Over the Counter but
Under the Radar:
Direct-to-Consumer Genetics Tests
and FDA Regulation of
Medical Devices

ABSTRACT

Direct-to-consumer genetic tests are laboratory-developed tests that are marketed and sold directly to consumers. They typically do not require a prescription or any other involvement from a consumer’s health care provider. Consumers order these tests online and return a specimen, usually a saliva sample, directly to the laboratory. The results are mailed directly to the consumer, and no health care provider or insurance company need ever learn the contents of these results. The FDA does not currently regulate direct-to-consumer genetic tests, though tests for hundreds of different diseases are readily available to the public.

The FDA’s approach to regulating genetic tests is not uniform. The FDA regulates “test kits,” or genetic tests developed by a manufacturer independent from the clinical laboratory that distributes them, as medical devices. These test kits are not available directly to consumers; instead, the laboratories send them to health care providers for patient diagnosis.

Absence of FDA regulation of direct-to-consumer genetic tests means that consumers utilize these tests without any assurance of their reliability, accuracy, or usefulness in helping individuals make prudent health care decisions. Furthermore, individuals often receive their test results directly from the laboratory without any formal genetic counseling regarding the meaning of these results, which are often less straightforward than consumers may expect.

This Note differentiates between test kits and home brews, identifying the hazards that direct-to-consumer genetic tests pose to the public due to the fact that they are unregulated. It also analyzes the FDA regulatory process that medical devices undergo in order to be marketed and sold. Finally, the Note advocates for FDA regulation of
direct-to-consumer genetic tests as medical devices, just as test kits are, based on the protections that this regulatory process affords consumers.

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Notions of patient autonomy and informed consent are paramount in clinical research in the United States. Such ethical

1. Nat’l Insts. of Health, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979), http://ohsr.od.nih.gov/guidelines/belmont.html [hereinafter THE BELMONT REPORT] (requiring that researchers treat their research subjects as autonomous individuals, and that researchers fully inform their subjects about the potential risks and benefits that stem from participation in a particular research study). An autonomous individual is one who is
constructs extend to general patient care, as physicians are now discouraged from abiding by the traditional professional paradigm of medical care, under which “professionals, as experts, make core decisions for patients,” and instead are encouraged to treat patients as informed consumers who should actively participate in medical decision-making. As consumers become more sophisticated and informed about their medical care, their desire to know more about any underlying medical conditions they may have is inevitable, as this information is vital to their ability to make educated decisions about their care.

Genetic tests offer consumers a figurative crystal ball with respect to their need for medical information. Medical history can be fairly easily obtained through inspection of medical records, but only within the last few decades have individuals been able to obtain information about their medical predispositions, as well as the predispositions of their unborn children. Simple methods of DNA extraction, such as a cheek swab or blood sample, allow doctors to diagnose an individual’s current illness, future illness, or future health risks. These tests also allow physicians to predict future drug responses, as well as genetic disorders that an individual’s child may inherit.

“capable of deliberation about personal goals and of acting under the direction of such deliberation.” Id. Informed consent may be described as a voluntary decision that an individual makes to undergo a treatment, test, or procedure, with enough information, and sufficient understanding of the treatment, test, or procedure to which he consented. See id.


4. Editorial, Getting a Grip on Genetic Testing, NATURE MED., Feb. 2003, at 147 (noting that while genetic tests may seem like crystal balls to those who know little about genetics, the “subtleties of genetics” are such that it is important to have a genetic counselor help to interpret genetic test results that are likely to be more complicated than initially thought).

5. See Nancy Press, Genetic Testing and Screening, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 72, 72-73 (Mary Crowley ed., 2008), available at http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/genetic%20testing%20chapter.pdf (explaining that modern genetic testing and counseling has been available since the early 1970s, when prenatal testing emerged).


7. Burke, supra note 6, at 1867.
Genetic testing through one’s family physician or through a genetic specialist is fairly simple, often only requiring a phone call and a visit to the physician or laboratory where a biological sample will be taken and analyzed. However, the advent of science has made it easier for those who prefer that their test results be excluded from their medical records, or even those who dislike visiting a doctor’s office, to undergo genetic testing. With just a click of the mouse, a consumer interested in learning more about his genetic composition can place an order via the Internet for a laboratory test that will be mailed directly to him. The test typically requires the consumer to send a cheek swab back to the laboratory, and the results are then either directly mailed to the individual, or made accessible to the consumer on a secure website. No physician’s visit is required, and the test result never makes its way into the consumer’s medical record.

Such laboratory tests, commonly referred to in scientific journals and in the media as direct-to-consumer genetic tests or “home

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8. See Cheryl Berg & Kelly Fryer-Edwards, The Ethical Challenges of Direct-to-Consumer Genetic Testing, 77 J. BUS. ETHICS 17, 19 (2008) (noting that a benefit of direct-to-consumer genetic testing is that it saves the patient the fee that he would otherwise pay for the visit during which he underwent genetic testing, as well as the laboratory fee that the patient would incur).

9. A.J. Wolfberg, Genes on the Web – Direct-to-Consumer Marketing of Genetic Testing, 555 NEW ENG J. MED. 543, 544 (2006) (“[Direct-to-consumer genetic testing] provide[s] consumers who are concerned about genetic discrimination the opportunity obtain testing and genetic counseling without the results becoming part of their medical record.”). See also Berg & Fryer-Edwards, supra note 8, at 19 (noting that direct-to-consumer genetic tests eliminate the need to schedule a doctor’s appointment as well as the need to sit in a doctor’s office waiting room with sick people).


12. DNA Direct, for example, provides a consumer with a letter that he can give at his discretion to his physician that describes the test and its results. See DNA Direct, supra note 10.
brews,” are becoming more widely utilized due to their convenience and confidential nature. With these advantages, however, come significant disadvantages. Unlike genetic tests conducted in a physician’s office, commonly referred to as “test kits,” direct-to-consumer genetic tests are not regulated by the Food and Drug Administration (FDA). As a result, there is an increased chance of inaccuracy or ineffectiveness in detecting genetic disorders or conditions. Furthermore, consumers often receive the results without any counseling regarding the interpretation of these results, leaving an individual to interpret potentially life-changing information on his own.

Similar tests available through one’s personal physician, however, are regulated by the FDA, generally as Class II medical devices. They are subject to strict standards by which the FDA determines whether the device is sufficiently safe and effective to be sold on the open market. All approved medical devices are also subject to some form of additional FDA oversight after they are commercially distributed to further ensure their safety and effectiveness.

13. See Berg & Fryer-Edwards, supra note 8, at 19; Wolfberg, supra note 9, at 544. Direct-to-consumer genetic tests may also be referred to as “laboratory-developed tests” because the laboratories that create the tests are distributing them directly to the consumer. See infra text accompanying note 36.

14. See infra note 29 and accompanying text (discussing test kits).


16. See U.S. Food and Drug Administration, Classify Your Medical Device, http://www.fda.gov/cdrh/devadvice/313.html (last visited Apr. 2, 2009) (explaining that medical devices are regulated in such a way as to ensure their safety and efficacy for their users, e.g., by classifying medical devices according to risk level). Thus, because direct-to-consumer genetic tests do not undergo required external review processes prior to or after the marketing and sale of the tests, there is, by analogy, less assurance of their safety, accuracy, and efficacy.

17. See Douglas A. Grimm, FDA, CLIA, or a "Reasonable Combination of Both": Toward Increased Regulatory Oversight of Genetic Testing, 41 U.S.F. L. REV. 107, 112 (2006). Although physicians who conduct genetic testing in their offices may offer some sort of genetic counseling, some believe that only physicians who specialize in genetic disorders or conditions are in the best position to offer counseling regarding the results of a genetic test. Michael J. Malinowski & Robin J.R. Blatt, Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards, 71 TUL. L. REV. 1211, 1245 n.110 (1997).


Part I of this Note describes the types of genetic tests that are presently available to consumers and identifies the genetic tests that the FDA regulates. Part II discusses the issues that arise because direct-to-consumer genetic tests are not subject to FDA regulation. Next, Part III analyzes the classification and review process that the FDA uses to regulate medical devices. Part IV advocates for legislation mandating FDA review, approval, and oversight of all genetic tests, and explores alternative means of regulating direct-to-consumer genetic tests.

I. UNDERSTANDING GENETIC TESTS AS MEDICAL DEVICES

A. Introduction to Genetic Testing

In the late nineteenth century, Gregor Mendel studied how physical characteristics were passed through generations of pea plants. Mendel’s research is the foundation of our modern understanding of genetics—and in particular, our understanding of how dominant and recessive traits are inherited and manifested. Mendel’s research is applicable and vital today, because “[f]or better or for worse, people . . . want to know about their genomes. The human mind is prone to essentialism—the intuition that living things house some hidden substance that gives them their form and determines their powers.”

A genetic test is “the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes.” Genetic testing is now “a mainstream part of medical care” and is used to (1) diagnose genetic diseases in newborns, children, and adults; (2) identify a genetic disorder that has not yet presented in newborns, children, and adults; (3) predict drug responses; and (4) assess risks to future children.

22. Id.
24. Burke, supra note 6, at 1867.
26. Id.
More than 1,600 biological tests are currently available to detect genetic diseases or conditions.\(^{27}\)

**B. Types of Genetic Tests**

One way for an individual to undergo genetic testing is to visit a health care provider, such as a family physician or genetic specialist, who will obtain the necessary specimen for analysis.\(^{28}\) Genetic tests that are available through a physician or other medical professional are known as “test kits.”\(^{29}\) The test kits include the ingredients, called reagents, needed to perform the test, instructions for performing the test, and information on the mutations that the test will detect.\(^{30}\) The laboratory that analyzes the specimen does not generally manufacture the test kits itself; instead, a separate, generally unaffiliated company manufactures the test kits that are then are sold to the laboratory.\(^{31}\) Usually, a physician sends the individual’s specimen to a laboratory that analyzes the sample to determine whether the patient possesses the genetic marker about which he is concerned.\(^{32}\) Results are reported to the physician, who then consults with the patient about the test results.\(^{33}\)

The FDA regulates test kits such as in vitro diagnostic devices (IVDs).\(^{34}\) Thus, every aspect of the manufacturing, sale, and monitoring of these test kits is regulated, though the level of regulation to which these test kits are subject varies depending on the risks associated with the particular test.\(^{35}\)

Recently, however, clinical laboratories have begun selling genetic testing services directly to consumers.\(^{36}\) These tests are...
typically purchased over the Internet and mailed directly to the consumer, who provides a specimen—usually a saliva sample or cheek swab—and returns it directly to the laboratory. The laboratory then analyzes the specimen and reports the results directly to the consumer either by mail or on a secure website. No physician’s visit is required to obtain either the test or its results, which makes these home brews very convenient for consumers. Consumers receive the test results in the privacy of their homes and the results are not included in a medical record nor are they reported to any insurance companies or public health officials. However, these results may be provided without any interpretation or formal genetic counseling.

C. FDA Regulation of Medical Devices

The FDA has indicated that it is within its statutory mandate to regulate direct-to-consumer genetic tests, yet the agency declines to do so. The Food, Drug, and Cosmetic Act of 1938 (FDCA) authorizes order the test in lieu of the individual’s own health care provider. "Id. Also worth noting is that commercial distribution of diagnostic devices directly to consumers is not new. One commonly known test that is marketed directly to consumers for diagnosis of a medical disease or condition is the home pregnancy test. Home pregnancy tests first became available for commercial distribution in the mid-1970s, are sold today at most drug stores in the United States, and are relatively inexpensive to buy, costing around $20. The Office of NIH History, A Timeline of Pregnancy Testing, http://history.nih.gov/exhibits/thinblueline/timeline.html (last visited Apr. 2, 2009). See also CVS.com, http://www.cvs.com (last visited Apr. 2, 2009) (listing various pregnancy tests for sale). Cf. Lynch, supra note 11 (noting the cost of direct-to-consumer genetic tests). Home pregnancy tests, unlike direct-to-consumer genetic tests, however, are regulated by the FDA as IVDs. Gail H. Javitt, Erica Stanley & Kathy Hudson, Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can’t) Do to Protect the Public’s Health, 57 OKLA. L. REV. 251, 271-72 (2004). The FDA approved the first home pregnancy test in 1976. A Timeline of Pregnancy Testing, supra. In fact, the Medical Device Amendments of 1976 revised the definition of “medical device” to include the phrase “and other conditions” to allow for FDA regulation of pregnancy tests. Elizabeth C. Price, Does the FDA Have Authority to Regulate Human Cloning?, 11 HARVARD J. L. & TECH. 619, 635 (1998). 37. Hogarth et al., supra note 15, at 162. 38. See Wolfberg, supra note 9, at 543–44. 39. See id. at 543. 40. See id. at 544. This means, for example, that test results may report the presence of a gene sequence which is linked to a risk of developing a particular disease, but the results may not indicate what the incidence of disease is with respect to that sequence. See also Getting a Grip on Genetic Testing, supra note 4 (explaining that genetic counseling is important because of the complexity of genetic test results). 41. Genetics & Public Policy Center, Who Regulates Genetic Tests? (May 30, 2008), http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=10 (last visited Apr. 2, 2009). In 2007, however, the FDA issued guidance addressing a subset of laboratory-developed tests called in vitro diagnostic multivariate assays (IVDMIAs). See infra notes 170-172 and accompanying text (describing manufacturers’ resistance to regulation of the FDA's regulation of IVDIMAs).
the FDA to regulate the manufacture and sale of food, drugs, and cosmetics, and the Act has been amended numerous times to clarify the scope of the FDA’s ability to regulate.\footnote{Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 (2009).}

The FDCA defines a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is,” among other things, “intended for use in the diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.”\footnote{21 U.S.C. § 321(h)(2).}

A textualist interpretation of this definition suggests that any type of genetic test, whether it is marketed directly to the consumer or not, is a medical device because it is used for a defined purpose: to diagnose or prevent a disease.\footnote{Id.}

The FDA, however, has limited its regulation of genetic tests as medical devices to the physician-supervised test kits that are administered in physicians' offices.\footnote{Hogarth et al., supra note 15, at 172. See infra notes 169 & 172 and accompanying text (explaining that despite this definition, some opponents of FDA regulation of direct-to-consumer genetic testing argue that such testing is in fact a service and not a medical device, and thus not within the FDA's jurisdiction to regulate).}

The agency regulates some components that are part of the home brews, but it does not regulate these tests as a whole.\footnote{The fact that the FDA regulates some of the components of direct-to-consumer genetic tests, e.g., analyte specific reagents, see infra notes 47-51 and accompanying text, could serve as a compelling argument for FDA regulation of the tests as a whole.}

For example, clinical laboratories use ingredients called analyte specific reagents (ASRs), which are the active ingredients of a laboratory test that is used to diagnose genetic conditions.\footnote{Testimony on Technological Developments in Genetic Testing Before the Subcomm. on Tech. of the H. Comm. on Science, 104th Cong. (1996) (statement of Mary K. Pendergast, Deputy Comm’r and Senior Advisor to the Comm’r, U.S. Food and Drug Administration), available at http://www.hhs.gov/asl/testify/t960917c.html.}

The FDA regulates “ASRs that move[ ] in interstate commerce and . . . exempt[s] ASRs created in-house and used exclusively by the same laboratory for in-house testing.”\footnote{Gregorio M. Garcia, The FDA and Regulation of Genetic Tests: Building Confidence and Promoting Safety, 48 Jurimetrics J. 217, 227 (2008).}
regulation, even if the components of the tests are sold through interstate commerce, the FDA does not regulate the test as a whole. Furthermore, the “corresponding in-house genetic tests” are exempt from regulation, which means that laboratory-made ASRs that do not move in interstate commerce, along with the direct-to-consumer tests as a whole escape FDA regulation.

II. THE IMPACT OF THE LACK OF REGULATION OF DIRECT-TO-CONSUMER GENETIC TESTS

A. Effect on Clinical Validity, Clinical Utility, and Analytic Validity

Absence of any regulation means that consumers utilize home brew tests without any assurance of their clinical validity, clinical utility, or analytic validity. The sensitive nature of the DNA sample and the test results mean that these assurances with respect to genetic tests are essential for maintaining public health.

B. Concerns Related to Genetic Counseling

However, even if the home brew’s test results are accurate, many companies that sell these tests do not offer counseling to explain the meaning of the results to consumers who have undergone testing. The psychological impact of genetic test results may be extreme, particularly if the test results reveal unfavorable information to the consumer. Many conditions or disorders that genetic tests identify, such as Huntington’s disease, Gaucher’s disease, and Alzheimer’s disease, are incurable or offer limited treatment options.

49. See infra text accompanying notes 174-188 (discussing the regulations to which clinical laboratories are subject).
51. Id.
52. Javitt & Hudson, supra note 29, at 61. Analytic validity is defined as “the accuracy with which a particular genetic characteristic — such as a DNA sequence variant, chromosomal deletion or biochemical indicator — can be identified in a given laboratory test.” Wylie Burke & Ron L. Zimmern, Ensuring the Appropriate Use of Genetic Tests, 5 NATURE REVIEWS: GENETICS 955, 958 (2004). Clinical validity is defined as “the accuracy with which a test identifies or predicts a patient’s clinical status.” Id. Clinical utility is defined as “the risks and benefits resulting from test use.” Id.
53. Grimm, supra note 17, at 111-12.
55. Gniady, supra note 21, at 2431. Huntington’s disease is a genetic, neurological disorder that causes progressively “frequent, irregular, sudden jerks and movements of any of the limbs or trunk,” faulty speech, and an impaired memory. 2 HARRISON’S PRINCIPLES
Receiving a diagnosis of an incurable disease will likely change an individual’s perception of himself, his life, and how he plans to spend his remaining time.\footnote{56} Without a physician interpreting the test results, individuals may easily misunderstand the results of a home brew test.\footnote{57} In serious cases, individuals may interpret a test result as indicative of certain death, which could lead to “severe psychological trauma and [possibly] suicide.”\footnote{58} These extreme consequences might otherwise be avoided with a physician’s counseling.

\textbf{C. Knowledge is Not Always Power}

Additionally, individuals may go to great lengths to prevent the occurrence of conditions that pose risk to them. For example, women may undergo genetic testing to determine whether they carry the genes linked to an 85 percent likelihood of developing breast cancer.\footnote{59} Some women who learn that they possess the genes may elect to undergo a prophylactic double mastectomy rather than risk a breast cancer diagnosis later in life.\footnote{60} An inaccurate test result could therefore be devastating for an individual who undergoes such surgery.

Also of concern is “the release of the genetic test results or genetic materials to third parties to whom the individual never intended to impart the information or material.”\footnote{61} Some genetic testing services that market to consumers online allegedly sell their customers’ genetic information to research institutions.\footnote{62} The privacy and confidentiality issues, as well as property rights issues, associated

\footnote{56}{For example, an episode of \textit{House} featured a patient threatening Dr. Wilson, an oncologist, with a lawsuit because Dr. Wilson had incorrectly diagnosed him with cancer three months earlier. The patient claimed that the diagnosis allowed him to live in the present, and as a result, learning that he was not dying actually detracted from his happiness. \textit{House: Games} (FOX television broadcast Nov. 27, 2007).}


\footnote{58}{Id.}


\footnote{60}{Id.}

\footnote{61}{Kohlmeier, supra note 57, at 5.}

\footnote{62}{Id. at 26-27.}
with selling this information could have serious implications for the individual as well for his family members to whom the test results may be relevant.\textsuperscript{63} Although the genetic testing services may inform consumers that their genetic material or information may be sold to third parties and used for research purposes, questions arise as to whether individuals are aware of this practice and understand the ramifications of consenting to this use of their genetic material.\textsuperscript{64}

Also problematic is the fact that direct-to-consumer genetic tests, which are not FDA-regulated, are heavily marketed to consumers.\textsuperscript{65} However, because of the lack of assurance of these tests' clinical validity, clinical utility, or analytic validity,\textsuperscript{66} they may actually pose a public health hazard.\textsuperscript{67} Although the Federal Trade Commission (FTC) is authorized to regulate advertisement of direct-to-consumer genetic tests, critics contend that the FTC has declined to take action against these advertisements that may be false or misleading.\textsuperscript{68}

\begin{itemize}
\item \textsuperscript{63} Id. at 5. For example, an individual with Huntington's disease has a 50 percent chance of passing on the Huntington's disease gene. 2 HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, supra note 55, at 2354. Thus, a mother's diagnosis has implications for her child, who may have inherited the gene. See id. A breach of confidentiality with respect to this information, which could occur if identifying information is transmitted in addition to the test results, could cause the child to learn information that her mother was not ready to share.

\item \textsuperscript{64} Kohlmeier, supra note 57, at 27. See The Belmont Report, supra note 1 (defining "informed consent").

\item \textsuperscript{65} Critics of direct-to-consumer marketing of genetic tests allege that these advertisements "(1) fail[] to adequately explain complex genetic information; (2) [are] misleading in [their] failure to disclose the risks and limitations of testing; (3) allow[] tests without established clinical validity or utility to be promoted; and (4) do[] not include the counseling needed to put test results in proper context." Javitt, Stanley & Hudson, supra note 36, at 253.

\item \textsuperscript{66} See supra note 52 (defining clinical validity, clinical utility, and analytic validity).

\item \textsuperscript{67} See Jane E. Henney, Challenges in Regulating Direct-to-Consumer Advertising, 284 JAMA 2242, 2242 (2000) (describing the public health concerns that direct-to-consumer advertising of pharmaceuticals may pose, concerns which may, by analogy, be extended to medical devices). Consumers may make health care decisions based on inaccurate test results, or test results which require more genetic counseling to understand than is offered by the laboratory. Alternatively, as Henney suggests, the use of these tests may cause tension between physicians and their patients, thus prompting consumers to seek advice from their physicians less frequently. See id.

\item \textsuperscript{68} Javitt & Hudson, supra note 29, at 67. The FTC must assure that advertisements are not false or misleading. 15 U.S.C. § 45 (2006). The lack of enforcement has, to some extent, been attributed to a lack of resources. Javitt & Hudson, supra note 29, at 67.
\end{itemize}
D. A New Concern

The ability of entrepreneurs to offer genetic tests on the open market also means that consumers may use genetic testing for purposes unrelated to their health.69 For example, a new online dating service called Scientific Match presents a novel use for DNA collected via a genetic test available directly to consumers70—matchmaking for individuals who pay a fee and submit a DNA sample to the company’s laboratory.71 The company believes, based on a scientific study done in Europe approximately a decade ago, that individuals may find their soul mates through a system that matches people with differently composed immune systems.72

Scientific Match’s concept of DNA-based matchmaking is based on observations that women are more attracted to the scent of men with opposite major histocompatibility complexes, a component of the immune system.73 Individuals who register for the Scientific Match service complete a questionnaire that provides information about their marital status, criminal background, and personality, and submit a DNA sample, which is forwarded to a clinical laboratory.74 Scientific Match then analyzes the questionnaire responses and the DNA samples, and matches couples based on this information.75 The evaluation of DNA for matchmaking purposes represents a new concept for U.S. clinical laboratories, and the existence of companies like Scientific Match exemplifies a way in which home brew tests may be marketed to consumers if they remain unregulated.

The FDA’s refusal to regulate direct-to-consumer genetic tests has cleared the way for these types of business enterprises in the Internet marketplace, which means that genetic tests may now be marketed to consumers for strictly commercial purposes rather than for detecting diseases.76 Companies are more frequently offering genetic tests that detect issues that are not medically related, since many individuals are not only “interested in whether they have a ‘predisposition’ to, or elevated risk for, developing any of a number of

70. Id.
71. See id.
73. The Scent of a Woman (and a Man), THE ECONOMIST, Jan. 12, 2008, at 73.
74. Id.; Scientific Match, supra note 69.
75. Scientific Match, supra note 69.
76. The fact that modern genetic testing really began with prenatal testing to detect genetic diseases or conditions in unborn fetuses indicates that the initial purpose of genetic testing was to detect disease or diagnose an illness. See Press, supra note 5, at 73.
major diseases” but also whether they are at risk for “more benign social traits, such as baldness or intelligence . . . .”

Although Scientific Match purports to destroy all DNA samples after it has completed genetic testing, one cannot ignore the privacy and confidentiality risk that individuals incur by offering DNA samples to such an enterprise. The company’s website also notes that it restricts its examination to genes related to the immune system, and will not seek to diagnose any genetic conditions or disorders.

While the Scientific Match home page interestingly assures customers that their “genetic privacy is much more vulnerable when [they] get a haircut, or drink from a glass at a restaurant,” the “Your Privacy” page ignores the privacy issues associated with the collection of DNA samples and only discusses consumers’ privacy as it relates to the criminal background checks.

The scientific merit of such a matchmaking system is outside the scope of this Note; however, Scientific Match’s unique use of DNA raises interesting questions about the marketing, sale, and use of direct-to-consumer genetic tests. The lack of federal oversight of direct-to-consumer genetic tests means that such tests may easily be used for non-scientific or questionable scientific purposes, costing some consumers a great deal of money for very little valuable information.

It may furthermore affirm the general skepticism that direct-to-consumer genetic testing “opens up a niche for bottom-

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78. Scientific Match, supra note 69.


80. Scientific Match, supra note 69; c.f. Scientific Match, Your Privacy Is Our Top Concern, http://www.scientificmatch.com/html/your_privacy.php (last visited Apr. 2, 2009). This Note makes no comment on the accuracy of the statements on the Scientific Match website. However, there is a significant difference between getting a haircut and drinking from a glass in a restaurant, and sending a DNA sample to a laboratory for evaluation. In the case of the haircut and the glass, individuals do not intend for their DNA to be analyzed. The expectation is simply that the hair is discarded, and the glass is washed. However, the intentional submission of a DNA sample for analysis, even the minimal analysis that is performed by Scientific Match, may indeed not be less risky than as promised because the specimen is being evaluated along with specimens from other individuals, and some record of this analysis is made, even if the sample itself is ultimately destroyed.

81. This quandary may be just as much of a public health hazard as potentially unreliable test results that report a diagnosis of a fatal condition. For instance, if the laboratory test that the Scientific Match laboratory uses to examine an individual’s major histocompatibility complex is potentially flawed, this service becomes not much different from Match.com or any number of other dating websites— but comes at a much higher cost.
feeding companies to terrify hypochondriacs by turning dubious probabilities into Genes of Doom."82

E. The Power of the FDA

The FDA is the agency with the best legal authority and oversight capabilities to ensure the safety and efficacy of direct-to-consumer genetic tests.83 The FDA’s “technical demands, review procedures, and scientific quality make U.S. pharmaceutical regulation one of the world’s most stringent regimes,”84 and it is reasonable to believe that the same holds true for the FDA’s procedures regulating medical devices.

Admittedly, FDA regulation of genetic tests is not a flawless system for ensuring their quality and reliability.85 In recent years, the FDA's regulatory process has been the target of criticism during litigation regarding the safety of approved devices such as the Medtronic defibrillator and the Thoratec heart pump.86 The FDA has

83. See Anny Huang, FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship, 53 FOOD & DRUG L. J. 555, 591 (1998) (concluding that the FDA has the jurisdiction and expertise to regulate direct-to-consumer genetic tests, and that the FDA needs “not so much legislative authorization as a social and political mandate”).
85. See, e.g., Richard L. Cupp, Jr., Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach, 63 GEO. WASH. L. REV. 76, 104 (1994) (“[T]he FDA has experienced increasing difficulties related to understaffing and underfunding”); Malinowski & Blatt, supra note 17, at 1274 (“[T]he FDA is not a perfect agency. . . .”). The Government Accountability Office has also said that “it is imperative that F.D.A. take immediate steps’ to fix its system for approving devices.” Gardiner Harris, Report Criticizes F.D.A. on Device Testing, N.Y. TIMES, Jan. 15, 2009, http://www.nytimes.com/2009/01/16/washington/16device.html?_r=1&scp=1&sq=fda%20gao&st=cse. Nonetheless, the FDA remains the agency in the best position to regulate genetic tests, including those available directly to consumers. See infra Section IV.
86. See Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008) (holding that the FDA pre-market approval process establishes federal requirements for medical device review and that common law claims of strict liability, negligence, and implied warranty against Medtronic for a catheter that malfunctioned during the plaintiff’s husband’s angioplasty were pre-empted); Horn v. Thoratec Corp., 376 F.3d 163 (3rd Cir. 2004) (holding, at the conclusion of a trial in which a woman claimed that Thoratec’s heart pump was defective and caused her husband’s death, that the FDA pre-market approval pre-empts state common law tort claims). Numerous FDA-approved drugs, such as Fen-phen and Vioxx, have also been removed from the market due to the risks that they posed, so one should question whether the FDA’s approval process for both devices and drugs serves to protect the public. See U.S. Food and Drug Administration, FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine, http://www.fda.gov/CDER/news/phen/fenphenpr81597.htm (last visited Apr. 2, 2009); U.S. Food and Drug Administration, Merck Withdraws Vioxx, FDA Issues Public Health Advisory, FDA CONSUMER MAGAZINE,
also been criticized for delaying the commercialization of medical devices, and for preventing some devices from entering the market entirely. However, recent support from politicians, academics, and lobbyists for FDA regulation of genetic tests suggests that confidence in the FDA review process still exists. A closer look at FDA regulation of medical devices is warranted to better understand why the agency’s regulations are the best mechanism for ensuring the safety and efficacy of direct-to-consumer genetic tests.

III. FDA OVERSIGHT OF MEDICAL DEVICES

Medical devices are regulated in accordance with the FDCA and corresponding federal regulations which prescribe the manufacturing, marketing, and monitoring requirements of all medical devices in commercial distribution. The Medical Device Amendments of 1976 amended the FDCA to give the FDA “express authority to regulate the safety and effectiveness of medical devices.” The FDA regulates medical devices according to the level of risk that they pose to individuals, utilizing a classification system which identifies the level of regulatory oversight to which a device is subject in order to ensure the safety and efficacy of the device. The classification of the device determines the type of FDA application, review, and approval process that the device must undergo before it may be marketed.

Class I medical devices are only subject to general controls due to the low risk level that these devices pose, whereas Class II and III devices are subject to more stringent controls, which are discussed below. Class II devices generally pose more risk than Class I

See supra notes 120-160 (discussing FDA regulation of Class II and III devices).
devices, and are thus subject to additional oversight by the FDA. A medical device may be classified as a Class III device, however, if insufficient information exists to demonstrate that general or special controls will provide reasonable assurance of the safety and effectiveness of the device and the device is to be used in supporting or sustaining human life. A device may also receive Class III classification if the device may present an unreasonable risk of illness or injury to its user.

A. General Controls

All medical devices, regardless of their classification, may be subject to “general controls,” a relatively low level of oversight and control. The FDA has concluded that Class I devices are not “purported or represented to be for a use in supporting or sustaining human life” and do not “present a potential unreasonable risk of illness or injury.” General controls may include: (1) “establishment registration” of device manufacturers, which involves notifying the FDA of the location of medical device manufacturing facilities and importers; (2) provision of a medical device listing which lists all of the devices that a manufacturer has in commercial distribution; (3) compliance with good manufacturing practice (GMP) requirements; (4) compliance with labeling requirements; and (5) pre-market notification to the FDA of the intent to market a device. However,
most Class I devices are exempt from GMP requirements and pre-market notification due to the uncomplicated nature of devices categorized as Class I and the low risk that these devices pose to their users.102

1. GMP Requirements

Compliance with GMP requirements ensures that the devices are consistently produced according to the stated specifications.103 All medical devices, regardless of their classification, are subject to GMP requirements unless otherwise exempt.104 GMP requirements are contained in regulations that have been promulgated in accordance with the FDA’s authority under the FDCA.105 These regulations require that domestic or foreign medical device manufacturers have “a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices.”106 GMP requirements are an important general control for devices that must undergo the 510(k)107 or pre-market approval (PMA) process,108 especially while they are in the early production phase.109 This is because the FDA makes decisions regarding the safety and efficacy of a device based on its specifications listed in the 510(k) or PMA application.110

2. Label Requirements

All FDA-regulated medical devices are subject to the agency’s regulations regarding device labeling.111 Promulgated regulations address general device labeling,112 as well as the labeling

106. Good Manufacturing Practices (GMP)/Quality System (QS) Regulation, supra note 104.
107. See infra text accompanying notes 123-38 (discussing the 510(k) process).
108. See infra text accompanying notes 141-55.
110. Id.
111. See infra notes 111-119 (discussing FDA labeling requirements for medical devices).
112. 21 C.F.R. § 801 (2009).
requirements for in vitro diagnostic devices. The FDA has also established labeling regulations through its GMP regulations, which are relevant to genetic tests.

A “label” is written, printed, or graphic material on the container of a device, and “labeling” refers to all labels or other written, printed, or graphic material on the device or any of its containers, or accompanying the device. As regulated devices, test kits must comply with the appropriate labeling requirements for medical devices. However, the labeling of direct-to-consumer genetic tests remains unregulated. Thus, the content of any materials printed on or included with such a home brew test is created by the manufacturer without meaningful federal oversight.

If the FDA were to regulate all direct-to-consumer genetic tests, manufacturers would have to comply with relevant labeling regulations, which would likely alleviate the possibility that manufacturers will engage in potentially false or misleading advertising of these tests. Furthermore, although the FDA’s labeling requirements exist separate and apart from any advertising requirements that the FTC may impose with respect to direct-to-consumer genetic tests, perhaps the FTC will be more inclined to enforce its regulations if the FDA imposes regulations on the tests.

B. Special Controls

Class II medical devices are subject to more oversight and control than Class I devices through the use of special controls because the “general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device.”

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114. See 21 C.F.R. § 820.120. See also supra text accompanying notes 103-106 for a discussion of GMP regulations.
115. 21 U.S.C. § 321(k) & (m) (2009) (defining “label” and “labeling,” definitions that apply to all food, drugs, devices, and cosmetics regulated under the FDCA).
116. See Kathy Hudson et al., ASHG Statement on Direct-to-Consumer Genetic Testing in the United States, 81 AM. J. HUM. GENETICS 635, 636 (2007) (“[T]he FDA reviews the . . . labeling of commercial test kits before they are marketed.”).
117. See id.
118. See U.S. v. Research Labs., 126 F.2d 42, 45 (9th Cir. 1942) (“Most, if not all labeling is advertising. The term ‘labeling’ is defined in the [FDCA] as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.”).
119. See supra text accompanying note 68 (discussing FTC regulation of advertisements).
120. 21 U.S.C.S. § 360c(a)(1)(B). Class I devices are not subject to special controls because of their low risk level, and Class III medical devices are not subject to special
These special controls may include special labeling requirements, mandatory performance standards, and post-market surveillance.\textsuperscript{121}

C. Pre-Market Notification

Class II devices are also subject to the pre-market notification requirement. While some Class II devices are exempt from the pre-market notification process, more Class I devices than Class II devices qualify for exemption.\textsuperscript{122} Through this pre-market notification process, also referred to as the 510(k) process, the FDA must determine whether a device is safe and effective for its intended use, and thus may be marketed and sold to the public.\textsuperscript{123}

The 510(k) process derives its name from the original section of the FDCA that pertained to pre-market notification.\textsuperscript{124} Manufacturers of Class I and II medical devices that are not exempt from the pre-market notification process submit a 510(k) application to the FDA ninety or more days prior to introducing the device into commercial distribution.\textsuperscript{125} The 510(k) process requires manufacturers to demonstrate that their new medical device is “substantially equivalent” to a medical device currently on the market, called a “predicate.”\textsuperscript{126} A device is substantially equivalent if it has the same intended use as another legally marketed device and uses the same

\textsuperscript{121} Device Classes, supra note 19.
\textsuperscript{122} The FDCA authorizes the FDA to exempt certain types of medical devices from the pre-market notification process. 21 U.S.C.S. § 360c(c)(2)(B). More than 800 types of Class I devices are exempt from the pre-market notification process, while 60 Class II devices are exempt from pre-market notification. U.S. Food and Drug Administration, Class I/II Exemptions, http://www.fda.gov/cdrh/devadvice/3133.html (last visited Apr. 2, 2009). However, while many Class I devices are exempt from compliance with GMP requirements, no Class II device is so exempt. Medical Device Exemptions 510(k) and GMP Requirements, supra note 102.
\textsuperscript{124} Michael VanBuren, Note, Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation, 17 HEALTH MATRIX: J. OF L.-MED. 441, 448 (2007).
\textsuperscript{125} Id.; Device Classes, supra note 19.
\textsuperscript{126} Premarket Notification 510(k), supra note 123. If the FDA determines that no substantial equivalent for a new device currently exists on the market, the FDA issues a “not substantially equivalent” letter to the manufacturer, and the device receives a Class III designation. U.S. Food and Drug Administration, 510(k) Special Considerations, http://www.fda.gov/cdrh/devadvice/314c.html#denovo (last visited Feb. 20, 2009). Within 30 days of receipt of such a letter, manufacturers of low-risk devices may request a de novo classification of the device into Class I or II. Id.
technology as that device.\textsuperscript{127} If the new device has the same intended use as another legally marketed device but it uses a different technology, the new device is substantially equivalent to the old one if the manufacturer can demonstrate that this alternate technology is as safe and effective as the legally marketed device.\textsuperscript{128}

Review of a 510(k) is based on the FDA's evaluation of characteristics of the new device compared to its predicate.\textsuperscript{129} Such characteristics include “the bias or inaccuracy of the new device, the imprecision of the new device, and the analytical specificity and sensitivity” of the new device.\textsuperscript{130} If the FDA determines that the new device is substantially equivalent to the predicate device, the agency will issue an order clearing the device for commercial distribution.\textsuperscript{131}

In 2007 the FDA committed to reviewing 90 percent of 510(k) applications submitted to the agency within 90 days and 98 percent within 150 days.\textsuperscript{132}

The FDA may only request limited amounts of information from manufacturers regarding the substantial equivalence of a new device to a legally marketed device that uses different technology.\textsuperscript{133} The Department of Health and Human Services may only request information that is “necessary to making substantial equivalence determination[s]” and must “consider the least burdensome means of demonstrating substantial equivalence.”\textsuperscript{134} As a result, many manufacturers submit only pre-clinical data, obtained from animals,\textsuperscript{135} and not clinical data obtained from clinical trials with human subjects.\textsuperscript{136}

\textsuperscript{127} 510(k) Special Considerations, supra note 126.
\textsuperscript{128} Id.
\textsuperscript{129} Premarket Notification 510(k), supra note 123.
\textsuperscript{131} Id. Medical devices cleared through the 510(k) process are not “FDA-approved.” The term “clearance,” rather than “approval” is used because the 510(k) process is just a finding of substantial equivalence, and not necessarily safety and effectiveness. Edward M. Basile, Ellen Armentrout & Kelly N. Reeves, Medical Device Labeling and Advertising: An Overview, 54 FOOD & DRUG L.J. 519, 524 n.50 (1999).
\textsuperscript{133} VanBuren, supra note 124, at 453-54.
\textsuperscript{134} Id. at 454 (citing 21 U.S.C.S. § 360e(i)(1)(D) (2009)).
\textsuperscript{135} The FDA defines pre-clinical laboratory data as “results of testing . . . done in laboratory animals. . . .” U.S. Food and Drug Administration, A Guide to Drug Safety Terms, at 1, available at http://www.fda.gov/consumer/updates/drugterms041108.pdf.
\textsuperscript{136} VanBuren, supra note 124, at 454. Class III devices, however, must undergo clinical trials with human subjects prior to commercial distribution. 21 C.F.R. § 814.20(b)(3)(v)(B) (2009).
Although the 510(k) process is less time consuming and the application is shorter than other FDA review processes for medical devices, the 510(k) process should be used to ensure the safety and efficacy of genetic tests sold directly to consumers. Class II devices that are not exempt from pre-market notification need not necessarily undergo a lengthier, more expensive review than the 510(k) process if a substantial equivalent already exists, which is likely in the case of genetic testing. Furthermore, the FDA’s 2007 guidance document addressing regulation of in vitro diagnostic multivariate index assays (IVDIMA), indicates that Class II, and in some cases Class III, designation is appropriate. Thus, a Class I designation seems both unlikely, given the FDA’s past actions, and imprudent, given the public health implications and risks associated with these tests.

D. The Pre-Market Approval (PMA) Process

It would also be possible to classify direct-to-consumer genetic tests as Class III devices, but a Class III designation may not be appropriate or necessary for all of these devices. Because there is more uncertainty regarding the risk of Class III devices, manufacturers of a Class III device must submit a PMA application and await the FDA’s approval prior to marketing the device. Due to the unknown or high level of risk associated with Class III devices, the PMA process is more onerous than the 510(k) application process.

C.f. supra text accompanying note 132 with infra text accompanying note 148 (comparing the length of time it takes for the FDA to review a 510(k) application and a PMA application). See also infra note 141 (discussing the typical length of a 510(k) application and a PMA application).

See supra notes 126-131 (describing substantial equivalence).

See supra note 41 (discussing IVDIMA).

Garcia, supra note 48, at 223.

141. Devices on the market prior to the passage of the Medical Device Amendments in 1976 are not subject to PMA approval. Device Classes, supra note 19. Instead, companies wishing to market such devices may submit a 510(k). Id. This exception is likely to be inapplicable to genetic tests because the first genetic test was approved in 1976. See Press, supra note 5, at 73.

142. Compare U.S. Food and Drug Administration, Device Advice, Application Contents, http://www.fda.gov/CDRH/DEVADVICE/pma/app_contents.html (last visited Apr. 2, 2009) (detailing the elements of the PMA application process) with U.S. Food and Drug Administration, Device Advice, How to Prepare a Traditional 510(k) Application, http://www.fda.gov/cdrh/devadvice/3143.html (last visited Apr. 2, 2009) (listing the required content of a 510(k) application). PMA applications are typically more than 1,000 pages long, while 510(k) applications are, on average, less than ten pages. Richard C. Ausness, "After You My Dear Alphonse!": Should the Courts Defer to the FDA’s New Interpretation of a § 360(K)(A) of the Medical Device Amendments?, 80 TULANE L. REV. 727, 765 (2006); Lawrence S. Makow, Medical Device Review at the Food and Drug Administration: Lessons from Magnetic Resonance Spectroscopy and Biliary Lithotripsy, 46
1. The PMA Application

PMA applications are very detailed and must include specific information about the device. The PMA application must (1) summarize the disease or condition that the device will diagnose, treat, or prevent, as well as the population for whom the device is intended; (2) summarize how the device functions, any alternative practices or procedures for diagnosing, treating, or preventing the disease or condition for which the device is intended, and any marketing history of the device; and (3) summarize any non-clinical laboratory studies conducted, as well as clinical investigations involving human subjects, and the results of such studies. PMA approval hinges upon the FDA finding that “sufficient valid scientific evidence” exists that demonstrates the safety and effectiveness of the device.

2. Institutional Review Boards and Clinical Investigations

Class III devices undergoing the PMA process are subject not only to the FDA’s scrutiny but also to the scrutiny of an institutional review board (IRB) during the course of the required clinical investigations. Federal law requires institutions conducting clinical research involving human subjects to maintain an IRB—a committee charged with protecting human research subjects by evaluating prospective research protocols to ensure that they are consistent with

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STAN. L. REV. 709, 713 n.23 (1994). Class III devices, which are substantially equivalent to devices legally marketed prior to mid-1976, as well as devices that are not specifically required by regulation to undergo the PMA process, may be marketed through the 510(k) process. Device Classes, supra note 19.

143. 21 C.F.R. § 814.42(b) (2009).
146. See 21 C.F.R. § 814.20(b)(3)(v) (2009). Unlike a 510(k) application, a PMA application may not include only the results of pre-clinical studies. Id. Instead, there is an expectation that Class III devices undergo clinical trial testing with human subjects whose results will be reported in the PMA application. 21 C.F.R. § 814.20(b)(3)(v)(B) (2009).
148. 21 C.F.R. § 814.42(b) (2009). However, in 2002, the average review time for a PMA application was 213 days, and in 2003, the average review time was 221 days. Gregory J. Scandaglia & Therese L. Tully, Express Preemption and Premarket Approval Under the Medical Device Amendments, 59 FOOD & DRUG L.J. 245, 252 (2004).
basic ethical principles. The IRB's fundamental objective is to protect the health and welfare of the human subjects who ultimately enroll in clinical trials. Researchers planning to test a new medical device must submit a protocol to the IRB to explain how they plan to test the device. The IRB reviews the protocol and requires that necessary changes be made to the protocol, such as its methodology, recruitment strategy, or informed consent process, based on criteria established by federal regulation. Furthermore, IRBs must review and approve any changes made to a research protocol both before and after the committee approves it, ensuring that every aspect of the clinical trial is scrutinized.

3. The Benefits of the PMA process

The combination of the lengthy PMA review period and the IRB review process would likely ensure the safety and efficacy of a direct-to-consumer genetic test warranting a Class III classification. However, due to the rigorous nature of the PMA application for device

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150. See 45 C.F.R. § 46 (2009). Researchers not affiliated with an institution that has established its own IRB can request IRB review from a commercial IRB, which charges a fee for its review services. See, e.g., New England IRB, http://www.neirb.com (last visited Apr. 2, 2009). It is worth noting that FDA regulations govern IRB review of any protocols involving investigational drugs and devices. 21 C.F.R. § 56 (2009). Thus, the FDA's Center for Devices and Radiological Health oversees the FDA review of new medical devices, and the FDA's Office for Human Research Trials oversees the review of new medical devices during the clinical trial process.

151. See 45 C.F.R. § 46 (2009). Inhumane treatment of concentration camp prisoners under the guise of medical research conducted by Nazi scientists during WWII, the Tuskegee syphilis experiments, and other abuses of human subjects in research have led to the promulgation of these regulations regarding the conduct of the IRB and the conduct of research with human subjects. William H. Schneider, History of IRB, http://www.iupui.edu/~histwhs/G504.dir/irbhist.html (last visited Apr. 2, 2009).


154. Some may argue that many IRBs do not have the required expertise to review genetic test protocols adequately. Assessing Genetic Risks: Implications for Health and Social Policy 13 (Lori B. Andrews et al. eds. 1994), available at http://books.nap.edu/catalog.php?record_id=2057#toc. However, IRBs consist of a panel of at least five experts who have varying backgrounds, which helps to assure the “complete and adequate review” of research activities at the institution. 45 C.F.R. § 46.107(a) (2009). The committee must have a variety of expertise and experience, as well as individuals from diverse cultures who have varying sensitivities to community attitudes, and at least one member whose area of expertise is non-scientific. Id. Furthermore, IRBs may “invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.” 45 C.F.R. § 46.107(f) (2009). The varying expertise of the members of the committee as well as the IRB's ability to utilize consultants with specific expertise should it not already have adequate expertise on the committee reduces the likelihood that the IRB will lack the capacity to assess a genetic test protocol.
manufacturers, a proposal to regulate all genetic tests as Class III devices seems both unrealistic and unwarranted given the risks associated with many of these tests. The low risk of the genetic tests does not generally require such scrutiny, and thus, subjecting these devices to the PMA process would be inefficient. Furthermore, clinical research results demonstrating the safety and efficacy of genetic tests designed to locate predictors of a future disease or condition could take years to obtain, further delaying a test manufacturer’s ability to submit a PMA application.155

E. Post-Market Surveillance

The FDA’s oversight of medical devices that are already in commercial distribution provides additional assurance of the continuing safety and efficacy of medical devices, and would effectively monitor the clinical validity, clinical utility, and analytic validity of direct-to-consumer genetic tests.156 MedWatch, the FDA’s safety information and adverse event reporting program,157 reports information to the FDA from manufacturers and distributors of medical devices regarding safety or other problems with their products and posts important updates on the MedWatch website.158

Manufacturers of Class III devices must submit annual reports to the FDA that disclose all changes in how the device is manufactured, any adverse events that have occurred in any clinical studies, and any other information that supports the continued safety and efficacy of the device.159 Class I and II devices are also subject to annual reporting requirements, though less information is required to be submitted to the FDA than is required for Class III devices.160 Thus, FDA-regulated direct-to-consumer genetic tests would have to comply with relevant post-market approval regulations.

156.  *See supra* text accompanying *supra* note 52 (discussing clinical validity, clinical utility, and analytic validity, and the importance of assuring each of these with respect to genetic tests).
158.  *Id.* at 575.
159.  *Id.* at 576.
160.  *Id.* at 577.
IV. FDA Regulation is the Best Solution

Classification of direct-to-consumer genetic tests as Class II or III devices when the risk level of the test deems such a classification to be necessary is ultimately the most appropriate means of assuring that the FDA subjects these tests to sufficient oversight without unnecessary burden. Such a conclusion is consistent with recently proposed legislation, and would ensure that these tests undergo, at a minimum, the FDA’s 510(k) review process, but would not automatically impose a PMA application requirement.¹⁶¹

Pre-market notification and PMA approval would be costly, both in terms of time and money for the clinical laboratories that sell these tests.¹⁶² However, the benefits that FDA oversight over the marketing and sale of these tests offer outweigh these costs because they help to ensure the safety and effectiveness of these tests that could pose a public health hazard if left unregulated.¹⁶³ Furthermore, the costs are not a reasonable justification for leaving tests unregulated that may pose a public health hazard.

Indeed, members of Congress have made several attempts to enact legislation that would require the FDA to regulate direct-to-consumer genetic tests. In 2006, and again in 2007, then-Senator Barack Obama proposed legislation called the Genomics and Personalized Medicine Act which would have required additional federal oversight over direct-to-consumer marketing of genetic tests.¹⁶⁴ The bill specifically provided that the director of the Centers for Disease Control and Prevention “conduct an analysis of the public health impact of direct-to-consumer marketing; . . . analyze the validity of claims made in direct-to-consumer marketing; and make recommendations to Congress . . . to protect the public from potential harms of direct-to-consumer marketing . . . ”¹⁶⁵ In March 2007 Senators Edward Kennedy (D-MA) and Gordon Smith (R-OR)

¹⁶¹ See supra text accompanying notes 124-160 for a discussion of the 510(k) and PMA application process.
¹⁶² See supra text accompanying note 132 (noting average review time for a 510(k) application), 135 (noting the average review time for a PMA application). See also U.S. Food and Drug Administration, PMA Review Fees, http://www.fda.gov/CDRH/DEVADVICE/pma/userfees.html (last visited Apr. 2, 2009) (listing the fees for submitting a PMA and 510(k) application).
¹⁶³ See supra text accompanying notes 98–1630 (discussing the FDA’s regulatory process for medical devices that ultimately helps to ensure the public’s health and welfare).
¹⁶⁵ S. 3822, § 7(45N)(e)(1).
proposed a series of amendments to the FDCA that would have required the FDA to regulate all laboratory-developed tests as medical devices, which would include direct-to-consumer genetic tests.\(^{166}\) Under this bipartisan legislation, called the Laboratory Test Improvement Act, most laboratory tests would have been required to be classified as Class II devices.\(^{167}\) The bill would have also required that all manufacturers of laboratory-developed tests provide the FDA with information regarding the analytic and clinical validity of the tests.\(^{168}\) Neither of the proposed bills was enacted; however, they indicate that Congress may be moving toward imposing a requirement that the FDA regulate direct-to-consumer genetic tests.

Despite this advocacy from Congress, opponents of FDA regulation of direct-to-consumer genetic tests argue that these tests are in fact clinical laboratory services and not medical devices, and should therefore not be regulated as devices by the FDA.\(^{169}\) In February 2007 the FDA’s Center for Devices and Radiological Health convened a public meeting to discuss the proposed guidelines for regulation of IVDMIAs.\(^{170}\) At the meeting, manufacturers of direct-to-consumer genetic tests contested these proposed guidelines as too confusing, and said that they provided a “disincentive to innovation.”\(^{171}\) They even argued that the FDA may not have the authority to regulate direct-to-consumer genetic tests as medical devices.\(^{172}\) However, a challenge of the FDA’s power to regulate direct-to-consumer genetic tests seems unlikely to result in a decision that would render the FDA unable to regulate these tests, as courts generally defer to an agency’s interpretation of its statutory mandate unless the interpretation is arbitrary and capricious.\(^{173}\)

\(^{166}\) Laboratory Test Improvement Act, S. 736, § 3 (2007).
\(^{167}\) S. 736, § 5(a)(4)(A).
\(^{170}\) Caruso, supra note 169, cited in Gniady, supra note 21, at 2464. See also supra note 41 (discussing IVDMIAs).
\(^{171}\) Id.
\(^{172}\) Id.; see also Han, supra note 169, at 431.
\(^{173}\) See Chevron U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984). Although in \textit{FDA v. Brown & Williamson Tobacco Corp.}, 529 U.S. 120 (2000), the Supreme Court held that the FDA did not have the power to regulate tobacco as a drug, the decision was made primarily based on the fact that Congress had enacted a number of tobacco-specific laws, and that the FDA had never exercised any control over tobacco. \textit{Id.} Thus, the court concluded that Congress did not intend to delegate authority to the FDA to regulate tobacco. \textit{Id.} In the case of direct-to-consumer genetic tests, Congress has enacted no legislation related to this technology, so the \textit{Brown & Williamson} rationale is not likely to apply here. Furthermore,
A. Alternatives to FDA Regulation

One alternative to FDA regulation of direct-to-consumer genetic tests is exclusive regulation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), but this is likely to be an insufficient solution. CLIA regulations, which govern all clinical laboratories in the United States, are administered and enforced through the Centers for Medicare and Medicaid Services (CMS), an office within the Department of Health and Human Services. CLIA imposes quality standards on clinical laboratories regarding the tests that they use to “ensure the accuracy, reliability, and timeliness of patient test results,” and also imposes standards for the types of personnel and qualifications of personnel that clinical laboratories employ. While CLIA regulations “govern protocols and reagents used in genetic tests by laboratories providing clinical testing services,” no specific CLIA regulations govern genetic testing as a separate category of tests. In 2000, the Clinical Laboratory Improvement Advisory Committee (CLIAC) published a notice of intent, proposing amendments to CLIA that would create a specific genetic testing section in the regulations. However, CLIA was never amended as proposed.

CLIA regulation of direct-to-consumer genetic testing is a more viable alternative to FDA regulation of these tests than any of the other alternatives mentioned in this Note because of the CLIA regulatory scheme governing laboratory testing and personnel. However, CLIA regulation is ultimately an inadequate solution to the problems associated with direct-to-consumer genetic testing because too many CLIA-certified laboratories are in need of oversight, and CLIA is “marred by reporting deficiencies and laboratory inspections.

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179. Gniady, supra note 21, at 2439.
180. Id. at 2440.
182. Id. at 220.
that are infrequent and insufficient.”\textsuperscript{183} Thus, CLIA cannot reliably assure the quality of the laboratories themselves, and as a result, certainly cannot reliably assure the quality of the tests.\textsuperscript{184}

Furthermore, CLIA cannot guarantee that laboratories provide counseling services with their genetic tests because CLIA only regulates the tests themselves and not any accompanying services.\textsuperscript{185} For this same reason, CLIA cannot regulate laboratory compliance with informed consent and confidentiality requirements associated with the sale of genetic tests directly to consumers.\textsuperscript{186} Also complicating the ability of CLIA to adequately regulate direct-to-consumer genetic testing is the fact that CLIA currently requires laboratories to assure only the analytic validity, and not the clinical validity and utility, of tests.\textsuperscript{187} A major reason for advocating for federal regulation of direct-to-consumer genetic tests is to ensure the analytic validity, as well as the clinical validity and utility, of these tests.\textsuperscript{188}

Another alternative to FDA regulation of direct-to-consumer genetic tests is to remove these tests from the market altogether and require that all genetic testing be done through a health care provider.\textsuperscript{189} Such a solution, however, violates the spirit of autonomy that individuals value as part of their health care decisions.\textsuperscript{190} It is also wasteful of the technology that is available and in demand, which could be, with proper monitoring, accurate and useful.\textsuperscript{191} Eliminating these tests from the marketplace entirely would also prevent individuals from taking advantage of the benefits of direct-to-consumer genetic testing. These benefits include, for example, the

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\item \textsuperscript{183} Malinowski, supra note 175, at 42.
\item \textsuperscript{184} Id.
\item \textsuperscript{185} See id.
\item \textsuperscript{186} Id. Issues such as informed consent, confidentiality, and counseling are “complicated patient care issues,” and are really unrelated to laboratory quality assurance under the purpose of CLIA. Id.
\item \textsuperscript{187} Neil A. Holtzman, FDA and the Regulation of Genetic Tests, 41 JURIMETRICS J. 53, 57 (2000). A major reason that direct-to-consumer genetic tests should be federally regulated is to assure the clinical validity and utility of these tests. See supra text accompanying note 50. CLIA would have to be amended to require assurance of clinical validity and utility of laboratory tests, and “the surveyors [who assure compliance] are not trained to assess clinical validity and utility . . . and have their hands full assessing each laboratory’s analytic validity and its other efforts to assure quality.” Holtzman, supra, at 57. See supra note 52 (defining clinical validity and clinical utility).
\item \textsuperscript{188} See supra text accompanying note 52 (discussing analytic validity, clinical validity, and clinical utility).
\item \textsuperscript{189} See Gniady, supra note 21, at 2455–57, 2470.
\item \textsuperscript{190} See id. at 2470.
\item \textsuperscript{191} See id.
\end{enumerate}
\end{footnotesize}
ability of an individual to test for particular diseases or conditions in the privacy of his own home, and the ability to learn of these test results without the risk that the information will be included in a medical record, potentially resulting in insurance discrimination.\textsuperscript{192} 

A third alternative would be state regulation. Some states currently prohibit the sale of direct-to-consumer tests, which includes direct-to-consumer genetic tests.\textsuperscript{193} However, these states have difficulty enforcing such a ban on tests that are sold through the Internet.\textsuperscript{194} Recent statistics indicate that twenty-five states and the District of Columbia permit all forms of direct-to-consumer testing, while thirteen states prohibit all direct-to-consumer testing.\textsuperscript{195} Twelve states permit some direct-to-consumer testing, though genetic tests are likely not among the permissible tests.\textsuperscript{196} This varying attitude among states regarding the permissibility of direct-to-consumer testing is indicative of the inconsistency with which direct-to-consumer genetic tests would be regulated if regulation is left to the states, rather than the federal government. Thus, state regulation of direct-to-consumer genetic tests is not a satisfactory alternative to FDA regulation, as inconsistent regulations would do little to ensure the safety and effectiveness of these tests.

As an alternative to promulgating regulations governing the marketing and sale of direct-to-consumer genetic tests, the FDA could just publish guidance documents that would indicate to manufacturers how the FDA prefers that these tests be made and monitored. Indeed, the FDA has already published draft guidance that proposed that the FDA regulate all IVDMIAs,\textsuperscript{197} including any that are laboratory-
developed and marketed directly to consumers. However, guidance documents, unlike regulations, do not have the force of law, and are instead merely advisory.\textsuperscript{198} It is therefore unlikely that manufacturers will be inclined to follow guidance documents that advocate for lengthier and more expensive research and development, and more stringent marketing requirements.

\textbf{B. An Argument for FDA Regulation}

Thus, to assure the safety and effectiveness of direct-to-consumer genetic tests whose safety and effectiveness is not currently assured, the FDA must promulgate regulations that subject these tests to the same requirements as other medical devices, including test kits. The publication of guidance documents is an insufficient guarantee that laboratories will develop tests that comply with the relevant regulations,\textsuperscript{199} and regulation of these tests through CLIA is inadequate to assure the clinical validity and utility of these tests.\textsuperscript{200} State regulation will not promote a consistent standard with which direct-to-consumer tests must comply, as each state will inevitably adopt different standards which will ultimately depend on the attitudes of the legislature and constituents on the matter.\textsuperscript{201} Such regulations should designate most direct-to-consumer genetic tests as Class II devices, with some designated as Class III devices where the risk level is appropriate for such a classification. The FDA should regulate these tests regardless of ASR production source. Specific regulations with respect to labeling or marketing may help to assure the quality of any content that direct-to-consumer test manufacturers issue, including the test itself, any accompanying materials, as well as its results.

\textbf{V. Conclusion}

The benefits of offering direct-to-consumer genetic tests to the public likely outweigh the potential disadvantages and risks posed by these tests.\textsuperscript{202} However, these benefits can only be realized if the

\begin{itemize}
\item \textsuperscript{198} 2 AM. JUR. 2D Administrative Law § 235 (2008).
\item \textsuperscript{199} \textit{See supra} text accompanying notes 197-198 (discussing the insufficiency of FDA guidance).
\item \textsuperscript{200} \textit{See supra} text accompanying notes 174–188 (discussing CLIA as an alternative to FDA regulation of direct-to-consumer genetic tests).
\item \textsuperscript{201} \textit{See supra} text accompanying notes 193–196 (discussing the possibility of state regulation of direct-to-consumer genetic tests).
\item \textsuperscript{202} \textit{See supra} text accompanying notes 13-17 (noting the advantages and disadvantages of genetic tests offered directly to consumers).
\end{itemize}
government, through the FDA, exercises its right to regulate the marketing and sale of these genetic tests. Because these tests are available directly to consumers without a visit to a health care provider, genetic testing may be offered with greater convenience and confidentiality than if doctors’ visits were required.\textsuperscript{203} Furthermore, individuals may be more likely to seek genetic testing because of such benefits, which may lead to earlier detection and better treatment of genetic disorders or conditions.

Without federal regulation, there exists the possibility of consumers relying on flawed tests that deliver inaccurate results, and acting upon results without adequate guidance as to their meaning.\textsuperscript{204} Whether through legislative mandate or on its own initiative, the FDA should promulgate regulations governing the marketing and sale of all genetic tests, including direct-to-consumer tests, as medical devices. The process that the FDA requires medical devices to undergo in order to be commercially distributed will help to ensure the analytic validity, clinical validity, and clinical utility of these tests, and in turn ensure the safety of the consumers who will purchase these tests.

Lauren B. Solberg*