ONE STEP AT A TIME: ETHICAL BARRIERS TO HOME GENETIC TESTING AND WHY THE U.S. HEALTH CARE SYSTEM IS NOT READY

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Introduction: Facing the New Challenges of Home Testing

Over the past decade, swift advances in medical genetics¹ combined with the increasing popularity of consumer-driven health care have contributed to a sharp rise in the availability of home genetic tests.² Home (also known as direct-to-consumer or direct access) ge-

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^{1.} According to the American College of Medical Genetics, medical genetics refers to "a branch of biomedical science that studies the relationship between genes and health." American College of Medical Genetics, Genetics Frequently Asked Questions, http://www.acmg.net/AM/Template.cfm?Section=genetics_Frequently_Asked_Questions_GFAQs_&Template=/CM/HTMLDisplay.cfm&ContentID=2217 (last visited Feb. 20, 2008). Clinical genetics is "a primary medical specialty focused on health and illness of individuals and their families."

^{2.} See Associated Press, Home Genetic Tests for Disease, CBS News HEALTHWATCH, Mar. 6, 2005, http://www.cbsnews.com/stories/2005/03/06/health/ main678386.shtml [hereinafter CBS News]. Consumer-driven, or consumer-directed, health care emerged as the philosophy behind many of the health care reform initiatives of President Bush and Republican leaders in Congress. It underlies the Bush Administration's advocacy of Health Savings Accounts, which President Bush discussed during the 2006 State of the Union and which were authorized as part of the 2003 Medicare Modernization Act. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1201, 117 Stat 2066 (2003). See Robert Pear, Health Care, Vexing to Clinton, Is Now at Top of Bush's Agenda, N.Y. TIMES, Jan. 29, 2006, at 1.1; Timothy S. Jost & Mark A. Hall, The Role of State Regulation in Consumer-Driven Health Care, 31 Am. J.L. & Med. 395 (2005). See also Marshall B. Kapp, Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice, 2 J. HEALTH & BIOMEDICAL L. 1 (2006) (arguing that objections to consumer-driven health care are inconsistent with general conceptions of patient autonomy in bioethics); Michele Melden, Guarding Against the High Risk of High Deductible Health Plans: A Proposal for Regulatory Protections, 18 Loy. Consumer L. Rev. 403 (arguing that the rhetoric about con-

netic tests encompass a huge range of products and services; including tests to determine paternity or the sex of a fetus, an individual's likelihood to develop certain diseases, or the expected efficacy of particular pharmaceuticals and dietary choices. The availability of home genetic tests has surged as companies appeal to consumers' desire for information about their genetic makeup and fear that the release of this information to employers and insurance companies could lead to adverse employment or insurance coverage decisions.³

Consumer access to health care information has expanded in recent years through the availability of detailed health information on websites such as WebMD,⁴ as well as through significant increases in advertising for pharmaceuticals and other health products.⁵ While empowering patients to take charge of their own health status ideally could lead to better health, clinical testing for genetic conditions has not developed to the point that the industry can safely incorporate it into the home setting. Genetics experts have increasingly scrutinized the scattershot regulation of genetic tests and advocated integrating home testing into a comprehensive plan for stricter regulation of all genetic tests.⁶

This Comment argues that the regulation of home tests should not take place until after the federal government has successfully regulated genetic tests in the traditional setting. While the home testing industry advocates home testing as a solution to access disparities and genetic discrimination concerns in traditional genetic testing, home

sumer choice in health care leads to policies that actually constrain consumer choice). During the 2008 Presidential primary campaign, several of the Presidential candidates made consumer empowerment and choice the foundation of their health platforms. Though Health Savings Accounts and other "consumer-driven" health care ideals have been more traditionally espoused by Republicans, *see*, *e.g.*, Mitt Romney for President, Reducing Spiraling Health Care Costs, http://www.mittromney.com/health care (last visited Aug. 14, 2008); John McCain, Straight Talk on Health System Reform, http://www.johnmccain.com/Informing/Issues/19ba2f1c-c03f-4ac2-8cd5-5cf2ed b527cf.htm (last visited Nov. 12, 2007), Democratic candidates used concepts like individual choice in describing health care plans as well. *See*, *e.g.*, John Edwards 08, Universal Health Care Through Shared Responsibility, http://www.johnedwards.com/about/issues/health-care-overview.pdf (last visited Aug. 14, 2008).

- 3. See Sandra G. Boodman, Too Much Information: Results of Home DNA Tests Can Shock, Misinform Some Users, Wash. Post, June 13, 2006, at F1 [hereinafter Too Much Information].
 - 4. WebMD, http://www.webmd.com (last visited Mar. 10, 2008).
- 5. Spending on direct-to-consumer advertisements of pharmaceuticals increased by 330 percent from 1996 to 2005. Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertisement of Prescription Drugs*, 357 New Eng. J. Med. 673, 675 (2007).
- 6. See, e.g., Gail H. Javitt & Kathy Hudson, Federal Neglect: Regulation of Genetic Testing, Issues in Sci. & Tech., Spring 2006, at 59.

testing does not solve these problems. Only after policymakers better understand the ethical implications of genetic testing should they consider whether genetic tests can be offered directly to consumers in a safe and ethically sound manner. Part I of this Comment describes the history of genetic diagnosis and the laws and regulations that currently govern this aspect of the health care system. Part II identifies the primary types of genetic tests currently available through the home test market. Part III explores some of the ethical concerns that arise in the context of home genetic testing, including the challenge of obtaining truly informed consent for testing and the difficulty in ensuring test accuracy. Part IV argues that home genetic testing should be outlawed at least until genetic testing as a whole is better regulated and that, in the meantime, policymakers should educate the public about the dangers of home testing.

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THE RECENT HISTORY AND CURRENT REGULATORY STRUCTURE OF GENETIC DIAGNOSIS

Virtually all diseases stem at least partially from our genetic make-up.⁷ The completion of the Human Genome Project, which mapped the entire human genome, accelerated the development of the field of medical genetics and the understanding of the genetic components of disease.⁸ The National Center for Human Genome Research, now the National Human Genome Research Institute of the National Institutes of Health, began the Project in 1990 and completed it in 2003.⁹

Currently, genetic tests can provide information about over one thousand diseases, though the types of tests and the types of information available vary widely. Genetic tests look for changes in a person's genes that could indicate the presence of an inherited disorder. Carrier testing identifies unaffected individuals who carry a recessive

^{7.} National Human Genome Research Institute, A Brief Guide to Genomics, http://www.genome.gov/18016863 (last visited Aug. 14, 2008).

^{8.} National Human Genome Research Institute, About the Institute: A History and Timeline, http://www.genome.gov/10001763 (last visited Aug. 14, 2008).

^{9.} Id.

^{10.} Gail H. Javitt & Kathy Hudson, Public Health at Risk: Failures in Oversight of Genetic Testing Laboratories 5 (2006), *available at* http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf [hereinafter Public Health at Risk].

^{11.} National Human Genome Research Institute, Frequently Asked Questions about Genetic Testing, http://www.genome.gov/19516567 (last visited Aug. 14, 2008).

genetic mutation.¹² Many couples choose to undergo this form of testing when they are planning to have children and want to know if they are at an increased risk of giving birth to a child with certain genetic diseases.¹³ Genetic prenatal tests identify genetic abnormalities in a developing fetus, and preimplantation genetic diagnosis identifies abnormalities in an embryo that was created by in vitro fertilization.¹⁴

For individuals with symptoms of certain genetic diseases, some genetic tests can confirm the diagnosis. Tests can also predict one's propensity to develop a particular disease in the future by identifying genes that increase the chance of getting a disease. For example, tests exist for an increased propensity to develop certain cancers, such as breast cancer and colon cancer. A number of testing companies now offer "pharmacogenetic testing," a new technology that may predict an individual's reaction to particular drugs. Some types of pharmacogenetic tests look at an individual's genes for signs that a certain pharmaceutical product would be beneficial to that person. Others look for alterations in genes that could indicate how well a person's body will break down particular drugs.

A. The Current Regulatory Structure: Clinical Laboratory Improvement Amendments

Genetic testing "falls between several regulatory 'cracks' within the federal government" because several government entities oversee genetic testing, but no single entity covers all genetic tests.²⁰ The Centers for Medicare and Medicaid Services (CMS) has primary authority for regulating laboratory testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).²¹ CLIA covers all laboratories that conduct testing on human specimens to diagnose or treat

^{12.} 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, 258 (2004) [hereinafter *Direct-to-Consumer Genetic Tests*].

^{13.} Cf. Frequently Asked Questions about Genetic Testing, supra note 11.

^{14.} Direct-to-Consumer Genetic Tests, supra note 12, at 258-59.

^{15.} Id. at 259-60.

^{16.} Frequently Asked Questions about Genetic Testing, supra note 11.

^{17.} Direct-to-Consumer Genetic Tests, supra note 12, at 260.

^{18.} Frequently Asked Questions about Genetic Testing, supra note 11.

^{19.} Id.

^{20.} Direct-to-Consumer Genetic Tests, supra note 12, at 254.

^{21.} Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (2000); U.S. Dep't of Health and Human Servs., Ctrs. for Medicare & Medicaid Servs., Clinical Laboratory Improvement Amendments (CLIA): Overview, http://www.cms.hhs.gov/clia/ (last visited Aug. 14, 2008).

diseases or conditions, including labs in physician offices or hospitals and independent labs.²² Congress passed the original version of CLIA, the Clinical Laboratory Improvement Act, in 1967 and revised it after finding that a significant percentage of U.S. laboratories were subject to limited, or no, federal regulation.²³

Before the 1988 Amendments, a confusing system of regulation, weak enforcement tools, and lack of federal government access to information about lab quality resulted in minimal oversight and compromised quality of laboratory testing as a whole.²⁴ As much as twenty-five percent of testing took place in laboratories that were subject to "diminished or ambiguous regulatory standards" or no standards at all.²⁵ Laboratories in physicians' offices and laboratories that performed a low volume of testing were particularly likely to face little or no regulation.²⁶ The starkest example of the dangers of inadequate laboratory standards emerged from reports of a nationwide pattern of labs reporting a high number of false negatives on pap smear tests, resulting in preventable illness and death for unknown numbers of women.²⁷

CLIA prohibits laboratories from performing clinical laboratory tests without being issued a federal certificate. CLIA regulations categorize all laboratory tests as waived, of moderate complexity, or of high complexity.²⁸ Waived tests are those which are "so simple and accurate as to render the likelihood of erroneous results negligible" or which "pose no reasonable risk of harm to the patient if the test is performed incorrectly."²⁹ Other tests are graded according to a series of criteria to determine if they are of "moderate complexity" or "high complexity." These criteria include the difficulty of the scientific and technical knowledge necessary to conduct the tests, the stability and

^{22.} CTRS. FOR MEDICARE & MEDICAID SERVS., CMS INITIATIVES TO IMPROVE QUALITY OF LAB. TESTING UNDER THE CLIA PROGRAM 1 (2006), available at http://www.cms.hhs.gov/CLIA/downloads/060630.Backgrounder.rlEG.pdf. "Laboratory" is defined in CLIA as "a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." 42 U.S.C. § 263a(a) (2000).

^{23.} H.R. Rep. No. 100-899, at 12-13 (1988), as reprinted in 1988 U.S.C.C.A.N. 3828, 3833.

^{24.} Id., as reprinted in 1988 U.S.C.C.A.N. 3828, 3833-34.

^{25.} Id. at 13-14, as reprinted in 1988 U.S.C.C.A.N. 3828, 3834.

^{26.} Id. at 14, as reprinted in 1988 U.S.C.C.A.N. 3828, 3835.

^{27.} Id. at 16-17, as reprinted in 1988 U.S.C.C.A.N. 3828, 3837.

^{28. 42} C.F.R. § 493.5 (2007).

^{29. 42} C.F.R. § 493.15 (2007).

reliability of the materials used for testing, and the level of judgment required by those administering the tests.³⁰

High complexity and moderate complexity tests are grouped into specialty and subspecialty areas that establish the standards that labs must follow in order to be CLIA certified. For example, the Chemistry specialty includes four subspecialties including Urinalysis and Toxicology.³¹ Laboratories that conduct high or moderate complexity tests must adhere to laboratory inspection, registration, and quality assurance requirements, and comply with proficiency testing.³² Proficiency testing assesses whether a laboratory can get the "correct result" on a sample and is based on standards specific to specialties and subspecialties under CLIA.33 Laboratories must enroll in a proficiency testing program for any specialty or subspecialty in which it wishes to be certified.³⁴ The proficiency testing program provides the lab with a testing sample to evaluate the accuracy of the laboratory's testing procedures.³⁵ The lab must test the sample in the same manner that it conducts patient tests and must document the testing process.³⁶ For those areas of testing for which there is no relevant specialty or subspecialty, the laboratory does not have to adhere to specific proficiency standards, but it "must establish and maintain the accuracy of its testing procedures"37 by twice annually verifying the accuracy of the tests.³⁸ Some of the ways that laboratories might verify the accuracy of the tests without proficiency standards are by comparing results with another laboratory or conducting statistical analyses of patient outcomes.39

Genetic testing regulation falls within the general regulation of lab testing. Despite the fact that genetic tests qualify as "high complexity," there is no genetic testing specialty under CLIA, meaning that labs conducting genetic tests do not have to verify the accuracy of

^{30.} For each of seven criteria, the test is given a score of 1 to 3, with 3 representing the highest level of complexity, and the scores are totaled. Tests with a total score of 12 or less are categorized as moderate complexity; tests with a score of more than 12 are categorized as high complexity.

^{31.} Centers for Medicare & Medicaid Services, Lab. Certification (LC) Codes: CLIA Specialty & Subspecialty Info. (Oct. 26, 2007), *available at* http://www.cms.hhs.gov/CLIA/downloads/lccodes.pdf.

^{32.} See 42 C.F.R. § 493.17 (2007).

^{33. 42} C.F.R. § 493.901 (2007).

^{34. 42} C.F.R. § 493.801 (2007).

^{35.} See id.

^{36. 42} C.F.R. § 493.801(b).

^{37. 42} C.F.R. § 493.801(a)(2)(ii).

^{38. 42} C.F.R. § 493.1236(c)(1) (2007).

^{39.} American Academy of Dermatology Association, CLIA Quick Facts, http://www.aad.org/pm/resources/clia_facts.html (last visited Mar. 13, 2008).

these tests in accordance with any particular standards.⁴⁰ CLIA itself does not address the "clinical validity" of specific genetic tests. This means that a genetic test can be approved under CLIA even if there is not a strong connection between the genetic information being tested for and the disease or condition that a positive test is supposed to predict.⁴¹

Genetics experts and lawmakers have called for the establishment of a genetic testing specialty under CLIA to standardize proficiency requirements for genetic tests.⁴² Until the summer of 2006, it appeared that federal regulators agreed. In 2000, the Secretary's Advisory Committee on Genetic Testing (now the Secretary's Advisory Committee on Genetics, Health, and Society) of the Department of Health and Human Services (HHS) recommended that specific standards for genetic testing be incorporated into CLIA.⁴³ Also that year, HHS published a Notice of Intent to issue a proposed rule to create a CLIA genetic testing specialty.⁴⁴

In March 2006, after HHS had not acted on the Notice of Intent for several years, Genetic Alliance, an umbrella organization for numerous genetic disease advocacy groups, called on then-CMS Administrator Mark McClellan to develop a genetic testing specialty under CLIA.⁴⁵ In April 2006, HHS put the release of such a rule on its Semiannual Regulatory Agenda.⁴⁶ However, CMS officials failed to follow through on this commitment.

During a Senate Aging Committee hearing in July 2006, Thomas Hamilton, Director of the CMS's Survey and Certification Group, testified that CLIA already covers genetic testing, as genetic tests fall

^{40.} See Am. Soc'y of Human Genetics Bd. of Dirs., ASHG Statement on Direct-to-Consumer Genetic Testing in the United States, 81 Am. J. Human Genetics 635, 636 (2007), available at http://www.dnapolicy.org/resources/ASHG_DTC_statement.pdf [hereinafter ASHG Statement].

^{41.} Id. at 635-36.

^{42.} See, e.g., id. at 636, 637. In March of 2007, Senators Ted Kennedy and Gordon Smith introduced legislation that would, among other provisions, require the Secretary of HHS to issue a proposed rule establishing a specialty area for genetic testing. S. 736, 110th Cong. § 7(d) (2007). However, there has been no action on the legislation since its introduction.

^{43.} Sec'y's Advisory Comm. on Genetic Testing, Enhancing the Oversight of Genetic Tests: Recommendations of the SACGT, 25–28 (2000), http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf.

^{44.} Notice of Intent; Genetic Testing Under the Clinical Laboratory Improvement Amendments, 65 Fed. Reg. 25,928 (May 4, 2000).

^{45.} Genetic Alliance, February 2006 Press Release calling for a Genetic Testing Specialty Under CLIA (March 2, 2006), http://www.geneticalliance.org/ws_display.asp?filter=policy.clia.release.

^{46.} Regulatory Agenda, 71 Fed. Reg. 22,537, 22,544 (Apr. 24, 2006).

under various specialties covered by CLIA.⁴⁷ CMS confirmed its decision not to create a genetic testing specialty during a meeting between CMS officials and representatives of the Genetics and Public Policy Center in August 2006.⁴⁸ Senator Gordon Smith, Chairman of the Aging Committee, issued a statement in October 2006 imploring HHS Secretary Michael Leavitt to reconsider or explain the decision.⁴⁹ In August 2007, the Director of the Center for Medicaid and State Operations within CMS, Dennis G. Smith, wrote a letter to Kathy Hudson, Director of the Genetics and Public Policy Center, reiterating CMS's decision not to create a genetic testing subspecialty under CLIA.50 In the letter, Smith explains that he does not believe that creating such a specialty will lead to the development of more proficiency tests.⁵¹ Smith is pessimistic about the likelihood of developing proficiency tests for genetic tests in the foreseeable future, citing the "slow and painstaking" development of proficiency tests and the swift development of new genetic tests.⁵² He cites as an example the fact that proficiency tests for cytogynelogical examinations, or Pap smears, were not available nationwide until 2005, despite being specifically called for in the 1988 CLIA legislation.⁵³

Smith believes that CMS "can more effectively oversee genetic testing under existing regulations and infrastructure."⁵⁴ He cites to CMS' "Action Plan for Oversight of Genetic Testing," which calls for "targeted application" of current laws, collaboration among federal agencies to improve availability of proficiency testing, and improvements in the information available to those responsible for surveying laboratories.⁵⁵ Though Smith's letter and the existence of the "Action"

^{47.} At Home DNA Tests: Marketing Scam or Medical Breakthrough?: Hearing Before the S. Spec. Comm. on Aging, 109th Cong. 9 107–108 (2006) [hereinafter Hearing on Aging] (statement of Thomas Hamilton, Director, Survey & Certification Group, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services).

^{48.} Public Health at Risk, *supra* note 10, at 11 (citing meeting between representatives of the Genetics and Public Policy Center and representatives of the Centers for Medicare and Medicaid Services, August 3, 2006).

^{49.} Press Release, Smith Questions CMS' Failure to Ensure Competency of Genetic Testing Labs (Oct. 31, 2006), http://aging.senate.gov/minority/index.cfm?Fuse Action=pressReleases.Detail&PressRelease id=565&Month=10&Year=2006.

^{50.} Letter from Dennis G. Smith, Director, Center for Medicaid and State Operations, to Kathy Hudson, Director, Genetics and Public Policy Center (Aug. 15, 2007), available at http://www.cms.hhs.gov/CLIA/downloads/Kathy%20Hudson%20-%20signed%20response.pdf.

^{51.} Id. at 2.

^{52.} Id. at 3.

^{53.} Id.

^{54.} Id. at 8.

^{55.} Id. at encl. 2.

Plan" indicate that federal regulators are aware of the particular challenges of assuring the safety and reliability of genetic tests, the letter also confirms that CMS has no plans to use CLIA to more specifically regulate genetic tests. Given the apparent resistance of the federal agency responsible for CLIA to developing a specialty for genetic tests or making other changes to the relevant laws, it is unlikely that genetic tests will face additional regulation in the foreseeable future.

B. Other Genetic Testing Regulations

The Food and Drug Administration (FDA) also plays a role in the patchwork regulation of genetic testing. Under the Food, Drug, and Cosmetic Act,⁵⁶ the FDA regulates genetic tests that qualify as "in vitro diagnostic devices," which are freestanding products intended for use in the diagnosis of a disease or medical condition.⁵⁷ However, many testing products avoid FDA regulation because they qualify as "home brews," tests developed internally by laboratories and marketed to the public as laboratory services rather than as freestanding test kits.⁵⁸

The Centers for Disease Control and Prevention (CDC) also shares responsibility for the regulation of laboratory testing through the Clinical Laboratory Improvement Advisory Committee (CLIAC).⁵⁹ CLIAC's charter authorizes the committee to advise HHS, CMS, FDA, and CDC regarding the need for any revisions to clinical laboratory regulations.⁶⁰

The Federal Trade Commission (FTC) administers a large number of consumer protection laws, especially those relating to unfair or

^{56. 21} U.S.C. §§ 301-397 (2000).

^{57.} See Direct-to-Consumer Genetic Tests, supra note 12, at 268.

^{58.} *Id.* at 272. A test is a "home brew" if each of its components has been developed within the laboratory that conducts the test. The FDA has recently considered regulating certain home brew tests, specifically in vitro diagnostic multivariate index assays (IVDMIAs). IVDMIAs use an algorithm along with patient data (such as genetic information) to diagnose diseases or conditions. U.S. Food & Drug Admin., FDA Drafts Regulatory Guidance to Industry and Labs for Group of Medical Tests (Sept. 5, 2006), *available at* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01445. html. The FDA released a draft guidance for the regulation of these tests on July 26, 2007. However, such a guidance is not legally enforceable, but represents the FDA's "current thinking" on a topic. Center for Biologic Evaluation and Research, U.S. Food and Drug Administration, Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays 3 (2007), *available at* http://www.fda.gov/cdrh/oivd/guidance/1610.pdf.

^{59.} Department of Health and Human Services, Charter: Clinical Laboratory Improvement Advisory Committee (Jan. 25, 2006), *available at* http://www.phppo.cdc.gov/cliac/pdf/CliacCharter2006.pdf.

^{60.} Id.

deceptive practices.⁶¹ Though the FTC has claimed jurisdiction over the advertising of genetic tests, it has not taken action against any company for a deceptive advertisement or test.⁶² However, in July 2006, the FTC, in cooperation with the FDA and CDC, published a notice for consumers warning about the dangers of home genetic tests.⁶³ The notice explains that home genetic tests may be inaccurate, have inadequate privacy protections, or make erroneous claims about their ability to diagnose, predict, or treat certain diseases.⁶⁴ The FTC recommends that consumers avoid home tests unless under a physician's supervision.⁶⁵

State laws regarding testing standards vary considerably. Most state agencies implement the CLIA standards but do not add to the requirements.⁶⁶ New York and Washington are the only two states exempt from CLIA requirements because their state standards for laboratory certification are more stringent than federal standards.⁶⁷ The New York Clinical Laboratory Evaluation Program (CLEP) provides permits to New York State laboratories that undergo successful inspections and pass proficiency evaluations on an annual basis.⁶⁸ CLEP includes genetic testing as one of the categories for which it grants laboratory permits.⁶⁹

State laws specifically applying to direct-to-consumer testing vary as well, with eighteen states prohibiting all direct-to-consumer testing.⁷⁰ New York's Public Health Law limits consumers' direct ac-

^{61.} Federal Trade Commission, Guide to the Federal Trade Commission (March 2004), http://www.ftc.gov/bcp/edu/pubs/consumer/general/gen03.shtm.

^{62.} Genetics and Public Policy Center, Direct-to-Consumer Genetic Testing: Empowering or Endangering the Public? (July 25, 2006), http://www.dnapolicy.org/policy.issue.php?action=detail&issuebrief_id=32.

^{63.} FEDERAL TRADE COMMISSION, FTC FACTS FOR CONSUMERS, AT-HOME GENETIC TESTS: A HEALTHY DOSE OF SKEPTICISM MAY BE THE BEST PRESCRIPTION 1 (July 2006), http://www.ftc.gov/bcp/edu/pubs/consumer/health/hea02.pdf.

^{64.} Id. at 1-3.

^{65.} Id. at 1-2.

^{66.} Direct-to-Consumer Genetic Tests, supra note 12, at 273-74.

^{67.} CENTERS FOR MEDICARE AND MEDICAID SERVICES, CMS INITIATIVES TO IMPROVE QUALITY OF LABORATORY TESTING UNDER THE CLIA PROGRAM 2 (July 2006), http://www.cms.hhs.gov/CLIA/downloads/060630.Backgrounder.rlEG.pdf; Centers for Medicare and Medicaid Services, List of Exempt States Under the Clinical Laboratory Improvement Amendments (CLIA), http://www.cms.hhs.gov/CLIA/downloads/Exempt.States.List.pdf.

^{68.} New York State Department of Health, Clinical Laboratory Evaluation Program, http://www.wadsworth.org/labcert/clep/clep.html (last visited Dec. 20, 2006).

^{69.} New York State Dep't of Health, New York State 2007-2008 Laboratory Permit Category Descriptions 5 (Feb. 2007), http://www.wadsworth.org/labcert/clep/Administrative/categorydescriptions.pdf.

^{70.} Direct-to-Consumer Genetic Tests, supra note 12, at 274 n.134.

cess to testing services to tests that have been FDA-approved for use without a prescription from a medical professional.⁷¹ Other states allow direct-to-consumer testing for certain types of tests. For example, Maine allows for testing without a physician's referral for glucose, colon cancer, pregnancy and cholesterol tests.⁷²

Despite the existence of state laws prohibiting direct-to-consumer testing, the accessibility of products on the Internet makes it difficult to effectively ban consumer access in states where direct access testing is illegal. The online testing company DNA Direct, discussed further below, states explicitly on its website that it ships tests to all U.S. states.⁷³ The lack of specific regulations for genetic tests coincides with the availability of a growing array of tests of unknown reliability and creates an increasingly dangerous situation for consumers.

11.

THE CURRENT HOME GENETIC TESTING MARKET

Four types of genetic testing dominate the home testing market: paternity or other relationship-based testing, nutrigenetic testing, pharmacogenetic testing, and predictive genetic information testing. Each of these categories of tests has been scrutinized for problems with accuracy, conclusiveness, and safety, highlighting the problems of the widespread lack of regulation.

A significant number of home genetic testing companies focus primarily or exclusively on paternity or other relationship-based testing.⁷⁴ For example, the "Baby Gender Mentor" test professes to reveal the sex of a fetus as early as five weeks into a pregnancy.⁷⁵ The paternity and other relationship tests use DNA from cheek swabs submitted in test kits to provide information for either private use or for legal purposes. The "Baby Gender Mentor" uses a blood test to look for male or female genetic materials.⁷⁶

^{71.} N.Y. Pub. Health Law § 576-b (2008).

^{72.} Me. Rev. Stat. Ann. tit. 22, § 2030(2) (1964).

^{73.} DNA Direct, About DNA Direct: Shipping Information, http://www.dnadirect.com/about/shipping.jsp (last visited Mar. 13, 2008).

^{74.} Some companies offering home paternity tests include: *IDENTIGENE*, www. dnatesting.com (\$249–\$649), Genelex, http://www.genelex.com/paternitytesting/paternityindex.html (\$400–\$900), and Metaphase Paternity Testing, www.metaphase genetics.com (\$89–\$440).

^{75.} Acu-Gen Biolab, Inc., Baby Gender Mentor, http://babygendermentor.com/information.php?information_id=6 (last visited Nov. 10, 2007) [hereinafter Baby Gender Mentor].

^{76.} Id.

Nutrigenetic or nutrigenomic home tests claim to use genetic information to provide consumers with customized nutrition and lifestyle advice.⁷⁷ For example, Sciona, Inc. offers the "Mycellf Program," which uses the results of tests of nineteen different genes and a "diet and lifestyle questionnaire" to create a "personalized diet and lifestyle plan."78 The program generates an "Action Plan" for the individual with nutrition and lifestyle recommendations.⁷⁹ The company's website includes "Action Plan Samples," which focus on goals such as increasing vitamin D and calcium intake, minimizing caffeine intake, and lowering body weight.80 Nutrigenetic tests have been the subject of recent scrutiny, as a Government Accountability Office (GAO) investigation uncovered numerous quality issues with tests offered by several companies.81 GAO found that test results from several companies included predictions that were "medically unproven and so ambiguous that they do not provide meaningful information to consumers."82 GAO concluded that the companies derived results from the general lifestyle information the sample consumers submitted rather than the genetic material itself.83 In addition, nutrigenetic test companies often recommend vitamins and other dietary supplements along with their treatment plans, which are then sold by the same companies.84

Pharmacogenetics is a newly emerging kind of genetics test that purports to analyze the efficacy and safety of particular drug treatments for individual patients.⁸⁵ Companies such as Genelex claim to determine whether pharmaceuticals such as blood thinners, antidepressants, and allergy medications are appropriate for an individual pa-

^{77.} Hearing on Aging, supra note 47, at 3 (statement of Gregory Kutz, Managing Director, Forensic Audits and Special Investigations, U.S. Government Accountability Office).

^{78.} Sciona, Inc., Mycellf Online – How Mycellf Works, http://www.mycellf.com/how-Mycellf-works2.aspx (last visited Feb. 22, 2008).

^{79.} Sciona, Inc., Mycellf Online – Action Plan Samples, http://www.mycellf.com/action-plan-samples-more.aspx (last visited Feb. 22, 2008).

^{80.} Id.

^{81.} *Hearing on Aging, supra* note 47, at 3–4 (statement of Gregory Kutz, Managing Director, Forensic Audits and Special Investigations, U.S. Government Accountability Office).

^{82.} Id. at 6.

^{83.} *Id.* at 6. The GAO study submitted multiple samples of the same individual's DNA along with different lifestyle profiles and found that the test results and recommendations had much more to do with the survey than the genetic information.

^{84.} Id. at 20.

^{85.} Direct-to-Consumer Genetic Tests, supra note 12, at 260.

tient, and if so, in what dosage.⁸⁶ Though pharmacogenetics has shown promise in determining appropriate dosages for cancer and HIV treatments, pharmacogenetics is still in an early stage of development.⁸⁷ Though Genelex warns on its website that individuals should not alter the dosage amount for their medications without consulting a medical professional,⁸⁸ the early stage of this area of medicine makes the involvement of a physician throughout the process of testing essential. There may be information in an individual's medical history that changes the import of pharmacogenetic test results or makes pharmacogenetic testing inappropriate for a certain individual. Without the involvement of a medical professional throughout the testing process, an individual might spend a substantial amount of money on a test with little medical significance in his or her situation.

Other home products focus on carrier status of genetic diseases and predictive genetic information. For example, alterations in the BRCA1 and BRCA2 genes indicate a higher risk of developing breast cancer and ovarian cancer.⁸⁹ Home genetic tests are also available to test whether individuals carry genes for diseases such as clotting disorders, cystic fibrosis, and Tay-Sachs disease.⁹⁰ San Francisco-based DNA Direct, one of the most prominent home-based testing companies,⁹¹ offers home tests of carrier status or predictive information for numerous genetic diseases, with prices ranging from several hundred to several thousand dollars per test.⁹² DNA Direct markets itself as the upper echelon of Internet-based genetic testing in terms of quality control, range of services available, and involvement of medical professionals for pre- and post-test counseling.⁹³ A company official was

^{86.} Genelex, Health & DNA: Drug Reaction Testing, http://www.healthanddna.com/drugreactiontest.html (last visited Feb. 22, 2008).

^{87.} National Institute of General Medical Sciences, National Institutes of Health, Frequently Asked Questions about Pharmacogenetics, http://www.nigms.nih.gov/Initiatives/PGRN/Background/pgrn_faq.htm (last visited Feb. 22, 2008).

^{88.} Genelex, supra note 86.

^{89.} National Cancer Institute, National Institutes of Health, Genetic Testing for Breast and Ovarian Cancer Risk: It's Your Choice, http://www.nci.nih.gov/cancertopics/Genetic-Testing-for-Breast-and-Ovarian-Cancer-Risk (last visited Feb. 22, 2008).

^{90.} See, e.g., DNA Direct, Tests and Pricing, http://www.dnadirect.com/patients/tests/test_pricing.jsp (last visited Mar. 13, 2008).

^{91.} CBS News, supra note 2; Too Much Information, supra note 3, at F1; Sandy Kleffman, Genetic Test May Sound False Alarm: Firms Make Medical Predictions Using Results From Home DNA Kit, but Investigators Question Accuracy, Knight Ridder Trib. Bus. News, Aug. 6, 2006, at 1.

^{92.} DNA Direct, Tests and Pricing, http://www.dnadirect.com/patients/tests/test_pricing.jsp (last visited Mar. 13, 2008).

^{93.} See Victoria Colliver, Home DNA Tests: When You Just Have to Know, SAN FRANCISCO CHRON., Aug. 21, 2007, at C1. "The company's founder. . .said she tries to distinguish DNA Direct from other players in a largely unregulated market by using

quoted distinguishing DNA Direct's products from nutrigenetic tests, which he described as lacking a basis in "solid science." In contrast, the official described the tests offered by DNA Direct as ones "that have been proven, that have been out there, that you can get through your doctor's office." 95

III.

ETHICAL CHALLENGES IN GENETIC TESTING

The ethical issues implicated by home genetic testing reflect the larger ethical concerns surrounding genetic testing as a whole. The debate over whether to create a genetic testing specialty within CLIA is part of a larger argument about whether genetics should be considered a distinct medical specialty. Some academics argue that the probabilistic nature of genetic tests, the implications for family members, and the "aura of immutability" about genetic information distinguish genetics from the rest of medicine. However, others warn that "genetic exceptionalism" results from misunderstandings about genetics and believe policies treating genetics and genetic information as indistinguishable from traditional medicine and medical information better protect patients' interests.

The American College of Medical Genetics (ACMG) released a statement in 2004 that "at the present time, genetic testing should be provided to the public only through the services of an appropriately qualified health professional." ACMG cited potential dangers of home testing including "inappropriate test utilization, misinterpretation of test results, lack of necessary follow-up, and other adverse consequences." ACMG acknowledged the importance of patient autonomy in medical genetics but explained that autonomy in genetic

federally certified labs, licensed genetic counselors and an individual report written for consumers." *Id.*

^{94.} Kleffman, supra note 91, at 1.

^{95.} *Id*.

^{96.} See Direct-to-Consumer Genetic Tests, supra note 12, at 260–62. But see Letter from Dennis G. Smith, supra note 50 (arguing that creation of a genetic testing specialty within CLIA would pull tests out of other specialties where they currently exist).

^{97.} Direct-to-Consumer Genetic Tests, supra note 12, at 261.

^{98.} See Lainie Friedman Ross, Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV, 29 J.L. Med. & Ethics 141, 145 (2001); Sonia M. Suter, The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?, 79 Wash. U. L.Q. 669, 705–06 (2001).

^{99.} American College of Medical Genetics Board of Directors, *ACMG Statement on Direct-to-Consumer Genetic Testing*, 6 GENETICS IN MED. 60, 60 (Jan./Feb. 2004), *available at* http://www.acmg.net/resources/policies/Direct_Consumer_Testing.pdf. 100. *Id.*

decision-making stems from the nondirective nature of genetic counseling. Effective nondirective counseling cannot exist without adequate information, something that the home testing format cannot provide. ¹⁰¹ In September 2007, ACMG released an updated statement acknowledging that "more genetic tests are available than ever before" and stating that this greater availability brings "increased risks to the public." ¹⁰² The statement warned that many available tests are of "dubious validity" and that it is "critical" to involve a genetic counselor or medical geneticist in the genetic testing process. ¹⁰³

This Part describes three primary ethical concerns with genetic testing, all of which are more significant in the home testing context: the inability of home testing to provide for adequate informed consent, the problem of ensuring accuracy of test results, and the potential impact of home testing on access to the health care system. It also describes countervailing advantages of home testing, including protection from genetic discrimination, and compares home genetic testing to home HIV testing, which raised many similar ethical challenges when it emerged in the 1980s.

A. Informed Consent and the Need for Counseling

The process of informed consent involves a medical professional informing a patient of the patient's diagnosis and the risks and benefits of a proposed treatment or procedure and its alternatives (including not undergoing a treatment or procedure). To provide for truly informed consent, a patient must be given an opportunity to ask questions so as to make an informed decision about undergoing a course of treatment. The existence of the genetic counseling discipline to guide individuals undergoing, or considering undergoing, genetic testing points to the difficulty of many of the personal decisions involved in testing, specifically the complicated nature of consent for genetic tests. To secure informed consent, genetic counselors employ a multistep process including "a careful explanation of the scientific aspects

^{101.} Linda L. McCabe & Edward R.B. McCabe, *Direct-to-Consumer Genetic Testing: Access and Marketing*, 6 Genetics in Med. 58, 58 (Jan./Feb. 2004).

^{102.} Press Release, American College of Medical Genetics, Statement on Direct-to-Consumer Genetic Testing: Genetics Professionals Should be Part of Testing Process Says American College of Medical Genetics (Sept. 24, 2007), available at http://www.acmg.net/AM/Template.cfm?Section=Home3&Template=/CM/ContentDisplay.cfm&ContentID=2395.

^{103.} Id

^{104.} Am. Med. Ass'n, Informed Consent (2007), http://www.ama-assn.org/ama/pub/category/4608.html.

^{105.} Id.

of genetic testing, addressing test sensitivity, specificity, possibility of indeterminate test results, actions the patient may take given a positive or negative test result (anticipatory guidance), and the cost of testing."¹⁰⁶ Anticipatory guidance involves nondirective counseling, which encourages patients to imagine various "what-if" scenarios and anticipate how they might react to different test results.¹⁰⁷

Informed consent is particularly challenging when preparing patients for the possibility of an indeterminate test result. ¹⁰⁸ Inconclusive results may cause patients even more anxiety and distress than a positive diagnosis. ¹⁰⁹ It is essential that patients understand the possibility that they may undergo the stress and expense of genetic testing without learning anything conclusive about their current or future health status. ¹¹⁰ In addition, genetic counselors help patients understand that a negative diagnosis often does not mean a total elimination of risk. ¹¹¹

Current home genetic testing services fail to provide adequate processes to ensure informed consent for testing, as home testing likely cannot mimic the process of nondirective genetic counseling. 112 Even when home test companies offer genetic counseling, they do not mandate that customers undergo counseling as a prerequisite for taking any test. 113 For example, DNA Direct "encourage[s] consumers to raise questions or concerns to board-certified experts at any point before, during, and after testing at no additional cost—either by phone or email," but it only requires pre-test counseling for a limited selection of tests. 114 Without mandatory counseling, consumers who are

^{106.} Shelly Cummings, *The Genetic Testing Process: How Much Counseling Is Needed?*, 18 J. CLINICAL ONCOLOGY 60s, 62s (2000).

^{107.} *Id.*; see also Mary Terrell White, Making Responsible Decisions: An Interpretive Ethic for Genetic Decisionmaking, Hastings Center Rep., Jan.–Feb. 1999, at 14, 15–16.

^{108.} Dorothy C. Wertz & John C. Fletcher, *Communicating Genetic Risks*, Sci, Tech., & Human Values, Jun. 1988, at 60, 60.

^{109.} Cummings, supra note 106, at 63s.

^{110.} Id

^{111.} See id. In many cases, the presence or absence of a particular genetic marker is not conclusive, but only shows an increased or decreased chance of developing a disease or condition.

^{112.} Critics have found that websites underemphasize risk and overemphasize benefits of testing, and provide insufficient counseling to help consumers understand the context of test results. *See Direct-to-Consumer Genetic Tests*, *supra* note 12, at 253; Sarah E. Gollust, Benjamin S. Wilfond & Sarah C. Hull, *Direct-to-Consumer Sales of Genetic Services on the Internet*, 5 Genetics in Med. 332, 334–36 (2003).

^{113.} See DNA Direct, About DNA Direct: Our Standards, http://www.dnadirect.com/about/standards.jsp (last visited Dec. 20, 2006).

^{114.} *Id.*; DNA Direct, Schedule a Consultation, http://www.dnadirect.com/patients/testing_services/consultation.jsp#schedApp (last visited Aug. 14, 2008).

most worried about the results of their tests, or who least understand the seriousness of potential results, may be the most reluctant to speak to a counselor.

The home testing context is not conducive to a patient making the decision not to take a test. The involvement of a medical professional in predictive genetic testing is essential for patients to effectively weigh options and adequately consider the option of not testing.¹¹⁵ Home test companies' profit motives could reduce employees' motivation to emphasize to patients the option not to test.¹¹⁶ Though conflicts in medicine between clinical and financial motivations are hardly unique to genetic testing, these conflicts are often tempered by insurance coverage and other intermediate steps between a medical professional's clinical decision and the financial impact on the individual making the decision.¹¹⁷ In home testing, the risk of weighing financial considerations over patients' needs is profound as the company depends on out-of-pocket payments by patients with whom the company's employees have no personal stake or ongoing relationship.

The potential implications of genetic test results for family members of those who are tested also point to complicated consent issues that may not be adequately addressed without the personal involvement of a physician or genetic counselor. Individuals who consent to certain tests also consent to receive potentially serious medical information about their relatives. Without having considered in advance how they would handle this kind of knowledge, patients may feel traumatized and confused by the information. Though DNA Direct includes information in patient reports about discussing test results with

^{115.} Sara Chandros Hull & Kiran Prasad, *Reading between the Lines: Direct-to-Consumer Advertising of Genetic Testing*, Hastings Center Rep., May-Jun. 2001, at 33, 34–35.

^{116.} Though DNA Direct prominently states on its website that "DNA Direct informs you of the pros *and* the cons of genetic testing and won't hesitate to tell you if genetic testing is not appropriate for you," this guarantee is not backed up by any descriptions of protective actions taken by the company, such as stating that employees do not work for a commission. *See generally* DNA Direct, About DNA Direct: Shipping Information, http://www.dnadirect.com/patients/about/shipping.jsp (last visited Feb. 29, 2008).

^{117.} Financial considerations also could impact individuals' decision whether to undergo pre-test counseling at all. DNA Direct charges \$75 to \$250 for a pre-test counseling service, which is included in the test price if the individual chooses to test. DNA Direct, Pre-Test and Post-Test Consultations, http://www.dnadirect.com/patients/testing_services/consultation.jsp (last visited Nov. 10, 2007).

^{118.} See Nat'l Cancer Inst., Nat'l Insts. of Health, Genetic Testing for Breast and Ovarian Cancer Risk: It's Your Choice 5 (2006), http://www.nci.nih.gov/cancertopics/Genetic-Testing-for-Breast-and-Ovarian-Cancer-Risk/pdf; Jeffrey P. Kahn, Genetic Testing Is All in the Family, CNN.com, Jul. 25, 2000, http://archives.cnn.com/2000/HEALTH/07/25/ethics.matters/.

family members,¹¹⁹ this one-size-fits-all information may be useless or counterproductive in navigating complex family relationships.¹²⁰

The probabilistic nature of most genetic tests means that consent issues are inherently more complicated than in many other areas of medicine. Though patients, not physicians, should be ultimately responsible for decisions about their own health care, the difficulty of understanding the results of genetic tests makes the involvement of health professionals essential. 122

The problem of informed consent in home genetic tests is exacerbated when the information for consumers on home test websites is unclear or misleading. For example, under the heading, "Science Behind Facts: Informed Consent is a Must Before Taking the Test," the Baby Gender Mentor website includes a long paragraph of seemingly unconnected scientific statements, footnoted with forty-two scientific articles. Though this is an extreme example, and companies like DNA Direct do strive to include layperson-friendly information on their sites, it is very likely that an individual will be unable to understand what exactly a genetic test is testing for or what results mean. For example, DNA Direct's "sample report" for Cystic Fibrosis (CF)

^{119.} DNA Direct, Sample Report for Cystic Fibrosis, http://www.dnadirect.com/tests/sample_reports/CF.html#fam_ch4 (last visited Dec. 20, 2006) [hereinafter Sample Report for Cystic Fibrosis].

^{120.} See Kahn, supra note 118; Karen H. Rothenberg & Sharon F. Terry, Before It's Too Late – Addressing Fear of Genetic Information, Sci., Jul. 2002, at 196, 197.

^{121.} The New York State Civil Rights Law has specific consent procedures for "predispositional" genetic testing, or testing that tests an individual's likelihood of developing certain diseases. The law singles out this kind of testing because of the additional level of confusion it presents to patients, since the tests cannot definitively predict the likelihood that an individual will develop a disease. Press Release, Dep't of Law, Attorney General Andrew Cuomo Reaches Agreement on Genetic Testing Disclosures with Columbia University and N.Y.-Presbyterian Hospitals (Apr. 3, 2007), http://www.oag.state.ny.us/press/2007/apr/apr03a_07.html.

^{122.} Id.

^{123.} See Baby Gender Mentor, supra note 75. The "informed consent" information begins as follows [the bracketed numbers refer to footnotes which are not included here]: "PCR has become the standard approach for the detection of the presence of a specific target nucleic acid due to its unprecedented sensitivity [1, 2]. Real-time quantitative PCR allows detection and quantification in a closed system and further extends the linear resolution range of the target dosage with greater accuracy [3-12]. Recent studies show that optimized qPCR can be adopted as an automated routine technique with near-perfect specificity and sensitivity [13, 14, 15]. Acu-Gen Biolab employs AmpliSensor qPCR technique for the quantitative detection of the presence of the DYZ-1 DNA, a highly repetitive Y chromosome sequence [16], which can be detected in the peripheral blood of pregnant woman [17-22]. In contrast to the single-stage amplification technique, AmpliSensor qPCR is a hemi-nested qPCR technique with exquisite sensitivity and specificity [23]." Acu-Gen Biolab, Inc., Science Behind Baby Gender Mentor Test, http://babygendermentor.com/information.php?information_id=3 (last visited Nov. 12, 2007).

screening states that the "patient" did not test positive for a CF gene. However, the report then explains that since "this test does not look for every possible change in the CFTR [cystic fibrosis transmembrane conductance regulator] gene," the patient now has a 1 in 240, rather than 1 in 25, chance of being a CF carrier. The report states that this "negative test result is reassuring" if the sample patient is planning to have a family but warns that the patient still has "residual risk." A consumer reading this information would likely have no idea how to interpret "residual risk" or the relationship between an individual's level of risk and plans to have a family.

The controversial history of home HIV testing provides insight into how consent processes for testing may be incorporated into the home setting. The FDA banned home HIV testing in 1988, but in 1996 it approved one test—manufactured by Home Access Health Corporation—for home use.¹²⁷ The Home Access test remains the only FDA-approved home HIV test.¹²⁸ Critics of home HIV tests objected to the tests primarily because of the lack of in-person counseling and the trauma of receiving a positive diagnosis while isolated at home.¹²⁹ Critics further argued that telephone counseling could not gauge whether an individual was prepared to consent to learn a potentially traumatic diagnosis.¹³⁰

Advocates of home testing criticized the FDA for considering "secondary" safety and efficacy issues such as individuals' reactions to their diagnoses. ¹³¹ Ultimately, the same forces that resulted in the widespread availability of anonymous HIV testing—the fear of driving the epidemic farther underground and the importance of high risk individuals learning their HIV status so as to prevent transmission—led the FDA to reconsider its ban on home testing. ¹³² Studies have indicated that the availability of anonymous and non-reportable HIV

^{124.} Sample Report for Cystic Fibrosis, supra note 119.

^{125.} Id.

^{126.} Id.

^{127.} U.S. Food and Drug Administration, Testing Yourself for HIV-1, the Virus that Causes AIDS, http://www.fda.gov/cber/infosheets/hiv-home2.htm (last visited Mar. 13, 2008).

^{128.} *Id*.

^{129.} See AIDS File, Am. J. Nursing, July 1996, at 14, 14.

^{130.} *Id*.

^{131.} Steven R. Salbu, HIV Home Testing and the FDA: The Case for Regulatory Restraint, 46 HASTINGS L.J. 403, 406 (1995).

^{132.} Press Release, Food and Drug Admin., FDA Approves First HIV Home Test System (May 14, 1996), http://www.fda.gov/bbs/topics/NEWS/NEW00535.html.

testing encourages some people to be tested who otherwise would not.¹³³

There are, however, key distinctions between home HIV tests and home genetic tests. The approved home HIV test makes counseling available after the test to all individuals who test and mandates that all positive test results be provided by a counselor on the telephone. In addition, while a positive result of an HIV test may be traumatic to an individual, one receiving the result likely understands its implications. In contrast, genetic test results such as that of cystic fibrosis, described above, could be confusing for the patient, who would probably have difficulty understanding how their likelihood of being a CF carrier should impact their decision making.

Informed consent involves patients making informed choices based on understanding the option that they are considering as well as any alternatives. As contrasted with HIV testing, there are many cases in which undergoing genetic testing does not provide an individual with reliable health information, and offering complicated tests based on a description on a website may lead to emotional trauma and unwarranted medical decisions.

B. Ensuring Accuracy of Genetic Tests

Another ethical concern is the difficulty of assuring accuracy of genetic tests, in general, and home tests, in particular. The absence of CLIA standards for genetic tests¹³⁶ means that it is difficult to confirm the accuracy of genetic test results, even if tests are conducted in CLIA-certified laboratories. Under current law, there is no way to confirm that different labs use the same standards for the same test, especially if the labs use "home brew" tests.¹³⁷ Furthermore, results of genetic tests are far less determinative than most other forms of medical testing. Not only is it difficult for many patients to understand the meaning of the test and the results, but the same result may have very different implications for different individuals, depending on their health as a whole, the availability of genetic information about other family members, and environmental and lifestyle fac-

^{133.} Scott Burris, Law and the Social Risk of Health Care: Lessons from HIV Testing, 61 Alb. L. Rev. 831, 855 (1998).

^{134.} U.S. Food and Drug Admin., Premarket Approval #BP950002, Home Access HIV-1 Test System: Summary of Safety and Effectiveness 1, 3 (July 22, 1996), available at http://www.fda.gov/Cber/PMAsumm/P950002S.pdf.

^{135.} See supra text accompanying notes 124–126.

^{136.} See supra Part I.A.

^{137.} See supra note 58.

tors. 138 As speaking to a counselor is not a mandatory component of genetic testing processes, patients could inadvertently fail to report facets of their family health history that would have an impact on results. Also, even an accurate test result may mean little if not properly explained to the patient in the context of recommendations for future testing, treatment options, and other recommended follow up.

In contrast, the FDA-approved home HIV test kit can identify 100% of HIV positive test samples and 99.5% of HIV negative test samples without any other information about the patients' medical history. ¹³⁹ Even if home genetic test services incorporate the type of counseling services available in the approved HIV home test, the accuracy of the result and the reliability of the resulting advice depend on numerous factors other than the specific test result.

C. Patient Autonomy, Genetic Discrimination, and Access to Care

Encouraging patient autonomy has been provided as an ethical justification for expanding access to genetic testing. Patient autonomy is usually defined as the ability of patients to make their own choices about their care, even if their physicians disagree with these choices. Thus, patient autonomy in genetic testing comes from patients' greater access to information about their own health care status, which can allow them to make more educated decisions about accessing care. Advocates of home genetic testing tend to collapse the values of autonomy, privacy, and confidentiality together as justifications for expanding the availability of home tests, arguing that the lack of comprehensive genetic discrimination laws renders home testing the only way that patients can control their own health care information.

^{138.} See Cummings, supra note 106, at 60s, 62s.

^{139.} U.S. Food and Drug Administration, Testing Yourself for HIV-1, the Virus that Causes AIDS, http://www.fda.gov/cber/infosheets/hiv-home2.htm (last visited Feb. 22, 2008).

^{140.} See, e.g. Hearing on Aging, supra note 47, at 92–97 (statement of Howard Coleman, Founder and CEO, Genelex Corporation, Seattle, WA).

^{141.} See, e.g., Kapp, supra note 2, at 1–3; When Refusal of Care Endangers Patient Safety, Med. Ethics Advisor, Mar. 1, 2007; Marah Stith, The Semblance of Autonomy: Treatment of Persons with Disabilities Under the Uniform Health-Care Decisions Act, 22 Issues L. & Med. 39, 42 (2006).

^{142.} See, e.g. Hearing on Aging, supra note 47, at 92–96 (statement of Howard Coleman, CEO, Genelex Corporation, Seattle, WA); Amy Harmon, Fear of Insurance Trouble Leads Many to Shun or Hide DNA Tests, N.Y. TIMES, Feb. 24, 2008, at A1 (describing how fear of genetic discrimination and privacy concerns may cause patients to avoid genetic testing or to seek such testing on their own and withhold the results from insurers or health care providers).

Proponents of testing argue that without home genetic testing, certain genetic tests would be unavailable to many patients, either because they cannot find a physician to offer the tests or because they fear consequences, such as genetic discrimination, that prevent them from taking a test in the context of the traditional medical system. 143 Genetic discrimination occurs when entities like health insurers or employers use genetic information to the detriment of an individual.¹⁴⁴ This includes insurers refusing to provide health coverage to someone or charging higher rates for the same coverage, or employers firing or refusing to hire someone because they anticipate that the individual will be unable to work or will expose the employer to significant health care costs. Until recently, no federal law comprehensively addressed genetic discrimination. On May 21, 2008, President Bush signed into law the Genetic Information Nondiscrimination Act of 2008 (GINA),¹⁴⁵ the culmination of Congressional efforts over more than a decade to pass federal genetic discrimination legislation.¹⁴⁶ Previously, federal and state law provided some protection against genetic discrimination. The Health Insurance Portability and Accessibility Act (HIPAA) prohibits insurers from denying coverage based on genetic predisposition to disease. 147 HIPAA labels genetic information as protected health information¹⁴⁸ and prohibits insurers from treating predictive genetic information as a pre-existing condition¹⁴⁹ but does not prohibit insurers from forcing applicants for insurance to undergo genetic testing or charging higher rates based on a genetic diagnosis.150

Former President Clinton issued an executive order preventing the federal government from using genetic information in hiring decisions, but the order did not cover private employers.¹⁵¹ Many states

^{143.} See Too Much Information, supra note 3; see also Harmon, supra note 142.

^{144.} National Human Genome Research Institute, Genetic Discrimination Fact Sheet, http://www.genome.gov/10002328 (last visited Mar. 13, 2008).

^{145.} National Human Genome Research Institute, Genetic Information Nondiscrimination Act of 2008, http://www.genome.gov/10002328#3 (last visited Jun. 7, 2008).

^{146.} Amy Harmon, Congress Passes Bill to Bar Bias Based on Genes, N.Y. TIMES, May 2, 2008, at A1 [hereinafter Harmon, Congress Passes Bill].

^{147.} Health Insurance Portability and Accessibility Act of 1996, 29 U.S.C. § 1182(a)(1)(F) (2006).

^{148.} See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,621 (Dep't of Health & Human Servs. Dec. 28, 2000).

^{149.} See 26 U.S.C. § 9801(b)(1)(B) (2000).

^{150.} Genetic Discrimination Fact Sheet, *supra* note 144; *see also* Health Insurance Portability and Accessibility Act, Pub. L. No. 104-191 (1996).

^{151.} Genetic Discrimination Fact Sheet, supra note 144.

followed suit by adding their own laws prohibiting genetic discrimination.

State genetic discrimination statutes provide varying degrees of protection. New York's insurance law precludes insurers from making eligibility decisions based on a range of factors, including genetic information. In contrast, some states have no health insurance genetic discrimination laws at all. Massachusetts' and Connecticut's law do not have provisions regarding mandatory genetic tests for applicants, and Connecticut does not have provisions requiring informed consent for disclosure of information. However, even comprehensive state laws have limited utility, since under the federal Employee Retirement Income Security Act (ERISA), federal law preempts state law for employers' self-funded health insurance plans. Is

Before 2008, comprehensive federal legislation had been introduced many times but had never passed out of Congress. GINA prohibits employers from using genetic information to make employment decisions, and prohibits health insurance companies from using such information to raise premiums or deny benefits. It also prohibits health insurers from requiring individuals to undergo genetic testing, though insurers can urge individuals to take the tests. The passage of the law was applauded by patient groups and genetics experts, but its efficacy remains to be seen. Experts have pointed to potential problems with enforcement, and the law does not cover life insurance, disability insurance, and long-term care insurance.

^{152.} N.Y. Ins. Law § 3221(q)(1)(F) (2008). New York's law is more comprehensive than many other states, as it applies to both individual and group insurance plans, forbids the use of genetic information to establish eligibility rules, forbids plans from requiring applicants to take genetic tests, forbids the use of genetic information for risk classification, and allows for the disclosure of genetic information only with informed consent

^{153.} National Conference of State Legislatures, Genetics and Health Insurance: State Anti-Discrimination Laws, http://www.ncsl.org/programs/health/genetics/ndishlth.htm (last visited Apr. 5, 2008).

^{154.} Id.

^{155.} Employee Retirement Income Security Act, 29 U.S.C. § 1144(a) (2000); Janet L. Dolgin, *Personhood, Discrimination, and the New Genetics*, 66 Brook. L. Rev. 755, 782 (2001).

^{156.} Id.

^{157.} Harmon, Congress Passes Bill, supra note 146.

^{158.} Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 101 (2008); Harmon, *Congress Passes Bill, supra* note 146.

^{159.} Harmon, Congress Passes Bill, supra note 146.

^{160.} National Human Genome Research Institute, Genetic Information Nondiscrimination Act of 2008, http://www.genome.gov/10002328#3 (last visited Jun. 7, 2008).

The potential benefits of home testing in protecting individuals from genetic discrimination are counterbalanced by the risk that the availability of home genetic testing will compromise access to the health system generally. As the variety of home tests offered grows, it becomes more likely that people, especially those for whom health insurance is prohibitively expensive, may see home testing as an alternative to involvement with the traditional health care system and specifically as a reason not to access preventive care. The founder of one home test company stated, "If a test is (positive), then they obviously go in to the doctor to have further evaluation . . . If everything is fine, then you don't have to waste half a day going to the stupid doctor." Given the lack of determinacy for many genetic diagnoses, the idea of using tests to justify eliminating physician visits may set a dangerous precedent.

Though those who home test for HIV may also choose to disengage themselves from the health care system because of fear of stigma and the high cost of care, several federal and state programs provide health care and other forms of support for HIV-positive individuals. ¹⁶³ In addition, the availability of anonymous HIV testing means that many who test in person receive results outside of the traditional physician-patient relationship anyway. ¹⁶⁴ Therefore, unlike home genetic tests, which likely differ substantially from the process of meeting with a genetic counselor before deciding which tests to take, if any, home HIV tests do not differ in substance and form from many tests administered directly by a medical professional.

Simply giving patients access to information does not improve their ability to make autonomous decisions about their own health care. 165 In fact, people who learn that they have a genetic susceptibil-

^{161.} Julie Davidow, *Surge in Home Diagnostic Kits Provides Doctor in a Box*, Seattle Post-Intelligencer, Mar. 29, 2006, at A1 (parentheses in original) (quoting Ken Adams, owner of AbDiagnostics Inc.).

^{162.} See supra notes 124–26 and accompanying text. In this sample case, a negative test result indicated that an individual has a 1 in 240 chance of carrying the cystic fibrosis gene. Positive results in genetic tests are similarly not definitive, as in many cases a positive result does not indicate that a person will develop a particular disease, but only that the individual has an increased chance. Direct-to-Consumer Genetic Tests, supra note 12, at 260.

^{163.} Henry J. Kaiser Family Foundation, HIV/AIDS Policy Fact Sheet: The HIV/AIDS Epidemic in the United States (July 2007), http://www.kff.org/hivaids/upload/3029-071.pdf.

^{164.} Salbu, *supra* note 131, at 419–20.

^{165.} Some experts have argued that the shift towards more patient autonomy in the doctor-patient relationship has gone too far, with patients sometimes feeling abandoned by physicians who do not give them sufficient guidance in decision-making. See, e.g., Jan Hoffman, Frantic Patients, Lonely Decisions on Treatment: 'None of Us

ity to particular diseases might feel that their options for treatment are limited because of fears of genetic discrimination. Keeping genetic test results a secret from one's physician in order to protect privacy compromises the effectiveness of patient care and sets a bad precedent for medicine as a whole. It is impossible to build a comprehensive system of healthcare based on keeping confidential information entirely out of the health care system.

The ethical concerns surrounding genetic testing cut both ways in terms of home testing. Though the past several decades have seen a move toward involving patients in their own health care decisions, it is necessary for medical professionals to strike a balance between allowing patients to make their own decisions and using their own expertise to provide them with sufficient information to make truly informed decisions. An individual who chooses to take a home genetics test without the participation of his or her doctor is exercising autonomy. But without truly understanding the purpose or the results of the test, that individual cannot use the results to make informed decisions about care. Further, an individual who, through a genetic test, learns significant genetic information about family members may violate the autonomy and privacy of those other family members. Because of the complicated nature of these ethical issues and the fact that many forms of genetic testing are still in early stages of development, genetic testing should not be conducted outside of the physician-patient relationship at the present time, as discussed in the following section.

IV.

POLICYMAKERS SHOULD RESTRAIN THE USE OF HOME GENETIC TESTS IN THE UNITED STATES

Currently, genetic testing is not sufficiently established inside of the traditional health care system to be able to be safely translated outside of the system. The swift rise in home genetic testing points to

Know What You Should Do,' a Doctor Advises a Victim of Cancer, Int'l Herald Trib., Aug. 15, 2005, at 2 (quoting David Mechanic, medical sociologist at Rutgers University, and Meg Gaines, co-founder of the Center for Patient Partnerships); Alan Mozes, Doctors, Patients Take Different View on Tough Medical Choices, But Both Perspectives Are Necessary and Valuable, Study Shows, Health Day, Jun. 2, 2006 (quoting Dr. Ezekiel Emanuel, Chair of the Department of Bioethics at the Clinical Center at the National Institutes of Health as saying, "There has been a tendency for doctors to be a little bit resistant about putting forward their opinions because of the increase in patient autonomy over the last 20 years. And I think that's clearly a mistake.").

166. Harmon, supra note 142, at A1.

the weaknesses of the current regulatory system for genetic testing as a whole. Standards for ensuring that genetic test results are accurate and patients are appropriately informed about the risks and benefits of testing are insufficient to ensure patient safety.

It is premature to incorporate this nascent area of health care into the home setting, especially when home tests are being offered by Internet companies whose products have not been evaluated by any federal agency. As with HIV testing, there may come a time when genetic testing can be safely conducted in the home. However, this should not take place until the standards for genetic testing as a whole are much better established.

A. Creating a CLIA Genetic Testing Specialty

Congress should continue to pressure CMS to honor its previous commitment to establish a genetic testing specialty under CLIA. 167 CMS's assertion that genetic testing falls under other CLIA specialties is inconsistent with the fact that creating a genetic testing specialty was on CMS's agenda for much of the last decade. 168 Even if CMS insists that genetic testing should be incorporated into existing CLIA categories—for example, if testing for a genetic predisposition to cancer should be incorporated into the CLIA cancer specialty—genetic testing is sufficiently distinct from the general category of cancer tests to necessitate the creation of a subspecialty for genetic testing within the cancer specialty.

As the agency responsible for CLIA, CMS should establish proficiency standards for genetic tests. In addition, CDC should establish standards for the other aspects of the testing process. These standards could include mandatory counseling for those undergoing certain kinds of genetic tests, such as those for susceptibility to or presence of life-threatening diseases. Once these standards exist, policymakers can evaluate how, if ever, home tests can adhere to them.

If, as CMS currently believes, there are too many kinds of genetic tests available to develop proficiency tests for most of them in the near future, ¹⁶⁹ this is an added reason why the decision to test should be made under a doctor's supervision. Physicians are more likely than patients to understand if a particular test is likely to be inconclusive or to come up with an incorrect result, and if so, what that means for the patient.

^{167.} See supra Part I.

^{168.} See supra notes 40-50 and accompanying text.

^{169.} See supra notes 51-54 and accompanying text.

B. Discouraging the Use of Home Genetic Tests

Improving regulatory oversight of all genetic tests will help policymakers understand what protections are necessary to allow genetic testing at home. However, this does not solve the problem of protecting consumers from the dangers of genetic home tests in the near term. Simply banning the tests, on either a state-by-state or a federal basis, is unlikely to succeed because of the difficulty of comprehensively banning or regulating anything sold over the Internet. For example, a simple Google search for prescription drugs reveals thousands of websites where consumers can purchase prescription drugs (even carefully regulated painkillers) without a prescription. The fact that lawful websites exist for the sale of prescription drugs (such as websites for brick and mortar pharmacies like Wal-Mart and CVS or web-based companies like drugstore.com) does not limit the online availability of illegal products to U.S. consumers.

Internet gambling exemplifies the difficulty of banning or regulating Internet commerce. Though the U.S. government has taken the position that Internet gambling violates the Wire Act, which bans betting on sporting events through a wire communication facility,¹⁷¹ enforcement of Internet gambling laws has been sporadic at best.¹⁷² Federal jurisdiction to ban Internet gambling is complicated, and one federal circuit has disagreed with the federal government about the applicability of the Wire Act to all Internet gambling.¹⁷³ In defiance of U.S. efforts to prevent residents from gambling over the Internet, some foreign gambling operations have openly acknowledged their widespread use by American customers.¹⁷⁴

National or state-by-state bans on home genetic tests would likely fare similarly to those against Internet gambling. Despite the fact that more than one-third of states ban direct access testing, DNA Direct explicitly states on its website that it ships test kits to all fifty states.¹⁷⁵

^{170.} See, e.g., medrx-one, Prescription Drugs Without a Prescription. Online Pharmacy, http://www.medrx-one.com/ (last visited Aug. 14, 2008); ShopMedsNow.Com, Online Pharmacy: No Prior Prescription Required, http://www.shopmedsnow.com/ (last visited Apr. 6, 2008).

^{171.} Christine Hurt, *Regulating Public Morals and Private Markets: Online Securities Trading, Internet Gambling, and the Speculation Paradox*, 86 B.U.L. Rev. 371, 414–15 (2006) (citing the Wire Communications Act, 18 U.S.C. § 1084 (2000) and accompanying Congressional hearings).

^{172.} See id. at 431.

^{173.} *Id.* at 414–15 (citing *In re* Mastercard Int'l Inc. Internet Gambling Litig., 313 F.3d 257, 263 (5th Cir. 2002)).

^{174.} See, e.g., id. at 416.

^{175.} DNA Direct, About DNA Direct: Shipping Information, http://www.dnadirect.com/about/shipping.jsp (last visited Feb. 29, 2008).

The fact that most tests are sold via the Internet means that, similar to prescription drugs and gambling operations, they will remain available despite any bans. ¹⁷⁶ A blanket ban on home genetic testing will likely serve only to shut down the companies that are currently operating as legitimately as possible within the patchwork of non-comprehensive U.S. laws. It will push the industry further underground and likely encourage the worst actors—companies that provide the least assurance of clinical validity and the most potential to endanger patients through incomplete or inaccurate results.

A more productive federal policy would address the demand for rather than the supply of direct-to-consumer genetic testing. Companies like DNA Direct appear as though they are federally approved because they claim to use only CLIA-regulated labs for testing.¹⁷⁷ A federal policy that all genetic testing websites include a disclaimer that the services of any website offering genetic testing services are not federally regulated or approved and that individuals should not rely on any medical information gleaned from the tests could inform consumers of some of the dangers of accessing the testing. This disclaimer could be modeled after the disclaimers that appear on dietary supplement containers, which warn consumers, "this statement [of the supplement's purported benefits] has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."178 Though, as with a comprehensive ban, the most dangerous products are least likely to carry the disclaimer, consumers shopping around for genetic testing products would probably view the warning on at least some sites. Though this is far from a perfect solution, it has the potential to prevent home genetic testing (and the most dangerous genetic testing) by more consumers than a blanket ban, which would likely have the effect of leaving the most egregious prod-

^{176.} See supra notes 127–133 and accompanying text; see also CBS News, supra note 2 (noting the "increasing number" of startup companies are marketing home genetic tests that are available online); Jennifer A. Gniady, Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution, 76 FORDHAM L. Rev. 2429, 2472 (2008) ("[C]ompanies that choose not to voluntarily enter the FDA device approval process would continue to be subject to state-imposed bans on direct-to-consumer tests. . [I]t is unlikely that such complete bans would be particularly effective given the options for online ordering and delivery of tests via standard parcel post carriers.") (citation omitted).

^{177.} DNA Direct, About DNA Direct: Our Standards, http://www.dnadirect.com/patients/about/standards.jsp (last visited Mar. 14, 2008).

^{178.} U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Overview of Dietary Supplements, http://vm.cfsan.fda.gov/~dms/ds-oview.html (last visited Mar. 13, 2008).

ucts in the marketplace, especially if companies chose to incorporate outside of the country.

These regulatory efforts should be matched with a public education campaign to inform consumers about the dangers of home testing, which could be conducted through grants to states. Improving public knowledge of the reasons that these tests should only be conducted under a physician's supervision could limit their use and may also increase public pressure for regulation of tests as a whole.

The regulatory approach toward home genetic testing should involve convincing the public that home genetic testing is dangerous and unnecessary and taking steps toward making these tests both less dangerous and less necessary. By monitoring the enforcement of the new Genetic Information Nondiscrimination Act, Congress can remove some of the fear that drives people to take tests outside of their relationship with the health care system. By improving regulatory oversight for genetic testing as a whole, the federal government can help improve the safety and accuracy of all genetic tests and can help medical professionals conclude what tests, if any, are appropriate for the home setting.

Conclusion

The burgeoning home genetic testing market exemplifies a central conflict in the U.S. health care system between those who advocate for change within the system and those who choose instead to opt out of the system to avoid its limitations. When actors in the health care system feel constrained, they sometimes opt out of the system. For example, physicians sometimes stop accepting insurance and choose to only treat patients who are able to pay out of pocket, thereby avoiding the system entirely.

Ideally, the rise of the home genetic testing industry will push Congress to ensure the enforcement of the new genetic discrimination law and HHS to work toward the development of standards for safe and effective genetic testing. Highlighting the issue of genetic discrimination may also bring attention to the need for comprehensive health reform in this country. Americans' fears of losing insurance coverage have been an impetus behind genetic discrimination legislation. Once a standard for safe genetic testing has been established, policymakers will be able to make educated decisions about incorporating these standards into the home setting.