
Alexander van Voorhees
NOTE

TRUTH IN TESTING LAWS: A SHOT IN THE ARM FOR DESIGNER GENE TESTS

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Only four years ago, President Clinton announced that the human genome had been successfully sequenced; the federal project encompassed nine years of research at a cost of nearly three billion dollars.1 This past year, a genomics startup revealed that it could successfully decode a person’s DNA in about ten days.2 In the fifty years that have passed since Watson and Crick first announced the famous double-helical structure of DNA to the world,3 scientists have made astounding progress towards understanding human genetics: recent breakthroughs have inspired both hope and alarm.4

The technology has developed so fast that genetic tests like sports-aptitude profiling are closer to reality than to science fiction.5 Recently, scientists in Australia began using DNA samples collected from elite athletes to attempt to identify children who may be future stars.6 The group has identified two genes they believe provide power and stamina, and the Australian company Genetic Technologies now

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2 David Stipp, Speed-Reading Your Genes; Using Biochips, Perlegen Could Turn Our Genetic Uniqueness into Gold, FORTUNE, Sept. 1, 2003, at 150.
3 For an interesting discussion of the events leading up to the announcement, see Bill Bryson, A Short History of Nearly Everything 397-417 (2003).
5 In fact, a rugby team in Australia is already using the technology to tailor its training programs. Carina Dennis, Rugby Team Converts to Give Gene Tests a Try, 434 NATURE 260, 260 (2005).
sells a test for these genes. They market the product as "designer athlete" technology under the pretext that it can tell parents whether their child may be predisposed to excel at a particular sport. Genetic Technologies's home testing kit is now sold to Australians for about one-hundred U.S. dollars via the Internet; next year, the genetic test will be available at sporting clubs and gyms. Using the test is simple: you swipe the inside of someone's mouth with a cotton swab contained in the package and then send it to a laboratory in a preaddressed envelope.

Wouldn't almost every parent want to know if their child might be a future Michael Jordan? Wouldn't many people like to have known about their unexpected knack for golfing when they were young enough to pursue it more seriously? Or, as in my case, to have known about their complete lack of ability, so as not to waste any additional time?

There are now more than one thousand tests available to analyze genetic conditions, and the market for genetic testing is increasing at a rate of 30 percent per year. Many of these tests are the product of an emerging trend to study complex human genetic traits rather than disease-causing single-gene defects. Within the next ten years, scientists will almost certainly be able to test for genes that implicate an array of specific athletic abilities. This Note refers to such predictive athletic testing as "non-pathologic elective testing" or "NPET" in or-

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8 Wallace, supra note 6, at 5.
10 Id.
11 April Lynch, Advances in Genetics Bringing Hope and New Hazards for Health, MERCURY NEWS (San Jose, Cal.), JUL. 25, 2004.
der to distinguish it from other types of genetic tests, especially those that diagnose latent physical or behavioral pathology. The first generation of genetic tests designed as commercial ventures has already entered the American market with virtually no regulatory oversight. Despite their dubious clinical validity, many new tests are being sold without a physician intermediary.

Obtaining personal health information may implicate important aspects of privacy and autonomy, and there may be social and individual benefits to being able to plan. On the other hand, the potential "harms" of unregulated testing may warrant some state intervention. Balancing these and other competing interests requires examining whether the concepts of "medicine" and "consent" that have developed over the last half-century are relevant in this context. Perhaps, they are not. Non-pathologic genetic testing might raise unique concerns about consumer protection that are more analogous to problems successfully addressed outside of the medical arena, such as legal rules concerning lending practices and vaccines.

This Note argues that non-pathologic elective testing raises concerns that should not be addressed by simply extending the informed consent framework; instead, it proposes an information-based intervention based on the "truth in lending" paradigm. Part I traces the intersection of law and genetics from eugenics to modern concerns.

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15 Letter from Reed V. Tuckson, M.D., SACGHS Chair, Dep't. of Health & Human Servs., to the Honorable Tommy G. Thompson, Sec'y of Health & Human Servs. (Dec. 8, 2004) (on file with author) [hereinafter Thompson]. See Neil A. Holtzman, FDA and the Regulation of Genetic Tests, 41 JURIMETRICS J. 53, 56 (2000) (noting the conflict of interest inherent in physicians and patients only receiving information from the producers of a specific test). Interestingly, The U.K. Human Genetics Commission, the U.K. government's advisory body, recently issued a report noting that some home-testing products, e.g., a test for cystic fibrosis carrier status, were withdrawn from the market due to weak consumer demand. However, the report also noted that the market for direct-to-consumer genetic tests might gain momentum as quickly as the home pregnancy kits did. HUMAN GENETICS COMM'N, DEP'T OF HEALTH, GENES DIRECT: ENSURING THE EFFECTIVE OVERSIGHT OF GENETIC TESTS SUPPLIED DIRECTLY TO THE PUBLIC 8, 11 (2003) (U.K.), http://www.hgc.gov.uk/UploadDocs/DocPub/Document/genesdirect_full.pdf [hereinafter HUMAN GENETICS COMM'N U.K.].

16 Thompson, supra note 15.


18 Legal commentators agree that some regulation is needed to fill the void that currently exists for genetic testing. E.g., Anny Huang, FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship, 53 FOOD & DRUG L.J. 555, 591 (1998).

towards differentiating non-pathologic elective testing from other genetic tests. Part II sets out the conventional legal framework for patient-physician decision-making and traces the history of regulation to the modern void. Part III begins by demonstrating the strong analogy between non-pathologic genetic tests and consumer lending in the 1960s. It proceeds by proposing a similar solution to problem at hand and making the case. This Note concludes by advocating that an information-based regulatory regime would be the most efficient and effective way of ensuring consumer protection without hindering growth in this exciting new area of biotechnology.

I. NOT ALL GENETIC TESTS ARE THE SAME

A. The Historical Intersection of Law and Genetics

Genetic technology is often criticized as an extension of this country’s eugenic movement. In *The Republic and the Laws*, the Greek philosopher Plato promoted selective breeding as a means towards a utopian world. It was the first time in recorded history that someone had advanced eugenics, a term that would later be invented and defined by the biologist Francis Galton in the wake of his uncle Charles Darwin’s theories of evolution and natural selection. Galton intended “eugenics” to mean “well-born” and to capture his concept of using knowledge about genetics and quantitative analysis to better the human condition.

At the turn of the century, eugenics involved a social, scientific, and political movement both in the United States and Europe; the ideas were pervasive and well-distributed across the geography and

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21 PLATO, LAWS 145-46 (Benjamin Jowett trans., Prometheus Books 2000) (stating that “[t]he bride and bridegroom should consider that they are to produce for the state, . . . ”); PLATO, THE REPUBLIC OF PLATO 98 (I.A. Richards trans., W.W. Norton & Company 1942) (stating that “the best men [should be] married to the best women as frequently as possible” because “you get the best offspring only by uniting the best, . . . ”).


socioeconomic classes of western civilization. An American Eugenics Society was created in Cold Spring Harbor, NY. The society’s propaganda included publications assuring readers that eugenics was not a plan for making supermen or for breeding human beings as if they were animals; instead, the group promised eugenics would “increase the number of geniuses,” foster “more selective lovemaking,” and “produce more love in marriage.” Politicians awarded “fittest family” and “better babies” awards to local families at fairs across the country. The American eugenics movement is often said to have culminated in the landmark Supreme Court decision of Buck v. Bell in which Justice Holmes upheld Virginia’s compulsory sterilization law with the now infamous language:

It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. Three generations of imbeciles are enough.

“Eugenics,” however, quickly shifted from a term inspiring praise and connotations of social patriotism to a moniker associated with intolerance, human violation, state oppression, and mad science. The horrors of the Holocaust and forced sterilization programs inspired by the eugenic movement still provoke strong views concerning genetics. Indeed, this historic pseudo-science is often invoked to criticize new genetic technology despite the attenuated and often forced connection.

Perhaps the closest link between historical eugenics and today’s genetic testing (including testing for disease) involves the prenatal use of genetic tests. There are reasonable arguments that in limited cir-

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26 Id. at 202-03.
27 DANIEL J. KEVLES, IN THE NAME OF EUGENICS 61 (2d ed. 1995).
28 E.g., Lombardo, supra note 25, at 210.
30 See, e.g., KEVLES, supra note 27, at 164-75.
31 E.g., Lombardo, supra note 25, at 202.
cumstances preimplantation genetic diagnosis (PGD\textsuperscript{33}) as well as pre-natal testing used in conjunction with abortion share some ethical similarities to the old eugenics movement.\textsuperscript{34} However, in relation to NPET the discussion has little practical application.

While PGD and selective abortion are already employed as a prophylactic against diseases like Cystic Fibrosis, Huntington’s disease, and Down’s syndrome,\textsuperscript{35} there is little risk that the same procedures will be used for NPET. Assuming people were interested in pre-natal NPET and a physician were willing to provide it (neither of which is likely), the medical procedures currently used to collect genetic information \textit{in vitro} present a risk of fetal death.\textsuperscript{36} Depending on which procedure is used, the risk may be as high as 2–6 percent.\textsuperscript{37} In addition to the risk of killing the fetus, any information that might be provided by the current tests would be very low quality. Not only do the tests lack empirical support, but recent research increasingly illustrates the importance of non-genetic factors in human development.\textsuperscript{38} In fact, many geneticists now believe that a person’s environment is not only critical to development but might change human genes themselves.\textsuperscript{39} Some researchers even believe that gene expression might be so sensi-

\textsuperscript{33} This is also often referred to as preimplantation genetic testing (PGT). Both names refer to the process of testing embryos for particular genetic traits before implanting them in the uterine wall—in a general sense, this is an extension of the more commonly known process of \textit{in vitro} fertilization (IVF).

\textsuperscript{34} David S. King, \textit{Preimplantation Genetic Diagnosis and the “New” Eugenics}, 25 J. MED. ETHICS 176 (1999) (arguing that the current regime of genetic testing is “eugenic in purpose and outcome” and asserting that surveys of doctors in other areas of the world view that as acceptable). \textit{See} Galton & Galton, \textit{supra} note 23, at 100-01 (discussing the sterilization of those with “inferior” traits to eliminate those less suitable for reproduction on the eugenics register); Solveig Magnus Reindal, \textit{Disability, Gene Therapy and Eugenics - A Challenge to John Harris}, 26 J. MED. ETHICS 89 (2000).


\textsuperscript{36} \textit{Id.} at 968.

\textsuperscript{37} \textit{Id.} (chorionic villi sampling and amniocentesis are the most common procedures).


tive that it is affected by seemingly minor factors like a person's diet.\textsuperscript{40}

Non-pathologic testing is unlike eugenics in another important way: it does not infringe on personal autonomy because of governmental or societal pressure. Unlike state-sponsored forced sterilization programs or the Nazi practices, people would be able to make their own choices about whether to test and what to test for. The increasingly global modern community might have viewpoints as diverse about the importance of a set of physical qualities as they do about which athletic competitions are exciting.\textsuperscript{41} The chance that parents would feel compelled to test their progeny to prevent them from being beneath the rising bar of normalcy is relatively small with NPET.\textsuperscript{42} It would be virtually impossible to test for a range of characteristics. For example, a predisposition to muscular legs would not necessarily be accompanied with a particular hair color or body size. Would it be desirable to test positive for bulk muscle, if the chances were higher that it would mean a hulking behemoth with nothing upstairs? Finally, there is little risk that ideological rationales will masquerade as science in the same way they did in the middle of the last century.

Broad concerns that genetic testing might lead to societal change are more academic than immediate, and a considerable amount of scholarship already addresses them. On a more practical level, direct-to-consumer marketing of NPET creates a pressing problem that needs to be addressed: NPET is already being sold to consumers around the world. The risks presented by these tests are unlike eugenic concerns and also unlike the concerns presented by the genetic diagnosis of disease more generally.

B. General Concerns of Genetic Testing

Traditional, disease-centered genetic testing poses potential psychological and socioeconomic risks to both individuals who are tested as well as people with whom they share genes. Unlike traditional medicine where many of the risks stem from direct physical intervention, the principal risks of genetic testing relate to the information that


\textsuperscript{41} Parents desiring a star sumo wrestler would target very different physical characteristics than those who desired a jockey.

\textsuperscript{42} But see Bryan Appleyard, \textit{Brave New Worlds: Staying Human in the Genetic Future} 85-86 (1999) (discussing the possibility that a rising bar of normalcy might make people feel compelled to test).
is revealed about the patient's genetic status.\textsuperscript{43} Intuitively, a person's self-image and relationship to others might drastically change upon learning about their carrier status. In the case of Huntington's disease, this might involve discovering an accurate age range in which you are likely to die of the disease.\textsuperscript{44}

Latent diseases that can be detected through the use of genetic tests include Huntington's disease, Tay-Sachs disease, X-linked muscular dystrophies, and cystic fibrosis.\textsuperscript{45} People affected by some disorders begin life asymptomatic and appear healthy at birth.\textsuperscript{46} For example, the symptoms of someone affected by Huntington's disease generally begin between the ages of twelve and thirty-five.\textsuperscript{47} Symptoms of that disease typically begin with jerking movement of limbs, mental illness, and progressively get worse until death.\textsuperscript{48} New genetic technology might be able to detect increased risk for things like cancer, hypertension, and Alzheimer disease.\textsuperscript{49}

The psychological harms caused by receiving information about such a serious condition include deflated self-image, anxiety, guilt, and perceived and actual social stigma.\textsuperscript{50} There is no question that psychological reactions to the results of a genetically-diagnosed disease can be strong and unpredictable.\textsuperscript{51} Stanford University's recommendations on genetic testing bluntly state "[that] genetic counseling is the linchpin of good care," and "[r]eleasing test results to uninformed or unprepared patients can cause serious psychological

\begin{footnotes}
\item[44] See DR Langbehn et al., \textit{A New Model for Prediction of the Age of Onset and Penetrance for Huntington's Disease Based on CAG Length}, 65 Clinical Genetics 267 (2004) (detailing how the number or length of trinucleotide expansions correlates with the onset and manifestation of symptoms).
\item[45] David Botstein & Neil Risch, \textit{Discovering Genotypes Underlying Human Phenotypes: Past Successes for Mendelian Disease, Future Approaches for Complex Disease}, 33 Nature Genetics Supplement 228, 228 (2003) (outlining the history of connecting phenotypes to genotypes and noting that the gene for Huntington's disease was mapped relatively early); Gideon Bach et al., \textit{Tay-Sachs Screening in the Jewish Ashkenazi Population: DNA Testing Is the Preferred Procedure}, 99 Am. J. Med. Genetics 70 (2001) (arguing that the preferred method to diagnose Tay-Sachs should be DNA testing rather than testing blood samples for the Hex A enzyme despite the impressive success of earlier models).
\item[46] See, e.g., Langbehn et al., supra note 44, at 269-70.
\item[47] Id.
\item[48] Id.
\item[49] Id.
\item[50] Id.
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harm."\textsuperscript{52} Nancy Wexler, the psychologist largely credited with discovering the gene that controls Huntington's disease, describes a man who was devastated to learn that he was perfectly healthy.\textsuperscript{53} Apparently, the man conducted his whole life believing that he would only live until thirty; thus, he dropped out of three colleges, never had a long-term relationship, and was even arrested on white-collar criminal charges.\textsuperscript{54}

Psychological harms can also be caused by factors external to the individual. Genetic testing for disease often leads to distortion of the parents' perception of their child.\textsuperscript{55} For obvious reasons, people in families with a history of genetically-linked disease also often claim that genetic testing creates intra-family conflict.\textsuperscript{56} In one representative scenario, the genetic diagnosis of a latent disease led family members to favor one child over another.\textsuperscript{57} Can you guess which child? Finally, family members that test positive and others who test negative may also experience feelings of resentment or guilt.\textsuperscript{58}

The second type of risk implicated by disease-centered testing is not psychological but socioeconomic. Because of the predictive nature of genetic tests, individuals who undergo disease-centered genetic testing have reason to be concerned about the financial implications.\textsuperscript{59} Some of the risks reported in the mainstream media included people being denied insurance or losing their job because of their genetic status.\textsuperscript{60} Indeed, the Equal Employment Opportunity Commission received widespread media attention when they brought an action against a railroad genetically testing employees who filed claims for work-related injuries.\textsuperscript{61}

\textsuperscript{52} Bonnin, supra note 12, at 178 (quoting Barbara Koenig et al., Genetic Testing for BRCA1 and BRCA2: Recommendations of the Stanford Program in Genomics, Ethics, and Society, 7 J. WOMEN'S HEALTH 531, 538 (1998)).

\textsuperscript{53} Greely, supra note 51, at 384.

\textsuperscript{54} Id.

\textsuperscript{55} See generally Dorothy C. Wertz, Ethical Issues in Pediatric Genetics: Views of Geneticists, Parents and Primary Care Physicians, 6 HEALTH L.J. 3, 8 (1998).

\textsuperscript{56} Greely, supra note 51, at 383.

\textsuperscript{57} See Wertz, supra note 55, at 8.

\textsuperscript{58} Id. at 9 (describing "survivor guilt" and the strain on intra-family relationships caused by genetic diagnosis of disease).

\textsuperscript{59} See HUMAN GENETICS COMM'N U.K., supra note 15, at 12.

\textsuperscript{60} E.g., id. at 47. See Phil Bereano & Richard Sclove, Life, Liberty, and the Pursuit of Genetic Testing, WASH. POST, Mar. 22, 1998, at C5 (noting that scientists have documented hundreds of cases in which otherwise healthy people were denied insurance because of genetic indications of a latent condition).

\textsuperscript{61} Anita Silvers & Michael Ashley Stein, An Equality Paradigm for Preventing Genetic Discrimination, 55 VAND. L. REV. 1341, 1349-51 (2002); Press Release,
The risks are real and siblings, parents, decedents, and others who share the same genetic makeup necessarily have reverberative concerns, because genes are shared among family members and genetic information is easily stored. Potential discrimination might also create another kind of secondary problem, if fear preempts best medical practice or people are forced outside of the medical system for genetic testing.

Many commentators have discussed the wide variety of topics at the intersection of genetics and discrimination, and there is an especially robust amount of scholarship discussing insurers' use of genetic information and the possibility of discrimination against people with latent health condition(s). No federal laws directly or comprehensively address these issues, and existing state legislation provides only uncertain and inconsistent safeguards. However, legislation recently introduced in Congress addresses many of these concerns. The two virtually identical bills are both called the Genetic Information Nondiscrimination Act of 2005, and appear to have wide support in both houses. The protection of the Act, if it eventually becomes law, would also assuage the more minor concerns implicated by NPET.

C. Not Your Mom's Genetic Testing: Why Non-Pathologic Elective Testing is Different

In one sense, non-pathologic elective testing is not a significant departure from current practice. Scouts for major college and university athletic programs scrutinize middle school students across the country in the hope of finding great talent. And many athletic...
coaches already use non-genetic medical technology, like muscle biopsies, to help select athletes. Perhaps most significantly, no one needs technology to understand that height correlates with success as a basketball player, and parents already routinely use this type of non-scientific assessment. Most commentators argue that the biggest difference between current practice and genetic testing may just be the quality of the information. Beyond the discussion of genetic exceptionalism, though, many of the potential “harms” of disease-oriented testing are not applicable in the context of NPET.

Non-pathologic genetic tests would not have the same serious psychological consequences as disease-oriented testing. Genetic tests that diagnose disease typically involve pathologies that have no cure or effective therapeutic intervention; affirmative test results mean the person must live with the prospect of unavoidable illness. Unlike individual beliefs about longevity, people generally do not become heavily invested in convictions related to athletic stardom. Many children dream of becoming a professional basketball or baseball player, but few would be devastated to hear that the odds are against them. Realistically, many parents already impart this quickly-learned life

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67 Farrey, supra note 14 (describing how Olympic rowers undergo muscle biopsies and blood tests to help determine athletic potential and quoting the national team coach’s desire for genetic profiling). These coaches claim they would welcome genetic profiling as another means of saving time and energy. Id.

68 Some commentators have suggested that while the quality of the information remains suspect, non-therapeutic genetic tests should have legal restrictions, because people confuse scientific information with proved information. Patrik S. Florencio, Genetics, Parenting, and Children’s Rights in the Twenty-First Century, 45 McGill L.J. 527, 530 (2000).

69 “Genetic exceptionalism” captures the discussion about whether or not genetic information and genomics should be treated differently from types of medical information. There is a common misconception that genes dictate a person’s future. Many commentators argue that this view is specious and dangerous. These arguments are only tangentially relevant and comprise an interesting and important area of legal scholarship that I could not begin to rehearse here. See generally Lawrence O. Gostin & James G. Hodge, Jr., Genetic Privacy and the Law: An End to Genetics Exceptionalism, 40 Jurimetrics J. 21, 33-34 (1999); Henry T. Greely, Genotype Discrimination: The Complex Case for Some Legislative Protection, 149 U. Pa. L. Rev. 1483 (2001); Hellman, supra note 4; Glenn McGee, Foreword: Genetic Exceptionalism, 11 Harv. J.L. & Tech. 565 (1998); Mark A. Rothstein, Why Treating Genetic Information Separately Is a Bad Idea, 4 Tex. Rev. L. & Pol. 33 (1999); and Sonia M. Suter, The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?, 79 Wash. U. L. Q. 669 (2001).

70 Green & Thomas, supra note 43, at 572-73.

71 In light of recent realizations about steroid use in professional baseball, perhaps soccer would have been a more appropriate example.
lesson leaving children to live with an understanding that they will almost certainly not become a professional athlete.

Beyond being less invested in the outcome, the results of the new variety of tests are also far less reliable. The first successful genetic tests diagnosed a mutation in a single series of genes or specific location. However, these new types of tests often require analyzing mutations in many different genes at the same time; logically, this is inherently more complicated. Moreover, the presence of different mutations may have varying degrees of significance: even if the combination exists, it may only represent a slight increase in the probability that something occurs. What could a person do with this information? Would a rational person who is told that there is a 60 percent probability that she will be a good tennis player act any differently than the person who is told that they have only a 50 percent chance? Many individuals might find information like this useless, even if it was clinically very accurate.

The potential of institutional discrimination is also mitigated by the quality and nature of information that might realistically be provided by NPET. Unlike genetic diagnosis of disease, non-pathologic tests do not implicate risks that most people insure. It is common to purchase insurance that protects against risks associated with automobile accidents or death, but these are things people are adverse to. The chance of becoming a stellar athlete is really a probability of success and insurance against it not happening would give an athlete an adverse incentive to intentionally fail. Insurance companies would probably not be interested in this type of information, and, at this point, it is unclear who might be practically capable of capitalizing on it.

Discrimination on the basis of NPET results is perhaps most likely where the decision to invest resources has already been made, i.e., where there is already significant financial investment. Sporting organizations of all kinds might use the information to manage and select employees. An organization might choose to expend fewer resources on an employee-athlete whose genetic profile indicates frequent injury. Alternatively, educational institutions might use the tests to select scholarship recipients and help allocate athletic resources.

72 Andrews & Zuiker, supra note 19, at 803-05.
73 Id. at 805.
74 Id. at 806.
76 Id. at 210.
The danger which arises in this context is not from the tests actual ability to predict potential, because research has yet to establish a definitive link. The danger arises because athletic organizations might act on the information either hoping the tests prove accurate or under the false impression that the tests have some clinical utility. The actual discrimination aspect is addressed in the Genetic Information Nondiscrimination Act mentioned earlier, which is currently pending before Congress. The Act defines “genetic test” broadly enough to encompass these tests and provides restrictions that would limit the use of the results. Discrimination is also proscribed in the Universal Declaration of the Human Genome and Human Rights, which was adopted unanimously by the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1997. While the declaration is a non-binding instrument, it is evidence of how seriously the international community appears to respond to potential discrimination. Finally, potential abuses in the educational arena would most likely incite a quick domestic legislative response, as problems affecting our children often do.

Of course, there is one critical caveat. The relative seriousness of potential individual and social harms assumes that the public understands the limitations of non-pathologic tests, and they might not. Many individuals believe that genetic information is the same as scientific or proven information; obviously, quite the opposite is true. Genetic tests of all kinds are only predictions, and they vary greatly in terms of quality and importance.

Until recently, medical academics judiciously employed genetic testing technology on an investigational basis. The academic institutions focused on research rather than profit. And the

77 Id. at 213.
78 Id.
80 S. 306, § 201(7); H.R. 1277 § 101(7)
82 C.f. Janet L. Dolgin, The Law’s Response to Parental Alcohol and “Crack” Abuse, 56 BROOK. L. REV. 1213, 1213 (1991) (asserting that the popular reaction that led to protecting children of crack users created a regulatory regime that was too stringent).
83 Florencio, supra note 68, at 530.
84 See Andrews & Zuiker, supra note 19, at 804.
85 Holtzman, supra note 15, at 54.
86 E.g., id. at 56.
physicians followed detailed informed consent requirements established by the major medical organizations to ensure patients made appropriate decisions before testing for latent disease.\cite{87} The market for genetic tests has now grown beyond the virtually self-regulating world of medical academia, but the regulatory framework has yet to catch up.

II. FIRST PRINCIPALS TO THE CURRENT REGIME

A. Informed Consent Yesterday & Today

In 1914, Judge (later Justice) Benjamin Cardozo eloquently asserted that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body[]."\cite{88} Cardozo’s declaration that a physician needed to obtain the patient’s consent became a fundamental concept to American jurisprudence and is quoted or cited in almost every informed consent case.\cite{89} However, it was not until 1957 that the courts started to recognize a logical extension of the physician’s requirement to obtain consent: patients should be given enough information to allow them to make a meaningful decision about the course of their medical treatment.\cite{90}

The requirement that the healthcare provider give enough information to allow the patient to make an informed choice forms the second prong of the doctrine and gives substance to the requirement of consent. In hindsight, this basic requirement may seem an obvious extension of the idea that physicians should not perform any procedure against the patient’s wishes, but it marked the beginning of dramatic changes in the social mores about the rights of patients and was a significant departure from contemporary beliefs.\cite{91}

\footnotesize{\cite{87} See Andrews & Zuiker, supra note 19, at 807-08. The American College of Medical Genetics recently “developed a policy statement discouraging direct access to genetic testing without the involvement of an appropriately qualified health care professional to ensure appropriate use, interpretation, counseling, and follow-up.” See DEP’T OF HEALTH & HUMAN SERVS., SEC’Y’S ADVISORY COMM. ON GENETICS, HEALTH, & SOCIETY, A ROADMAP FOR THE INTEGRATION OF GENETICS AND GENOMICS INTO HEALTH & SOC’Y 57 (2004) [hereinafter ROADMAP], http://www4.od.nih.gov/oba/sacghs/reports/SACGHSPriorities.pdf.

\cite{88} Schloendorff v. Soc’y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914).

\cite{89} SCOTT BECKER, HEALTH CARE LAW: A PRACTICAL GUIDE § 19.02[1][a] (2d ed. 2005); Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972) (asserting that the concept of consent expressed by Cardozo in Schloendorff was a “root premise . . . fundamental in American jurisprudence . . . ”).

\cite{90} JAMES M. MORRISSEY ET AL., CONSENT AND CONFIDENTIALITY IN THE HEALTH CARE OF CHILDREN AND ADOLESCENTS: A LEGAL GUIDE 13 (1986).

\cite{91} Id. at 12-13.}
The doctrine of informed consent evolved for thirty years before this country's legal system universally accepted that a healthcare provider must 1) give the patient adequate information about her choices and 2) obtain consent for the proposed treatment. While there is still no consensus concerning the quality and nature of the information that must be discussed, every state now has a specific informed consent standard that dictates what a healthcare provider must do before any medical diagnosis or treatment. Healthcare providers who do not provide the appropriate amount or type of information before receiving the approval of the patient can be sued for medical malpractice or an intentional tort.

There is a common misconception that informed consent is merely the signing of a form that releases the physician from liability; this grossly mischaracterizes the dynamic nature of the process. Generally, informed consent is comprised of authorization that is given knowingly, rationally, and with volition, i.e., without coercion. It is not a single event or episode, but a complex process where patient decisions are made in conjunction with healthcare providers. This process respects patients' interest in autonomy and hopefully concludes in a decision about the best course of treatment for the patient.

Unlike traditional medical procedures, NPET should not require the kind of informed consent typically employed by physicians in the medical context. The doctrine of informed consent was designed as a response to very different problems, and the potential harms of NPET are less serious and less numerable than they are in either the traditional medical context or even other areas of genetic testing. Despite these tests relating to the human body, users are much more like consumers than patients.

94 Popper, supra note 92, at 821.
97 See generally TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 57-104 (5th ed. 2001) (discussing the ethical principles of patient autonomy).
The principal that every human being has a right to make decisions based on accurate information is still important in this context though. Important life decisions might be based on erroneous information if users have unwarranted faith in the results of NPET: this is a real problem. This unwarranted faith might exist because of popular misconceptions about genetics, but it could be exploited by charlatans who will no doubt take advantage of vulnerable consumers. Obviously, the regulatory regime should attempt to eliminate these misconceptions, thus ensuring that consumers understand and freely choose the risks they assume. But there is currently little, if any, protection.

B. The Current Regulatory Regime

Discussions concerning the public policy implications of regulating genetic testing began in the late 1990s against the background of the American eugenics movement and in the face of impressive and promising new discoveries. In response to escalating public concern and calls from two working groups commissioned jointly by the National Institutes of Health (NIH) and the Department of Energy (DOE), the former Secretary of Health and Human Services chartered the Secretary's Advisory Committee on Genetic Testing (SACGT) in June, 1998. SACGT was formed "to advise the Department of Health and Human Services (DHHS) on the medical, scientific, ethical, legal, and social issues raised by the development and use of genetic tests." SACGT concluded that changes in the regulatory framework were necessary to bring all types of genetic tests under the U.S. Food and Drug Administration (FDA) control and to educate the public about the benefits and concerns of genetic tests. The first task SACGT undertook was a thorough evaluation of the oversight of genetic tests. SACGT's charter was not renewed by the current administration, but a new committee named the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) was chartered.

See generally Geetter, supra note 20 (discussing how the American eugenics movement has continually colored reactions to genetic science).

99 Notice of Establishment of the Secretary's Advisory Committee on Genetic Testing, 63 Fed. Reg. 35242 (June 29, 1998); About SACGT, http://www4.od.nih.gov/oba/sacgt/aboutsacgt.htm (last visited Feb. 26, 2006); Bonnin, supra note 12, at 151. SACGT's charter was not renewed by the current administration, but a new committee named the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) was chartered.


101 Id. This report continues to serve as a useful summary of U.S. regulatory mechanisms.
A wide range of commentators have agreed with the Committee's assessment. Despite the numerous calls for a defined regulatory regime, there have been few changes since the committee's initial report, and the FDA only recently began to solicit comments about potential increases in regulation.

Because the existing regulatory scheme does not distinguish between genetic and non-genetic testing, by default, genetic tests are subject to the same type of federal oversight as any other medical test. The failure to alter the approach has led to a patchwork of federal regulations based more on the form of the genetic test than the substance. Essentially, genetic tests fall into two camps: tests sold as kits and tests that are offered as a service by the laboratories themselves (these are often referred to as "home brews"). Although regulation appears imminent, at this point there is little oversight of the latter of type of test.

Genetic tests that are sold as kits and distributed to laboratories or physicians require approval by the Food and Drug Administration under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). The FDA classifies tests into three categories according to the level of risk associated with their use. Because of their inherent complexity, genetic tests generally fall into the most stringent category: Class III devices. This class of devices requires pre-market approval by the FDA. In order to get this approval, manufacturers must submit an application that includes em-

102 *Id.* at 16, 27.
103 *See*, e.g., Holtzman, *supra* note 15, at 53-54 (endorsing SACGT's proposal to have the FDA oversee all genetic testing).
106 *Huang*, *supra* note 18, at 587.
107 Assuming there has been no illegal trade in kits, the buyers have been limited exclusively to laboratories.
108 *Huang*, *supra* note 18, at 557 n.16.
110 *Id.* at 159-60.
111 *Id.*
112 *Id.* at 160.
113 *Id.*
pirical data about clinical validity. The application is then reviewed by an FDA examiner who specializes in genetic tests.

While the FDA reviews tests sold as kits, the majority of genetic tests are developed and marketed as clinical laboratory services for which there is virtually no oversight. Companies that accept samples in the mail would be included in this category, as would the vast majority of the 105 unique Internet sites that were offering genetic testing services directly to consumers in 2003. Current regulations do not ensure the utility or clinical validity of any of these services. Genetic tests that fall into this category are only indirectly regulated through the Clinical Laboratory Improvement Amendments (CLIA). CLIA was passed by Congress in 1998 to establish minimum quality levels in laboratory testing practices. Under the authority granted by CLIA, the Health Care Financing Administration (HCFA) reviews laboratories across the country for technical competence and analytic validity.

In addition to the limited oversight provided by CLIA and the FDA, existing federal regulations govern research that "involves human subjects or identifiable samples of their DNA." The Human Research Subject Protection Laws are administered by two different federal agencies. Both agencies require Institutional Review Board (IRB) studies that focus on "1) safety of the subjects; 2) sufficiency of the informed consent process; and 3) balance of the risks and potential benefits of the study." However, test developers that do not receive federal funding and develop tests as services, fall outside the ambit of the human research laws. As a result, the majority of new ventures

114 Huang, supra note 18, at 588; Holtzman, supra note 15, at 58.
115 Id. The FDA's process for approving new products is complex. The specific details of the process and related issues are beyond the scope of this Note.
116 Id. at 587.
117 Id.
118 ROADMAP, supra note 87, at 56.
119 Id. at 57.
120 Huang, supra note 18, at 587.
121 Bonnin, supra note 12, at 163.
122 Holtzman, supra note 15, at 57. One frequently mentioned example of the regulation of laboratories qua laboratories is the requirement that manufacturers who sell analyte specific reagents (ASRs), which is an indispensable component of genetic testing, must register with the FDA. However, laboratories that manufacture reagents for their own use do not have to register. Id. at 59.
123 SACGT RECOMMENDATIONS, supra note 100, at 10.
124 Bonnin, supra note 12, at 164-65.
125 Id.
126 Id. at 165.
developing non-pathologic tests are under no obligation to comply, and few have sought IRB approval.\(^{127}\)

Beyond the limited federal regulation, state governments have an oversight function that might eventually play a more prominent role. For the time being, though, state legislation shares many of the same problems of the federal regime. State health agencies, particularly state public health laboratories, have licensure requirements for personnel and facilities that perform genetic tests.\(^{128}\) A handful of states "have promulgated regulations that go beyond the [quality assurance] requirements" imposed by the federal Clinical Laboratory Improvement Amendments.\(^{129}\) And a few have even established licensing requirements for genetic counselors.\(^{130}\) Besides the indirect oversight provided through laboratories and licensure, non-pathologic genetic tests fall outside the bounds of most existing state legislation.

State legislation regulating the practice of medicine and medical professionals has traditionally been left to the police powers of the states, rather than the federal government. Practicing medicine without a license is illegal in every state, and each state has its own licensure requirements.\(^{131}\) However, several states have codified formal definitions of what qualifies as practicing medicine, and genetic tests do not fit that definition.\(^{132}\) For example, Texas's statute defines "practicing medicine" as "the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method."\(^{133}\) New York state defines the practice of medicine as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition."\(^{134}\) Most genetic testing does not diagnose physical injury or disease; rather, it

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\(^{127}\) Holtzman, supra note 15, at 59.


\(^{131}\) Id.

\(^{132}\) Id.

\(^{133}\) TEX. OCC. CODE ANN. § 151.002(a)(13) (Vernon 2004) (providing the full definition of "practicing medicine" which requires a public profession of status as a "physician or surgeon", or for compensation for services).

\(^{134}\) N.Y. EDUC. LAW § 6521 (McKinney 2001).
provides information about the possibility of a latent condition in an
otherwise healthy person. Non-pathologic genetic testing is even fur-
ther beyond the ambit of these statutes, because no disease or pathol-
ogy is involved.

Many states have also codified definitions of "genetic testing" as
part of legislation designed to prevent discrimination by insurance
companies and employers. Non-pathologic tests fall outside the
bounds of these laws as well. Rhode Island's relatively recent legisla-
tion defines "genetic testing" as "analysis of an individual's DNA . . .
to detect heritable disease-related genotypes." Non-pathologic
tests would also be outside of the bounds of the Texas statute that
defines "genetic test" as a "presymptomatic laboratory test of an indi-
vidual's genes . . . associated with the individual's having a statisti-
cally increased risk of . . . developing a clinically recognized disease,
disorder, or syndrome. . . ."136

Of the approximately one thousand genetic tests that are now
available in the clinical setting, many of them fall outside the bounds
of the existing system.137 But the solution is not simply to attempt to
bring all genetic tests back into the medical profession, because these
new tests pose little threat to the informed consumer and unwarranted
intervention might slow the growth in this exciting new area of


III. PROPOSAL

A. Truth in Lending

The historical events leading up to policy discussions about con-
sumer credit and ultimately the passage of the Truth in Lending Act138
(TIL Act) bear a striking resemblance to the recent developments in
non-pathologic elective genetic testing. During the 1960s, the con-
sumer credit market was expanding at a ferocious pace.139 As the
market blossomed, increased confusion about the terms of credit
agreements amplified the existing predatory lending problem. Many consumers unwittingly contracted for complex products, which lenders were using to keep them uninformed about the important aspects of the agreement.

Some of the more innocent practices that lenders employed involved creating their own informational barriers in the marketplace by disguising the true cost of consumer debt and other information necessary for consumers to make informed decisions. For example, lenders quoted interest rate charges in a variety of ways that made comparisons for the average consumer very difficult. They advertised "simple" interest rates with fees as well as "discount" or "add-on" rates, but no figure approached the true annualized cost of the agreement. The use of these obfuscations and others to take advantage of vulnerable consumers was made possible by the lack of uniformity in state legislation and local practices.

Congress passed the TIL Act in 1968 to combat these problems. Historically, the legislative responses to predatory lending included mandating interest rate maximums, i.e., usury laws, or providing amnesty for debtors. However, the various types of market-controlling strategies were either generally ineffective or eventually caused the market to breakdown. The TIL Act approach was a significant departure from these conventional interventions; rather than control the market, the act used techniques to help the market correct itself by addressing the information asymmetry. In order to do this, Congress attempted to empower the consumer with information that would facilitate the informed use of credit by making various credit terms

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140 See, e.g., ROHNER & MILLER, supra note 139, at 12.
141 Griffith, supra note 139, at 266-68.
144 See Peterson, supra note 142, at 880. Interestingly, one contemporary high-cost lending manager contrasted the legal doctrine of informed consent with the widespread practice in the lending industry of "assumed consent." Id. at 892.
145 Id. at 879-80.
146 See generally id.
147 Id. (noting that when statutory maximums and other market controls did not keep pace with market rates, the market stopped functioning).
148 Id. at 809-10.
more readily comparable and allowing borrowers to harness their own judgment.149

Essentially, the TIL Act mandated meaningful disclosure in a format that was both understandable and uniform across the country. The Act focused on assuring “standardized, complete, and accurate disclosure of credit terms.”150 It made the terms “finance charge” and “annual percentage rate”151 part of modern daily life.152

Indeed, this type of solution, i.e., an informational approach, allowed consumers to understand what they were contracting for and compare their options. Adopting an information-based approach also balanced the need to protect people at risk with the desire not to hinder socially useful trade and had a number of regulatory advantages, e.g., the low cost.

While the seemingly simple goals of the TIL Act were initially difficult to implement, major difficulties, like problems with litigation and compliance, have largely been resolved.153 More importantly, two and a half decades of experience has provided invaluable insight into the regulatory benefits and challenges of addressing informational deficiencies in the consumer market.154

B. Truth in Testing—The Proposed Mandatory Disclosures

The underlying problems of the 1960s consumer credit market are virtually identical to modern concerns about non-pathologic elective genetic testing. Despite occurring in different eras, the two situations are analogous. From a historical perspective, non-pathologic elective tests recently entered a stage of market development similar to the one that afforded unscrupulous lenders the ability to take advantage of consumers in the 1960s. Consumer credit was then the fast-growing market that genetic testing is today. The market for genetic testing is growing at a ferocious rate.155 Charlatans have already begun to prey on vulnerable consumers.

149 Truth in Lending Act, 15 U.S.C. § 1601(a) (2000) (stating that the purpose for the TIL Act is to inform consumers about the use of credit and to foster competition among financial institutions).
150 ROHNER & MILLER, supra note 139, at 11.
151 APR, the acronym derived from the phrase, is perhaps even more identifiable and surely as ubiquitous.
152 See Peterson, supra note 142, at 880.
153 E.g., id. at 886. See also Abbott & Campbell, supra note 139, at 3-4 (asserting that the lending laws were a “morass of complex and sometimes contradictory rules” in the 1970s).
154 Note that these techniques are now used to address market deficiencies with similar consumer products. See infra Part II.E-F.
155 E.g., Bonnin, supra note 12, at 153.
In both situations the lack of accurate and understandable information leaves consumers ill-equipped to make very important personal decisions. Moreover, the varying state responses to the credit market contributed to even greater consumer confusion in the same way that the modern patchwork of incoherent state and federal regulation will hurt NPET consumers today. The scheme of intervention crafted by Congress more than two decades ago is an ideal strategy for regulating non-pathologic genetic tests today.

Drawing from the TIL paradigm, the framework for a NPET regime would serve two important functions: mandating disclosure to the consumer and ensuring national standards to describe the quality of genetic tests. Towards this end, the FDA should issue regulations mandating that all genetic tests—both NPET and pathologic—sold to consumers in the United States include a one page information sheet drafted by the FDA, which would include easy-to-read information about the technological state of genetic testing as well as the potential benefits and harms. The FDA should also mandate that the tests themselves be accompanied by limited manufacturer-provided information, including what specific genes are being tested, a succinct statement of the test’s purpose, recent and relevant research supporting the test’s conclusion, and other relevant medical information. Both types of disclosure should accompany genetic tests and be available from the manufacturer to any potential consumers.

C. The FDA Should Promulgate and Enforce the Proposed Regulations

Among the current morass of regulatory bodies, the FDA and the Federal Trade Commission (FTC) will likely play some role in the federal oversight of genetic testing, because sales will likely take place in the broader context of direct-to-consumer marketing of medical products. For the reasons outlined below, though, the FDA is the most appropriate government actor for the intervention proposed here.

At the most general level, the FDA has primary jurisdiction over labeling and advertising prescription drugs and certain medical devices. The Administration’s given mission is to “protect the public health by ensuring that . . . there is reasonable assurance of the safety

156 See, e.g., Abbott & Campbell, supra note 139, at 3-4, 9.
and effectiveness of devices intended for human use."\textsuperscript{158} On the other hand, the FTC regulates advertising more generally, including advertising for medical products other than those that are "restricted medical devices."\textsuperscript{159}

These new tests pose interesting questions about the two agencies' jurisdiction. Home brew sales are likely to occur on the Internet,\textsuperscript{160} where it is unclear whether it would be possible for the FDA to regulate the content as "advertising," which is not defined in the federal FDCA.\textsuperscript{161} It is also unclear whether such web content would be within the jurisdiction of the FDA or that of the FTC.\textsuperscript{162} But even if regulating web content is beyond the ambit of the current regulatory regime, the damage of the potentially misleading statements could be mitigated by mandating the disclosure proposed here. And this information is more closely related to the FDA's authority to regulate the labeling of medical devices than any authority it has to regulate advertising. Moreover, current legislation arguably already provides the FDA the authority to mandate the inserts proposed here.\textsuperscript{163}

Section 701 gives the FDA general "authority to promulgate regulations for the efficient enforcement" of the FDCA as well as a general definitional power.\textsuperscript{164} The most difficult legal hurdle appears to be fitting home brew tests into the definition of "device," which typi-

\begin{footnotesize}
\begin{enumerate}
\item\textsuperscript{158} 21 U.S.C. § 393 (2000).
\item\textsuperscript{159} Working Agreement Between Federal Trade Commission and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9850.01 (June 9, 1954) (as originally enacted); Updated FTC-FDA Liaison Agreement—Advertising of Over-the-Counter Drugs, 36 Fed. Reg. 18,539, 4 Trade Reg. Rep. (CCH) ¶ 9851 (Sept. 16, 1971).
\item\textsuperscript{160} ROADMAP, supra note 87, at 56.
\item\textsuperscript{161} Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (2000). The FDA's Center for Drug Evaluation and Research promulgated regulations that define "advertising," but the definition is not comprehensive and only relates to advertisements that are subject to section 502(n) of the FDCA. See 21 C.F.R. § 202.1(a)(1) (2004).
\item\textsuperscript{162} A spokesman from the FTC reported to the SACGHS last spring that the Commission is currently looking for a test case and is concentrating on claims where the actual harm is serious and has already occurred. Masny, supra note 64.
\item\textsuperscript{163} One commentator asserted that regulation does not require legislative action, but simply a social and political mandate. Huang, supra note 18, at 591 (making an interesting argument that the biggest problem is that intra-state laboratory services might be beyond the ambit of the constitutional limits of federal powers). Note that these concerns appear to have been laid to rest in a recent Supreme Court decision. Gonzales v. Raich, 125 S. Ct. 2195, 2211 (2005) (holding the production of marijuana solely for home use, while an intrastate activity, still affects interstate commerce to a substantial degree, thus allowing for Congressional regulation under the Commerce Clause).
\item\textsuperscript{164} 21 U.S.C. § 371(a) (2000).
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TRUTH IN TESTING LAWS

cally excludes laboratory services. The relevant definitional language includes instruments “intended for use in the diagnosis of disease or other conditions. . . .” Here, a case could be either be made that a combination of analytic specific reagents (ASR) and lab processing is a statutory device or that advertising a specific use for ASR creates a statutory device; thus, requiring pre-market approval and making further regulation possible.

After establishing that the home brew tests are a medical device, Section 201(m) of the FDCA states that labeling includes “all labels and other written, printed, or graphic matter . . . accompanying such article.” The definition of “label,” in turn, has been interpreted broadly enough that the FDA could mandate the inserts proposed here. From a practical perspective, it would make sense for the agency to promulgate the regulations and hope for Congressional response if the statutory basis is later successfully challenged.

To be clear, whether the FDA posses the authority to regulate is not dispositive of either whether they are the most appropriate actor or whether the regulations make sense from a practical perspective. In this case, though, the FDA is the most attractive choice. And perhaps more importantly, the proposed intervention would be a low cost solution to a pressing problem.

The modern era of the FDA began with the first wave of federal regulatory legislation during the Roosevelt administration. With more than a century of regulatory experience, it is now one of the largest and oldest government agencies. It has tended to grow in spurts with public crisis. Under the authority it has been granted to regulate medical “devices,” the agency claims responsibility for regulating products as diverse as the toothbrush and processed human heart valves.

165 Holtzman, supra note 15, at 59-60.
167 See cf. Susan Bartlett Foote & Robert J. Berlin, Can Regulation Be as Innovative as Science and Technology? The FDA’s Regulation of Combination Products, 6 Minn. J. L. Sci. & Tech. 619 (2005) (noting many ways through which the FDA has expanded its regulatory mandate).
169 See generally Foote & Berlin, supra note 167.
170 In 1906 Congress passed the Pure Food Act, which established the agency’s first regulatory power. Pure Food Act, Pub. L. No. 59-384, 768 Stat. 3915 (1906).
171 Huang, supra note 18, at 572-73.
Beyond its size and history, the FDA has the technical expertise to effectively implement and enforce the regulations proposed here. The agency already regulates many other aspects of genetic testing.\textsuperscript{173} For example, the FDA currently regulates labeling and sales of ASRs.\textsuperscript{174} The FDA also regulates genetic tests that are sold as kits to qualified clinical laboratories.\textsuperscript{175} Twelve such kits have already been approved.\textsuperscript{176}

D. Negligible Cost of Proposed Regulation

Regulations have become an indispensable part of the governing process in this country. Federal oversight through administrative rules and regulations has minimized damage to the environment, reduced airplane disasters, and corrected market defects. However, such benefits do not come without considerable costs. These costs and benefits must be seriously considered in our world of limited resources. Generally, successful regulations generate social value because the benefits outweigh the burdens.\textsuperscript{177} But how do we know when this is true? Often there is no simple and accurate way to make these calculations even if there was consensus about the correct methodology.\textsuperscript{178}

Every year the Office of Management and Budget (OMB) estimates the cost of the more significant recent domestic regulation in a report it sends to Congress. In 2003, the OMB estimated the cost of

\textsuperscript{173} See supra Part II.B (delineating the various types of genetic tests currently regulated by the FDA); Michael J. Malinowski & Maureen A. O'Rourke, \textit{A False Start? The Impact of Federal Policy on the Genotechnology Industry}, 13 \textsc{Yale J. On Reg.} 163, 170-78 (1996) (noting the many new areas of biotechnology and how they are being stifled by current regulation).

\textsuperscript{174} 21 \textsc{C.F.R.} \textsection 809.30 (2005) (restricting the sale, distribution and use of analyze specific reagents).


107 federal regulations to be between $36 and $42 billion a year.\textsuperscript{179} On the other hand, the OMB estimated that the benefit of the same regulations was approximately $146 to $230 billion.\textsuperscript{180} The OMB estimated the cost of major rules in the health and human services sector alone to be more than $481 million.\textsuperscript{181}

These figures are significant in relation to the size of the overall domestic economy.\textsuperscript{182} Serious thought should be given to the costs and benefits of regulation before interfering in any sector of the economy, let alone one that promises as many benefits as genetic testing. Here, the net benefit of mandating the proposed inserts appears to be high and the costs low.

There are two principal costs associated with government regulation that need to be estimated when weighing the burdens. The first is the cost to the government itself. Here, the cost of promulgating and enforcing the package inserts and other information is low. As noted above, the FDA already has personnel approving genetic testing kits and much of the infrastructure for the labeling is already in place; thus, the additional cost to the government will be both small on the margin, i.e., the FDA is the least-cost provider, and in aggregate. Moreover, having one agency responsible for the inserts will avoid redundancy and help accumulate institutional expertise, which will reduce costs over time.\textsuperscript{183}

The second cost of regulation is incurred by industry and society at large. These costs can be both actual private expenditures as well as less tangible costs, both of which are generally greater and more important than the first type. But, this type of expenditure tends to be difficult to measure. Unfortunately, the costs of regulation to a particular business are not divided up into line items like other expenses; rather, regulatory expenses tend to be scattered across financial statements or not included at all. For example, if fire regulations require that no office worker sit within five feet of a fire exit, employees might not have to be moved or might have to be moved for other rea-


\textsuperscript{180} \textit{Id.}

\textsuperscript{181} \textit{Id. at 9 tbl.3.}


\textsuperscript{183} Huang, \textit{supra} note 18, at 574.
sons anyway. Either way, the expense of moving an employee might be recorded in the financial statements in any number of ways. It might be recorded as either a cost to human resources or to maintaining the plant, or in both places.

Sometimes costs tend to be high up front, but decrease after the initial outlay. For example, a drug manufacturer might have to make a significant outlay to institute quality control procedures. But after the system is set up, the cost of ongoing compliance could be dramatically lower. Here, the costs to industry of including the proposed inserts would be initially low and not increase. Cost of the inserts to industry is likely to be dominated by expenses incurred to gather and write the information.

The biggest potential cost might be stalling growth in this industry. Future biotechnology will likely afford society an incredible amount of benefits. Hindering the market with unneeded regulations would slow the progress in this incredibly promising industry. While mandating disclosure for all genetic tests might be somewhat overinclusive, hopefully the burden of disclosure in the form of paper handouts is relatively minimal on all fronts.

E. Information-Based Solutions in the Healthcare Context

Similar techniques are employed successfully in other healthcare contexts. FDA-approved patient labeling is variously described as “Information for the Patient,” “Patient Information,” “Medication Guide,” and “patient package inserts.” One example of this labeling is the method of disclosure employed to impart information before children receive vaccinations. Vaccinations, like non-pathologic genetic tests, are administered to otherwise healthy children; in fact, vaccinations are the only medical intervention mandated for healthy children in the United States. Before administering a vaccination, information regarding the benefits and risks must be provided to a child’s guardian. This formal disclosure information is provided by the Centers for Disease Prevention and Control (CDC). It comes in

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188 Karin Schumacher, Note, Informed Consent: Should It Be Extended to
the form of a standardized one-page, double-sided vaccine information sheet (VIS) that presents the major risks and benefits of vaccinations at a fifth to seventh grade reading level.\textsuperscript{189}

In addition to the VIS, the manufacturer is required to include a patient package insert.\textsuperscript{190} Patient package inserts are included in the vial of each vaccine and include more detailed information than is provided on the VIS.\textsuperscript{191} These mandatory inserts supplement drug manufacturers’ traditional duty to warn the consumer directly about the potential harms and benefits of the product.\textsuperscript{192} The manufacturer-provided data is available to anyone, but physicians seldom provide it to the patients when administering vaccines.\textsuperscript{193} Presumably, physicians are accustomed to acquiring informed consent for other procedures and impart the necessary information in an understandable way. The same type of patient inserts, though, do reach patients when they are included with medical products received directly by the consumer.\textsuperscript{194} The FDA has mandated inserts for various medicines, including estrogenic products, some asthma devices, and progestational drug products.\textsuperscript{195}

HIV home test kits are perhaps an even closer analog to the intervention proposed here. In the late 1980s, the FDA incurred significant criticism for its complete ban on HIV home testing kits, which was imposed to protect the public from receiving serious health information without a trained intermediary.\textsuperscript{196} The FDA reversed their position in 1995 and now uses similar techniques to those proposed here.\textsuperscript{197} The FDA already mandates and helps create the disclosures that accompany home HIV test kits.\textsuperscript{198} The two tests share some


\textsuperscript{191} Schumacher, supra note 188, at 96-97.

\textsuperscript{192} See id.

\textsuperscript{193} See id. at 92.

\textsuperscript{194} See Moody, supra note 190, at 33-34.

\textsuperscript{195} See id. at 33.

\textsuperscript{196} See Moody, supra note 190, at 33-34.

\textsuperscript{197} See id. at 33.

\textsuperscript{198} See id. at 572.

\textsuperscript{199} See id. at 572.

\textsuperscript{190} See Moody, supra note 190, at 33-34.

\textsuperscript{191} Schumacher, supra note 188, at 96-97.

\textsuperscript{192} See id.

\textsuperscript{193} See id. at 92.

\textsuperscript{194} See Moody, supra note 190, at 33-34.

\textsuperscript{195} See id. at 33.

\textsuperscript{196} See Moody, supra note 190, at 33-34.

\textsuperscript{197} See id. at 33.

\textsuperscript{198} See id. at 572.

\textsuperscript{199} See id. at 572.

\textsuperscript{200} See Moody, supra note 190, at 33-34.

\textsuperscript{191} Schumacher, supra note 188, at 96-97.

\textsuperscript{192} See id.

\textsuperscript{193} See id. at 92.

\textsuperscript{194} See Moody, supra note 190, at 33-34.

\textsuperscript{195} See id. at 33.

\textsuperscript{196} See Moody, supra note 190, at 33-34.

\textsuperscript{197} See id. at 33.

\textsuperscript{198} See id. at 572.

\textsuperscript{199} See id. at 572.

\textsuperscript{200} See id. at 572.
common features. The distribution system of the HIV home test system—consumers purchase the tests directly from the manufacturer—mirrors how NPET is currently being distributed.\footnote{William O. Fabbri, Note, Home HIV Testing and Conflicts with State HIV Testing Regulations, 21 AM. J.L. & MED. 419, 420 (1995) (noting that home HIV tests will include a special paper for a blood sample and a return envelope).}

The nature of the information being imparted is perhaps even more serious with HIV testing where there have been similar problems of institutional discrimination.

F. Advantages of a National Disclosure Regime

Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents . . . .\footnote{Fair Packaging and Labeling Program, Fair Packaging and Labeling Act, 15 U.S.C. § 1451 (2000).}

If different state actors created or enforced disclosures, the market would experience problems similar to consumer credit in the 1960s. States would adopt different regimes and the patchwork of regulation would remain ineffective. Communicating specific information to consumers is complicated and needs to be done on the national level. Specific word choice, format, and other seemingly mundane aspects may be the difference between success and failure.\footnote{Cf. Leda Cosmides & John Tooby, Are Humans Good Intuitive Statisticians after All? Rethinking Some Conclusions of the Literature on Judgment under Uncertainty, 58 COGNITION 1 (1996) (reporting that changing minor diction substantially increased performance on an otherwise identical problem).}

And studies show that too detailed a warning about health risks confuses consumers.\footnote{W. Kip Viscusi, Using Warnings to Extend the Boundaries of Consumer Sovereignty, 23 HARV. J.L. & PUB. POL’Y 211, 230 (1999) (noting a study the author conducted on hazard warnings used for pesticides that concluded very detailed risk information confused consumers).}

In regards to non-pathologic genetic tests, reinforcing the basic idea that the clinical validity is dubious might sufficiently address many of the potential problems even if more complicated ideas are lost. In order to ensure that the enclosures impart the necessary information, the designers could draw on lessons about effectively warning consumers outside of healthcare.\footnote{See generally Moody, supra note 190.} The expansive body of scholarship related to warnings digests the sum of regulatory experience and offers the following lessons:

\footnotetext[199]{}{William O. Fabbri, Note, Home HIV Testing and Conflicts with State HIV Testing Regulations, 21 AM. J.L. & MED. 419, 420 (1995) (noting that home HIV tests will include a special paper for a blood sample and a return envelope).}
\footnotetext[201]{}{Cf. Leda Cosmides & John Tooby, Are Humans Good Intuitive Statisticians after All? Rethinking Some Conclusions of the Literature on Judgment under Uncertainty, 58 COGNITION 1 (1996) (reporting that changing minor diction substantially increased performance on an otherwise identical problem).}
\footnotetext[202]{}{W. Kip Viscusi, Using Warnings to Extend the Boundaries of Consumer Sovereignty, 23 HARV. J.L. & PUB. POL’Y 211, 230 (1999) (noting a study the author conducted on hazard warnings used for pesticides that concluded very detailed risk information confused consumers).}
\footnotetext[203]{}{See generally Moody, supra note 190.}
[1.] The information should be presented as simply and as clearly as possible, focusing on that which most affects the consumer.

[2.] The information should be tailored as much as possible to the individual consumer.

[3.] A common format for the information provided should be used throughout the industry, if possible.

[4.] The information should be provided in such a way that its meaning or import cannot easily be misrepresented or explained away by a seller of a good or service.

[5.] Informational remedies should avoid, to the extent possible, presenting the information in terms of probabilities.\(^{204}\)

Following these guidelines, a manufacturer-provided patient package insert and an information sheet should mitigate the problem that consumers would misapprehend the nature of a non-pathologic elective test and genetic tests more generally. Relevant and accurate information would dispel false expectations about the results of NPET. Federal disclosure laws would also guarantee that the information is presented in a uniform fashion. Finally, appropriate disclosure would empower individual consumers to make decisions about whether to buy genetic tests; thus, creating an important prophylactic against charlatans taking advantage of vulnerable consumers by disguising the true nature of the service they are providing.

Information-based solutions, similar to those found in the TIL Act, have political and theoretical advantages over other regulatory responses.\(^{205}\) From a political standpoint, disclosure appeases both advocates of consumer protection and advocates of laissez-faire solutions.\(^{206}\) Consumer-protection advocates support mandating disclosure as a way to empower the consumer. On the other end of the spectrum, proponents of market-based solutions perceive disclosure as a relatively non-intrusive technique. In addition, many parties who would typically argue for less regulation recognize that there is a net benefit

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\(^{205}\) See Peterson, *supra* note 142, at 880.

\(^{206}\) See id.
from disclosure laws, because disclosure facilitates a functional market.\textsuperscript{207} There is a more efficient market because participants engaged in fraudulent transactions will be forced to concede market share when they are unable participate in a competitive market in which purchasers can acquire adequate information. For these reasons, the disclosure approach has garnered significant support in the consumer credit context\textsuperscript{208} where it even receives "grudging acceptance" from an industry that is vocal about its aversion to government oversight.\textsuperscript{209}

From a theoretical perspective, information-based strategies work well in quickly growing markets, in which the inherent changes constantly create regulatory challenges. Classical economic thought recognizes that government action may be necessary to facilitate competition when externalities or imperfect information cause market failure in these environments.\textsuperscript{210} Fast growing markets, like genetic testing and consumer credit in the 1960s, often experience this type of problem. Genetic tests could be sold over the Internet and analyzed by laboratories in other countries.\textsuperscript{211} Alternatively, genetic tests might be packaged with other services in an effort to place them beyond the bounds of regulation.\textsuperscript{212} Market controls, especially on the state level, would simply be too difficult to implement.

Standardizing disclosure provided by manufacturers as well as mandating an information sheet similar to the one created by the CDC for vaccines would ensure that people receive sufficient information to make an informed decision.\textsuperscript{213} With or without regulation, non-pathologic tests will likely be sold directly to the consumer, so mandating information eliminates the possibility that patients would not receive at least some objective and easily comprehensible information. Because this industry is changing so rapidly, this sort of program can also adapt to accommodate unforeseen changes. Variations in the

\textsuperscript{207} See id. at 902.
\textsuperscript{209} Peterson, supra note 142, at 881.
\textsuperscript{210} Id. at 880. Confronted with new competition, lenders unable to vie for market share were forced to erect additional barriers to price shopping by increasing "shopping costs" and targeting non-English speaking consumers. Id. at 892-94.
\textsuperscript{211} One government body addressing the issue expressed concern that this sort of activity might be difficult to regulate and strain international relations. HUMAN GENETICS COMM'N U.K., supra note 15. Obviously, the possibility that genetic testing is done overseas creates a problem more aptly addressed by the federal government.
\textsuperscript{212} HUMAN GENETICS COMM'N U.K., supra note 15, at 7.
\textsuperscript{213} See supra Part III.B.
accuracy or quality of individual genetic tests would be apparent from the disclosure the manufacturer would include with the package. Changes concerning the nature of the industry could easily be incorporated into the government-written disclosure.

CONCLUSION

Many critics of genetic tests raise concerns about direct-to-consumer marketing and the harms that genetic testing for disease might cause to the consumer in the absence of a healthcare provider or genetic counselor. These critiques focus on how the tests are sold and lament the lack of federal oversight of the process. Unfortunately, the Internet and other technology are making it more difficult to control the process of how consumers acquire goods. Genetic testing services with laboratories in offshore locations which advertise over the Internet would be almost impossible to regulate, especially on the state level. Rather than concentrating on the process, I believe the more appropriate focus is on empowering parents and consumers with the information they need to make informed decisions. Raising individual knowledge about genetics would indirectly accomplish the goal of making society at large more aware of the risks and benefits of the new technology; thus, it would help dispel many of the unfounded concerns and misunderstandings that are so common about genetic technology.

Predictive testing for athletic ability is one of the first non-pathologic tests that might have some clinical validity, but it will not be long before many more begin to enter the stream of commerce. The types of harms implicated by these new predictive tests are very different from both traditional medicine and other genetic tests. The limited harms in the non-pathologic context do not justify the cumbersome process of informed consent that is conventionally employed in the medical context; rather, consumers should be empowered with a basic understanding of genetic testing and its clinically validity, so that they can make informed choices. Society should draw on the lessons it has learned from addressing similar market deficiencies, rather than stifling growth through over-regulation in this exciting new area of biotechnology.

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214 Javitt et al., supra note 129, at 298.
215 Id. at 298, 301.