FDA, CLIA, or a “Reasonable Combination of Both”: Toward Increased Regulatory Oversight of Genetic Testing

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GENETIC TESTING—testing a person’s genetic makeup for glimpses into future health—is probably the most rapidly growing field of laboratory testing in the world. The idea that a great majority of diseases have their roots in genetics is increasingly popular, leading many to seek out genetic testing.1 The field has enormous importance as “a person’s genetic information is the blueprint to their very being”2 and is “certainly the language of nature and all living things.”3 But the phenomenal growth of genetic testing has led some to describe the field as in a “research stage,” where the actual benefits of testing are still being uncovered and understood.4

However, some potential benefits have emerged, including the possibility of early intervention for treatment of a disease, the elimina-

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4. See Octavi Quintana-Trias, Preface to Society and Genetic Information: Codes and Laws in the Genetic Era 17 (Judit Sandor ed., Central European University Press 2003). “Human genetics is at a research stage . . . . There is no doubt that today genetics is the cornerstone for advances in the life sciences; but the benefits of human genetic research are not yet clearly perceived.” Id.
tion of uncertainty for an individual with a family history of disease, and the proliferation of information on the possible courses a disease may take as well as on the potential benefits or risks of a certain course of treatment.\(^5\) While the actual direct physical risk of genetic testing is minimal, more generalized risks include social, economic, and psychological damage. The potential for a false positive or a false negative result can have dramatic effects on an individual. For instance, the individual may decide to undergo or abstain from surgical or other medical intervention.\(^6\) These decisions carry their own emotional and psychological burdens. Further, testing can create social risks through discrimination based on testing results.\(^7\)

Due to the rapid scientific advances and general popularity of genetic testing, it has proven difficult to set guidelines and rules for the analysis of genetic data.\(^8\) Genetic and non-genetic tests continue to receive the same level of oversight from the federal government.\(^9\) Genetic tests are primarily regulated by the Food, Drug, and Cosmetic Act ("FDCA") and the Clinical Laboratory Improvement Amendment of 1988 ("CLIA").\(^10\) When considering a genetic test as a product for use in diagnosis of a condition, the Food and Drug Administration ("FDA")\(^11\) has authority through the FDCA. When considering a genetic test as a commercial service available through a commercial laboratory, the Center for Medicare and Medicaid Services ("CMS") has


6. See id.

The person who learns of susceptibility or predisposition towards a condition like heart disease may adopt a lifestyle with a preventative effect. Another person might enjoy a false sense of security after "testing negative" for the presence of a particular genotype, only to suffer from the condition in the future.


7. See Sec'y's Advisory Comm., supra note 5, at 8.


9. See Sec'y's Advisory Comm., supra note 5, at 8.


11. It is common practice among health lawyers to refer to the Food and Drug Administration as "FDA" and not "the FDA." Thus, the article "the" will not precede "FDA" for the remainder of the text unless quoted material contains it.
authority through CLIA. However, problems with this system arise because “[t]he ambiguity about the legal status of genetic testing, as well as arguably underzealous exercise of available authority . . . has led to insufficient oversight of genetic testing.”

That there is “no governmental review of whether [genetic] tests work or the claims made for them are accurate” compounds these problems, especially given FDA’s regulation of other laboratory testing. With the absence of clear criteria for gauging the accuracy of genetic tests, providers and patients face the risk that errors have occurred in the testing process. Adding to the confusion, not only do physicians and hospitals provide genetic testing, but commercial laboratories also market genetic testing directly to consumers.

Today, there are more than 1100 genetic diseases and conditions that genetic testing can uncover—twice that of five years ago. With over 500 laboratories performing tests, it should come as no surprise that there are an increasing number of mistakes. These errors can have horrific consequences for the patient and family, and more could be done to avoid them.

This Article examines the current regulatory scheme for genetic testing and calls for a unification of the testing standards. It advocates consolidating the standards under a single governmental agency, FDA, in order to ameliorate the potential for immediate and future harm to patients and their families. In order to be effective, future regulations must apply to all providers of genetic testing and create meaningful, reasonable criteria for testing processes and outcomes. Moreover, failure to meet these criteria must result in a market ban for those genetic tests. Because it is ever more evident that “the rap-

12. See Javitt et al., supra note 1, at 268.
13. Id. at 271–73.
14. Id. at 273.
16. Javitt et al., supra note 1, at 271. “While the majority of clinical laboratories market their services primarily, if not exclusively, to physicians and health care institutions, there is no federal prohibition on marketing genetic tests directly to consumers.” Id.
17. See Ariana Eunjung Cha, Labs Turn DNA into Personal Health Forecasts, WASH. POST, Apr. 7, 2005, at A01.
19. See George C. Cunningham, A Public Health Perspective on the Control of Predictive Screening for Breast Cancer, 7 HEALT i-MATRIX 31, 33 (1997) (“To ensure safety, effectiveness, and necessity, federal and state public health agencies must ensure that screening tests satisfy reasonable criteria.”).
idly expanding field of genetic testing is not everything its gleaming molecular image would suggest,"20 reorganizing the system is a necessity.

I. The Importance and Availability of Genetic Testing

A genetic test is an analysis performed on human DNA, RNA, genes, and/or chromosomes to detect heritable or acquired genotypes, mutations, phenotypes, or karotypes that cause or are likely to cause a specific disease or condition. A genetic test also is the analysis of human proteins and certain metabolites, which are predominantly used to detect heritable or acquired genotypes, mutations, or phenotypes.21

Genetic tests are used for “predicting risks of disease, screening of newborns, directing clinical management, identifying carriers [of a disease], and establishing prenatal or clinical diagnoses or prognoses in individuals, families, or populations.”22 The results of these tests “inform individuals, or at least are perceived as informing individuals, about their destiny in a way that other medical information does not.” One popular perception is that they can predict the future. The tests work by “[probing] for tiny alterations in crucial genes,”24 and they “can predict, with varying degrees of reliability, a healthy adult’s odds of succumbing to a deadly disorder later in life, in some cases providing an opportunity to prevent the disease.”25 Embryonic testing has also become common. The results of this type of genetic testing can have an enormous effect on a woman’s decision to carry a pregnancy to term or to have an abortion.26

There are several reasons for a provider to order a genetic test. These include: identifying the potential for genetic disease, testing embryos for genetic defects, establishing or confirming diagnoses, determining if there is a potential for future increased disease risk, or

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20. Rick Weiss, Genetic Testing’s Human Toll: In Unregulated Field, Errors Can Upend Lives and Mean Unneeded Surgery, Wash. Post, July 21, 1999, at A1. The article describes the experience of a woman who underwent surgery for removal of her ovaries based on the results of a genetic test. Eight months later, the testing company informed her that the test result was incorrect—she had no disposition to ovarian cancer. “Everybody had believed that this information was so true, and I’d had this surgery based on it, and I’d lived for the past eight months with this horror and anxiety and all the trauma of how to tell the kids. I felt like I’d been forced to confront my own death prematurely.” Id.
21. See Sec’y’s Advisory Comm., supra note 5, at 1.
22. Id. at 1–2.
23. See Javitt et al., supra note 1, at 262.
24. Weiss, supra note 20, at A12.
25. Id.
26. Id.
determining medication responses.\textsuperscript{27} Further, there are several different types of genetic testing. Individuals can undergo diagnostic testing to identify diseases and to predict the course of the disease and the effectiveness of treatment modalities.\textsuperscript{28} Carrier testing can identify the potential for a genetic disease, and physicians usually recommend it for patients who are pregnant or planning a pregnancy.\textsuperscript{29} Prenatal tests can detect genetic defects in embryos, and they are often conducted through ultrasound or blood analysis.\textsuperscript{30} Preimplantation genetic diagnosis detects genetic defects in an embryo created through in vitro fertilization.\textsuperscript{31} Using this type of testing, infants can be screened for genetic defects in order to provide early treatment for the condition.\textsuperscript{32} Finally, pharmacogenetic testing can predict the type of response an individual will have to a specific drug.\textsuperscript{33}

Most genetic tests must be ordered by a health care provider; they are not directly available to members of the public.\textsuperscript{34} However, a recent study revealed the existence of over one hundred websites offering genetic testing directly to the public.\textsuperscript{35} The types of services “range from ‘mainstream’ genetic tests, or those generally accepted and used as part of patient care, to those that do not have a history of clinical use or the usual indicia of scientific support.”\textsuperscript{36}

Counseling and interpretation of genetic tests by a qualified provider is essential.\textsuperscript{37} Otherwise, there is no one to explain the meaning of the test results.\textsuperscript{38} Specifically, there is no one to explain to the patient that a single gene may be associated with more than one disease, that genes can alter each other, or that the presence of a mutated

\begin{footnotesize}
\begin{enumerate}
\item Javitt et al., \textit{supra} note 1, at 257.
\item Id. at 259.
\item Id. at 258–59.
\item Id.
\item Id.
\item Id. at 259.
\item Id. at 260.
\item Id. at 262 (“The major laboratories generally sell their testing services to health care providers and hospitals and not directly to consumers.”).
\item Id.
\item Id. at 263. “Mainstream” tests included tests for sickle-cell anemia and cystic fibrosis. Other less-accepted tests included genetic profiling, tests to detect possible addictive behavior, and tests to match dermatologic products with skin type. Id.
\item While all other laboratory testing also requires interpretation by qualified providers, the interpretation focuses on a diagnosis of an immediate condition. With genetic testing, the diagnosis is for a condition that might not actually exist, but if it does, it lies in the future.
\item See Javitt et al., \textit{supra} note 1, at 265. Other concerns include the overall validity of the tests and the “lack of sufficient information for pretest decision-making.” Id.
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gene might not result in the indicated disease or condition. Further, patients must be reminded that genetic test results only deal with probabilities of risk.

Thus, a ninety-nine percent chance of contracting a certain disease also means that there is a one percent chance that the disease will not occur. What one cannot predict from the test is "[w]hether a person who tests positive will manifest the disease, and how severe the disease will be." However, patients may not receive this crucial advice from genetic labs that directly market to consumers via the internet—at times creating unwarranted fear and anguish. For this reason, some critics are calling for an individual ban on each company offering genetic testing through the internet—at least until the company proves that counseling and interpretation by a qualified provider accompany the test results.

II. Regulation of Genetic Tests by FDA

A. A Brief History of FDA

The United States Food and Drug Administration is the oldest federal regulatory agency, and many consider it to be "our most venerable and respected regulatory institution." It is also considered one of the most important agencies of the federal government, as it regulates five categories of products: cosmetics, food, therapeutic drugs, medical devices, and dietary supplements.

The roots of the agency date back to 1862, when the Division of Chemistry was created as a subset of the United States Department of

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39. Sternesky, supra note 10, at 1. There is no one to counsel or advise the patient on "the method and type of testing; the purpose of the test; the validity of the test; the authorization to order a genetic test; the entities responsible for informed consent; the laboratory personnel requirements; and the regulatory requirements for different types of laboratories." Id.
40. See Javitt et al., supra note 1, at 265.
41. Id.
42. See id. "While the majority of clinical laboratories market their services primarily, if not exclusively, to physicians and health care institutions, there is no federal prohibition on marketing genetic tests directly to consumers." Id. at 271. The complex nature of genetic information is not explained, risks and limitations are not adequately disclosed, tests that lack clinical utility or validity are marketed, and there is no counseling regarding the results. See id. at 265.
43. See id. at 265–67.
44. LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 5 (2002) (quoting Peter Barton Hutt, The Transformation of United States Food and Drug Law, 60 J. Ass'n Food & Drug Officials 9, 30 (1996)).
Agriculture ("USDA"). At the time, there were no laws on the books for the Chemistry Division to enforce, so it analyzed the food supply and provided advice to other parts of the USDA on agricultural chemistry. In 1906, Congress passed the Federal Food and Drugs Act, which created FDA. That legislation was followed in 1938 by the Federal Food, Drug, and Cosmetic Act, which created statutory authority for FDA to regulate the manufacture and sale of foods, drugs, and cosmetics, making it the first agency charged with citizen protection. In 1953, FDA made its final move away from the Department of Agriculture to the Department of Health and Human Services, where it remains today.

The 1938 FDCA has been amended frequently to narrow the broad scope that the originally drafted statute had. The original act contained provisions that were written as mandates—not as operational rules or guidelines for FDA. Yet, in the last thirty years, Congress has not engaged in a comprehensive review of the Act, choosing instead to revise it provision by provision. Thus, the Act has slowly become inconsistent in both its terms and scope. Specifically, "[d]ifferent words are used to mean the same thing in different parts of the statute, different types of authority are granted with respect to similar matters, different enforcement powers are provided for comparable violations, and the relationship among all of the provisions in the statute is increasingly ambiguous." But, despite these inconsistencies, the scale of FDA’s role continues to expand. Growth in the food and drug industries has led FDA to regulate one quarter of the

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46. See Noah & Noah, supra note 44, at 2.
47. See id.
50. See Noah & Noah, supra note 44, at 3, 5.
51. Id. at 3.
52. Id.
53. Id. at 3–4.
United States economy and to employ approximately 10,000 people with a budget of $1.7 billion.

B. An Overview of FDA Oversight of Drugs and Medical Devices

1. The General Premarket Approval Process

A visitor to FDA once recalled seeing a placard in someone’s office that read: “In God we trust. . . . Everyone else must bring data.”

Hard data is necessary because Congress assigned FDA the important task of regulating pharmaceuticals and medical devices, among other things. The agency regulates through a lengthy and thorough review process that culminates in the evaluation of a sponsor’s New Drug Application (“NDA”). An NDA functions as the summary document of all the studies involving the drug or medical device, and it should provide sufficient information to FDA’s investigators for them to determine if the drug or medical device is safe and effective.

Courts have granted great discretion to FDA in promulgating these premarket approval requirements. The agency’s requirements

54. Id. at 5. The value of about one quarter of the United States economy is approximately $1.5 trillion. See Eve E. Slater, Today’s FDA, 352 NEW ENG. J. MED. 293, 293 (2005); THE FOOD AND DRUG ADMINISTRATION’S STRATEGIC ACTION PLAN: PROTECTING AND ADVANCING AMERICA’S HEALTH: RESPONDING TO NEW CHALLENGES AND OPPORTUNITIES (2003), http://www.fda.gov/oc/mcclellan/strategic.html [hereinafter ACTION PLAN].

55. See Slater, supra note 54, at 293.


[A sponsor] shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug.

Id.


60. See Edison Pharm. Co. v. FDA, 600 F.2d 831 (D.C. Cir. 1979), discussed in David J. Wu, A Pharmacogenomics Standard for FDA Drug Approval: Arbitrary and Capricious or Safe and Effective?, 23 BIOTECH. L. REP. 733, 738 (2004). In this case, the agency’s requirement of a double-blind controlled study was challenged by a drug manufacturer. Wu, supra at 738. The court upheld the requirement as an appropriate measure of the agency’s discretion to ensure the safety and effectiveness of a product. Id. “The FDA may refuse [product] ap-
for premarket approval are thus specific and substantial. FDA estimates that it takes approximately eight-and-a-half years to study and test a new drug before it can be approved for the general public.\textsuperscript{61} Other sources estimate that the approval process is much longer and more expensive. According to a Pharmaceutical Research and Manufacturers of America estimate, a mere one out of every five thousand medicines tested is eventually approved for patient use.\textsuperscript{62} Moreover, it takes twelve to fifteen years to bring a new medicine to market, and "the average cost of doing so is $800 million."\textsuperscript{63}

FDA has a couple of primary objectives during the approval process. On the one hand, the agency aspires to ensure that a treatment is safe and effective.\textsuperscript{64} On the other hand, the agency tries to "make promising treatments available as quickly as possible to the people most in need of them."\textsuperscript{65} To meet these two objectives, FDA must make three critical determinations during the approval process. First, it must determine if the benefits of a treatment are outweighed by the risks. Second, it must continue monitoring progress reports from clinical trials to ensure that the treatment is effective. Last, upon conclusion of the clinical trials, it must determine "whether or not the treatment should be sold to the public and, if so, what claims the drug manufacturer can make and what the label should say about directions for use, side effects, and warnings."\textsuperscript{66}

FDA requires that a drug sponsor submit data on safety prior to beginning the first phase of clinical studies. Sponsors can comply in several ways, but they usually do so by submitting data on laboratory
and animal studies.\textsuperscript{67} In these studies, sponsors seek to develop a pharmacological profile of the drug and to determine toxicity of the drug in at least two species of animals.\textsuperscript{68} The purpose of the studies “is to develop adequate data to undergird a decision that it is reasonably safe to proceed with human trials of the drug.”\textsuperscript{69}

The studies on animals measure the degree of the drug’s absorption into the blood, its chemical breakdown, its toxicity, and the speed in which the drug passes from the body.\textsuperscript{70} Animal testing can last from several weeks to several years, depending on the intended use of the drug. In some situations, such as the use of oncologic drugs, testing may continue after human trials have begun in order to determine if cancer or birth defects will result from the use of the drug.\textsuperscript{71} If animal lab tests are favorable, the sponsor files an Investigational New Drug (“IND”) application with the Center for Drug Evaluation and Research (“CDER”) or the Center for Biologics Evaluation and Research (“CBER”).\textsuperscript{72} If the CDER or the CBER grants the IND, then the company may begin clinical trials under the supervision of FDA.\textsuperscript{73} Human testing cannot begin without FDA approval,\textsuperscript{74} and only one out of a thousand chemical compounds passes the animal studies stage to go on to human trials.\textsuperscript{75}

Human clinical trials have three phases. In Phase I treatment trials, a small number of volunteer patients (usually between fifteen and thirty) are given the experimental treatment in gradually larger doses to test for any side effects or complications, as well as to determine a

\textsuperscript{67} See Ctr. for Drug Eval. and Res., Pre-clinical Research, in The CDER Handbook, supra note 61, at 5. Two other methods for compliance are compiling data from previous clinical testing or marketing of the drug in the United States or another country whose population is relevant to the United States population; or undertaking new preclinical studies designed to provide the evidence necessary to support the safety of administering the compound to humans. Id.


\textsuperscript{72} See 21 C.F.R. § 312.42 (2000).

\textsuperscript{73} See Nat’l Cancer Inst., supra note 57.

\textsuperscript{74} Id.

\textsuperscript{75} FDA Off. of Pub. Aff., supra note 63.
safe dose of the treatment.\textsuperscript{76} Phase II treatment trials test the effectiveness of the drug and usually involve several hundred patients.\textsuperscript{77} Following Phase II trials, a decision must be made whether to proceed with Phase III testing.\textsuperscript{78} Protocols are developed, specific data is exchanged, and an agreement is reached between FDA and the treatment sponsor regarding the plan and design of the study.\textsuperscript{79} Phase III trials begin after the agreement is reached.\textsuperscript{80} These trials seek to determine the "overall benefit-risk relationship of the drug," both standing alone and in relation to existing treatments.\textsuperscript{81} Participation can vary from several hundred to several thousand subjects.\textsuperscript{82}

If the clinical trials show that the treatment is safe and effective, then the company or sponsor submits a New Drug Application to FDA.\textsuperscript{83} The NDA is the "vehicle through which ... sponsors formally propose that FDA approve a new pharmaceutical for sale in the United States."\textsuperscript{84} The NDA must include: the exact chemical makeup of the drug; results of animal studies; results of clinical trials; the method by which the drug is made, processed, and packaged; and the standards used for quality control.\textsuperscript{85} FDA works towards a ten-month review period of the NDA. But that time period has actually ranged from forty-two days to several years.\textsuperscript{86}

\textsuperscript{76} See CTR. FOR DRUG EVAL. AND RES., Phase 1 Clinical Studies, in THE CDER HANDBOOK, supra note 61, at 8. "Phase 1 studies ... evaluate drug metabolism structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes." Id.

\textsuperscript{77} See CTR. FOR DRUG EVAL. AND RES., Phase 2 Clinical Studies, in THE CDER HANDBOOK, supra note 61, at 8. "Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition." Id.

\textsuperscript{78} See CTR. FOR DRUG EVAL. AND RES., Sponsor-FDA Meetings (End of Phase 2), in THE CDER HANDBOOK, supra note 61, at 10.

\textsuperscript{79} Id. at 10–11. The sponsor must provide the following to FDA: "data supporting the claim of the new drug product, chemistry data, animal data and proposed additional animal data, results of Phase 1 and 2 studies, statistical methods being used, specific protocols for Phase 3 studies, as well as a copy of the proposed labeling for a drug, if available." Id.

\textsuperscript{80} See CTR. FOR DRUG EVAL. AND RES., Phase 3 Clinical Studies, in THE CDER HANDBOOK, supra note 61, at 9.

\textsuperscript{81} Id.

\textsuperscript{82} Id.

\textsuperscript{83} See 21 C.F.R. § 314 (2003).

\textsuperscript{84} See CTR. FOR DRUG EVAL. AND RES., Clinical Studies (Overview), in THE CDER HANDBOOK, supra note 61, at 7.

\textsuperscript{85} See NAT'L CANCER INST., supra note 57.

\textsuperscript{86} Id.
FDA looks at all the data submitted and the results of its own review; it applies two benchmark questions to each application: Do the results of well-controlled studies provide substantial evidence of the treatment’s effectiveness? Do the results show the product is safe under the conditions of use in the proposed labeling?  

Once FDA rules on an NDA, its decision is virtually unchallengeable. If the treatment is approved, CDER’s Office of Compliance provides post-approval monitoring “to make sure that [the sponsor] complies with current standards and regulations.” The Drug Oversight Safety Board then monitors drugs approved by FDA to ensure continuing safety and communication of information to physicians and patients, to resolve disputes over drug safety, and to develop a national drug safety policy.

2. FDA Regulation of Genetic Tests

Diagnostic laboratory tests that are sold widely to hospitals, doctors’ offices, and commercial laboratories are classified as medical devices by FDA and must go through an FDA approval process. Generally, a medical device is any health care product that does not achieve its principal intended purposes by chemical action in or on the body. “But tests developed by a single laboratory and offered as a


88. See Lars Noah, Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research, 25 J. LEGAL Med. 267, 284 (2004). “Patients, physicians, and other interested persons generally have no direct opportunity to ask a court to review an agency decision to approve or reject an NDA.” Id. “Although courts show tremendous deference to the agency’s scientific judgments, the FDA could not revoke a license on a whim or just because of a shift in the political winds.” Lars Noah, A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics, 36 WAKE FOREST L. Rev. 571, 592–93 (2001) (citing Henley v. FDA, 77 F.3d 616, 620–21 (2d Cir. 1996) and Schering Corp. v. FDA, 51 F.3d 390, 399 (3d Cir. 1995)).

89. NAT’L CANCER INST., supra note 57.


92. Food and Drug Administration, Statement of Policy for Regulating Biotechnology Products, 49 Fed. Reg. 50,878 (Dec. 31, 1984). A more comprehensive definition is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: . . . recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, . . . intended for use in the diagnosis of disease or other conditions, or in the 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, and which does not achieve
service by that laboratory do not require such approval, although the laboratory has to meet certain quality standards. These tests are sometimes known as 'home-brew' tests. 93

FDA has established some regulations on home-brew tests. For instance, it regulates the active ingredients used to perform these tests by classifying the ingredients, known as analyte-specific reagents ("ASRs"), as medical devices. 94 However, the premarket approval process described above is not applied to ASRs; 95 instead, the reagents must comply only with "General Controls," which still fall within the jurisdiction of FDA but face a lower standard. 96 By understanding the way in which FDA regulates ASRs and home-brew tests, one can begin to see the problems inherent in the system. Companies are free to skirt FDA approval process by simply employing home-brew type testing. "Instead of selling a complete test requiring [FDA] approval, [companies] sell the basic ingredients of a test to clinical laboratories. The labs then use the ingredients to make home-brew tests." 97 And the public is none the wiser, as currently FDA does not regulate "[the] communications made by the laboratories providing genetic tests, or the manner in which such tests are sold or provided to patients." 98

93. See Pollack, supra note 91, at C2.
94. See Javitt et al., supra note 1, at 272–73; Sternesky, supra note 10, at 1–2. ASRs typically are chemicals or pieces of DNA. See Pollack, supra note 91.
95. See supra Part II.B.1.
96. See Javitt et al., supra note 1, at 273. General Controls are the basic provisions of the Amendments to the Food, Drug, and Cosmetic Act that provide FDA with the means of regulating devices to ensure their safety and effectiveness. See also Food and Drug Administration, General Controls for Medical Devices, http://www.fda.gov/cdrh/devadvice/363.html (last visited Aug. 17, 2006). General Controls apply to all medical devices, but are the only level of regulation for Level I devices. Id. Level I devices are the least complex devices regulated by FDA. See id. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments. See CDA Design Group, FDA Regulatory Requirements and Approvals, http://www.cdaservices.com/fdaapproval.htm (last visited Aug. 17, 2006). It is difficult to lump the safety issues surrounding genetic testing in with safety issues regarding latex gloves or an ACE bandage.
97. See Pollack, supra note 91. But it seems that it is a fine line these companies walk. "Roche, one of the leaders in the diagnostic testing business, is marketing its gene-chip test in such a way. But the [FDA] said the test appeared to be a complete medical device that should have gone through the regulatory approval process." Id.
98. See Javitt et al., supra note 1, at 273.
Thus, the current approach results in a bipolar system. The rigorous, methodical analysis required for the approval of new drugs, devices, or other blood tests is easily bypassed for genetic testing through the use of home-brew tests. This system leaves "commercial biotechnology companies and other laboratories, which already are offering more than 400 genetic tests to a largely uneducated public, . . . free to decide how accurate their tests need to be before marketing them and what they will say in their advertisements to doctors and others."  

What is the response? FDA currently states that "it lacks the resources" to regulate genetic tests.

III. Regulation of Genetic Tests Under CLIA

The Clinical Laboratory Improvement Amendment of 1988 is the other primary means of regulating genetic tests at the federal level. In 1988, Congress was not yet focused on genetic testing. Instead, Congress passed CLIA as a response to increasing public concern over the quality of clinical laboratory testing in general.  

The Center for Medicare and Medicaid Services implements CLIA, which applies to approximately 175,000 laboratories and sets quality standards designed to assure the reliability and accuracy of test results. Under CLIA, the CMS and the Center for Disease Control's ("CDC") Division of Laboratory Systems "develop[ ] standards for laboratory certification." The standards require laboratories to undergo on-site inspections biannually, and the inspections cover the environment of the lab, the competency of the personnel, as well as quality control and

99. See Weiss, supra note 20.
100. Id. And this might very well be true.

In comparison with other government agencies, the FDA is tiny. It constitutes less than one half of one percent of the federal government's [two] million workers . . . . Over the years, tasks have been routinely assigned to the agency by Congress without the funds to carry them out, so a central problem of the agency over the past century has been to spread the very limited budget over an increasing array of jobs.

HILTS, supra note 49, at xv.


104. Sec'y's ADVISORY COMM., supra note 5, at 9.
assurance mechanisms. However, the focus of these inspections is on “intra-laboratory processes as opposed to the clinical uses of test results.”

The standards set by CLIA are substantial, and they provide for quality control and assurance, proficiency testing, and patient test management. The quality control standard requires the creation of manuals to document processes within the lab, the calibration and validation of instruments, and the written documentation of quality control activities. The quality assurance standard covers the availability and ordering of tests, the level of patient preparation, the adequacy of specimen collection, and the interpretation of lab results. The patient test management standard involves rules to assure the integrity and identification of patient specimens during the testing process.

However, “CLIA does not address additional aspects of oversight that are critical to the appropriate use of genetic tests, such as clinical validity including clinical sensitivity and clinical specificity, clinical utility, and issues related to informed consent and genetic counseling.” Clinical test validation is one of the most important quality assurance measures. As a concept, it determines whether the test actually works and provides accurate results for the patient. Thus, clinical test validation seeks to answer some of the real questions about genetic tests: whether a patient who tests positive for a condition or disease actually has it, and, if so, whether that person will become symptomatic.

105. See id.
106. Id.
107. See 42 C.F.R. § 493.1100 (2000); Schwartz, supra note 101, at 740. See also Javitt et al., supra note 1, at 269 n.108 (quoting 42 U.S.C. § 263a(f)(1) (2000) (“CMS is charged with 'issuing standards to assure consistent performance... of valid and reliable laboratory examinations and other procedures.'”)).
108. See Schwartz, supra note 101, at 740.
109. Id.
110. Id.
111. Sec'y's Advisory Comm., supra note 5, at 9. “Clinical validity refers to the accuracy of the test in diagnosing or predicting risk for a health condition and is measured by the sensitivity, specificity, and predictive value of the test for a given health condition. Clinical utility involves identifying the outcomes associated with positive and negative test results.” Id. at 16.
112. See Am. C. of Med. Genetics, supra note 15. Clinical test validation involves reviewing the literature available on the test, performing correlation studies, defining the test limitations, determining the variables that will be monitored to ensure continued accuracy, addressing any legal, social, or ethical issues, and collecting data on the test procedure and results in order to best inform providers and patients. Id.
113. See Lusky, supra note 56.
After the passage of CLIA, the Secretary of Health and Human Services ("HHS") issued standards for laboratories that included proficiency standards for specific areas such as hematology and cytology\(^1\)—standards that must be met before a test can be performed. However, even though laboratories that offer genetic testing are subject to CLIA, CMS has not mandated proficiency testing standards for genetic testing.\(^1\) Thus, there is no "nationwide proficiency testing or even licensing process for laboratories that perform genetic tests."\(^1\)

### IV. The Movement Towards Increased Regulation of Genetic Tests

#### A. Clinical Laboratory Improvement Advisory Committee

The 1988 CLIA amendments also created an advisory committee—the Clinical Laboratory Improvement Advisory Committee ("CLIAC").\(^1\) CLIAC is an ongoing committee, still in existence today. The committee provides non-binding guidance to the Secretary of HHS.\(^1\) It has twenty members—all of whom have expertise in the specialties surrounding clinical laboratory testing.\(^1\) The members are drawn from FDA, the CMS, and the CDC.\(^1\) However, at the time that CLIAC was formed, genetic testing was in a nascent stage, and it was not represented by a member on the committee.\(^1\)

CLIAC recommendations have addressed staffing, confidentiality and informed consent, quality control, contamination, proficiency testing, test validation, record retention, and specimen reuse.\(^1\)

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114. See Javitt et al., supra note 1, at 268–69.
115. See Sternesky, supra note 10 at 1. "While genetic testing laboratories are subject to CLIA, the amendments offer no genetic-specific regulations other than the cytogenetics specialty, resulting in limited evaluation and quality assurance oversight." Id.
116. Weiss, supra note 20, at A12. Whether this is because the science is moving at such a brisk pace or because testing has not been sufficiently prioritized is unclear at this point.
117. See Schwartz, supra note 101, at 740.
118. Id. at 741.
119. Id.
121. See Schwartz, supra note 101, at 741.
122. Id. at 742–44.

Health and Human Services will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of CLIA. CLIAC will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology . . . . CLIAC . . . will review and
CLIAC has also addressed a myriad of areas relating to genetic-testing procedures.128

But, perhaps due to the absence of an expert on genetic testing on the committee, CLIAC issued no guidance for the field until 1997. At that time, a subgroup within the committee produced a strategic plan for genetic testing that called for the establishment of "standards, regulations and guidelines to ensure the accuracy, validity and precision of laboratory procedures [for genetic testing] and to ensure that other quality assurance issues [were] addressed as well."124 Ultimately CLIAC concluded that a discrete genetic-testing section should be added to CLIA.125 The committee members felt that "the high degree of precision and accuracy required for genetic testing required stringent regulations."126

CLIAC adopted two definitions of genetic testing—one addressing the analysis of DNA, RNA, and chromosomes, the other addressing the analysis of proteins and metabolites.127 Both testing types seek to "predict[ ] risk of disease, [to] identify[ ] carriers, and [to] establish[ ] prenatal or clinical diagnos[e]s or prognos[e]."128 Regulating these tests was a step in the right direction. Yet, despite this move towards increased specific oversight, CLIAC has made little mention of regulating test results or of verifying a test's clinical validity.

B. Task Force of the National Human Genome Research Institute

Independent of the direct federal regulatory structures of FDA and CLIA, the Task Force of the National Human Genome Research Institute was created in April 1995, primarily by the National Institutes of Health and the Department of Energy.129 Its mission was to review

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123. Id. at 740–41.
124. Id. at 742–44.
125. See Schwartz, supra note 101, at 741–42. “This conclusion was based on the fact that although the testing technology is similar to that used in other laboratory areas, the sensitivity of genetic testing results and the social, economic, and legal aspects of such tests require[d] a separate section in CLIA.” Id. at 742.
126. Id. at 742.
127. Id.
128. Id.
genetic testing in the United States and to ensure it was safe and effective. The Task Force defined safety and effectiveness to include "not only the validity and utility of genetic tests, but their delivery in laboratories of assured quality, and their appropriate use by health care providers and consumers." It recognized that, while genetic testing was a growing field, there were still many things unknown.

For example, there were, and still are, no means by which to alter or improve conditions caused by inherited diseases. Negative test results cannot definitively rule out a future occurrence of disease, nor can a positive test result be relied upon as definitive evidence that a disease will occur. Thus, the Task Force emphasized the need for regulation, pointing out that some genetic tests were introduced into the marketplace prior to being proved safe and effective. It also highlighted the need for continued monitoring once a test reaches the marketplace.

Further, the Task Force suggested that test developers should provide data to a primary regulating body in order to develop standards for routine use. Ultimately, the Task Force recommended the formation of a group that could have a more direct effect on the regulatory process. That group became the Secretary's Advisory Committee on Genetic Testing ("SACGT").

C. Secretary's Advisory Committee on Genetic Testing

The Secretary's Advisory Committee on Genetic Testing was formed by the Secretary of HHS in June 1998. Its purpose was "to advise the Department of Health and Human Services on the medical, scientific, ethical, legal, and social issues raised by the development and use of genetic tests." SACGT worked on several issues: the criteria used to assess the benefits and risks of genetic testing, how those criteria could be used to differentiate between tests, how to analyze and publish data on a test, and how genetic testing could be moni-

131. Id.
132. See id.
133. See id.
134. See id. "When preliminary data indicate a test is likely to have validity and utility, the test should be approved for marketing but developers must continue to collect data until more definitive answers are obtained." Id.
135. See id.
136. See id.
137. Sec'y's Advisory Comm., supra note 5, at 1.
SACGT identified several options for oversight of genetic testing: the strengthening of the current CLIA and FDA regulations, the formation of interagency review boards, and the formation of professional organizations. Public comments on the options yielded a wide variety of suggestions—one of the more popular being the designation of FDA as the agency to oversee tests. This suggestion was adopted by SACGT.

SACGT also recommended that CLIA regulations be revised for increased specificity on quality standards for labs, and in 1999, SACGT formally supported CLIAC’s recommendations for increased oversight. In July 2000, SACGT refined its support of CLIAC by submitting a report to the Secretary of HHS that outlined its recommendations on genetic testing. The report called for FDA regulation of genetic tests, including home-brews. CLIAC/SACGT further attempted to develop a proposed rule for genetic tests by publishing a Notice of Intent. It announced that HHS would prepare a Notice of Proposed Rulemaking based on recommendations from CLIAC.

The Notice of Intent addressed definitions and categories of genetic testing, clinical validity issues, informed consent, confidentiality, genetic counseling, as well as pre-analytic, analytic, and post-analytic issues, which included test requisition, retention, quality control and proficiency testing, and personnel qualifications and responsibilities. It also recommended that the agency’s “review processes must minimize the time and cost of review without compromising the quality of the assessment of test validity.” Public responses to the Notice of Intent demonstrated that most supported the creation of the specialty but felt that the proposed definitions were too broad.

One of the primary questions that emerged was whether a method could be instituted to assign levels of oversight for a test based

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138. *Id.* at 4.
139. *Id.* at 25.
140. *Id.* at 25, 27. “FDA should be the federal agency responsible for the review, approval, and labeling of all new genetic tests that have moved beyond the basic research phase . . . . FDA must delineate review processes for pre-market evaluation of genetic tests.”
141. *Id.* at 27.
142. *See* Boone, *supra* note 120.
143. *Id.*
145. *See* Ctrs. For MEDICARE And MEDICAID Services, *supra* note 102.
146. *See* Boone, *supra* note 120.
147. SEC’Y’S ADVISORY COMM., *supra* note 5, at x.
148. *See* Boone, *supra* note 120.
on its characteristics. For example, should a genetic test that is more complex receive greater oversight than a more basic test? Such a solution would lead to more efficient use of resources, making it a common-sense choice for the fast-growing field. Thus, in August 2000, SACGT submitted an addendum to the July 2000 oversight report that addressed this classification system.149

The committee used four criteria to classify a genetic test: “[T]est volume; whether the test would be used for population-based testing; whether the test [was] diagnostic or predictive; and a set of three questions related to the availability of an intervention, the predictive value of the test, and potential for medical or social harms associated with the test.”150 The classification methodology was a bifurcated system. A test would be assigned to either Scrutiny Level I (“SL I”) or Scrutiny Level II (“SL II”) based on values associated with the criteria above.151

However, problems became evident when pilot testing began. For instance, problems arose with the criterion of test volume “since some low volume tests, which according to the proposed methodology would warrant SL I, might have heightened ethical and social implications that would warrant an SL II review.”152 The criteria were therefore changed to include analytical validity and disease frequency, and public comment was sought.153 The responses that were received raised significant concerns regarding the ability of the criteria to successfully classify genetic testing. SACGT “concluded that fundamental, irresolvable questions had been raised about the feasibility of categorizing tests for oversight purposes based on a limited set of elements in a simple, linear fashion”154 and, thus, “decided that further efforts to develop a classification methodology for genetic tests should be


150. Id. Test volume was used for its public health concerns, ensuring that resources are directed at the population most likely to benefit from the test. Id. Population-based screening, the second criterion, was defined as “testing of groups or populations of currently healthy people rather than individuals or families.” Id.

151. Id.

152. Id. at 8.

153. Id. Analytical validity was defined as “the ability of a test to measure or detect the analyte it is intended to measure or detect.” Id. at 8. Frequency of disease “divided tests by whether they tested for a common or rare disease.” Id. at 10.

154. Id. at 11.
curtailed."\textsuperscript{155} Essentially, SACGT deferred the task of developing a classification methodology, leaving it to FDA.\textsuperscript{156}

The Secretary's Advisory Committee on Genetics, Health, and Society recently replaced SACGT, and this new committee is supposed to "address the broader implications resulting from the development and application of genetic technologies."\textsuperscript{157} However, the current administration has tabled SACGT's recommendations pending a new review.

V. Options for Increased Regulatory Oversight of Genetic Tests

Taking into consideration the actual progress made towards a regulatory scheme for genetic testing, or the lack thereof, there are several basic options that could improve the current system. First, existing FDA and CLIA regulations could be strengthened. If federal coordination was emphasized, and the agencies were to work in concert, then the situation would likely progress from its current state. This would represent an improvement because "CLIA's regulatory tools are different than those available to the FDA," so "some reasonable combination of both might be used to address the concerns regarding genetic testing."\textsuperscript{158} However, this combination of efforts would create a significant risk of inefficiency, necessitating that any new regulations explicitly delineate a focus on interagency cooperation and coordination in order to ensure that the agencies do not work in parallel. The agencies would

have to be careful to avoid duplicating oversight efforts[.] For example, if CLIA were to do clinical reviews of lab-developed tests, and the FDA did some form of premarket reviews, that's double work. Also, CLIA oversees labs, not manufacturers. And when a lab takes an ASR and creates a new test system, the lab becomes a manufacturer. CLIA is not really intended to oversee that [function].\textsuperscript{159}

A second option is to place regulation of genetic tests under the sole purview of FDA. As detailed above, FDA's experience regulating all other types of laboratory tests, as well as foods and drugs, makes it well-equipped to implement CLIAC's recommendations for genetic

\textsuperscript{155} \textit{Id.}

\textsuperscript{156} \textit{See id.}


\textsuperscript{158} Lusky, \textit{supra} note 56.

\textsuperscript{159} \textit{Id.}
testing. If FDA lacks the resources to regulate genetic tests, then the needed resources should be allocated to FDA. Further, by overlaying some of the ongoing monitoring programs, which FDA currently maintains for drugs and medical devices, the quality of genetic-testing results would arguably be improved. A larger, more comprehensive, and current system of monitoring could eclipse the fragmented programs that are now in place, leading to the creation of databases on the accuracy of genetic testing, an important objective in the area.

A third option is to empower professional associations, such as the American College of Medical Genetics or the American Society of Human Genetics, to self-police the field. There are a growing number of professional organizations becoming involved with the genetic-testing issue. A partial list includes: the Association of Public Health Laboratories; the American College of Medical Genetics; the College of American Pathologists; the National Committee on Clinical Laboratory Standards; the Commission on Office Laboratory Accreditation; the American Society of Human Genetics; the Working Group on Ethical, Legal, and Social Implications of the Human Genome Project; and the National Advisory Council for Human Genome Research.

These associations, through consultation with experts in the field, could set guidelines for genetic testing. Or perhaps a group similar in membership to the now-disbanded SACGT could be formed as a certification board, and it could be tasked with the review and approval of genetic tests. Merely forming this group would not, of course, overcome the problem that SACGT failed to solve: creating an actual evaluation system. Whether the system would mirror the current FDA process or assume another identity entirely still needs to be addressed—as does the creation of a framework that would give these groups legal authority to regulate. This option would likely only function if it were derived from federal or state statutes.

Assuming enhanced regulatory oversight of genetic tests can be achieved, timing then becomes a critical issue. Due to rapid advancements in the field, a regulatory system could become obsolete—or at

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160. See supra note 100 for further discussion on this point. In regards to FDA’s budget, it is worth noting that
the Agriculture Department, which focuses on a far narrower range of products and activities, is ten times larger in personnel and fifty times larger in budget. The Army Corps of Engineers has a budget three times that of the FDA; NASA’s budget is about a dozen times larger . . . . [FDA’s] chief failures to this day result from the lack of people and resources to carry out the tasks mandated.
Hilts, supra note 49, at 15.

161. See Cunningham, supra note 19, at 37; Sternesky, supra note 10 at 1.
least ineffective—in a very short period of time. It remains clear that genetic testing has a rich future, but that future might require a period of waiting for the “research stage” of the genetic-testing science life cycle to end. When this ending will come is impossible to predict. Simply put, is there enough knowledge within this field to institute an effective regulatory framework right now, or is it imprudent to do so? It seems clear that the home-brew issue must be addressed now, either through a wholesale reclassification of genetic tests as medical devices or through a movement to sweep home-brews under the umbrella of medical devices. But what about other aspects of genetic testing?

On a high level, at least something is apparent. While each option for oversight has its proponents and detractors, there seems to be unanimity in the scientific community on one point: physicians must become educated on genetics.

Increased oversight and vigilance by third parties are useless gestures without informed care options from a qualified physician. Thus, as to this regard, the American College of Medical Genetics has recommended that only health care professionals should be authorized to order and receive genetic test results. Patients should not be granted direct access to genetic tests, as they must be educated on probabilities and the levels of doubt associated with the process.

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162. See Quintana-Trias, supra note 4, at 17.

163. See Weiss, supra note 20 at A1. “A 1995 survey found that one-third of medical schools still did not require course work in genetics. And a 1997 study of 177 patients who underwent testing for an inherited colon cancer gene found that doctors misinterpreted the results about one-third of the time.” Id.


165. Id.

166. See Weiss, supra note 20 at A1. This might be more difficult than it appears. For example, a recent British study analyzed stroke victims’ consent processes, revealing that thirty-nine percent of the patients surveyed did not know that one in four was a twenty-five percent reduction. Letter from Simon J. Ellis et al. to the Editors (Jan. 13, 2001), in Informed Consent Is Flawed, 357 LANCET 149, 150 (2001) (citing National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group, Tissue Plasminogen Activator for Acute Ischaemic Stroke, 333 New Eng. J. Med. 1581–87 (1995)). “44% did not know that a reduction of 25% was a reduction of a quarter; and 43% did not know that a reduction of 25% was equivalent to a reduction of 25 in 100.” Id. The report concluded that “[a] substantial minority of people in this population . . . could not process simple statistical information . . . .” Id.
VI. Criticism of Increased Regulatory Oversight

Detractors of the call for increased regulation point to several factors. First, they note that increased regulation will provide no guarantee of improved quality. Errors still occur with blood testing that has been widely available for decades. This testing is currently subject to CLIA and FDA regulation. But proponents of increased regulation answer that guarantees are not the goal; rather, the goal is merely to provide or improve a certain measure of quality—just as with the current testing systems.

A second criticism is that regulation would increase the time and costs of bringing a genetic test to the marketplace. Some have argued that certain tests, such as those for rare genetic diseases, "would not be economical to develop if FDA approval were required" and that "the greater the level of federal oversight of those tests, the less likely someone might be to try to develop the test." Recent publicity regarding FDA has not been helpful. It merely reinforces the idea that FDA's approval process is "notorious for its slow pace and bureaucracy" and that its close ties to the food and pharmaceutical industries destroy its objectivity.

Regardless of the possible veracity of these perceptions, they cannot serve to detract from imposition of a regulatory system. While FDA's reputation has suffered setbacks in recent times, any weak-


170. See supra Part V.

171. See Mark B. McClellan, FDA: Protecting and Advancing America's Health, 14 HEALTH MATRIX 357, 365 (2004). "[D]evelopers of new medical products that are designed to treat serious illnesses increasingly need to set aside billions of dollars or redirect their research activities from potentially valuable directions in anticipation of the potentially unlimited risk of mass tort lawsuits." Id.; see also Epps, supra note 6.


174. See Richard Horton, Commentary, Lotronex and the FDA: A Fatal Erosion of Integrity, 357 LANCET 1544, 1544 (2001); see also Kellman, supra note 90.
nesses in its architecture must be addressed, regardless of the issues involving regulatory oversight of genetic testing.

Finally, some have remarked that the law often serves as a blunt instrument. With a field as fraught with uncertainty as genetics, perhaps the law should be fashioned to function as a surgical probe or scalpel, rather than a police baton. However, to the extent it functions in that manner, perhaps a more important question needs to be addressed: When should laws ever be made? How much evidence of abuse must be gathered and documented before a more robust regulatory system is implemented?

VII. Conclusion

As early as 1997, clear concerns were being voiced for genetic testing:

Science may outstrip public health policy... and policy decisions made as a “knee jerk” reaction may impede access to medical care;... policy decisions may be made by individuals with narrow fiscal interests;... actions by certain groups may exceed reasonable interventions and cause emotional reactions in the scientific and public policy communities; and... patients and practitioners will be faced with information overload... .  

But undeniably, the power and significance of genetic information in society continues to grow. The recent passage, in the United States Senate, of the Genetic Information Nondiscrimination Act attests to this. Thus, it has become increasingly evident that—regardless of the composition of the ultimate regulatory scheme for genetic testing—the regulations will need to anticipate the future of the science and undergo frequent analysis to ensure they are keeping pace with the expansion.

175. Interview with Sara Rosenbaum, Professor, The George Washington University School of Law (discussing how legal scholars have described the use of law).
176. See Javitt et al., supra note 1, at 263, 265.
At some point, the government must intervene in the current scheme and provide increased oversight of genetic testing.\textsuperscript{181} Again, when this should actually occur is still an open question. It rightly offends the sensibilities of qualified clinicians to have the doctor-patient relationship so thoroughly co-opted by directly marketed genetic tests. Yet, there are not, at least at this point, parades of abuses arising in the media and elsewhere that highlight any negative impact the commercial laboratories are having on an unsuspecting public. But why should society wait for the negative impacts to mount before planning a solution?

The current disparate regulatory structure provides little necessary protection to consumers and patients. By increasing the resources of FDA and charging the agency with total oversight of genetic testing, efficiencies of scale and scope could be realized. As the sole overseer of genetic testing, FDA would be equipped to determine where the cracks in the armor of genetic regulation are and to fix those cracks. A good place to begin would be with the adoption of CLIAC and SACGT’s recommendations. They contain the fruits of much work by genetic experts and provide an excellent foundation for a specific genetic-testing regulatory system.

Genetic testing is already within the radar of Mark McClellan, the current Commissioner of FDA. His strategic plan lists as one of its first objectives: “Direct agency research programs and develop standards to effectively handle emerging technologies, especially in areas of pharmacogenomics, gene therapy, and combination devices” in order to achieve the goal of “more efficient and rapid translation of new scientific developments and breakthroughs into safe and effective medical products.”\textsuperscript{182}

\textsuperscript{181} The United States is not alone in this regard. From an international standpoint, European countries are also seeking to address the issue of quality assurance and regulations for genetic testing. But they, too, have yet to settle on a format. See Cox, \textit{supra} note 157, at 178, 179. “[T]he European Thematic Network for Cystic Fibrosis and the European Genetics Quality Network . . . have supported external quality assessment schemes and development of ‘best-practices’ protocols through the consensus process among its international participants.” \textit{Id.}

There are more than 400 laboratories in the networks. “Thus, there has been wide acknowledgement among the international community that genetic testing requires additional measures to assure quality in laboratory practices and that this can be achieved by a combination of enhanced regulatory oversight, adherence to recommendations developed by professional organizations, and participation in voluntary quality assurance programs.” \textit{Id.} “An internationally recognized accreditation system for genetic testing laboratories does not yet exist.” \textit{Id.} at 180.

\textsuperscript{182} See \textit{Action Plan, supra} note 54.
Thus, the tide may be slowly turning to a unified regulatory strategy, but it must turn with some alacrity, as advances in the field are not waiting for federal oversight efforts to catch up. Because FDA already regulates most laboratory tests as medical devices, the transition should not be difficult when the appropriate time comes. Only "with adequate quality assurance and education about the meaning of the results"\textsuperscript{183} can we achieve the rich potential of genetic tests—the ability to effectively realize the meaning of the phrase "planning for the future."\textsuperscript{184}

\textsuperscript{183} See Epps, supra note 6.
\textsuperscript{184} See id.