Lewis, *supra* note 188, at 533. Further, the only two appellate decisions regarding the *Christensen/Mead/Barnhart* tests, which address the level of deference owed to informal documents, came to different conclusions as to what level of deference is appropriate for these documents. *Id.* at 533–34. Additionally, an analysis of "all federal cases involving both FDA and the *Christensen/Mead/Barnhart*" tests found that "[w]hile most district court cases that address the issue withhold *Chevron* deference from informal guidance documents issued by FDA, they do so for starkly different reasons." *Id.* at 534. Thus, there is no clear answer as to what level of deference is appropriate for analyzing informal FDA documents.

190. See *supra* note 187 and accompanying text.

191. Chaffin, *supra* note 24, at 529.

192. *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

193. Krotoszynski, *supra* note 24, at 739–40.

194. *Skidmore*, 323 U.S. at 139. The Court established a balancing test for reviewing the agency's statutory interpretation: granting deference would depend upon "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* at 140.

195. The APA was enacted on June 11, 1946. The Administrative Procedure Act, Pub. L. No. 79-404, 60 Stat. 237 (codified as amended in scattered sections of 5 U.S.C. (2012)). Under section 706(2)(B), courts must "hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(B) (2012).

agency expertise continued to play a central role in deference determinations.<sup>196</sup> One year after the APA's enactment, the Supreme Court "reaffirmed expertise . . . as the source of judicial deference to agency work product."<sup>197</sup> In *SEC v. Chenery Corp.*,<sup>198</sup> the Court justified upholding an agency's interpretation of an ambiguous statute by endorsing an expertise-based rationale.<sup>199</sup> Further, the Court reiterated this justification for deference in *FTC v. Cement Institute*.<sup>200</sup> The majority opinion explained that Congress creates agencies so that they have the relevant experience and knowledge to interpret and enforce applicable federal laws.<sup>201</sup> These functions then give the agencies important expertise, which is used in decisionmaking.<sup>202</sup> Taken together, these three cases—*Skidmore*, *Chenery*, and *Cement Institute*—show the central role that expertise plays in the deference inquiry because "all invoke enhanced agency expertise as the rationale for affording agency work product deference on judicial review," even though the latter two cases were decided immediately after Congress weighed in on deference standards with the passage of the APA.<sup>203</sup>

The Court's deference jurisprudence shifted in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,<sup>204</sup> but not as

196. Krotoszynski, *supra* note 24, at 740–41.

197. *Id.* at 740.

198. *SEC v. Chenery Corp.*, 332 U.S. 194 (1947).

199. The Court noted:

The Commission's conclusion here rests squarely in that area where administrative judgments are entitled to the greatest amount of weight by appellate courts. It is the product of administrative experience, appreciation of the complexities of the problem, realization of the statutory policies, and responsible treatment of the uncontested facts. It is the type of judgment which administrative agencies are best equipped to make and which justifies the use of the administrative process. Whether we agree or disagree with the result reached, it is allowable judgment which we cannot disturb.

*Id.* at 209 (citing *Republic Aviation Corp. v. NLRB*, 324 U.S. 793, 800 (1945)).

200. *FTC v. Cement Inst.*, 333 U.S. 683 (1948).

201. Krotoszynski, *supra* note 24, at 741; *see id.* at 720 (noting that the agency's "long and close examination of the questions it here decided has provided it with precisely the experience that fits it for performance of its statutory duty").

202. *Id.* at 741; *see Cement Inst.*, 333 U.S. at 720 (noting that, in a previous case, the Court "called attention to the express intention of Congress to create an agency whose membership would at all times be experienced, so that its conclusions would be the result of an expertness coming from experience").

203. Krotoszynski, *supra* note 24, at 741.

204. *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Under the *Chevron* test, the court first determines whether "Congress has directly spoken to the precise question at issue." *Id.* at 842. If Congress's intent is clear, the agency must follow this expressed intent. *Id.* at 842–43. If the court finds that Congress did not "directly address[] the precise question at issue," and "the statute is silent or ambiguous with respect to the specific issue," the court must determine whether the agency's construction is "based on a permissible construction

significantly as one might think. Some scholars argue that the *Chevron* decision “relocated the basis for judicial deference from expertise to an implied delegation of lawmaking power.”<sup>205</sup> But there is ample evidence that *Chevron* did not erase the importance of the expertise-based rationale for deference.<sup>206</sup> In a case decided shortly before *Chevron*, the Court characterized judicial deference to “[a]n agency’s construction of its own regulations” as “traditional acquiescence in administrative expertise.”<sup>207</sup> It seems unlikely that the Court would abandon this deference justification, particularly without a clear explanation of its decision to do so, only a few years later in *Chevron*. Further, the Court in *Chevron* also explicitly recognized the role that agency expertise has in conferring deference when it noted that, unlike agencies, “[j]udges are not experts in the field” and are limited in their abilities to discern “the incumbent administration’s views of wise policy” for making judgments.<sup>208</sup> Thus, though *Chevron* certainly marked a shift in the Court’s justification for judicial deference, this change did not indicate a complete abandonment of the long established expertise-based rationale.

The Court’s most recent decisions on judicial deference suggest a resurgence in the importance of the expertise-based rationale.<sup>209</sup> In *United States v. Mead Corporation*<sup>210</sup> and *Barnhart v. Walton*,<sup>211</sup> the Court created new formulations for deciding whether the *Chevron* test applies to an agency’s interpretation at all.<sup>212</sup> In *Mead*, the Court considered whether it should defer to an agency’s informal determination—as opposed to formal processes—under *Chevron*.<sup>213</sup>

---

of the statute.” *Id.* at 843. Thus, an agency’s interpretation stands unless it is “arbitrary, capricious, or manifestly contrary to the statute.” *Id.* at 844.

205. Krotoszynski, *supra* note 24, at 742. Under this theory, agencies are entitled to judicial deference because it is implied that Congress wanted to give them interpretive discretion if the elements of the *Chevron* test are met.

206. See Chaffin, *supra* note 24, at 529 (arguing that “recent judicial precedent suggests that agency expertise remains a central rationale for judicial deference”).

207. *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 566 (1980); Chaffin, *supra* note 25, at 528.

208. *Chevron*, 467 U.S. at 865; Krotoszynski, *supra* note 24, at 743.

209. See Chaffin, *supra* note 24, at 530 (noting that recent precedent suggests “the continued centrality of agency expertise to judicial deference”).

210. *United States v. Mead Corp.*, 533 U.S. 218 (2001).

211. *Barnhart v. Walton*, 535 U.S. 212 (2002).

212. Lewis, *supra* note 188, at 529. This formulation is also known as the “*Chevron* Step Zero” analysis. *Id.*

213. See *Mead*, 533 U.S. at 221–27 (considering whether a tariff classification by the U.S. Customs Service, which did not use formal processes, was entitled to judicial deference).

The Court determined that *Chevron* analysis did not apply to the agency's informal action,<sup>214</sup> and its reasoning for doing so supports the proposition that agency expertise has a crucial role in determining judicial deference.<sup>215</sup> First, the majority opinion referenced *Skidmore*'s emphasis on expertise when describing the Court's understanding and application of deference.<sup>216</sup> Second, the Court "orient[ed] *Skidmore* deference as a function of expertise"<sup>217</sup> when it held that the agency might be able to raise a *Skidmore* claim even though the Court determined that *Chevron* did not apply.<sup>218</sup>

In the follow-up case, *Barnhart*, the Court reaffirmed and clarified *Mead*'s test for whether an agency's informal decision is entitled to *Chevron* deference.<sup>219</sup> The Court's standard in *Barnhart* also supports the expertise-based rationale for deference because it included "the related expertise of the Agency" as a factor for consideration in applying the *Chevron* test.<sup>220</sup> Thus, the reaffirmation of the expertise-based rationale in *Mead* also suggests that agency expertise is the central justification for judicial deference.

---

214. Here, the U.S. Customs Service issued a tariff classification which did not use formal processes. *Id.* at 221–24. The Court determined that this action was "far removed not only from notice-and-comment process, but from any other circumstances reasonably suggesting that Congress ever thought of classification rulings as deserving the deference claimed for them" under *Chevron*. *Id.* at 231.

215. See Krotoszynski, *supra* note 24, at 749 (noting that "Justice Souter orient[ed] *Skidmore* deference as a function of agency expertise").

216. "The fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position." *Mead*, 533 U.S. at 228 (internal footnotes omitted).

217. Krotoszynski, *supra* note 24, at 749.

218. *Id.* The Court explained that "[t]here is room at least to raise a *Skidmore* claim here, where the regulatory scheme is highly detailed, and Customs can bring the benefit of specialized experience to bear on the subtle questions in this case." *Mead*, 533 U.S. at 235.

219. See Lewis, *supra* note 188, at 531 (noting that *Barnhart* clarified the "unidentified circumstances" referenced in *Mead* for instances in which "deference could be warranted in the absence of procedural formality and force of law" (quoting Cass Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 216 (2006))).

220. See Chaffin, *supra* note 24, at 530–31 (noting that "Justice Breyer's opinion in *Barnhart v. Walton* suggests that expertise remains important to the *Chevron* analysis" because it "appears to collapse *Skidmore* and *Chevron* into a sliding scale"). The test in *Barnhart* established that courts should consider "the interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time" to determine whether "*Chevron* provides the appropriate legal lens through which to view the legality of the Agency interpretation." *Barnhart v. Walton*, 535 U.S. 212, 222 (2002).

Although the Court's major cases regarding judicial deference—*Skidmore*, *Chevron*, *Mead*, and *Barnhart*—address different issues within the process of adjudicating the appropriate level of agency deference, one justification for deference plays a critical role in all of these decisions: the expertise-based rationale. Also, this justification is often used in practice: many courts “emphasize the importance of an agency’s careful consideration and agency expertise when determining the amount of deference an agency should receive when interpreting a complex statutory scheme.”<sup>221</sup>

Furthermore, courts usually afford scientific agencies “super deference” based on the scientific nature of their statutory interpretations.<sup>222</sup> The FDA has often enjoyed this “super deference” because of its status as a scientific agency; it is typically afforded a “high level of deference” in cases interpreting its scientific or technical decisions within its realm of expertise.<sup>223</sup> For example, the District Court for the District of Columbia explained in a recent decision upholding an FDA action<sup>224</sup> that when facing an issue framed in terms of scientific and technological uncertainty, courts “must proceed with particular caution, avoiding all temptation to direct the agency in a choice between rational alternatives.”<sup>225</sup> In another case, the same court deferred to the FDA’s decision to approve a drug because the dispute was “fundamentally a scientific one over which the court lack[ed] expertise and over which the FDA is the expert.”<sup>226</sup> The court

---

221. Lewis, *supra* note 188, at 535.

222. This principle came from the Supreme Court’s decision to uphold the Nuclear Regulatory Commission’s decision about how to treat nuclear waste disposal issues. Meazell, *supra* note 25, at 741–42. The Court made it clear that the Commission was entitled to deference because of its scientific expertise: “[A] reviewing court must remember that the Commission is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.” *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983).

223. *Rempfer v. Von Eschenbach*, 535 F. Supp. 2d 99, 107 (D.D.C. 2008), *aff’d*, 583 F.3d 860 (D.C. Cir. 2009) (quoting *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998)).

224. In this case, military personnel challenged the FDA’s determination that an Anthrax vaccine was effective. *Id.* at 101.

225. *Id.* at 107 (quoting *All. for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 177 (D.D.C. 2000)).

226. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 220 (D.D.C. 1996). In this case a drug company challenged the FDA’s decision to approve a competitor’s application for a generic version of their drug. The plaintiff argued in part that the FDA’s process for establishing that the bioequivalence of the generic drug was incomplete because the agency changed its policy to only require *in vitro* testing rather than both *in vitro* and *in vivo* testing. Thus, the issue in this case was

further justified this decision by noting that the FDA “examined the relevant data and ‘articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.’”<sup>227</sup> Thus, the FDA normally receives this super deference when it acts within its scientific and technical expertise.

2. *The FDA Did Not Use and Should Not Have the Relevant Expertise To Consider How Consumers Might React to Information When Determining Whether a Device is Safe.* As this Note argues in Part II, over the past several decades the FDA has relied on its concerns about consumer reactions to test results to justify its strict regulation of devices providing personal medical information in the convenience of one’s own home.<sup>228</sup> This Note argues that the courts should not defer to this interpretation of “safety” under the MDA because these considerations regarding consumer reactions to test results do not fall under courts’ typical deference to the FDA’s scientific expertise. Further, as a policy matter, the FDA should not have the expertise to make these determinations because they involve making value judgments about access to personal medical information that are best left to individuals.

First, the FDA should not be entitled to deference under an expertise-based rationale because it did not rely on its scientific expertise when it banned HIV home-testing kits and initially restricted DTC genetic testing. As noted in the previous Section,<sup>229</sup> the FDA normally enjoys super deference because the agency has a “reputation for superior science and expertise,”<sup>230</sup> which gives the courts confidence in the FDA’s role as a “gatekeeper” for new drugs and devices.<sup>231</sup> Further, the language of the MDA suggests that scientific expertise plays a crucial role in determinations about medical devices: in the provisions that specify the qualifications relevant for members of device classification panels, areas of scientific expertise are the only

---

not whether the FDA had conducted any scientific testing, but rather whether its requirements were sufficiently rigorous. *Id.* at 214–16.

227. *Id.* at 219–20 (quoting *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (internal quotation marks omitted)).

228. For a discussion of the FDA’s regulation of HIV home tests and DTC genetic tests based on consumer protection considerations, see *supra* Part II.

229. For a discussion of the super deference that the courts usually grant the FDA as a scientific agency, see *supra* Part II.B.2.

230. James T. O’Reilly, *Losing Deference in the FDA’s Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 949 (2008).

231. *Id.*

qualifications listed.<sup>232</sup> But when the FDA considered taking its initial actions against HIV home-testing kits and DTC genetic testing services, it did not use scientific expertise. The FDA did not demonstrate in its statements or enforcement actions that it relied on studies or data showing that people would react a certain way,<sup>233</sup> rather, it based its decision on unsubstantiated assumptions about potential negative reactions from consumers.

When considering whether to ban applications for HIV home-testing kits, the FDA relied on testimony focusing on concerns about how people would respond to receiving results.<sup>234</sup> When the FDA reconsidered and ultimately overturned the ban, it attempted to cloak its reasoning in scientific considerations, citing as motivating factors “scientific and technological developments and the changing nature of the HIV epidemic.”<sup>235</sup> In reality, the scientific community’s understanding of the importance of diagnostic tools in the fight against HIV had not wavered during the five-year ban.<sup>236</sup> In fact, one company even applied for approval for testing devices using “essentially the same data” from studies conducted before the ban.<sup>237</sup> This evidence indicates that the FDA did not utilize its scientific expertise in considering the safety of the HIV home-testing kits. Rather, it relied on fears unsupported by scientific data.

Similarly, the FDA also premised its significant restrictions on DTC genetic testing on overprotective considerations of consumer safety instead of on scientific findings. Before it sent the Warning Letter to 23andMe, its recommended restrictions on genetic tests were based at least in part on concerns about consumer behavior.<sup>238</sup> And when the FDA sent 23andMe the Warning Letter, it notified 23andMe

---

232. For a discussion of the statutory requirements for device classification panels, see *supra* notes 50–52 and accompanying text.

233. For a discussion of the FDA’s reliance on speculation about consumer responses to HIV and DTC genetic test results for restrictively regulating both types of devices, see *supra* Parts II.B and II.C.

234. For a discussion of testimony given on the danger of allowing HIV home-testing at the FDA’s public forum for its ban on device applications, see *supra* notes 102–04 and accompanying text.

235. For a discussion of the FDA’s proffered rationale for overturning the ban, see *supra* notes 112–13 and accompanying text.

236. For a discussion of the enduring importance of diagnostic tools to combat the spread of HIV throughout this time period, see *supra* notes 117–18 and accompanying text.

237. FDA Blood Prods. Advisory Comm., *supra* note 120.

238. For a discussion of the FDA Molecular and Clinical Genetics Panel’s early concerns about consumer reactions to DTC genetic testing results, see *supra* notes 141–43 and accompanying text.

that it was concerned about consumers using the test results as the sole basis for taking drastic actions, noting that certain genetic test results could prompt individuals to discontinue medical therapies or undergo unnecessary treatments.<sup>239</sup> Although the FDA has approved some carrier and disease-risk tests, it forced 23andMe to meet cumbersome requirements to demonstrate clinical validity during this process.<sup>240</sup> Additionally, the FDA seems unwilling to consider approving tests for important genetic information, such as the BRCA breast cancer genes, simply because the results could be used for diagnostic purposes.<sup>241</sup> The FDA's expressed fears about potential negative reactions, swift action against DTC genetic testing manufacturers, and strict clinical validity requirements indicate that the agency is acting at least partially on concerns about whether consumers can effectively weigh the risks and benefits of seeking this information.

In both cases—the HIV-testing kits and DTC genetic tests—the FDA based its decisions to restrict consumers' access to their own medical information on notions of consumer protectionism rather than on scientific inquiries into the safety and effectiveness of the devices. This basis is unlike that used in cases in which courts defer to the FDA's judgment. For example, in *Bristol-Myers Squibb Co. v. Shalala*,<sup>242</sup> the District Court for the District of Columbia deferred to a drug approval decision by the FDA not only because the dispute was “a scientific one” in which “the FDA is the expert,” but also because the FDA had “examined the relevant data and ‘articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.’”<sup>243</sup> Although the HIV-testing kit and DTC genetic testing cases deal with the FDA's determinations on the safety of the devices, a court's rationale for deferring to the FDA's decisions should be the same—it should rely on studies and show a reasonable connection between the data and its conclusions. The FDA

---

239. For a discussion of the Warning Letter, see *supra* note 147 and accompanying text. Although the FDA has a legitimate concern that the tests might give false positive results, it should be noted that “most (if not all) significant clinical decisions made on behalf of such information must be made utilizing additional technologies under physician consultation.” *Paternalism vs. Empowerment*, *supra* note 10.

240. For a discussion of the requirements that the FDA placed on 23andMe for demonstrating the analytical and clinical validity of these tests, see *supra* notes 150, 157–58 and accompanying text.

241. For a discussion of the FDA's rationale for effectively banning DTC genetic tests that could be used for diagnostic purposes, see *supra* notes 165–66 and accompanying text.

242. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212 (D.D.C. 1996).

243. *Id.* at 219–20 (internal quotation marks omitted).

did not do this data-based or scientific analysis when it banned HIV home-testing-kit applications or when it placed burdensome restrictions on DTC genetic testing manufacturers like 23andMe. Instead, the FDA simply asserted that it had these concerns, suggesting that its fears over how consumers might use the information sufficiently justified its actions. Accordingly, courts should not afford the FDA the deference that it typically enjoys as a scientific agency because, in these instances, it did not use its scientific expertise when it considered potential consumer reactions to the information given by these devices.

Not only did the FDA not use its expertise to make these determinations, but, as a policy matter, courts should not defer to the agency's expansive interpretation of "safety," even if the FDA used the relevant expertise and based its restrictions for these devices on scientific data about consumer reactions. The FDA certainly has the ability to convene advisory panels to consider the scientific evidence on the analytical validity of these devices to ensure that they give accurate results,<sup>244</sup> and it can weigh the benefits of a device with the risks of potential side effects or direct physical harms. However, when evaluating the safety of a purely informative device, the FDA should not be permitted to consider the actions that consumers might take after receiving test results for two reasons.

First, considering how consumers will react to test results disregards the distinction between "providing information and providing opportunities to act upon information."<sup>245</sup> The DTC genetic test has fulfilled its entire purpose once the consumer receives the result; any action taken by the recipient in response to the information is "entirely separate from the services directly provided."<sup>246</sup> For instance, 23andMe's test results—interpretations of genetic variants—"relate only indirectly to preventing or diagnosing disease."<sup>247</sup> Using these interpretations is thus analogous to "inferences drawn about

---

244. These considerations would certainly constitute ensuring "safety and effectiveness" under the MDA because one of the motivating factors for passing the statute was giving the FDA greater authority to take action against ineffective and fraudulent devices. Further, the MDA provides that device classification panels are comprised of individuals with the relevant scientific expertise for evaluating the "safety and effectiveness of devices." For further discussion of the classification panel, see *supra* notes 50–51 and accompanying text.

245. *Paternalism vs. Empowerment*, *supra* note 10.

246. *Id.*

247. Green & Farahany, *supra* note 2, at 286.

rapid weight loss measured by a bathroom scale.”<sup>248</sup> Additionally, most significant clinical decisions made after receiving genetic test results, such as a woman getting a mastectomy in response to learning that she has a high risk of getting breast cancer, require further testing and physician consultation.<sup>249</sup> Accordingly, the FDA should not consider potential consumer reactions to information when determining whether a device is “safe” because those considerations are outside the scope of the device’s purpose.

Second, we should not give the FDA the ability to weigh the costs and benefits of potential reactions because these considerations involve value judgments that take effective testing options out of the hands of consumers. Some might argue that social scientists, psychologists, and other experts on human behavior could serve on FDA advisory panels to help the agency make these determinations. This argument ignores the underlying problem with these considerations; in making these inquiries, the FDA steps into the shoes of the consumer and decides whether she can be trusted with weighing the benefits of learning the results against the potential risks of an upsetting outcome. Essentially, the FDA is making a paternalistic value judgment—that it is better to ensure zero negative reactions by limiting consumer access to this information across the board than to allow people to make their own choices about whether the tests are appropriate for them. However, consumers are able to make assessments about the risks and benefits of pursuing DTC genetic testing for themselves, especially in light of the abundance of online resources available regarding genetic testing and gene variants.<sup>250</sup>

The value judgments based on concerns about consumer reactions to test results are similar to one of the predominant motivations underlying the FDA’s early seizure of pregnancy tests—that women should only get test results in a clinical setting.<sup>251</sup> There, the FDA did not trust women with information about their pregnancy. In the case

---

248. *Id.*

249. See *Paternalism vs. Empowerment*, *supra* note 10 (noting that any “significant clinical decisions made on behalf of [information from test results] must be made utilizing additional technologies under physician consultation”).

250. For instance, the NIH has created a “Genetics Home Reference,” which “provides consumer-friendly information about the effects of genetic variation on human health.” *Genetics Home Reference*, NIH U.S. NAT’L LIBRARY MED. (2017), <https://ghr.nlm.nih.gov> [<https://perma.cc/MUN6-4T5R>]. This website seems to cover all aspects of genetic testing and is aimed at public consumption. *Id.*

251. For a discussion of the FDA’s early hostility towards pregnancy tests, see *supra* Part II.A.

of DTC genetic testing, the FDA does not trust consumers with information about their genetic variants linked to certain diseases or conditions. After decades of home pregnancy test use, this overprotective FDA action is almost unimaginable; although some women might be distraught by their test results, we trust their personal judgment in seeking this information through home pregnancy tests. This rationale should apply to all devices that seek solely to provide personal medical information, such as DTC genetic testing, as long as the test meets the normal standards for safety and effectiveness.

Ultimately, the FDA's self-prescribed role as a gatekeeper of personal medical information significantly interferes with individual autonomy.<sup>252</sup> The FDA's current restrictive regulation of DTC genetic testing significantly limits access to genetic information. Before 23andMe received the FDA Warning Letter, it was offering over two hundred health reports based on genetic test results for ninety-nine dollars.<sup>253</sup> Currently, consumers must go to a medical professional to access those genetic tests that 23andMe offered, but which the FDA has still not approved.<sup>254</sup> These tests ordinarily cost between one hundred and two thousand dollars each,<sup>255</sup> and also involve other hurdles, including access issues in nonmetropolitan areas, concerns about confidentiality of medical records, and genetic discrimination.<sup>256</sup> Thus, courts should adjudge the FDA's value judgment in its efforts to restrict DTC genetic testing impermissible because it relies on overprotective notions of consumer safety and severely limits individuals' access to their own medical information.

---

252. See *Paternalism vs. Empowerment*, *supra* note 10 (“Preventing people from accessing genetic tests . . . calls into question the FDA’s authority to limit the dissemination of information. In order to justify such a limitation, we would have to strip individuals of their autonomous capacities and challenge the scope of First Amendment rights to information.”).

253. Hof, *supra* note 1.

254. See *Help Me Understand Genetics: How Is Genetic Testing Done?*, NIH U.S. NAT’L LIBRARY MED. 8 (2017), <https://ghr.nlm.nih.gov/primer/testing/procedure> [<https://perma.cc/Z7SF-UCZJ>] (explaining that “[o]nce a person decides to proceed with genetic testing, a medical geneticist, primary care doctor, specialist, or nurse practitioner can order the test”).

255. *Help Me Understand Genetics: What Is the Cost of Genetic Testing, and How Long Does It Take To Get the Results?*, NIH U.S. NAT’L LIBRARY MED. 17 (2017), <https://ghr.nlm.nih.gov/primer/testing/costresults> [<https://perma.cc/M8YJ-7TXG>].

256. Kathryn Hock et al., *Direct-to-Consumer Genetic Testing: An Assessment of Genetic Counselor’s Knowledge and Beliefs*, 13 GENET. MED. 325, 326 (2011).

## CONCLUSION

Over the past several decades, the FDA has successfully restricted consumers' access to home-testing applications based on a paternalistic notion of protecting them from their own potential reactions to test results. In the 1970s, the FDA wanted to restrict women's access to pregnancy tests and keep these devices in the hands of laboratories. Throughout the late 1980s and 1990s, the FDA categorically banned applications for HIV home-testing technology based on the fear that consumers could not handle the results without the assistance of a counselor. And more recently, the agency placed burdensome restrictions on DTC genetic testing companies because it was concerned that consumers would make irrational medical decisions based on genetic variant results. These restrictions illustrate a disturbing trend with major consequences for current and future technologies. Ultimately, the FDA's decision to act as gatekeeper, limiting consumers' access to their medical information, is premised on an impermissible value judgment that significantly restricts individual autonomy.