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## 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

GAIL H. JAVITT,\* ERICA STANLEY,\*\* AND KATHY HUDSON\*\*\*

### *I. Introduction*

In the past few years, advisory bodies and public health advocates in both the United States and abroad have raised concerns about marketing<sup>1</sup> genetic tests directly to consumers. In the United States, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS),<sup>2</sup> which advises the

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1. One definition of marketing is "the process or technique of promoting, selling, and distributing a product or service; an aggregate of functions involved in moving goods from producer to consumer." MERRIAM-WEBSTER ONLINE DICTIONARY, at <http://www.m-w.com> (last visited Aug. 23, 2004). This definition encompasses the advertising of the product to gain consumer awareness and foster consumer demand, and the steps of transferring the good or service from seller to buyer.

2. Establishment of the Secretary's Advisory Committee on Genetics, Health, and Society, 67 Fed. Reg. 65,126 (Oct. 23, 2002); CHARTER OF THE SECRETARY'S ADVISORY COMMITTEE

Secretary of the Department of Health and Human Services (HHS), indicated that the issue would be a priority of the group.<sup>3</sup> In the past two years, government-sponsored reports in the United Kingdom,<sup>4</sup> Canada,<sup>5</sup> and Australia<sup>6</sup> have advocated stricter controls on direct-to-consumer (DTC) marketing of genetic tests. Most recently, the American College of Medical Genetics issued a policy statement recommending that genetic testing “should

ON GENETICS, HEALTH, AND SOCIETY (Sept. 23, 2002), at [http://www4.od.nih.gov/oba/sacghs/SACGHS\\_charter.pdf](http://www4.od.nih.gov/oba/sacghs/SACGHS_charter.pdf). The SACGHS replaced the Secretary’s Advisory Committee on Genetic Testing (SACGT), see SECRETARY’S ADVISORY COMMITTEE ON GENETIC TESTING, at <http://www4.od.nih.gov/oba/sacgt/aboutsacgt.htm>, which in 2000, issued a report calling for greater regulation of genetic testing by the federal government, see ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT (2000), at [http://www4.od.nih.gov/oba/sacgt/reports/oversight\\_report.pdf](http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf).

3. At its inaugural meeting, the SACGHS requested to hear testimony from several federal agencies concerning oversight of genetic tests. Notice of Meeting, 68 Fed. Reg. 32,044 (May 29, 2003). Representatives of several government agencies, including the Federal Trade Commission (FTC), Food and Drug Administration (FDA), and National Institutes of Health (NIH), testified at the Committee’s October 2003 meeting. Notice of Meeting and Request for Public Comment, 68 Fed. Reg. 53,171 (Sept. 9, 2003). Transcripts of these meetings are available at [http://www4.od.nih.gov/oba/sacghs/SACGhsMTG\\_Past.htm](http://www4.od.nih.gov/oba/sacghs/SACGhsMTG_Past.htm).

4. In March 2003, the United Kingdom’s Human Genetics Commission — an independent advisory body examining social and ethical issues in human genetics — issued a report addressing whether genetic tests should be promoted directly to the public. The report made several recommendations, including that most genetic tests that provide predictive health information should not be offered directly to the public and that the government should ensure that consumers are provided accurate information about genetic testing services. HUMAN GENETICS COMM’N, GENES DIRECT: ENSURING THE EFFECTIVE OVERSIGHT OF GENETIC TESTS SUPPLIED DIRECTLY TO THE PUBLIC §§ 3.32, 3.57-3.62 (Mar. 2003), at [http://www.hgc.gov.uk/genedirect/genesdirect\\_full.pdf](http://www.hgc.gov.uk/genedirect/genesdirect_full.pdf).

5. In 2002, the Ontario Government issued a report to the Provinces and Territories discussing concerns similar to the concerns raised over pharmaceuticals. The report addressed (1) the potential impact of DTC advertising of genetic testing from U.S. media on Canadian perceptions and demands with regard to genetic testing services, and (2) whether DTC advertising undermines the patient-provider educational and counseling relationship. The report recommended that the federal government enact legislation to prohibit or limit direct marketing of genetic testing. ONTARIO MINISTRY OF HEALTH & LONG-TERM CARE, GENETICS, TESTING & GENE PATENTING: CHARTING NEW TERRITORY IN HEALTHCARE § 8.5 (Jan. 2002), at [http://www.health.gov.on.ca/english/public/pub/ministry\\_reports/geneticsrep02/report\\_e.pdf](http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf).

6. While the Australian Law Reform Commission (ALRC) and the Australian Health Ethics Commission (AHEC) recognized the difficulty of regulating the distribution of products over the Internet, they issued a report in 2003 that favored limitations on the marketing of genetic tests over the Internet. ALRC & AHEC, ESSENTIALLY YOURS: THE PROTECTION OF HUMAN GENETIC INFORMATION IN AUSTRALIA (2003), at <http://www.austlii.edu.au/au/other/alrc/publications/reports/96/>. The report stemmed from an inquiry established by the Australian government in 2000, which was directed jointly to the ALRC and the AHEC. *Id.*

be provided to the public only through the services of an appropriately qualified health care professional.”<sup>7</sup>

Several concerns have been raised regarding the marketing of genetic tests directly to consumers. It has been argued that DTC marketing is confusing to consumers because it: (1) fails to adequately explain complex genetic information; (2) is misleading in its failure to disclose the risks and limitations of testing; (3) allows tests without established clinical validity or utility to be promoted; and (4) does not include the counseling needed to put test results in proper context.<sup>8</sup> On the positive side, however, even those opposed to DTC marketing acknowledge its potential to provide consumers with greater awareness about testing options and relevant medical information.<sup>9</sup>

Critics of DTC marketing raise concerns about the sale of genetic tests directly to consumers and the advertising of these tests to consumers. In reality, however, these marketing activities require separate legal analysis. With respect to the sale of consumer products and services in the United States, particularly those products with an impact on health, the government has the legal authority to use several different regulatory tools to limit consumer access and protect public health.<sup>10</sup> Government oversight of genetic

7. American College of Medical Genetics Board of Directors, *ACMG Statement on Direct-to-Consumer Genetic Testing*, 6 GENETICS MED. 60, 60 (2004).

8. Sarah E. Gollust et al., *Limitations of Direct-to-Consumer Advertising for Clinical Genetic Testing*, 288 J. AM. MED. ASS'N 1762 (Oct. 9, 2002) [hereinafter Gollust et al., *Limitations*]; see also Sarah E. Gollust et al., *Direct-to-Consumer Sales of Genetic Services on the Internet*, 5 GENETICS MED. 332 (2003) [hereinafter Gollust et al., *Sales*]; Sara Chandros Hull & Kiran Prasad, *Reading Between the Lines: Direct-to-Consumer Advertising of Genetic Testing*, HASTINGS CENTER REP. 31, 33 (May-June 2001); Bryn Williams-Jones, *Where There's a Web, There's a Way: Commercial Genetic Testing and the Internet*, 6 COMMUNITY GENETICS 46, 54 (2003).

9. Gollust et al., *Limitations*, *supra* note 8, at 1762; Gollust et al., *Sales*, *supra* note 8, at 332; Williams-Jones, *supra* note 8, at 54.

10. One mechanism the federal government uses is its power to allocate or withhold funding to the states. For example, in 1984, Congress passed the Uniform Drinking Age Act, which mandated reduced federal transportation funds to states that failed to raise the minimum legal drinking age to twenty-one. Uniform Drinking Age Act § 6(a), Pub. L. No. 98-363, 98 Stat. 435, 437 (1984) (codified at 23 U.S.C. § 158 (2000)); AM. MED. ASS'N, THE MINIMUM LEGAL DRINKING AGE: FACTS AND FALLACIES, at <http://www.ama-assn.org/ama/pub/article/3566-3640.html> (last updated Apr. 2, 2004). Similarly, in 1992, Congress passed the Synar Amendment, which requires states to pass and enforce laws prohibiting the sale and distribution of tobacco products to persons under the age of eighteen. Alcohol, Drug Abuse, and Mental Health Reorganization Act, tit. VIII, § 801, Pub. L. No. 102-321, 106 Stat. 323, 441-42 (1992) (codified at 42 U.S.C. § 300x-26 (2000)). The statute mandated up to a 40% reduction in federal funds to noncomplying states for the Substance Abuse Prevention and Treatment Block Grant. 45 C.F.R. § 96.1(d) (2003); U.S. DEP'T OF HEALTH & HUMAN SERVS., SYNAR AMENDMENT: PROTECTING THE NATION'S YOUTH FROM NICOTINE ADDICTION, at <http://>

testing services, however, currently falls between several regulatory “cracks” within the federal government, and is therefore arguably both ambiguous and insufficient. As this Article discusses, most genetic tests do not require approval before they can be sold. Although the Food and Drug Administration (FDA) regulates a small number of tests, it has refrained from regulating most genetic tests, in part because its jurisdiction to do so is unclear. Furthermore, while the Center for Medicare and Medicaid Services (CMS) oversees laboratories providing genetic testing services, this oversight is quite limited.

With respect to advertising — the communication of information to promote the sale of lawful products or services — government regulation is subject to the constraints of the First Amendment to the U.S. Constitution, which prohibits the government from “abridging the freedom of speech.”<sup>11</sup> Historically, the First Amendment has been recognized to prohibit government censorship of political, social, scientific, or artistic expression. Since the 1970s, the U.S. Supreme Court has interpreted this provision to include “commercial speech,” which is speech solely intended to sell products or services.<sup>12</sup> Moreover, in recent years the Court has imposed an increasingly high burden of proof on government attempts to restrict commercial speech, even when the government has asserted a public health objective, as discussed in Part VI of this Article.

Though some DTC marketing critics have advocated restricting the advertising of genetic tests through television, the Internet, and print media, any such restrictions must be consistent with the constraints imposed by the First Amendment, particularly in light of recent Supreme Court jurisprudence. This Article analyzes the extent to which the government may lawfully restrain advertising of genetic tests directly to consumers. Further, this Article argues that a court would likely hold the government’s attempt to categorically prohibit such advertising unconstitutional if challenged in court. Limited restrictions on advertising could potentially withstand judicial scrutiny, but

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prevention.samhsa.gov/tobacco.

State governments use their police powers to promote public health through a variety of mechanisms, such as inspections of commercial and residential premises, and licensing of health care providers. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW, POWER, DUTY, RESTRAINT* 50-51 (2000).

11. U.S. CONST. amend. I. “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.” *Id.*

12. The U.S. Supreme Court has defined “commercial speech” as speech that does “no more than propose a commercial transaction” or service. *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 385 (1973).

only if supported by adequate evidence demonstrating the link between such restrictions and protecting consumers, and if carefully tailored to achieve that goal. The government could require the use of disclaimers to prevent consumer confusion or deception, and although this approach would likely succeed from a constitutional standpoint, it may be the least satisfying to some public health advocates.

Part II of this Article defines genetic testing and describes the array of genetic tests currently available. Part III addresses the concerns that have been raised regarding the potential for harm from both DTC advertising and direct consumer access to genetic testing services. Part IV discusses the current regulatory status of genetic tests, with particular emphasis on the role of various agencies within HHS in regulating the sale of these products. Part V discusses the regulation of DTC prescription drug advertising in the United States and the extent to which this model is applicable to advertising of genetic tests to consumers. Part VI reviews the commercial speech doctrine as it has evolved through Supreme Court and lower court decisions. Finally, Part VII analyzes the types of advertising restrictions that a court may find constitutional and identifies the governmental entities that could potentially implement such regulations.

## *II. The Current Status of Genetic Testing*

### *A. What Are Genes*

Genes serve as the basic building blocks of heredity and provide the blueprint for growth and development.<sup>13</sup> Genes are made up of deoxyribonucleic acid (DNA), which is composed of individual units called nucleotides.<sup>14</sup> The particular arrangement of the nucleotides constitutes a code that the body can translate to produce specific proteins.<sup>15</sup> Each protein has a unique structure and a specific function in the body.<sup>16</sup> Different genes are active in different cell types, depending on what protein products are required.<sup>17</sup>

The human genome comprises about thirty thousand to fifty thousand genes that are arranged into structures called chromosomes.<sup>18</sup> All cells in the human body, except sperm and egg cells, contain twenty-three pairs of chromosomes,

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13. ROBERT H. TAMARIN, *PRINCIPLES OF GENETICS* 9-10 (5th ed. 1996).

14. JAMES THOMPSON & MARGARET THOMPSON, *GENETICS IN MEDICINE* 17, 20 (Robert L. Nussbaum et al. eds., W.B. Saunders Co. 5th ed. 2001) (1966).

15. *Id.* at 18-24.

16. TAMARIN, *supra* note 13, at 195-97.

17. THOMPSON & THOMPSON, *supra* note 14, at 10.

18. *Id.* at 203.

or forty-six total chromosomes.<sup>19</sup> The first twenty-two chromosome pairs hold the instructions for the body's growth, development, and proper functioning.<sup>20</sup> The last pair holds the instructions that determine sex. Males usually have one X and one Y chromosome, while females typically have two X chromosomes.<sup>21</sup>

Individuals inherit genetic information from their biological parents. Half of the genetic information comes from the mother, and the other half comes from the father.<sup>22</sup> Sperm and egg cells, also known as gametes, each carry a single copy of each chromosome.<sup>23</sup> When sperm and egg combine during fertilization, the resulting cell contains a new and complete genome. This cell now has forty-six chromosomes and, under the right conditions, can develop into an embryo, fetus, and ultimately a child.<sup>24</sup>

### *B. Genetic Basis of Disease*

Scientists increasingly believe that most, if not all diseases, or human responses to diseases, likely have a genetic component.<sup>25</sup> Genetic disorders can arise from abnormalities in a chromosome or in a gene.<sup>26</sup> Chromosomal abnormalities can be numerical, with either too many or too few of each chromosome within cells,<sup>27</sup> or structural, meaning some change in the structure of the chromosome.<sup>28</sup> Gene mutations involve changes to the DNA sequence of a single gene.<sup>29</sup> Some mutations will lead to disease, whereas others will increase a person's risk of future disease.

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19. *Id.* at 5.

20. *Id.*

21. *Id.*

22. TAMARIN, *supra* note 13, at 46.

23. *Id.*

24. THOMPSON & THOMPSON, *supra* note 14, at 5.

25. *Id.* at 181.

26. *Id.* at 79.

27. *Id.* at 79-80. Examples of conditions caused by numerical mutations are Down Syndrome, the result of an extra chromosome number 21 (forty-seven total chromosomes), and Turner Syndrome, the result of a missing X chromosome (forty-five total chromosomes). TAMARIN, *supra* note 13, at 182-83.

28. THOMPSON & THOMPSON, *supra* note 14, at 79-80. Structural abnormalities include: (1) translocations (in which segments of DNA are exchanged between two different chromosomes); (2) inversions (in which a portion of the chromosome flips its orientation with respect to the rest of the chromosome); (3) deletions (in which a segment of the chromosome is lost); and (4) duplications (in which a segment of the chromosome is repeated). *Id.* at 79, 140-44. Changes in segments of the chromosome can lead to changes in the way the genes housed on those chromosomes are expressed. TAMARIN, *supra* note 13, at 168-77.

29. THOMPSON & THOMPSON, *supra* note 14, at 79-80.

### C. What Is a Genetic Test

A genetic test is the laboratory analysis of DNA, RNA, chromosomes, or gene products.<sup>30</sup> In healthcare, such analysis is conducted to detect genetic abnormalities associated with a disease or condition.<sup>31</sup> Currently, more than seven hundred genetic tests are available for clinical use.<sup>32</sup>

A health care provider may order a genetic test for one of several reasons: (1) to identify carriers of genetic disease; (2) to test embryos, fetuses, and newborns for disease-causing genetic abnormalities; (3) to establish clinical diagnoses or prognoses and inform clinical care; (4) to determine whether there is increased risk of developing a disease in the future; or (5) to predict response to a medication.<sup>33</sup> Genetic testing can be conducted at any stage in the developmental lifecycle.

Genetic tests can detect not only genetic changes associated with disease, but also normal variants within a gene, or traits. For example, genetic tests can be used to identify whether a person's tissue type will match that of a person needing a tissue transplant. As more genetic tests are developed, it is likely that more genetic contributors to traits will be detectable through testing.

30. GENETESTS, *What Is Genetic Testing*, in EDUCATIONAL MATERIALS, at <http://www.genetests.org> (updated weekly) [hereinafter *What Is Genetic Testing*]. RNA stands for ribonucleic acid. It is formed upon a DNA template and contains ribose instead of deoxyribose. There are several different types of RNA, including *Messenger RNA* (MRNA), which is the template on which polypeptides are synthesized. THOMPSON & THOMPSON, *supra* note 14, at 411.

31. *What Is Genetic Testing*, *supra* note 30. Genetic testing is used in other contexts as well. For example, forensic scientists use DNA "fingerprinting" to identify potential crime suspects, exonerate persons wrongly accused of crimes, and identify crime and catastrophe victims. Genetic testing is also used to establish paternity. See, e.g., BADGER-HAWKEYE RED CROSS, at <http://www.a2zdna.com> (last visited Apr. 14, 2004); DATAGENE, at <http://www.data.gene.com> (last visited Apr. 14, 2004); GENELEX, at <http://www.genelex.com> (last visited Apr. 14, 2004); SERVICES/PRODUCTS, DNA/PRINTGENOMICS, at <http://www.dnaprint.com> (last visited Apr. 14, 2004) [hereinafter DNA PRINT]. Genetic tests are also being used to trace the origins of different racial and ethnic groups by examining normal variations in DNA, known as polymorphisms. See, e.g., AFRICAN ANCESTRY, at <http://www.africanancestry.com> (last visited Apr. 14, 2004); DNA PRINT, *supra*; GENELEX, *supra*. The analysis is performed on a biological sample such as blood, cells from the inside of the cheek, or fetal cells in amniotic fluid. LYNN B. JORDE ET AL., MEDICAL GENETICS 218-19 (Emma D. Underdown ed., Mosby-Year Book, Inc. 1995).

32. GENETESTS, at <http://www.genetests.org> (updated weekly). Clinical genetic tests examine specimens to diagnose, prevent, or treat individual patients. Research genetic tests examine specimens for the purpose of understanding a condition or developing a clinical test. *Id.*

33. GENETESTS, *Uses of Genetic Testing*, in EDUCATIONAL MATERIALS, at <http://www.genetests.org> (updated weekly) [hereinafter *Uses of Genetic Testing*].



#### D. Types of Genetic Testing

Carrier testing identifies unaffected individuals who carry a recessive mutation, which is a change in one copy of a particular gene. A health care provider may recommend a carrier test because an individual has a known family history of a particular disease, or because the individual is a member of a population known to be at higher risk for a disease.<sup>34</sup> In the United States, carrier testing is most frequently offered to patients who are planning pregnancy or who are already pregnant.<sup>35</sup>

Prenatal tests are used to detect a genetic abnormality in a developing fetus.<sup>36</sup> Prenatal screening tests indicate the probability that a fetus is affected by a particular genetic condition or birth defect.<sup>37</sup> Screening tests include maternal blood tests<sup>38</sup> and ultrasound examinations.<sup>39</sup> If a screening test shows an increased risk, the mother may be offered genetic testing to determine whether the fetus actually has a genetic abnormality. Chorionic Villus Sampling (CVS) and amniocentesis are among the most common procedures used to obtain a sample of fetal cells that can be tested for genetic abnormalities.<sup>40</sup>

Preimplantation genetic diagnosis (PGD), the newest form of reproductive

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34. JORDE ET AL., *supra* note 31, at 210. There are many examples of this type of screening: cystic fibrosis screening in Caucasians, sickle-cell disease screening in African Americans, thalassemia screening in Asians and individuals of Mediterranean decent, and Tay-Sachs disease screening in Ashkenazi Jews.

35. *Id.* at 218.

36. *Id.*

37. *Id.* at 218-19.

38. For example, the maternal serum alpha-fetoprotein (MSAFP) test examines alpha-fetoprotein, a substance produced by the fetus that circulates in the mother's blood. Decreased levels can indicate an increased risk for Down syndrome. Physicians commonly screen three or four proteins in the mother's blood (called either a triple screen or a quadruple screen) to screen for Down syndrome, trisomy 18, and Turner syndrome. Peter A. Benn, *Advances in Prenatal Screening for Down Syndrome: I. General Principles and Second Trimester Testing*, 323 CLINICA CHIMICA ACTA 1, 3, 8 (2002).

39. Ultrasound examines the fetus by high frequency sound waves. It is routinely used to estimate fetal viability, the number of fetuses present, the position of the fetus, and fetal age. Fetal structures can also be examined depending on the age of the fetus and the extent of the evaluation, and some fetal malformations can be detected in utero. For example, an increase in nuchal fold thickness is correlated with an increased risk for Down syndrome, and neural tube and heart malformations can also be detected on ultrasound. When an abnormality is seen on ultrasound, amniocentesis or other invasive testing can be performed to sample fetal tissue and determine whether the abnormality is associated with a genetic disorder. *Id.*; see also GENE TESTS, *Fetal Ultrasound Examination*, in EDUCATIONAL MATERIALS, at <http://www.genetests.org> (updated weekly).

40. THOMPSON & THOMPSON, *supra* note 14, at 360-64.

genetic testing, is used to detect a genetic abnormality in an embryo created through in vitro fertilization.<sup>41</sup> This technique has been used to inform the selection of embryos that do not have a particular genetic abnormality and to select for particular traits, such as a tissue type that matches an ailing sibling or a particular sex.<sup>42</sup>

Newborn screening of infants can be used to identify genetic conditions and metabolic disorders shortly after birth. In many conditions, early detection and treatment prevent lifelong impairment or death. Newborn screening is typically performed as part of state public health programs.<sup>43</sup> The most common disorders screened for are phenylketonuria (PKU), congenital hypothyroidism, galactosemia, and sickle cell disease.<sup>44</sup>

Diagnostic testing is used to identify or confirm the diagnosis of a disease or condition in an affected individual.<sup>45</sup> This type of testing may be useful to help predict the course of a disease, determine the choice of treatment, and provide recurrence risk information to affected individuals and their family members.<sup>46</sup>

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41. In PGD, one cell from a six- or eight-celled embryo is biopsied, and the DNA is analyzed. Because it requires examination of an embryo outside the woman's body, PGD can be performed only in conjunction with in vitro fertilization. The error rate for PGD is estimated to be from 1% to 10% depending on the particular disease and testing mechanism used. AM. SOC'Y FOR REPROD. MED. (ASRM) & SOC'Y FOR ASSISTED REPROD. TECH. (SART), A PRACTICE COMMITTEE REPORT: PREIMPLANTATION GENETIC DIAGNOSIS 2 (2001). Accordingly, it is often recommended that PGD diagnosis be followed by CVS or amniocentesis. PGD was initially developed so that couples who were carriers of specific genetic mutations could avoid having a child with a genetic disease. It is also being used to screen for aneuploidy (incorrect number of chromosomes) in embryos of women undergoing IVF. See, e.g., Anver Kuliev & Yuri Verlinsky, *The Role of Preimplantation Genetic Diagnosis in Women of Advanced Reproductive Age*, 15 CURRENT OPINIONS IN OBSTETRICS & GYNECOLOGY 233 (2003); Santiago Munne, *Preimplantation Genetic Diagnosis and Human Implantation — A Review*, 24 PLACENTA S70, S70-S71 (2003).

42. For a broad discussion of PGD, its history, uses, and policy implications, see GENETICS & PUB. POLICY CTR., PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO THE GENETIC TESTING OF HUMAN EMBRYOS (2004), at [http://www.dnapolicy.org/downloads/pdfs/policy\\_pgd.pdf](http://www.dnapolicy.org/downloads/pdfs/policy_pgd.pdf).

43. All states, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands implement mandatory newborn screening programs. However, no federal standard exists and the number of disorders tested varies by state. Some states screen for as few as three conditions, while other states test up to thirty conditions. Most state programs, however, test for between four and ten disorders. JORDE ET AL., *supra* note 31, at 213; NAT'L NEWBORN SCREENING & GENETICS RES. CTR., U.S. NATIONAL SCREENING STATUS REPORT, at <http://genes-r-us.uthscsa.edu/resources/newborn/screenstatus.htm> (last updated Mar. 30, 2004).

44. JORDE ET AL., *supra* note 31, at 213-14.

45. *Uses of Genetic Testing*, *supra* note 33.

46. *Id.*

Presymptomatic, or predictive genetic testing, identifies individuals carrying a mutation in a gene for which that person does not currently manifest any symptoms. Detection of a gene mutation may indicate that the individual will eventually get the disease, or that the individual is at heightened risk for developing the disease.<sup>47</sup>

Pharmacogenetic testing aims to identify genetic variations that will predict an individual's response to drug therapy. This technology is in its infancy, with only a few tests developed for this purpose.<sup>48</sup> The goal is to eventually develop many tests that will determine whether an individual will respond positively or suffer adverse drug reactions from a particular drug and its dosage, and ultimately to prescribe the safest and most effective drug to each individual.<sup>49</sup>

#### *E. How Genetic Tests Are Different From or Similar to Other Medical Tests and Procedures*

Some of the concerns raised by the marketing of genetic tests to consumers mirror concerns raised with respect to other DTC marketing efforts, including those for prescription drugs.<sup>50</sup> Genetic testing, however, also differs from other diagnostic tests and medical treatments. First, when conducted for a person not experiencing any symptoms of a disease, a genetic test result is solely predictive, not diagnostic. A positive test result indicates the presence of a particular gene sequence that is associated with the occurrence of a particular disease. The presence of the gene sequence by itself does not mean the person will develop the disease. In other words, the information is probabilistic and not deterministic. Even in those cases where presence of the

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47. JORDE ET AL., *supra* note 31, at 215-16.

48. Pharmacogenetic testing can be used before symptoms of disease are present and after symptoms appear and a diagnosis has been made. An example of presymptomatic pharmacogenetic testing is the OtoDx test, currently offered by Athena Diagnostics, which tests for the A1555G mutation that has been associated with increased susceptibility to hearing loss after exposure to a certain class of antibiotics called aminoglycosides. See Athena Diagnostics, *OtoDx Aminoglycoside Hypersensitivity Test*, at [http://www.athenadiagnostics.com/hearingloss/otodx\\_amino.asp](http://www.athenadiagnostics.com/hearingloss/otodx_amino.asp) (last visited Apr. 14, 2004). An example of post-diagnostic pharmacogenetic testing is HER2 oncogene testing in breast cancer cells. Medical providers can use the results of this test to assess a patient's likely response to the medication Herceptin. Because this medication specifically targets breast cancer cells that contain an alteration in the HER2 gene, breast cancer cells without this alteration are unaffected. See Genentech, *HER2 Disease in Breast Cancer*, at <http://www.gene.com/gene/products/education/oncology/her2disease.jsp> (last visited Apr. 14, 2004).

49. THOMPSON & THOMPSON, *supra* note 14, at 252-53.

50. See *supra* notes 10-12 and accompanying text (discussing DTC marketing of prescription drugs).

gene has a complete correlation with development of a disease, the test cannot predict when the disease will manifest itself or its duration and severity.<sup>51</sup> To be sure, nongenetic medical tests provide probabilistic information as well, but the data from these tests are usually not the only clinical information used to make significant, potentially life-altering decisions, such as the termination of pregnancy or prophylactic mastectomy.<sup>52</sup>

Genetic tests also may have implications for other family members. If a child is a carrier, it necessarily means at least one parent is also a carrier. If the child carries two copies of a recessive gene, both parents are carriers. Other siblings may also be carriers or may develop the disease; likewise for the children of the tested individual. Individuals who choose to obtain genetic tests, therefore, are more likely to discover genetic information about their relatives and will face difficult questions about whether to inform these relatives of test results.<sup>53</sup> Health care providers may also face not only ethical, but also legal questions about the duty to inform relatives of a patient's genetic information that might have bearing on their health.<sup>54</sup>

Genetic test results, though not necessarily more informative than other health information, are often perceived as such in the popular media and society at large.<sup>55</sup> Genetic information carries with it an aura of immutability not found with other medical information. While medical conditions are often treatable, a person's genes are largely unalterable.<sup>56</sup> Thus, genetic test results

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51. For example, a person who has the mutation causing Huntington disease will always develop the disease, but the age of onset varies. THOMPSON & THOMPSON, *supra* note 14, at 240.

52. Women who carry the mutation in the BRCA 1 or 2 gene have a heightened risk of developing breast and ovarian cancer. Medical providers may recommend prophylactic mastectomy or oophorectomy or both to reduce the risk of developing disease. *Id.* at 394.

53. John Balint, *Issues of Privacy and Confidentiality in the New Genetics*, 9 ALB. L.J. SCI. & TECH. 27, 34-35 (1998).

54. Jeffrey W. Burnett, *A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease*, 36 HOUS. L. REV. 559, 575-80 (1999); Janet L. Dolgin, *Personhood, Discrimination, and the New Genetics*, 66 BROOK. L. REV. 755, 802-16 (2000/2001).

55. Ellen Wright Clayton, *Ethical, Legal, and Social Implications of Genomic Medicine*, 349 NEW ENG. J. MED. 562, 563 (2003).

56. Since the 1970s, scientists have endeavored to demonstrate that "gene therapy" is a viable therapeutic approach to alleviating many genetic disorders. Gene therapy, also called gene transfer, is an investigational technique that involves the transfer of a small segment of DNA into an individual's cells and the expression of that DNA in the body. THOMPSON & THOMPSON, *supra* note 14, at 269-70. The goal — largely unrealized to date — is to overcome the effects of an individual's incorrectly functioning genes through the introduction of additional genes. Such genes may correct the defect in a variety of ways, including "replacing" the nonfunctioning gene with a functioning one, or causing cells containing deleterious genes, such as those that cause cancer, to self-destruct. *See, e.g.*, Alan Fischer et al., *Gene Therapy of*

inform individuals, or at least are perceived as informing individuals, about their destiny in a way that other medical information does not.<sup>57</sup> Consequently, the information carries a certain power, and a potential stigma, that has led to concerns that it will be used to a person's disadvantage, for example, in insurance and employment.<sup>58</sup>

### *III. Concerns That Have Been Raised Regarding Direct Access Testing and Direct-to-Consumer Advertising of Genetic Tests*

#### *A. The Current Market*

Like most laboratory tests, most genetic tests are currently unavailable without the intervention of a health care provider.<sup>59</sup> The major laboratories generally sell their testing services to health care providers and hospitals and not directly to consumers. According to one source, only ten to fifteen percent of hospital and commercial laboratories offer DTC testing, but this estimate does not distinguish between genetic and nongenetic tests.<sup>60</sup> Laboratories that sell testing services directly to consumers have largely used the Internet to promote awareness and generate demand. A 2003 study that surveyed the Internet found 105 websites that offer genetic services directly to the public.<sup>61</sup> Health-related genetic testing services are offered through fourteen of these sites.<sup>62</sup>

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*Severe Combined Immunodeficiencies*, 2 NATURE REVIEWS IMMUNOLOGY 615 (2002); Frank McCormick, *Cancer Gene Therapy: Fringe or Cutting Edge?*, 1 NATURE REVIEWS CANCER 130 (2001). Researchers have encountered many difficulties along the path to the clinical use of gene therapy. In particular, gene delivery issues, such as how to transfer the segment of DNA into target cells in a manner that allows integration or gene expression without disrupting other processes, have continued to pose challenges. See, e.g., *Gene Therapy: Shining Hopes Dented — But Not Dashed*, 420 NATURE 735 (2002); Erika Check, *Gene Therapy: A Tragic Setback*, 420 NATURE 116 (2002).

57. Clayton, *supra* note 55, at 563.

58. Dolgin, *supra* note 54, at 764-65.

59. An increasing number of states permit consumers to obtain testing directly from a laboratory without a health care professional's involvement. Direct access testing, however, tends to be limited to those tests that are considered simple to perform, such as cholesterol testing. See Matthew Schulze, Am. Soc'y for Clinical Pathology (ASCP), *25 Percent More States Allow Direct Access Testing*, 32 LABORATORY MED. 661 (2001), at <http://www.ascp.org/general/media/1000422.pdf>.

60. Toby L. Merlin, Direct Access Testing, presentation at CLIAC Meeting (Mar. 2003) (on file with authors); Laurie Tarkan, *Blood-Test Labs Bypass Doctors, Spurring Debate*, N.Y. TIMES, Mar. 12, 2002, at F6 (quoting Jondavid Klipp, managing editor of *Laboratory Industrial Report*, a trade publication).

61. Gollust et al., *Sales*, *supra* note 8, at 333.

62. *Id.*

The types of services offered directly to consumers range from “mainstream” genetic tests, or those generally accepted and used as part of patient care, to those that do not have a history of clinical use or the usual indicia of scientific support. Those in the “mainstream” category include tests for cystic fibrosis, sickle-cell anemia, and other blood disorders.<sup>63</sup> Tests in the latter category include tests that (1) offer “genetic profiling” to recommend nutritional supplements tailored to an individual’s genetic makeup;<sup>64</sup> (2) claim to identify persons with increased tendencies toward addictive behavior and offer nutritional supplements to counteract this tendency;<sup>65</sup> and (3) offer personal skin care regimens tailored to DNA type.<sup>66</sup>

Laboratories that do not sell directly to consumers also generally do not advertise in consumer-oriented media. A notable exception is Myriad Genetics, a company that has undertaken a DTC promotion campaign for the BRCA genetic test. In September 2002, Myriad launched a five-month, “BRCAAnalysis — Be Ready Against Cancer” campaign to help educate women and their physicians about hereditary breast cancer, genetic testing, and ways to reduce cancer risk.<sup>67</sup> This pilot program, which ran in two cities, used television, print, and radio “to alert women with a family history of

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63. Health Check USA provides DNA testing for cystic fibrosis and inherited disorders of blood clotting. See HEALTHCHECKUSA, at <http://www.healthcheckusa.com> (2002). PEDIATRIX offers both newborn screening and carrier screening for many genetic conditions including cystic fibrosis, sickle-cell anemia, and galactosemia. See PEDIATRIX SCREENING, at <http://www.pediatrixscreening.com> (2003). Alpha-1 Foundation and the University of South Carolina offer genetic testing for alpha-1 antitrypsin deficiency. See ALPHA-1 FOUNDATION, at <http://www.alphaone.org> (last visited July 17, 2004).

64. GeneLink and its partner company, NuGenix, offer both genetic testing services and recommendations for dietary supplements based on test results. These corporations and their distributors, such as Custom Nutrition, promote the use of genetic technologies for “genetic profiling.” See CUSTOM NUTRITION, at <http://www.custom-nutrition.com/index.html> (2004); GENE LINK, at <http://www.bankdna.com> (last visited Apr. 17, 2004); NUGENIX, at <http://www.nugenix.com> (last visited Apr. 17, 2004).

65. Doc Blum Inc. offers genetic testing services that identify persons with increased tendencies toward addictive behaviors and offers the RDSsystem of supplements to counteract the “Reward Deficiency Syndrome.” See DOC BLUM INC., at <http://www.docbluminc.com> (last visited Apr. 17, 2004).

66. Lab21 offers personal skin care regimes that are tailored to a customer’s genetic test results. Their product, DNA Face Cream, is advertised as “the ultimate anti-aging skincare product customized based on results of a genetic test and answers to a skin questionnaire.” See LAB21, at <http://www.lab21.com/web/ordering.php?a=internet> (last visited Apr. 17, 2004).

67. Adam Marcus, *First Ad Campaign Touts Genetic Screening for Cancer*, HEALTH ON THE NET FOUND. (Sept. 23, 2003), at <http://www.hon.ch/News/HSN/509235.html>; Helen Pearson, *Genetic Test Adverts Under Scrutiny*, NATURE SCI. UPDATE (Mar. 19, 2003), at <http://www.nature.com/nsu/030317/030317-3.html>.

cancer to recent advances in cancer prevention and early disease detection.”<sup>68</sup> The advertising campaign did not offer or encourage testing directly to the consumer, but instead encouraged consumers to consult their physician about this genetic test.<sup>69</sup> Another exception is Genovations, which promotes the use of single nucleotide polymorphism (SNP) testing<sup>70</sup> to make nutritional and lifestyle recommendations, and suggests that these tests are relevant to patients “with chronic conditions who have been refractory to traditionally effective treatment,” those “with a ‘family history’ of chronic illnesses like heart disease, osteoporosis, chronic fatigue, or inflammatory disorders,” and those who are looking for “more precise, proactive health risk screening.”<sup>71</sup> The company markets these tests through a network of physicians and health care providers. Genovations does not allow consumers to directly order their testing, but instead refers them to a physician who orders the tests for them.<sup>72</sup> Finally, Seryx Signature Genetics also markets genetic testing for information on medication, nutrition and lifestyle directly to consumers, but requires a physician to order tests and receive results.<sup>73</sup>

### *B. Criticisms of Direct-to-Consumer and Direct Access Marketing*

Criticisms have been leveled against both the sale of genetic testing services and the advertising of these services to consumers. Critics, however,

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68. Myriad, *Myriad Genetics Launches Direct to Consumer Advertising Campaign for Breast Cancer Test* (Sept. 12, 2002), at [http://www.corporate-ir.net/ireye/ir\\_site.zhtml?ticker=mygn&script=413&layout=9&item\\_id=333030](http://www.corporate-ir.net/ireye/ir_site.zhtml?ticker=mygn&script=413&layout=9&item_id=333030).

69. Myriad, *BRACAnalysis: Be Ready Against Cancer*, at <http://www.bracnow.com> (2002).

70. Single nucleotide polymorphisms (SNPs) are common variations in a single base of a human DNA sequence that occur in approximately every one thousand bases. SNPs may be useful for two purposes: (1) they may be used as markers where they are in close proximity on a chromosome to a deleterious mutation, or (2) they may be used to analyze shifts in SNPs in certain groups of people and thereby trace the connection of widely dispersed ethnic groups and races. By studying SNP profiles that are associated with specific disease traits, scientists hope to better understand multigene disorders and enable physicians to screen individuals for susceptibility to a disease. NAT'L HUMAN GENOME RES. INST., TALKING GLOSSARY OF GENETIC TERMS, at <http://www.genome.gov/glossary.cfm?key=single%20nucleotide%20polymorphisms%20%28SNPs%29> (last visited Apr. 17, 2004); PERKINELMER, SNP AND GENOTYPING OVERVIEW, at <http://las.perkinelmer.com/content/snps/genotyping.asp> (2004); SNP CONSORTIUM, LTD., SINGLE NUCLEOTIDE POLYMORPHISM: AN INTRODUCTION, at <http://snp.cshl.org/about/introduction.shtml> (last updated Apr. 30, 2002).

71. GENOVATIONS, PHYSICIANS GUIDE TO CLINICAL GENOMICS, at [http://www.genovations.com/clinician\\_overview.html](http://www.genovations.com/clinician_overview.html) (last visited Apr. 17, 2004).

72. GENOVATIONS, FREQUENT QUESTIONS ABOUT GENOVATIONS TESTING, at [http://www.genovations.com/Genovations\\_Frequent\\_Questions.pdf](http://www.genovations.com/Genovations_Frequent_Questions.pdf) (last visited Apr. 17, 2004).

73. SERYX SIGNATURE GENETICS, HOW SIGNATURE GENETICS WORKS, at [http://www.signaturegenetics.com/en/int02\\_01.html](http://www.signaturegenetics.com/en/int02_01.html) (last visited Apr. 17, 2004).

tend not to clearly distinguish between sale and advertising. With respect to direct sale, critics argue that the assistance of a health care provider is necessary to explain the context and consequences of testing.<sup>74</sup> With respect to advertising, critics contend that the advertisements that currently exist “downplay the uncertainties of genetic testing, obscure the phenotypic variability expected with positive results, . . . distort disease risk information for the consumer . . . [and] draw on hyperbole to describe the utility of their genetic tests . . .”<sup>75</sup> Furthermore, some argue that mass media advertisements create an exaggerated message about disease risk and thereby increase consumer anxiety.<sup>76</sup> Advertisers “capitalize on the hope and fear that genetics evokes to sell their products and perpetuate a deterministic conception of genetics, thereby exacerbating consumers’ distorted beliefs.”<sup>77</sup> Advertisements can invoke images in consumers’ minds of the most severe clinical presentation of a disease, leading to increased demand for, and overuse, of genetic testing by consumers.<sup>78</sup> Some argue that advertisements can also stigmatize an entire ethnic group if they associate that group with an increased risk for a genetic disease.<sup>79</sup>

While critics concede that advertising has the potential to benefit the public through education,<sup>80</sup> they conclude that these benefits are limited by (1) the difficulty consumers may have in comprehending complex genetics information and the potential that they will misunderstand test results, (2) the lack of sufficient information for pretest decision-making, and (3) the availability of genetic tests without scientific consensus on their clinical validity or utility.<sup>81</sup>

With regard to problems of comprehension, critics contend that genetic information is difficult to understand because test results provide only probabilities of risk.<sup>82</sup> Whether a person who tests positive will manifest the disease, and how severe the disease will be, cannot be predicted from the test.<sup>83</sup> Explaining these subtleties is difficult to accomplish in an

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74. Hull & Prasad, *supra* note 8, at 34; Williams-Jones, *supra* note 8, at 54.

75. Gollust et al., *Limitations*, *supra* note 8, at 1764.

76. *Id.*; Hull & Prasad, *supra* note 8, at 34.

77. Gollust et al., *Limitations*, *supra* note 8, at 1766.

78. Williams-Jones, *supra* note 8, at 48.

79. Gollust et al., *Limitations*, *supra* note 8, at 1764.

80. Williams-Jones, *supra* note 8, at 48.

81. Gollust et al., *Limitations*, *supra* note 8, at 1763; Gollust et al., *Sales*, *supra* note 8, at 334.

82. Clayton, *supra* note 55, at 563.

83. *Id.* A positive test result detecting a mutation does not always indicate that an individual will develop symptoms of the disease. Differing phenotypic expressions of an abnormal genotype can occur because of, among other reasons, reduced penetrance (where some



advertisement.<sup>84</sup> Consequently, consumers may be at increased risk for misunderstanding the meaning or implications of test results that are provided directly to them.<sup>85</sup> Currently, only a limited number of websites offer physician consultations or genetic counseling services.<sup>86</sup> A few companies require that test results be sent directly to the consumer's health care practitioner. However, given the varying degree of knowledge that providers have regarding genetics, it is unclear how much assistance they can provide patients in interpreting test results.<sup>87</sup>

Of additional concern to critics is that websites often provide insufficient information for consumers to make informed pretest decisions.<sup>88</sup> They argue that websites often exaggerate the benefits and limit the disclosure of risks commonly associated with genetic testing.<sup>89</sup> These risks include concerns about privacy, implications to family members, and protection of the DNA sample — its storage, withdrawal, and possible future use.<sup>90</sup> Although privacy concerns apply to the purchase of any product over the Internet, genetic testing services involve the disclosure of personal health information, and such information could be misused by the companies that obtain it, or by those who obtain unauthorized access to the website.<sup>91</sup>

Finally, critics assert that advertisements for genetic tests that have no proven clinical validity have the potential to mislead consumers into believing that a test has proven benefits.<sup>92</sup> Critics are particularly concerned about the widespread use of the Internet to promote and sell genetic tests. Unlike

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individuals who have the genotype completely fail to express it) and variable expression (where severity of disease differs in people who have the same genotype). THOMPSON & THOMPSON, *supra* note 14, at 62.

84. Gollust et al., *Limitations*, *supra* note 8, at 1763.

85. Bryn Williams-Jones, *Re-Framing the Discussion: Commercial Genetic Testing in Canada*, 7 HEALTH L.J. 49, 60-61 (1999).

86. See, e.g., DATAGENE, at <http://www.datagene.com/about.html> (last visited Apr. 17, 2004) (providing genetic counseling services); KIMBALL GENETICS, at <http://www.kimballgenetics.com/about.html> (last updated Sept. 2003) (same); see also ALPHA-1 FOUNDATION, at <http://www.alphaone.org> (last visited July 17, 2004) (providing physician consultations or requiring physician participation); GENOVATIONS, at <http://www.genovations.com/index.html> (2002) (same); MYRIAD, at <http://www.myriadtests.com/testp.htm> (2002) (same).

87. Jon Emery et al., *A Systematic Review of the Literature Exploring the Role of Primary Care in Genetic Services*, 16 FAM. PRAC. 426 (1999); KJ Hofman et al., *Physicians' Knowledge of Genetics and Genetic Tests*, 68 ACAD. MED. 625 (1993).

88. Gollust et al., *Sales*, *supra* note 8, at 334-36.

89. *Id.* at 336.

90. *Id.*; see also Clayton, *supra* note 55, at 566-67.

91. Williams-Jones, *supra* note 8, at 51.

92. Gollust et al., *Limitations*, *supra* note 8, at 1764; Gollust et al., *Sales*, *supra* note 8, at 336.

television commercials, which are subject to review by the networks, anyone can establish an Internet presence for relatively little money and without any external scrutiny, thereby reaching millions of potential customers. It may be particularly difficult for a nongenetics expert to discern the veracity of claims made and information provided on such genetic testing websites.<sup>93</sup> Following certain test results, consumers may be persuaded to alter their behavior by changing their diet or medications. They may also pursue genetic testing instead of other appropriate treatment.

As a result of these concerns, some critics conclude that “health-related genetic testing should not be routinely available on the Internet for consumers to order or receive results without the involvement of an appropriate health care practitioner” in the absence of data demonstrating that consumers are not harmed by direct access testing.<sup>94</sup> Further, they assert that, “only once the public has a more sophisticated appreciation of genetics can advertisements appropriately promote genetic testing options directly to consumers.”<sup>95</sup>

#### *IV. Regulation of Genetic Tests In the United States*

Criticisms of DTC marketing comprise a critique of both sale and advertising.<sup>96</sup> This part discusses what various federal government entities currently do with respect to both of these components of marketing, and the role that states play with respect to genetic test regulation.

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93. Williams-Jones, *supra* note 8, at 48.

94. Gollust et al., *Sales, supra* note 8, at 336. International advisory commissions have made similar proposals. For example, the United Kingdom’s Human Genetics Commission (HGC) recommended that most genetic tests providing predictive health information should not be offered directly to consumers. Analogizing to prescription medication, HGC concluded that the presumption should be that genetic tests that are predictive of medical conditions are unsuitable for DTC access through a nonmedical health professional or other intermediary. In Australia, the government advisory commission recommended greater regulation of health-related genetic tests provided direct-to-consumers, though the commission recognized the difficulty in regulating the supply and advertising of genetic testing products provided over the Internet by foreign companies. ALRC & AHEC, *ESSENTIALLY YOURS, supra* note 6. In the United States, the Task Force on Genetic Testing issued a report in 1997 advising consumers to discuss testing options with a health care provider trained in genetics before undergoing genetic testing, and discouraged advertising or marketing of predictive genetic tests to the public. TASK FORCE ON GENETIC TESTING, *PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING 56* (Neil A. Holtzman & Michael S. Watson eds., Sept. 1997), available at <http://www.genome.gov/10001733>.

95. Gollust et al., *Limitations, supra* note 8, at 1764; see also *supra* note 94.

96. See *supra* notes 10-12 and accompanying text.

### A. Federal

Whereas the regulatory oversight of FDA and CMS relates to the sale of products and services respectively, including development, testing, production, and distribution, the Federal Trade Commission's (FTC) oversight pertains to advertising of commercial products and services.

Whether and to what extent genetic tests may be subject to regulation by the federal government depends on how they are classified. To the extent genetic testing is considered a commercial service provided through clinical laboratories, similar to blood or other metabolic tests undertaken by these entities, it is subject to regulation by CMS, which administers the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).<sup>97</sup> On the other hand, to the extent that a genetic test is construed as a freestanding "product" intended for use in the diagnosis of a disease or medical condition, it is subject to regulation as a medical device under the Federal Food, Drug, and Cosmetic Act (FD&C Act),<sup>98</sup> which is administered by the FDA. The ambiguity about the legal status of genetic testing, as well as arguably underzealous exercise of available authority by CMS, has led to insufficient oversight of genetic testing.

#### 1. CLIA 88

CLIA 88 amended the Clinical Laboratories Improvement Act of 1967.<sup>99</sup> It was intended to "strengthen federal oversight of clinical laboratories to assure that the tests results are accurate and reliable."<sup>100</sup> Congress found that laboratory testing played a critical role in the delivery of health services and maintaining good health, and that patients both expect and assume that such testing is done properly.<sup>101</sup> Congressional investigations, however, found significant problems in the quality of testing services being provided to the public. Many laboratories were not subject to the federal regulations then in place, and many of those laboratories that were subject to the law were not complying with its requirements. The major problems identified by Congress were "lax [f]ederal oversight and direction, lack of proficiency testing for many analytes, inconsistent criteria for acceptable laboratory performance, and improprieties by laboratories in handling specimen samples."<sup>102</sup> Deficiencies were particularly apparent in cytological screening of pap smears

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97. 42 U.S.C. § 263(a)-(q) (2000).

98. 21 U.S.C. §§ 301-397 (2000).

99. Clinical Laboratories Improvement Act of 1967, Pub. L. No. 90-174, § 5(a), 81 Stat. 533, 536.

100. H.R. REP. NO. 100-899, at 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829.

101. *Id.* at 10, *reprinted in* 1988 U.S.C.C.A.N. at 3831.

102. *Id.* at 16, *reprinted in* 1988 U.S.C.C.A.N. at 3836.

for cervical cancer. Congress determined that many laboratories were reporting false negative results. In other words, women with abnormal, and possibly cancerous, cells were being incorrectly informed that their pap smears were normal.<sup>103</sup>

In enacting CLIA 88, Congress directed the Secretary of HHS to issue standards for the certification of laboratories “to assure that such laboratories will consistently perform tests in a valid and reliable manner.”<sup>104</sup> The Secretary delegated authority to develop and enforce these standards to what is now CMS.<sup>105</sup>

CLIA 88 defines a “clinical laboratory” 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.<sup>106</sup>

The statute prohibits the solicitation or acceptance of “materials derived from the human body for laboratory examination or other procedure” unless CMS or a CMS-authorized entity issues the laboratory a certificate.<sup>107</sup> Certified laboratories must comply with standards issued by CMS, to the extent that such standards apply to the type of testing being performed.<sup>108</sup> In

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103. *Id.* at 17, reprinted in 1988 U.S.C.C.A.N. at 3838.

104. *Id.* at 27, reprinted in 1988 U.S.C.C.A.N. at 3848. Congress directed that the standards address: (1) maintenance of a quality assurance and quality control program by the laboratory; (2) maintenance of appropriate records; (3) equipment and facilities; (4) personnel standards; and (5) proficiency testing. It also added authority for the development of standards that the Secretary determined were “necessary to protect the health and safety of patients.” *Id.*

105. Some of the responsibilities for implementing the statute were assumed by FDA and CDC. See, e.g., CLIA Program; Transfer of Clinical Laboratory Complexity Categorization Responsibility, 64 Fed. Reg. 73,561 (Dec. 30, 1999); Centers for Disease Control; Statement of Organization, Functions, and Delegations of Authority, 57 Fed. Reg. 10,768 (Mar. 30, 1992); Centers for Disease Control; Statement of Organization, Functions, and Delegations of Authority, 54 Fed. Reg. 23,537 (June 1, 1989).

106. 42 U.S.C. § 263a(a) (2000).

107. *Id.* § 263a(b). Obtaining a certificate requires submitting an application describing the number and type of tests to be performed by the laboratory. One of several different certificates may be issued, depending on the type of testing to be performed. Before receiving a certificate, the laboratory must be inspected, either by CLIA personnel or by an approved third-party accrediting body, such as the College of American Pathologists. Accreditation by an approved third party is sufficient to obtain a certificate. *Id.* § 263a(d)-(e); see also CLIA, LIST OF APPROVED ACCREDITING ORGANIZATIONS UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS, at <http://www.cms.hhs.gov/clia/accredorg.asp> (last updated May 21, 2003).

108. CMS is charged with issuing “standards to assure consistent performance . . . of valid

particular, if the agency has established “proficiency testing standards” for a particular type of test, the laboratory must comply with those standards.<sup>109</sup>

There is no dispute that laboratories that conduct genetic testing to aid in the diagnosis, treatment, or prevention of disease or in assessing human health are subject to CLIA 88. What these laboratories must do in practical terms to assure quality testing, however, and whether current requirements are sufficient to do so, is less certain. Currently, with the exception of cytogenetics, CMS has not mandated proficiency standards for genetic testing.<sup>110</sup> From 1997 to 2000, the Clinical Laboratories Improvement Advisory Committee (CLIAC), within CDC, debated the need for proficiency testing standards for genetic testing.<sup>111</sup> Since 2000, CDC has been working to develop such standards. Although a Notice of Intent to issue a proposed regulation was published in 2000,<sup>112</sup> no proposed rule has been issued, nor is one expected in the near term.<sup>113</sup> Thus, laboratories must figure out how to

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and reliable laboratory examinations and other procedures.” 42 U.S.C. § 263a(f)(1). These standards “shall require each laboratory issued a certificate” to: (1) “maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and reporting of results”; (2) “maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory”; (3) use only personnel meeting the qualifications established by CMS; (4) “qualify under a proficiency testing program meeting the standards established by” CMS; and (5) “meet such other requirements” that CMS determines “necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.” *Id.* The statute directs the agency, in developing such standards, to take into account, among other factors: (1) “the examinations and procedures performed and the methodologies employed”; (2) “the degree of independent judgment involved”; (3) “the amount of interpretation involved”; (4) “the difficulty of the calculations involved”; (5) “the calibration and quality control requirements of the instruments used”; and (6) “the type of training required to operate the instruments used in the methodology.” *Id.* § 263a(f)(2).

109. Proficiency testing is “a method of externally validating the level of a laboratory’s performance.” H.R. REP. NO. 100-899, at 15 (1988), *reprinted in* 1998 U.S.C.C.A.N. 3828, 3836. According to the statute, proficiency testing standards “shall require” the laboratory to “be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate” unless CMS has determined that a proficiency test “cannot reasonably be developed” for a particular test or procedure. 42 U.S.C. § 263a(f)(3)(A).

110. 42 C.F.R. § 493.1267 (2003).

111. CLINICAL LAB. IMPROVEMENT ADVISORY COMM. (CLIAC), SUMMARY REPORT, Sept. 1997, SUMMARY REPORT, Jan. 1998, SUMMARY REPORT, Apr. 2000, SUMMARY REPORT, Sept. 2000, at <http://www.phppo.cdc.gov/cliac/default.asp>.

112. Notice of Intent, Genetic Testing Under the Clinical Laboratory Improvement Amendments, 65 Fed. Reg. 25,928 (May 4, 2000).

113. See generally CLIAC, SUMMARY REPORT, Sept. 2003, Addendum W, at <http://www.phppo.cdc.gov/cliac/pdf/CLIAC0903.pdf>.

comply with the statutory requirement for proficiency testing without guidance from the government.

CLIA does not regulate what tests a laboratory may offer — typically the laboratory director determines whether to offer a particular test to the public. In addition, neither CLIA 88 nor standards issued by voluntary accrediting organizations address advertising. Specifically, there are no regulations or guidelines concerning what laboratories may say in communications aimed at promoting genetic tests. Nor do the regulations impose any particular obligation on laboratories to communicate or explain to patients the meaning of test results or the limitations of specific tests.<sup>114</sup> While the majority of clinical laboratories market their services primarily, if not exclusively, to physicians and health care institutions, there is no federal prohibition on marketing genetic tests directly to consumers. Further, there are no regulatory provisions that limit the claims that may be brought for the tests.

## 2. FDA

The FD&C Act authorizes FDA regulation of drugs and medical devices, among other products.<sup>115</sup> The statute provides FDA the authority to require manufacturers of these products to submit data demonstrating that the products are safe and effective before they may be sold to consumers.<sup>116</sup> FDA also has the authority to approve the claims of benefit that manufacturers may make regarding these products, and to determine the conditions under which they may be sold, such as by prescription only.<sup>117</sup>

The statute defines a medical device as an “article” that is intended for use in the “diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease”<sup>118</sup> or that is “intended to affect the structure or any function of the body,”<sup>119</sup> but that “does not achieve its primary intended purposes through chemical action within or on the body of man . . . and . . . is not dependent upon being metabolized for the achievement of its primary intended purposes.”<sup>120</sup>

Diagnostic test kits, such as those used to diagnose human immunodeficiency virus (HIV) or detect pregnancy, are regulated by FDA as

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114. State laws vary about who may order and receive the results of laboratory tests. Schulze, *supra* note 59.

115. 21 U.S.C. §§ 301-397 (2000).

116. *Id.* §§ 355(b)(1), 360e(c).

117. *Id.* § 353(b).

118. *Id.* § 321(h)(2).

119. *Id.* § 321(h)(3).

120. *Id.*

in vitro diagnostic devices (IVDs).<sup>121</sup> Like other medical devices, IVDs are subject to premarket approval or clearance requirements.<sup>122</sup> FDA has published specific regulations applicable to in vitro diagnostic devices.<sup>123</sup>

Most genetic tests, however, are not marketed as freestanding products, but are developed in-house by laboratories and marketed as clinical laboratory services. These tests are referred to as in-house tests or "home brew" assays.<sup>124</sup> In the past, FDA has asserted regulatory jurisdiction over home brew assays, but, with one exception, has elected not to exercise that authority as a matter of enforcement discretion.<sup>125</sup> In 1997, FDA issued a regulation

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121. See 21 C.F.R. pt. 809 (2003).

122. A device that has not previously been marketed in the United States must file a premarket approval application (PMA). The PMA must contain data from clinical trials demonstrating the safety and effectiveness of the device. 21 U.S.C. §§ 360c(f)(1), 360e(c)(1). If the device is "substantially equivalent" to a device in commercial distribution in the United States before May 28, 1976, however, a PMA is not required. 21 C.F.R. § 807.81(a)(1). Instead, the manufacturer must submit a premarket notification, termed a "510(k)" submission. 21 U.S.C. § 360(j)-(k); 21 C.F.R. § 807.81. Premarket notification is significantly faster and less expensive and is used for the majority of devices currently on the market. See Howard M. Holstein & Edward C. Wilson, *Developments in Medical Device Regulation*, in 2 FUNDAMENTALS OF LAW AND REGULATION 275-77 (Robert P. Brady et al., eds., 1997); Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices*, 56 FOOD & DRUG L.J. 317 (2001).

123. 21 C.F.R. pt. 809. IVDs are defined as "those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." 21 C.F.R. § 809.3(a).

124. See Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents, 61 Fed. Reg. 10,484 (Mar. 14, 1996); Jeffrey K. Shapiro & Randy J. Prebula, *FDA's Regulation of Analyte-Specific Reagents*, at <http://www.device-link.com/mddi/archive/03/02/018.html> (last visited Apr. 15, 2004).

125. In the preamble to the proposed rule classifying analyte specific reagents, FDA stated: [I]n-house developed tests have not been actively regulated by the Agency and the ingredients used in them generally are not produced under FDA assured manufacturing quality control. Other general controls also have not been applied routinely to these products. FDA is not proposing a comprehensive regulatory scheme over the final tests produced by these laboratories and is focusing instead on the "active ingredients" (ASR's) provided to the laboratories. However, at a future date, the agency may reevaluate whether additional controls over the in-house tests developed by such laboratories may be needed to provide an appropriate level of consumer protection. Such controls may be especially relevant as testing for the presence of genes associated with cancer or dementing diseases becomes more widely available. Additional controls might include a broad array of approaches, ranging from full premarket review by FDA to use of third parties to evaluate analytical or clinical performance of the tests. The laboratories producing tests from ASR's and offering the tests as laboratory services are

classifying “analyte specific reagents” (ASRs) as medical devices.<sup>126</sup> ASRs are reagents used by clinical laboratories in developing home brew assays and can be considered the “active ingredients” of such tests.<sup>127</sup> Most ASRs, including those used in genetic tests, are not subject to premarket approval requirements, but must comply with “general controls,” such as labeling and good manufacturing practices (GMP) requirements.<sup>128</sup> In addition, laboratories must be certified to perform high complexity testing to purchase ASRs.<sup>129</sup>

Finally, with the exception of ASRs, FDA does not regulate — nor does it have clear jurisdiction at this time to regulate — communications made by the laboratories providing genetic tests, or the manner in which such tests are sold or provided to patients. The consequence is that, notwithstanding some involvement by FDA and CMS, little federal regulatory oversight of genetic tests exists in the United States. More specifically, there is no governmental review of whether tests work or the claims made for them are accurate.

### B. States

Under the U.S. federalist system of government, the federal government is one of enumerated powers.<sup>130</sup> Thus, states may regulate in all areas not specifically preempted by Congress, subject to the constraints of the U.S. Constitution. States generally have primary authority to protect the health, safety, and welfare of their citizens.<sup>131</sup>

For the most part, state agencies implement the CLIA program but do not

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currently regulated by the Health Care Financing Administration (HCFA) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) for compliance with general laboratory standards regarding personnel, proficiency testing, quality control, and quality assurance. However, these HCFA regulations do not include the same product controls provided by FDA. As a result, neither patients nor practitioners have assurance that all ingredients in the laboratory developed tests are of high quality and capable of producing consistent results.

Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents, 61 Fed. Reg. at 10,484.

126. Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents, 62 Fed. Reg. 62,243 (Nov. 21, 1997) (codified at 21 C.F.R. pts. 809, 864 (1997)).

127. *Id.*

128. 21 C.F.R. §§ 809.10, 809.30, 864.4020(b)(1) (2003).

129. *Id.* § 809.30(b)(2).

130. The powers of the legislative, executive, and judicial branches of the federal government are specified in Articles I, II, and III of the U.S. Constitution. The Tenth Amendment to the U.S. Constitution states that the “powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.” U.S. CONST. amend. X.

131. Gostin, *supra* note 10, at 47-51.



add to it. Though some states have enacted more stringent requirements,<sup>132</sup> these requirements fail to address advertising by laboratories or communications between laboratories and those seeking testing.

To varying degrees, states also regulate who may order a genetic test from a laboratory. Some states specifically permit enumerated tests, such as cholesterol or pregnancy tests, to be ordered by patients without a prescription from a health care provider.<sup>133</sup> Some states categorically prohibit direct access testing.<sup>134</sup> Still other state laws are silent on the issue, which leaves the question of whether to offer direct access testing up to individual laboratories.<sup>135</sup>

#### *V. Regulation of Direct-to-Consumer Pharmaceutical Advertisements by the FDA and FTC*

Some critics recommend that either the FDA or the FTC regulate advertising for genetic testing in a manner similar to the regulation of DTC pharmaceutical advertising.<sup>136</sup> This suggestion is problematic in several respects. First, FDA's jurisdiction to regulate genetic tests is not obvious. Second, FDA's attempt to restrict consumer-directed information of products that it unquestionably regulates has drawn sharp criticism from both the U.S. Supreme Court and the U.S. Court of Appeals for the D.C. Circuit, rendering the agency's burden for demonstrating the need for speech-restrictive regulation much greater. While the FTC's governing statute would in some respects provide greater jurisdictional flexibility, the agency needs to be

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132. For example, New York has received a waiver from CLIA 88 because its clinical laboratory certification program exceeds the federal minimum standards. See LABORATORY QUALITY CERTIFICATION: CLINICAL EVALUATION PROGRAM, at <http://www.wadsworth.org/labcert/clep/clep.html> (last visited Apr. 15, 2004).

133. Schulze, *supra* note 59. For example, California and Maine allow direct access testing for certain specified tests. The following thirty-four jurisdictions permit direct access testing of some kind: Alaska, Arkansas, California, Colorado, Delaware, District of Columbia, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Oklahoma, Puerto Rico, South Dakota, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin. *Id.*

134. *Id.* The following eighteen states prohibit direct access testing: Alabama, Arizona, Connecticut, Florida, Georgia, Hawaii, Idaho, Iowa, Kentucky, Massachusetts, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Wyoming. *Id.*

135. See *id.* Most states that permit direct access testing do so because their laws do not prohibit or otherwise provide guidance on the issue of whether patients may order laboratory tests without a medical order. *Id.*

136. Gollust et al., *Limitations*, *supra* note 8, at 1765.

cognizant of First Amendment constraints, as well as its own resource limitations, in undertaking any regulatory initiatives to constrain DTC testing.

With these caveats in mind, however, it is nevertheless useful to review the history of these agencies' regulation of DTC pharmaceutical advertising, and to determine whether and to what extent lessons can be drawn from this experience in determining appropriate regulations for DTC genetic testing advertising.

#### A. FDA Regulation of DTC Prescription Drug Advertising

FDA's current regulatory regime permits prescription drug manufacturers that have been approved by the agency to advertise directly to consumers, subject to a few constraints. In addition, the actual purchase of the prescription drugs must be mediated through a prescription from a health care provider.<sup>137</sup> This section provides an overview of FDA's regulation of DTC promotion of prescription drugs.

FDA regulates all labeling<sup>138</sup> and advertising<sup>139</sup> of prescription drugs. Section 502(n) of the FD&C Act, added to the statute in 1962, provides that a prescription drug will be deemed "misbranded" and subject to enforcement

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137. The FD&C Act provides that a drug may be dispensed only upon the prescription of a licensed practitioner if it is not safe to use except under practitioner supervision or if it is required under the terms of the approval. 21 U.S.C. § 363(b)(1) (2000). State laws vary regarding which health care providers are authorized to prescribe drugs. See, e.g., Mary Beck, *Improving America's Health Care: Authorizing Independent Prescriptive Privileges for Advanced Practice Nurses*, 29 U.S.F.L. REV. 951 (1995); Elizabeth Harrison Hadley, *Nurses and Prescriptive Authority: A Legal and Economic Analysis*, 15 AM. J.L. & MED. 245 (1989); James L.J. Nuzzo, *Independent Prescribing Authority of Advanced Practice Nurses: A Threat to the Public Health?*, 53 FOOD & DRUG L.J. 35 (1998).

138. The FD&C Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The range of material that FDA regulates as labeling is quite broad. In *Kordel v. United States*, 335 U.S. 345 (1948), the Supreme Court held that labeling "is not restricted to labels that are on or in the article or package that is transported," but that, information might accompany a product, and hence qualify as labeling, as long as "it supplements or explains [the product] . . . . No physical attachment one to the other is necessary. It is the textual relationship that is significant." *Id.* at 349-50.

139. Advertising subject to FDA oversight includes "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems." Prescription Drug Advertisements, 21 C.F.R. § 202.1(l)(1) (2003).

action<sup>140</sup> if it is not advertised in accordance with requirements enumerated in the statute.<sup>141</sup>

FDA regulations require, among other provisions, that an advertisement include a “true statement of information in brief summary relating to side effects, contraindications, and effectiveness.”<sup>142</sup> The “brief summary” requirement is generally fulfilled, at least in the print context, by including all or most of the information contained in the package insert — a lengthy, complicated, and consumer-unfriendly document.<sup>143</sup>

The regulations state that the “true statement” provision applies to the “entire advertisement” and that “[u]ntrue or misleading information in any part of the advertisement will not be corrected” by true information in a different part of the advertisement.<sup>144</sup> The regulations also list several instances in which an advertisement would not meet the “true statement” requirement, including if it “fails to present a fair balance between” risks and benefits or “fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.”<sup>145</sup>

140. Penalties for misbranding may include fines or imprisonment. 21 U.S.C. § 333. Incorrect labeling is also a form of misbranding, *id.* § 352(a), for which penalties of a fine or imprisonment may also apply, *id.* § 333.

141. The statute requires that the advertisement include the established name of the product, a list of ingredients, and “information in brief summary relating to side effects, contraindications, and effectiveness . . . .” *Id.* § 352(n).

142. 21 C.F.R. § 202.1(e). FDA recognizes three categories of advertisements, only one of which is subject to the brief summary requirement.

Reminder advertisements call attention to the name of the drug product, but do not include specifications of the drug product. An example of this would be a ballpoint pen imprinted with a drug brand name. Help-seeking or “see your doctor” ads typically describe the symptoms of a disease or condition, and encourage consumers to consult their physician to discuss treatment options, but do not mention the drug’s name. Reminder advertisements and help-seeking advertisements are exempt from the brief summary and fair balance requirements because they do not reveal information about the effectiveness of a drug. Product-claim advertisements reveal the drug’s name and indication, and thus must satisfy the brief summary requirements and maintain fair balance.

Francis B. Palumbo, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 428-29 (2002).

143. See generally 21 C.F.R. § 202.1(e)(4),(5); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 148-49 (1997).

144. 21 C.F.R. § 202.1(e)(3).

145. 21 C.F.R. § 202.1(e)(5)(ii), (iii).

The statute prohibits FDA from requiring preapproval of advertisements,<sup>146</sup> but the regulations require that advertisements be submitted at the time of publication.<sup>147</sup> FDA will also review advertising materials before they are launched upon the manufacturer's request.<sup>148</sup>

Historically, prescription drug advertising has been directed to physicians.<sup>149</sup> Until the 1980s, manufacturers did not view DTC advertising as advantageous<sup>150</sup> and preferred to focus marketing efforts on those primarily responsible for deciding what drugs to prescribe. In 1981, two manufacturers departed from this long-standing practice; in one case advertising the price of a specific drug product,<sup>151</sup> and in the other making specific product claims for a pneumonia vaccine.<sup>152</sup> Many manufacturers thereafter sought review of DTC ads by the agency. In 1983, the FDA Commissioner issued a formal request to the pharmaceutical industry to voluntarily cease product-specific DTC advertising,<sup>153</sup> with the exception of advertisements limited to price comparisons.<sup>154</sup> According to the FDA, the two purposes of the moratorium

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146. The statute states that "except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement . . ." 21 U.S.C. § 352(n)(3)(A).

147. 21 C.F.R. § 314.81(b)(3)(I).

148. DIV. OF DRUG MKTG., ADVER. & COMMUNICATIONS, FREQUENTLY ASKED QUESTIONS (FAQS), at <http://www.fda.gov/cder/ddmac/faqs.htm#dtc> (last updated May 28, 2003).

149. Palumbo, *supra* note 142, at 424.

150. One commentator has noted that "any drug company marketer that suggested a program of communicating directly with consumers likely would be categorized as suicidal because there was a fear that doctors would never accept a program that bypassed them." Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 *FOOD & DRUG L.J.* 489, 491 (1999).

151. This was a price advertisement by Boots Pharmaceuticals for Rufen, a prescription ibuprofen product. In 1983, Boots ran a product-claim advertisement for Rufen, which precipitated a letter from FDA threatening to initiate "regulatory action, such as seizure and injunction" if the ad was not cancelled. *Id.* at 500. According to FDA, the ad "failed to provide brief summary information and also failed to make 'adequate provision' for consumers to obtain the full package insert." *Id.* at 499-500. In addition, "[t]he letter called the commercial false and misleading because it" claimed to be completely interchangeable with a competitor's product, when, in fact, it was not available in the same dosages. *Id.* at 500.

152. *Id.* at 491-92. The product was Pneumovax, manufactured by Merck, Sharp & Dohme. FDA was more concerned about the Rufen pricing advertisements than those for Pneumovax because the agency saw a public health benefit in advertising a vaccine. *Id.*

153. FDA's request was first made in a speech by the Commissioner to the Pharmaceutical Advertising Council, which was delivered on February 17, 1983. This was followed by a policy statement issued on September 2, 1983. *Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium*, 50 *Fed. Reg.* 36,677 (Sept. 9, 1985).

154. Also excluded from the moratorium were company-sponsored ads that discussed specific diseases but did not mention a particular drug product. *Id.*

were to allow time (1) “for a dialogue among consumers, health professionals, and industry,” and (2) “for the conduct and interpretation of research by interested parties on aspects of consumer-oriented drug advertising.”<sup>155</sup> During the moratorium, FDA commissioned studies to gauge consumer attitudes toward DTC ads and to assess their impact on consumer audiences.<sup>156</sup>

FDA lifted the moratorium in 1985 after concluding that the existing statute and implementing regulations governing prescription drug advertising provided “sufficient safeguards to protect consumers.”<sup>157</sup> FDA stated that it would continue to enforce these provisions for all prescription drug advertising regardless of its intended audience.<sup>158</sup>

Consumer-directed advertising increased after FDA lifted the moratorium. Because of the amount of information that needed to be included to comply with the “brief summary” requirement, however, the television format was infeasible. In 1997, FDA issued a “draft guidance” that tailored the requirements for information disclosure to a broadcast format.<sup>159</sup> Instead of a brief summary, manufacturers were required to make “adequate provision” for disseminating the information contained in the brief summary to consumers. For example, manufacturers could provide a toll-free telephone number for consumers to call to request that information be sent to them or direct consumers to a website containing the information.<sup>160</sup> FDA issued a final guidance in 1999.<sup>161</sup> The agency’s change in policy opened the floodgates of DTC television ads and led to the plethora of ads that can currently be viewed on television. While the majority of all promotional spending by pharmaceutical companies is still directed toward physicians,<sup>162</sup>

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155. *Id.*

156. Pines, *supra* note 150, at 492; Palumbo, *supra* note 142, at 424 (according to one study, “consumers retained more information about the benefits of the products than the risks,” and, according to another study, “consumers wanted more information about prescription drugs and would view DTC advertising favorably”).

157. Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. at 36,677.

158. *Id.*

159. FDA, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS, at <http://www.privacysecuritynetwork.com/Library/docs/1804q&a.htm> (last updated June 8, 2000). FDA had previously encountered this problem with respect to cable networks directed at a physician audience and had made exceptions to make electronic advertisements feasible. FDA has also previously permitted commercial network advertisements that were not product-specific. Pines, *supra* note 150, at 494.

160. Pines, *supra* note 150, at 496-97.

161. FDA, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENT (Aug. 1999), at <http://www.fda.gov/cder/guidance/1804fnl.htm> (last visited Apr. 15, 2004).

162. U.S. GAO, *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*, GAO-03-177, 10-11 (Oct. 2002) [hereinafter GAO Report]. Promotional efforts

spending for DTC advertising is nevertheless substantial. In 2001, it comprised fourteen percent of all spending on pharmaceutical promotional activities.<sup>163</sup>

The path to DTC television advertising, however, has not been entirely smooth. In the first year that the new policy was in place, FDA undertook enforcement action, which consisted of letters to manufacturers warning them that the advertisements violated the law.<sup>164</sup> FDA sent these letters to about half of the ads that appeared,<sup>165</sup> requesting that they be discontinued. These ads had not been submitted to the agency for review before they were aired. FDA's predominant concerns regarding DTC ads concerned whether the ads (1) conveyed risk and benefit information, (2) clearly articulated the intended patient population and were consistent with the approved indication, and (3) had adequate support for the ads' claims of superiority over another product.<sup>166</sup>

FDA has issued fewer enforcement letters in recent years. Between 1999 and 2001, for example, FDA issued regulatory letters for only about five percent of the broadcast advertisements it reviewed.<sup>167</sup> This change has been attributed to both the industry's improved compliance<sup>168</sup> and to FDA's decreased enforcement efforts.<sup>169</sup> Overall, the agency issued eighty-eight letters between 1997 and 2002, most of which were for less serious violations.<sup>170</sup> A 2002 GAO report, however, concluded that FDA's

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to physicians include not only advertising, but also distribution of samples and visits by sales representatives to physicians. *Id.*

163. *Id.* at 11.

164. DDMAC issues two types of letters to companies to notify them of violations. A Notice of Violation (NOV) Letter (or "untitled letter") is sent for minor violations, and a Warning Letter is sent for more serious violations, and indicates that FDA will initiate enforcement efforts if the manufacturer fails to initiate corrective action. Palumbo, *supra* note 142, at 429.

165. *Id.* at 430.

166. Nancy Ostrove, FDA Div. of Drug Mktg., Adver. & Communications, Remarks at the Drug Information Association Annual Meeting (June 29, 1999), *cited in* Pines, *supra* note 150, at 498.

167. GAO Report, *supra* note 162, at 18.

168. Pines, *supra* note 150, at 504.

169. GAO Report, *supra* note 162, at 22.

170. DDMAC issues two types of letters to notify companies that they are in violation of FDA guidelines: (1) Notice of Violation (NOV) Letters (or "untitled letter") are sent for minor violations, and (2) Warning Letters are sent for more serious violations, as a precursor to FDA action that will be taken against the manufacturer if it does not initiate corrective action. Palumbo, *supra* note 142, at 429. Typically, DDMAC requires that companies take corrective action by discontinuing the advertisements in violation, responding to DDMAC in writing within ten to fourteen days indicating their intent to comply, listing all violative advertisements that will be discontinued, and providing the dates of discontinuation. *Id.*

enforcement efforts were of limited effectiveness.<sup>171</sup> The report found that FDA's enforcement actions "have succeeded in removing from dissemination misleading DTC advertisements,"<sup>172</sup> but that the agency's efforts were hampered by its inability to verify that it receives all newly disseminated ads from pharmaceutical companies. The report also cited a 2001 change in FDA policy that required all regulatory letters to be issued by FDA's Office of the Chief Counsel as hampering enforcement efforts.<sup>173</sup>

The benefits and harms of DTC advertising are widely debated between and within interest groups.<sup>174</sup> As FDA recently described:

Proponents argue that DTC promotion is of educational value, will improve the physician-patient relationship, will make consumers aware of conditions they have that could benefit from treatment, would potentially improve health care, and could lower long-term health care costs through early recognition and treatment. Opponents contend that: Consumers do not have the expertise to accurately evaluate and comprehend prescription drug advertising, DTC promotion is typically misleading because it fails to adequately communicate risk information, DTC promotion will damage the physician-patient relationship, it will increase drug prices, lead to over-medication and drug abuse, and it will lead to use of the most costly alternatives.<sup>175</sup>

The Internet has posed the newest challenge for FDA regulation of DTC prescription drug advertising, and FDA's approach to this medium is still

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171. GAO Report, *supra* note 162, at 17-23.

172. *Id.* at 21.

173. *Id.* at 21-22. This requirement has delayed issuance of warning letters for DTC advertisements, and may have allowed an advertisement to complete its broadcast cycle before the letter was issued. *Id.* at 23.

174. The pharmaceutical industry argues that DTC advertising enhances consumer knowledge, encourages discussion between consumers and physicians, and promotes patient compliance with drug regimens. The American Medical Association (AMA) has debated the benefits and harms of DTC advertising. Although many physicians have expressed concern about the impact on the doctor-patient relationship, the AMA in 1999 issued a policy favoring DTC advertising within specific guidelines. In contrast, the managed care and health insurance industries have expressed the concern that DTC advertising will lead to increased demand — and in turn increased cost — for prescription drugs. Some consumer groups have expressed concerns over deceptive advertising practices and the lack of objective information weighing risks and benefits, while others view the ads as positive in that they encourage consumers to seek health information from healthcare professionals. Palumbo, *supra* note 142, at 436-40; Pines, *supra* note 150, at 508-12; *see also* Council on Ethical & Judicial Affairs of the AMA, *Direct-to-Consumer Advertisements of Prescription Drugs*, 55 *FOOD & DRUG L.J.* 119 (2000).

175. Consumer-Directed Promotion; Public Meeting, 68 *Fed. Reg.* 47,920 (Aug. 12, 2003).

evolving. Although FDA has been aware for several years of misleading drug promotions on the Internet, it has been slow to respond. In 1996, after meeting individually with members of the pharmaceutical industry, FDA held a public conference to gather information on how the Internet was being used for drug promotion and what policies and guidance from FDA would be appropriate.<sup>176</sup> William Schultz, then Deputy Commissioner of Policy, stated that the agency had “no question” that its existing authority over drug promotion extended to Internet promotion, but acknowledged that “the Internet raises some new and important and very different issues regarding the regulation of promotion.”<sup>177</sup>

Since the 1996 conference, FDA has initiated enforcement efforts in response to specific Internet promotions it deems false or misleading or that promote unapproved drugs or uses.<sup>178</sup> The agency has also conducted periodic “sweeps” of the Internet to identify promotional materials that violate the law.<sup>179</sup> FDA continues to study the effect of DTC advertising on consumers and to seek input from the public.<sup>180</sup> Nevertheless, FDA has yet to issue a formal regulation or informal guidance document concerning the requirements for Internet drug promotions.<sup>181</sup>

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176. FDA, FDA AND THE INTERNET: ADVERTISING AND PROMOTION OF MEDICAL PRODUCTS, Oct. 16-17, 1996, at [http://www.fda.gov/opacom/morechoices/transcript\\_1096/fdainet.html](http://www.fda.gov/opacom/morechoices/transcript_1096/fdainet.html).

177. *Id.*

178. See Leah Brannon, *Regulating Drug Promotion on the Internet*, 54 FOOD & DRUG L.J. 599, 601 (1999).

179. *Id.*

180. On September 22-23, 2003, FDA held a public meeting on consumer-directed promotion of prescription drugs. “The purpose of the meeting [was] to enable the agency and other persons and organizations to present the results of their research on consumer-directed promotion of prescription drug products through print, broadcast, and other types of media.” Consumer-Directed Promotion; Public Meeting, at 68 Fed. Reg. 47,920; see, e.g., Nat Ives, *F.D.A. Ponders Pros and Cons of the Ways Prescription Drugs Are Promoted to Consumers*, N.Y. TIMES, Sept. 29, 2003, at C11; Marc Kaufman, *Drug Ads Do More Good Than Harm, FDA Told; Agency Reviewing Effects, Perceptions of Direct-to-Consumer Advertising*, WASH. POST, Sept. 23, 2003, at E4; Christopher Rowland, *A Dose of Reality: FDA to Push Firms to Make Ads Clearer About Drug Risks*, BOSTON GLOBE, Sept. 23, 2003, at D1. Following the meeting, on February 4, 2004, FDA issued three draft guidance documents that are “designed to improve communications to consumers and health care practitioners about health conditions and medical products.” *New FDA Draft Guidances Aim to Improve Health Information*, FDA NEWS, Feb. 4, 2004, at [http://www.fda.gov/bbs/topics/NEWS/2004/NEW\\_01016.html](http://www.fda.gov/bbs/topics/NEWS/2004/NEW_01016.html).

181. Among other issues that remain unclear is FDA’s jurisdiction over Internet promotion. FDA has not stated definitively whether Internet promotions are “labeling” or “advertising.” If they are advertising, then FTC would have primary enforcement jurisdiction over nonprescription drug promotion. Brannon, *supra* note 178, at 602-04.



### B. FTC Regulation of Nonprescription Drug Advertising

The FTC is an independent federal agency established by Congress in 1914.<sup>182</sup> Among its mandates, the agency is charged with protecting consumers against unfair, deceptive, or fraudulent trade practices. The Federal Trade Commission Act (FTC Act) declares unlawful “unfair or deceptive acts or practices in or affecting commerce”<sup>183</sup> and directs the Commission to prevent such activities.<sup>184</sup> The statute also specifically prohibits the dissemination of false advertising to induce the purchase of drugs, devices, food, or cosmetics<sup>185</sup> and defines the phrase “false advertisement” as “misleading in a material respect.”<sup>186</sup> The statute directs the agency to take into account not only representations made for the product, but also omissions of facts that are material given such representations.<sup>187</sup>

To avoid duplicative or inconsistent regulatory efforts, since 1954, FDA and FTC have operated under working agreements clarifying the roles each agency plays with respect to advertising oversight.<sup>188</sup> Under the most recent agreement, FDA has primary authority to regulate prescription drug advertising, and the FTC has primary authority to regulate OTC drug advertising.<sup>189</sup>

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182. Federal Trade Commission Act, Pub. L. No. 63-203, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. § 41 (2000)).

183. 15 U.S.C. § 45(a) (2000).

184. The 1914 statute prohibited only unfair methods of competition. The Wheeler Lea Amendment of 1938 expanded the agency’s jurisdiction to include unfair and deceptive trade practices and to prohibit false ads of drugs, cosmetics, etc. Wheeler-Lea Amendment of 1938 to § 5 of the FTC Act, Pub. L. No. 75-447, 52 Stat. 111 (codified as amended at 15 U.S.C. § 45 (2000)); see also *FTC v. Sperry & Hutchinson, Co.*, 405 U.S. 233, 244 (1972).

185. 15 U.S.C. § 52 (2000).

186. *Id.* § 55(a)(1).

187. *Id.*

188. Palumbo, *supra* note 142, at 427-28.

189. *Id.* at 428 n.38 (citing Memorandum of Understanding, 36 Fed. Reg. 18,538 (Sept. 9, 1971)). Before 1962, the FTC had primary jurisdiction over all drug advertising, both prescription and nonprescription. Wheeler-Lea Amendment of 1938 to § 5 of the FTC Act, Pub. L. No. 75-447, 52 Stat. 111 (codified as amended at 15 U.S.C. § 45 (2000)). At the time the Wheeler-Lea Act was enacted, the FD&C Act did not distinguish between prescription and over-the-counter drugs. The Durham-Humphrey Amendments of 1951 added a provision requiring that drugs that were not safe for use except under medical supervision be dispensed only by prescription of a licensed practitioner. Durham-Humphrey Amendments of 1951, Pub. L. No. 82-215, 65 Stat. 648 (codified as amended at 21 U.S.C. § 353(b)(2000)); see also Palumbo, *supra* note 142, at 426-27. In 1962, Congress amended the FD&C Act to give FDA authority over prescription drug advertising. Kefauver-Harris Drug Amendments of 1962 to Act of Oct. 10, 1962, Pub. L. No. 87-781, § 1, 76 Stat. 780.

The FTC Act does not define the phrase “deceptive acts or practices.” In 1983, the FTC issued a policy statement to “provide a concrete indication of the manner in which the Commission will enforce its deception mandate.”<sup>190</sup> According to the policy statement, the Commission will find that deception has occurred if there is “a representation, omission or practice that is likely to mislead the consumer acting reasonably under the circumstances, to the consumer’s detriment.”<sup>191</sup> The misrepresentation may be written or oral and may occur at any stage of the transaction.<sup>192</sup> The Commission uses a consumer-centered approach, asking whether the consumer’s interpretation or reaction is reasonable under the particular circumstances.<sup>193</sup> The representation, omission, or practice must be material, meaning that it is likely to affect a consumer’s choice or conduct regarding a product.<sup>194</sup> Certain claims or omissions are considered “presumptively” material, including those relating to health and safety.<sup>195</sup> A finding of materiality by the Commission “is also a finding that injury is likely to exist.”<sup>196</sup> Injury exists if “consumers would have chosen differently but for the deception.”<sup>197</sup>

During the same time period, the FTC also issued a policy statement concerning unfairness to explicate this provision of the statute.<sup>198</sup> The statement provides that in making a determination of unfairness, the agency will consider whether the practice (1) injures consumers, (2) violates established public policy, or (3) is unethical or unscrupulous.<sup>199</sup> Of the three considerations, the Commission focuses primarily on the injury criteria, using the other two criteria as additional tools in evaluating the injury.<sup>200</sup> According to the policy statement, for a practice to be unfair, the injury must be “substantial,” causing either monetary harm or “[u]nwarranted health and safety risks.”<sup>201</sup> “Emotional impact and other more subjective types of harm”

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190. FTC POLICY STATEMENT ON DECEPTION, Oct. 14, 1983, at <http://www3.ftc.gov/bcp/policystmt/ad-decept.htm> (last visited Apr. 15, 2004) (Commissioners Pertschuk and Bailey, dissenting).

191. *Id.*

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.*

198. FTC POLICY STATEMENT ON UNFAIRNESS, Dec. 17, 1980, at <http://www.ftc.gov/bcp/policystmt/ad-unfair.htm>.

199. *Id.*

200. *Id.*

201. *Id.*

alone, however, will not make a practice unfair,<sup>202</sup> nor will an advertisement that “offends the tastes or social beliefs of some viewers.”<sup>203</sup> In addition, “the injury must not be outweighed by any offsetting consumer or competitive benefits that the sales practice also produces”<sup>204</sup> and must not be one that the consumer could have avoided.<sup>205</sup>

Finally, FTC also has articulated through a policy statement its principles for determining whether an advertiser has an adequate level of substantiation to support a claim.<sup>206</sup> The statement is premised on the underlying legal requirement that advertisers must have a reasonable basis for advertising claims before they are disseminated.<sup>207</sup> When a claim of substantiation is “express,” meaning that the claim is literally stated in the advertisement itself, such as “contains 2 grams of fat,” the advertiser must possess “at least the advertised level of substantiation.”<sup>208</sup> When an advertisement implies a particular type or amount of substantiation, the advertiser must possess the level of support that the ad actually communicates to consumers.<sup>209</sup> In the absence of an express or implied level of substantiation, the advertiser must have a reasonable basis for the claim.<sup>210</sup> The factors that the agency will consider in determining what constitutes a reasonable basis include the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation that experts in the field believe is reasonable.<sup>211</sup>

Over the years, FTC has undertaken a number of enforcement actions — often culminating in consent decrees with the company — against manufacturers of OTC drug products for unfair or deceptive advertising practices. Most of these cases have involved false claims of therapeutic benefit, such as hair regrowth or cancer treatment.<sup>212</sup> A smaller number have

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202. *Id.*

203. *Id.*

204. *Id.*

205. *Id.*

206. FTC POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION, 1984, at <http://www.ftc.gov/bcp/guides/ad3subst.htm>; see also Policy Statement Regarding Advertising Substantiation Program, 49 Fed. Reg. 30,999 (Aug. 2, 1984).

207. FTC POLICY STATEMENT ON UNFAIRNESS, *supra* note 198.

208. *Id.*; see also *Kraft, Inc. v. FTC*, 970 F.2d 311, 318 n.4 (7th Cir. 1992).

209. FTC POLICY STATEMENT ON UNFAIRNESS, *supra* note 198.

210. *Id.*

211. *Id.*

212. See, e.g., *Warner-Lambert Co. v. FTC*, 562 F.2d 749 (D.C. Cir. 1977); *Keele Hair & Scalp Specialists, Inc. v. FTC*, 275 F.2d 18 (5th Cir. 1960); *Ward Labs. v. FTC*, 276 F.2d 952 (2d Cir. 1960); *Shafe v. FTC*, 256 F.2d 661 (6th Cir. 1958); *Koch v. FTC*, 206 F.2d 311 (6th Cir. 1953); *Excelsior Lab., Inc. v. FTC*, 171 F.2d 484 (2d Cir. 1948); *Irwin v. FTC*, 143 F.2d 316 (8th Cir. 1944); *Aronberg v. FTC*, 132 F.2d 165 (7th Cir. 1942).

involved products for which the advertiser claimed superiority to other products without adequate substantiation,<sup>213</sup> while a few cases involved claims that did not adequately limit the product's benefit<sup>214</sup> or that implied the presence of certain ingredients.<sup>215</sup>

Like FDA, FTC has broadened its mandate to include internet-based advertising. In 1999, FTC launched Operation Cure.All, a law enforcement and consumer education campaign, as a means to target false and unsubstantiated online health claims promoting products and services as cures or treatment for serious diseases.<sup>216</sup> Operation Cure.All provides information to consumers on how to recognize health fraud, and guidance for businesses on how to market health products and services truthfully.<sup>217</sup> FTC has conducted periodic sweeps of the Internet and sent email advisories warning companies of violations.<sup>218</sup>

### C. Lessons

FDA's arguable lack of jurisdiction over genetic testing services precludes wholesale application of its pharmaceutical advertising approach to genetic testing. Nevertheless, and notwithstanding the flaws in FDA's regulation of DTC pharmaceutical advertising, FDA's approach does contain elements that could be adapted to a policy aimed at genetic testing. FDA's advertising policy does not seek to ban advertising but rather to ensure that information is truthful and balanced. Both benefits and risks must be communicated, and consumers must be given the tools to find out more information. Any oversight strategy for genetic test advertising should ensure that both risks and benefits are disclosed, and aid consumers in finding out more information.

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213. See, e.g., *Novartis Corp. v. FTC*, 223 F.3d 783 (D.C. Cir. 2000); *Bristol-Myers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984); *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146 (9th Cir. 1984); *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681 (3d Cir. 1982); *FTC v. Sterling Drug, Inc.*, 317 F.2d 669 (2d Cir. 1963); *Bristol-Myers Co. v. FTC*, 185 F.2d 58 (4th Cir. 1950).

214. See, e.g., *J.B. Williams, Co. v. FTC*, 381 F.2d 884, 889-90 (6th Cir. 1967) (noting that claims for Geritol falsely implied benefit in those not experiencing iron deficiency anemia); *Feil v. FTC*, 285 F.2d 879, 901 (9th Cir. 1960) (requiring claims for enuresis device to include statement that product benefit limited to cases not involving organic defects or diseases).

215. See, e.g., *Thompson Med. Co. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986) (requiring disclaimer that Aspercreme does not contain aspirin).

216. FTC, "*Operation Cure.all*" *Targets Internet Health Fraud* (June 24, 1999), at <http://www.ftc.gov/opa/1999/06/opcureall.htm> [hereinafter FTC, *Operation Cure.all*]; FTC, OPERATION CURE ALL, at <http://www.ftc.gov/bcp/conline/edcams/cureall> [hereinafter FTC, OPERATION CURE ALL].

217. FTC, OPERATION CURE ALL, *supra* note 216.

218. FTC, *Operation Cure.all*, *supra* note 216; Washington Internet Project, *FTC Operation Cure.all*, at <http://www.cybertelexcom.org/emed.htm> (last visited Aug. 26, 2004).

Unlike prescription drugs, however, many genetic tests do not require a physician's prescription, which eliminates a potential gatekeeper and makes it more critical that consumers are given correct information.

FDA's experience with DTC pharmaceutical advertising has also shown that it is difficult for a government agency to monitor commercial communications despite clear regulatory jurisdiction, and also highlights the need for, but difficulty of, collecting data to demonstrate advertising's impact on consumers. In addition, FDA must also be increasingly cognizant of the potential legal challenges on First Amendment grounds to any enforcement effort undertaken by the agency.<sup>219</sup> Although no such action has been brought in the context of prescription drugs, both the U.S. Supreme Court and the Court of Appeals for the D.C. Circuit have struck down agency efforts to limit speech in other contexts on the ground that they violated the First Amendment.<sup>220</sup>

FTC, in contrast to FDA, regulates not by category of product but based on the content of speech. This is the case whether the advertisement promotes widgets, weight loss aids, or attorney services. Thus, no jurisdictional barrier exists to FTC oversight of advertising claims for genetic tests. As a practical matter, however, FTC is a fairly small agency and must make choices about where to focus its limited resources.<sup>221</sup> Historically, FTC has focused its efforts on health products whose false or deceptive claims would cause concrete harm to a large number of people. Thus, a decision by FTC to focus on genetic testing would be influenced, at least in part, by a showing of concrete harm to consumers from the use of these products as a result of claims made in advertising. Currently, such data does not exist.

In addition, FTC's authority is limited to ensuring that advertising claims do not deceive consumers. This is a relatively limited mandate because it does not permit FTC to evaluate whether there is an overall benefit to consumers from receiving certain information. Rather, the agency is limited to determining whether the information consumers are receiving is inaccurate or creates a false impression. To the extent FTC went beyond policing fraud and deception, it too could face a challenge that it was violating free speech rights of advertisers. The Supreme Court has not explored the boundary between

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219. *See infra* Part VI.

220. *See infra* notes 273-88 and accompanying text.

221. *See generally* Testimony of Matthew Daynard, Senior Attorney, Advertising Practices Division, Bureau of Consumer Protection, Federal Trade Commission, Before the Secretary's Advisory Committee on Genetics Health and Society, October 22-23, 2003, 2003, at [http://www4.od.nih.gov/oba/SACGHS/meetings/October2003/Daynard\\_tr.pdf](http://www4.od.nih.gov/oba/SACGHS/meetings/October2003/Daynard_tr.pdf) (last visited Apr. 15, 2004) (stressing the agency's need to leverage its resources to get the most "bang for the buck").

what is truthful and what is misleading, and drawing this line may be particularly difficult.

## VI. Commercial Speech Doctrine

### A. Evolution of Commercial Speech Doctrine

The First Amendment to the U.S. Constitution provides that "Congress shall make no law . . . abridging the freedom of speech, or of the press."<sup>222</sup> The First Amendment constrains the government, including both state governments and the federal government, from suppressing speech by private citizens, even if the subject matter is factually wrong or offensive.<sup>223</sup> Although government may, consistent with the First Amendment, exert some control over the physical and temporal attributes of speech, the so-called "time, place, and manner" restrictions,<sup>224</sup> it generally may not prohibit communications based on their content.<sup>225</sup> The general prohibition on content-based restrictions of speech applies equally to speech concerning matters of public health. In other words, the potentially detrimental effect of a particular communication on the health of an individual or population does not justify government suppression.<sup>226</sup>

Several rationales have been given for such broad protection of speech. The right of the individual to free expression is thought to advance the values of (1) individual self-fulfillment, (2) attainment of the truth, (3) societal participation in social and political decisionmaking, and (4) maintaining a balance between stability and change within society.<sup>227</sup> The second value, that of truth, has been encapsulated in the metaphor of a "marketplace of ideas."<sup>228</sup> In his 1919 dissent in *Abrams v. United States*, Justice Holmes, citing the writings of John Stuart Mill, stated that

222. U.S. CONST. amend. I.

223. See, e.g., *Cohen v. California*, 403 U.S. 15 (1971).

224. See, e.g., *Members of the City Council v. Taxpayers for Vincent*, 466 U.S. 789, 808 (1984). The Supreme Court has stated that time, place, and manner restrictions do not violate the First Amendment "provided that they are justified without reference to the content of the regulated speech, that they are narrowly tailored to serve a significant governmental interest, and that they leave open ample alternative channels for communication of the information." *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 293 (1984).

225. See, e.g., *Boos v. Barry*, 485 U.S. 312, 315 (1988).

226. See, e.g., *Lorillard v. Reilly*, 533 U.S. 525, 555 (2001).

227. Thomas I. Emerson, *Toward a General Theory of the First Amendment*, 72 YALE L.J. 877 (1963), excerpted in RUSSELL L. WEAVER & ARTHUR D. HELLMAN, *THE FIRST AMENDMENT: CASES, MATERIALS, AND PROBLEMS* 8 (2002).

228. *Bigelow v. Virginia*, 421 U.S. 809, 826 (1975); see also *Taxpayers for Vincent*, 466 U.S. at 804; *Abrams v. United States*, 250 U.S. 616, 630 (1919).

when men have realized that time has upset many fighting faiths, they may come to believe . . . that the ultimate good desired is better reached by free trade in ideas — that the best test of truth is the power of the thought to get itself accepted in the competition of the market . . . .<sup>229</sup>

Under the marketplace rationale, permitting unfettered expression exposes false ideas to debate and rejection, while permitting truth to be discovered. As Mill stated,

[T]he peculiar evil of silencing the expression of an opinion is, that it is robbing the human race; posterity as well as the existing generation; those who dissent from the opinion, still more than those who hold it. If the opinion is right, they are deprived of the opportunity of exchanging error for truth: if wrong, they lose, what is almost as great a benefit, the clearer perception and livelier impression of truth, produced by its collision with error.<sup>230</sup>

Certain classes of speech, however, have been categorically excluded from First Amendment protection. The exclusions stem not from the text of the First Amendment, but rather from Supreme Court interpretations. In *Chaplinsky v. New Hampshire*,<sup>231</sup> the Court opined that “[t]here are certain well-defined and narrowly limited classes of speech, the prevention and punishment of which have never been thought to raise any Constitutional problem.”<sup>232</sup> The Court listed these categories as: “the lewd and obscene, the profane, the libelous, and the insulting or ‘fighting’ words.”<sup>233</sup> From this and other cases, the following categories of speech have been historically excluded from First Amendment protection: (1) obscenity, (2) fighting words, (3) incitement, and (4) defamation.<sup>234</sup> Jurisprudence that has developed has attempted to define, and in some cases, strictly limit the exemption of each of these categories. In contrast to speech fostering the ideals discussed above, these excluded categories of speech have been considered to constitute “no essential part of any exposition of ideas, and are of such slight social value as

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229. *Abrams*, 250 U.S. at 630 (Holmes, J., dissenting).

230. JOHN STUART MILL, ON LIBERTY ch. 2 (1999) (1869), at <http://www.bartleby.com/25/2/2.html> (last visited Apr. 15, 2004).

231. 315 U.S. 568 (1942).

232. *Id.* at 571-72.

233. *Id.* at 572.

234. RUSSELL L. WEAVER & ARTHUR D. HELLMAN, THE FIRST AMENDMENT: CASES, MATERIALS AND PROBLEMS 89, 106, 435 (2002).

a step to truth that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality.”<sup>235</sup>

Until recently, many believed that speech relating to commercial transactions and activities — what has become known as “commercial speech” — was also categorically excluded from First Amendment protection.<sup>236</sup> In the 1942 case *Valentine v. Chrestensen*,<sup>237</sup> which was decided shortly after *Chaplinsky*, the Court upheld an ordinance prohibiting the use of city streets for “commercial and business advertising matter.”<sup>238</sup> In a terse opinion, the Court ruled that, whereas “the streets are proper places for the exercise of the freedom of communicating information and disseminating opinion”<sup>239</sup> and thus the government is constrained from prohibiting such activities,

the Constitution imposes no such restraint on government as respects purely commercial advertising. Whether, and to what extent, one may promote or pursue a gainful occupation in the streets, to what extent such activity shall be adjudged a derogation of the public right of user, are matters for legislative judgment.<sup>240</sup>

The Court did not revisit the issue again for over thirty years. In the 1975 case *Bigelow v. Virginia*,<sup>241</sup> however, the Court struck down an ordinance that would have prohibited a newspaper from carrying an advertisement informing the public that abortions were legal in New York and offering assistance in obtaining abortion services. The Court held that “speech is not stripped of First Amendment protection merely because it appears” in the form of a paid commercial advertisement.<sup>242</sup> The Court limited the effect of *Chrestensen*, stating that the case did not provide “authority for the proposition that all statutes regulating commercial advertising are immune from constitutional challenge,”<sup>243</sup> and “does not support any sweeping proposition that advertising

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235. *Chaplinsky*, 315 U.S. at 572.

236. *But cf.* Daniel E. Troy, *Advertising: Not "Low Value" Speech*, 16 YALE J. ON REG. 85, 92-93 (1999) (arguing that the Framers of the Constitution believed that the right to advertise was encompassed within the First Amendment's protection of freedom of the press and that they did not intend to distinguish between commercial and noncommercial speech, but rather between truthful and false speech).

237. 316 U.S. 52 (1942).

238. *Id.* at 53.

239. *Id.* at 54.

240. *Id.*

241. 421 U.S. 809 (1975).

242. *Id.* at 818.

243. *Id.* at 820.



is unprotected per se.”<sup>244</sup> While the *Bigelow* decision dealt with speech that had both commercial and noncommercial aspects, in that it “conveyed information of potential interest and value to a diverse audience — not only to readers possibly in need of the services offered,”<sup>245</sup> the Court confronted the issue of “pure” commercial advertising head-on the following year. In *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*,<sup>246</sup> the Court struck down a Virginia law prohibiting pharmacists from advertising the price of prescription drugs. The state argued that the restriction was necessary to protect consumers because permitting price advertising would undermine the professionalism of pharmacists and jeopardize the customer-pharmacist relationship.<sup>247</sup> By requiring pharmacists to compete as to price, the state feared that the quality of pharmacists’ service to customers would decline to the customers’ detriment.<sup>248</sup> The Court, after acknowledging that its holding in *Chrestensen* had “all but passed from the scene”<sup>249</sup> in the wake of subsequent cases, formally recognized that speech that does “no more than propose a commercial transaction”<sup>250</sup> was protected by the First Amendment. The Court noted the important interests furthered by commercial speech. “As to the particular consumer’s interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.”<sup>251</sup> With respect to pharmaceutical price advertising specifically, the Court noted that suppression of prescription drug price advertising would in particular harm the poor, the sick, and the disabled, who spend a disproportionate amount of their income on prescription drugs, but who have limited ability to comparison shop.<sup>252</sup> The Court also noted the societal interest in the free flow of commercial information:

Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter

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244. *Id.*

245. *Id.* at 822.

246. 425 U.S. 748 (1976).

247. *Id.* at 766-67.

248. *Id.*

249. *Id.* at 759.

250. *Id.* at 762 (quoting *Pittsburg Press Co. v. Human Relations Comm’n*, 413 U.S. 376, 385 (1973)).

251. *Id.* at 763.

252. *Id.*

of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.<sup>253</sup>

Responding to the concerns raised by the State that consumers would choose low-cost, low-quality pharmacy services, the Court stated:

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.<sup>254</sup>

The Court concluded that the state could not suppress truthful information about a lawful activity solely because of its concerns about the effect of the information on the disseminators and the recipients of that information.<sup>255</sup>

Notwithstanding its recognition of the value of commercial speech that warranted First Amendment protection, the Court nevertheless noted factors that distinguished commercial speech from other types of protected speech. First, whether commercial speech is truthful “may be more easily verifiable by its disseminator”<sup>256</sup> than other types of speech because the advertiser is in a position to know about the product. Second, commercial speech is more “durable” than other kinds of speech because the profit motive will insulate it from the chilling effect of government regulation.<sup>257</sup> “[T]he greater objectivity and hardiness of commercial speech . . . may make it less necessary to tolerate inaccurate statements for fear of silencing the speaker.”<sup>258</sup>

### *B. Central Hudson*

Following *Virginia State Board of Pharmacy*, the Court considered commercial speech in a variety of contexts,<sup>259</sup> including lawyer and other professional advertising.<sup>260</sup> Through these cases, the Court formalized its commercial speech doctrine, which was articulated in the 1980 case *Central*

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253. *Id.* at 765.

254. *Id.* at 770.

255. *Id.*

256. *Id.* at 772 n.24.

257. *Id.*

258. *Id.*

259. *Carey v. Population Servs. Int'l*, 431 U.S. 678 (1977); *Linmark Assocs., Inc. v. Willingboro*, 431 U.S. 85 (1977).

260. *Friedman v. Rogers*, 440 U.S. 1 (1979); *In re Primus*, 436 U.S. 412 (1978); *Ohralik v. Ohio State Bar Assoc.*, 436 U.S. 447 (1978); *Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977).

*Hudson Gas & Electric Corporation v. Public Service Commission*.<sup>261</sup> In this case, the Court articulated a four-part balancing test for determining whether a particular government restriction of commercial speech comported with the First Amendment. Under this test, a court must first determine whether the speech being restricted is misleading or concerns an unlawful activity.<sup>262</sup> Only speech that is truthful and relates to a lawful activity merits First Amendment protection. Assuming that this first criterion is satisfied, the burden shifts to the government to demonstrate that it has a substantial interest in restricting the speech at issue.<sup>263</sup> Third, the restriction must directly advance the state interest involved.<sup>264</sup> Restrictions that provide only “ineffective or remote support for the government’s purpose” will not be upheld.<sup>265</sup> Finally, the restriction must not be more restrictive than necessary to achieve the governmental interest.<sup>266</sup> This step examines the “fit” between the interest and means chosen to achieve it.<sup>267</sup> The government must not merely show that its regulation directly advances an important objective, but also that the means used are not more extensive than necessary to achieve that goal.<sup>268</sup>

Although some on the Court, most notably Justice Thomas, have advocated abolishing any distinction between commercial and fully protected speech,<sup>269</sup> the *Central Hudson* test has been repeatedly reaffirmed by a majority of the Court. What has changed, however, is the degree of rigor with which the test has been applied by some justices, in particular, with regard to the test’s third and fourth prongs.<sup>270</sup> While in earlier cases the Court had accepted a variety of restrictions to directly advance the state’s interest in a manner that was not unduly restrictive,<sup>271</sup> in recent years the Court, though highly fragmented, has

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261. 447 U.S. 557 (1980).

262. *Id.* at 563-66.

263. *Id.*

264. *Id.*

265. *Id.*

266. *Id.*

267. *Id.*

268. *Id.*

269. *See, e.g.,* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 572 (2001) (Thomas, J., concurring) (“I continue to believe that when the government seeks to restrict truthful speech in order to suppress the ideas it conveys, strict scrutiny is appropriate, whether or not the speech in question may be characterized as ‘commercial.’”); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 518 (1996) (Thomas, J., concurring) (arguing that where “legal users of a product or service [are kept] ignorant in order to manipulate their choices in the marketplace, the balancing test adopted in *Central Hudson* . . . should not be applied . . .”).

270. *See* Margaret Gilhooley, *Drug Regulation and the Constitution After Western States*, 37 U. RICHMOND L. REV. 901, 903 (2003) (noting that “while the Justices use the same [*Central Hudson*] test, they differ on its meaning in practice”).

271. *See, e.g.,* Posadas de P.R. Assoc. v. Tourism Co. of P.R., 478 U.S. 328 (1986)

imposed a much higher burden on the government to articulate the link between the ends sought and the means used.<sup>272</sup> In the 2001 case *Lorillard Tobacco Company v. Reilly*,<sup>273</sup> the Court struck down a Massachusetts regulation that, among other restrictions, would have prohibited the advertising of cigarettes, cigars, or smokeless tobacco products within one thousand feet of any school or playground.<sup>274</sup> Six members of the Court were satisfied that the state's interest was directly advanced by the restrictions on outdoor cigar and smokeless tobacco advertising,<sup>275</sup> thus meeting the standard in the third prong of *Central Hudson*. Five members of the Court, however, held that the one-thousand-foot rule was more extensive than necessary to serve the state's interests, thus failing to satisfy the fourth prong of *Central Hudson*.<sup>276</sup> Specifically, they found that the attorney general did not "carefully calculate the costs and benefits associated with the burden on speech imposed by the regulations."<sup>277</sup> For example, they stated that the attorney general did not consider the impact of the restriction in metropolitan areas, which would be greater than in rural areas such that "[t]he uniformly broad sweep of the geographical limitation demonstrates a lack of tailoring."<sup>278</sup> In the Court's opinion,

A careful calculation of the costs of a speech regulation does not mean that a State must demonstrate that there is no incursion on legitimate speech interests, but a speech regulation cannot unduly impinge on the speaker's ability to propose a commercial

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(upholding Puerto Rico law prohibiting casino advertising, finding that the government's interest in reducing the demand for casino gambling by residents of Puerto Rico was substantial, that the regulations directly advanced the government's interest, and the restrictions were no more extensive than necessary to serve the government's interest).

272. See, e.g., *44 Liquormart*, 517 U.S. at 504 (unanimously overturning state ban on liquor price advertising ban, but disagreeing on whether the state's failure related to the direct advancement or reasonable fit prong of *Central Hudson*); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 486-91 (1995) (finding that the federal government prohibition on the display of alcohol content on beer labels did not sufficiently advance the government interest in protecting the health, safety, and welfare of its citizens).

273. 533 U.S. 525 (2001).

274. *Id.* at 550-51.

275. Because the Court concluded that the restrictions on cigarette advertising were preempted by the Federal Cigarette Labeling and Advertising Act, it did not render an opinion regarding whether the cigarette advertising restrictions violated the First Amendment. *Id.* at 550.

276. *Id.* at 563-65.

277. *Id.* at 561 (internal quotation and citation omitted).

278. *Id.* at 563.

transaction and the adult listeners opportunity to obtain information about products.<sup>279</sup>

In the 2002 case of *Thompson v. Western States Medical Center*,<sup>280</sup> a six-member majority of the Court struck down a provision of the Food and Drug Administration Modernization Act of 1997 (FDAMA) that would have prohibited pharmacists from advertising compounded drugs.<sup>281</sup> Compounded drugs are those that are not commercially available and are tailored by pharmacists to meet the needs of a specific patient in response to a valid prescription.<sup>282</sup> The FDAMA exempted the activity of compounding from the premarket approval requirements under which new drugs ordinarily must demonstrate safety and effectiveness before they can be approved for marketing.<sup>283</sup> FDA argued that the restriction on advertising was necessary to balance the interest of providing compounded drugs to patients who require them and preserving the integrity of the premarket approval process by ensuring that compounding remains on a small scale.<sup>284</sup> While the Court agreed that the government's interest in achieving this objective was substantial and that the means chosen might directly achieve that objective, it concluded that the government had not shown its methods were not more restrictive than necessary.<sup>285</sup> The Court noted that several nonspeech restrictive alternatives could have been used to draw a line between compounding and large scale manufacturing, such as limiting the number of compounded drugs sold by a particular pharmacist or pharmacy, or by prohibiting the use of commercial scale equipment to compounded drugs.<sup>286</sup> According to the Court, "The Government simply has not provided sufficient justification here. If the First Amendment means anything, it means that regulating speech must be a last — not first — resort. Yet here it seems to have been the first strategy the Government thought to try."<sup>287</sup>

### C. Compelled Commercial Speech

Not only does the First Amendment protect the right to speak, but it also protects the right to refrain from speaking. The Court has articulated two

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279. *Id.* at 565.

280. 535 U.S. 357 (2002).

281. *Id.* at 377.

282. For example, a patient may require a dosage form not commercially available or have an allergy to a specific ingredient. *Id.* at 360-61.

283. *Id.* at 360.

284. *Id.* at 364.

285. *Id.* at 373.

286. *Id.* at 372.

287. *Id.* at 373.

complementary rationales for affording First Amendment protection to compelled speech. First, to compel a person to enunciate a view in which he does not believe violates the freedom of conscience or belief.<sup>288</sup> This reasoning was used to invalidate state laws that make flag salute and pledge compulsory,<sup>289</sup> or that require automobile owners to display license plates carrying the state motto, "Live Free or Die."<sup>290</sup> Second, government-compelled speech may deter speakers from expressing their own views.<sup>291</sup> The Court struck down state laws that prohibit anonymous handbills<sup>292</sup> or campaign literature<sup>293</sup> because the laws discouraged the person's underlying right to publish and disseminate written works.

The U.S. Supreme Court's compelled-speech jurisprudence is principally concerned with political and social discourse, as opposed to product health and safety.<sup>294</sup> In *United States v. United Foods, Inc.*,<sup>295</sup> however, the Court made clear that its compelled speech doctrine applies to commercial speech.<sup>296</sup> In that case, the Court held that a federal statute requiring mushroom producers and importers to pay for generic advertising promoting the mushroom industry is coerced speech: "First Amendment values are at serious risk if the government can compel [citizens to subsidize speech] on the side that it favors."<sup>297</sup>

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288. Lawrence O. Gostin & Gail H. Javitt, *Health Promotion and the First Amendment: Government Control of the Informational Environment*, 79 MILBANK Q. 547, 560 (2001).

289. *W.V. State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943).

290. *Wooley v. Maynard*, 430 U.S. 705 (1977).

291. Gostin & Javitt, *supra* note 288, at 560.

292. *Talley v. California*, 362 U.S. 60 (1960).

293. *McIntyre v. Ohio Elections Comm.*, 514 U.S. 334 (1995).

294. For example, in *Riley v. National Federation of the Blind of N.C.*, 487 U.S. 781, 796 (1988), the Court declined to use a commercial speech test in striking down a statute mandating professional fundraisers to disclose the percentage of charitable contributions actually turned over to charity. "[E]ven assuming . . . that [the mandated] speech in the abstract is indeed merely 'commercial,' we do not believe that the speech retains its commercial character when it is inextricably intertwined with the otherwise fully protected speech [involved in charitable solicitations]." *Id.*

295. 533 U.S. 405 (2001).

296. *Id.* at 413-16. The Court decided the case based on its compelled-speech jurisprudence and did not apply the *Central Hudson* test. Nevertheless, some legal commentators view the *United Foods* case as a victory for constitutional protections of commercial speech. See DAVID L. HUDSON, JR., COMPELLED ADVERTISING, at <http://www.firstamendmentcenter.org/Speech/advertising/topic.aspx?topic=compelled> (last updated Mar. 26, 2004).

297. *United Foods*, 533 U.S. at 411. Four years earlier, in *Glickman v. Wileman Bros. & Elliot, Inc.*, 521 U.S. 457 (1997), the Court upheld similar federal marketing orders requiring California fruit producers to fund a generic advertising program, characterizing the orders as economic regulation that did not impinge on First Amendment rights. See Nicole B. Casarez, *Don't Tell Me What to Say: Compelled Commercial Speech and the First Amendment*, 63 MO.

Lower courts have also grappled with the circumstances under which the government may compel disclosures in the commercial context. In *International Dairy Foods Ass'n v. Amestoy*,<sup>298</sup> dairy manufacturers challenged a Vermont law that required the labeling of products from cows treated with recombinant Bovine Somatotropin (rBST), a synthetic growth hormone that increases milk production. The U.S. Court of Appeals for the Second Circuit analyzed the regulation under *Central Hudson*, concluding that the asserted government interest of “consumer curiosity” was insufficiently strong to justify the regulation.<sup>299</sup>

In other circumstances, lower courts have viewed compelled disclosure as preferable to an outright ban on speech. In *Pearson v. Shalala*,<sup>300</sup> the U.S. Court of Appeals for the D.C. Circuit struck down an FDA regulation requiring prior approval of “health claims”<sup>301</sup> for dietary supplements.<sup>302</sup> FDA required that such claims be supported by “significant scientific agreement,” an agency-defined and enforced standard.<sup>303</sup> The court held that the significant scientific agreement standard was unconstitutional because it precluded manufacturers from making claims having less scientific support in conjunction with a disclaimer, stating:

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L. REV. 929, 930 (1998). The Court in *United Foods, Inc.* distinguished its prior ruling by reasoning that the exaction in *Glickman* was ancillary to a comprehensive regulatory program that included several competition-displacing features. *United Foods*, 533 U.S. at 411-12. In contrast, the federal statute in *United Foods* had no regulatory objective other than generic advertising. *Id.* at 412.

298. 92 F.3d 67 (2d Cir. 1996).

299. *Id.* at 74.

300. 164 F.3d 650 (D.C. Cir. 1999).

301. A “health claim” is “any claim made on the label or in labeling of a food, including a dietary supplement, that . . . characterizes the relationship of any substance to a disease or health-related condition.” 21 C.F.R. § 101.14(a)(1) (2003).

302. *Pearson*, 164 F.3d at 660-61. The claims at issue in the case were that consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer, that consumption of fiber may reduce the risk of colorectal cancer, that consumption of omega-3 fatty acids may reduce the risk of coronary heart disease, and that 0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. *Id.* at 652.

303. *Id.* at 653 (quoting 21 U.S.C. § 343(r)(3)(B)(I) (1972 & Supp. 1998)). The regulation at issue stated that FDA would authorize a health claim

only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 C.F.R. § 101.14(c).

It is clear . . . that when government chooses a policy of suppression over disclosure — at least where there is no showing that disclosure would not suffice to cure misleadingness — government disregards a ‘far less restrictive’ means.<sup>304</sup>

#### *D. Misleading Speech*

The first prong of the *Central Hudson* test makes clear that First Amendment protection will be afforded only to truthful commercial speech about a lawful activity. Commercial speech that is misleading, deceptive, or untruthful, or concerns illegal activity, is outside the protection of the First Amendment. As the Court explained in *Rubin v. Coors Brewing Co.*:<sup>305</sup>

Not only does regulation of inaccurate commercial speech exclude little truthful speech from the market, but false or misleading speech in the commercial realm also lacks the value that sometimes inheres in false or misleading political speech. Transaction-driven speech usually does not touch on a subject of public debate, and thus misleading statements in that context are unlikely to engender the beneficial public discourse that flows from political controversy. Moreover, the consequences of false commercial speech can be particularly severe: Investors may lose their savings, and consumers may purchase products that are more dangerous than they believe or that do not work as advertised. Finally, because commercial speech often occurs in the place of sale, consumers may respond to the falsehood before there is time for more speech and considered reflection to minimize the risks of being misled.<sup>306</sup>

The U.S. Supreme Court, however, has provided little guidance to aid in a determination of what is misleading commercial speech. For the most part, cases decided by the Court have involved challenges to government restrictions of speech acknowledged by both sides to be truthful. In a few instances — mostly involving professional advertising — the Court has addressed contentions by the government that certain types of advertising will mislead consumers.<sup>307</sup> These opinions have not dealt in any depth with what

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304. *Pearson*, 164 F.3d at 658.

305. 514 U.S. 476 (1995).

306. *Id.* at 496.

307. *See, e.g., Ibanez v. Fla. Dep’t of Bus. & Prof’l Regulation*, 512 U.S. 136 (1994) (finding that attorney’s use of CPA and CFT designation were not misleading provided that she held active CPA and CFT licenses); *Peel v. Attorney Registration & Disciplinary Comm’n*, 496



factors should be used to assess whether a particular communication is deceptive or misleading.<sup>308</sup> Additionally, the Court has indicated that even where speech is potentially misleading, the remedy is additional disclosure, such as mandated warning labels, and not a categorical ban.<sup>309</sup>

### *VII. Regulation of Genetic Tests Within the Bounds of the First Amendment*

Critics of direct-to-consumer marketing of genetic tests raise concerns implicating both the sale and advertising of these tests.<sup>310</sup> First, they argue that the tests should be available only through a health care provider and in the context of genetic counseling. This critique relates to how the tests are sold. To address this concern, regulations could be imposed regarding, for example, the level of data required before a test can be offered, who is authorized to provide the testing services, and who is permitted to order the test and receive the results. Regulations addressing the prerequisites for and manner of sale could be imposed at the federal or state level. Though it remains unclear whether federal agencies currently have sufficient jurisdiction to implement such requirements, there is no constitutional barrier to their moving forward,<sup>311</sup> and Congress could clarify, and if necessary, expand their

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U.S. 91 (1990) (holding that attorney's letterhead stating that he was a "Certified Civil Trial Specialist by the National Board of Trial Advocacy" was not actually or inherently misleading where the information was true and verifiable, and the potential for the information to mislead was insufficient to warrant a categorical ban); *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985) (affirming that advertising contingent fee arrangement without disclosing the need to pay legal costs was deceptive and misleading, but that advertisements offering to represent previous users of a defective birth control device were not, because the offer did not promise a successful outcome or suggest that the attorney had special expertise).

308. Gostin & Javitt, *supra* note 288, at 563.

309. For example, in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), the Court stated that

[e]ven if the Government did argue that it had an interest in preventing misleading advertisements, this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown.

*Id.* at 376.

310. See *supra* notes 10-12 and accompanying text.

311. The U.S. Constitution authorizes Congress to "regulate commerce . . . among the several states." U.S. CONST. art. I, § 8. Thus, the Commerce Clause permits Congress to enact legislation affecting a wide variety of activities and products, provided that the activities involve interstate commerce. Because clinical laboratories typically operate in more than one state, and receive materials and send test results across state lines, there is likely to be the requisite interstate commerce nexus present for federal legislation. States, through their police powers, have the authority to regulate to protect the health, safety, and welfare of their citizens, see Gostin, *supra* note 10, and such police powers could be invoked to enact laws regulating genetic

jurisdiction by enacting new legislation.

Second, critics argue that consumers may be confused or misled by the claims made in advertising for genetic tests and that the government should restrict consumer-directed advertising. With respect to restricting advertising claims, however, the constraints of the First Amendment require a cautious approach. A court would likely categorize promotional speech concerning genetic testing as commercial speech, and impose the *Central Hudson* analytical framework in evaluating any restriction. Thus, the first question a court would ask is whether the speech concerns a lawful activity.<sup>312</sup> In the absence of any laws prohibiting the sale of genetic tests, such speech would be lawful. Some states prohibit direct access testing; thus, to the extent an advertisement offered services directly to consumers in a state in which it was prohibited, this could be considered unlawful activity.

Assuming lawful activity, the next question under *Central Hudson* is whether the speech is misleading.<sup>313</sup> As discussed above, the U.S. Supreme Court has spent minimal time in its decisions discussing the parameters of misleading speech. Speech that is blatantly false would no doubt fail this component of *Central Hudson*. Thus, for example, an advertisement claiming that a genetic test can reveal information for which no scientific basis exists, such as predicting who you will marry, or whether you will win the lottery, would not be protected by the First Amendment. Indeed, these are the types of specious claims that FTC is clearly currently authorized to prohibit.<sup>314</sup> Whether FTC would choose to pursue blatantly false claims for genetic tests is a matter of enforcement discretion, and FTC would likely take into account the magnitude of the harm caused by such testing and the number of people affected in deciding whether to take action.<sup>315</sup>

It is likely that at least some genetic testing advertisements are not false on their face, but may nevertheless have the potential to mislead because, for example, they overstate the potential benefits, minimize potential risks, or imply a greater level of scientific support than actually exists to support the claim. A court might agree with a government assertion that such speech was potentially misleading. Nevertheless, based on the limited precedent available, a court would also likely conclude that an appropriate remedy for such misleading speech is not a wholesale ban on all genetic testing

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tests.

312. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 563-64 (1980).

313. *Id.*

314. *See supra* Part V.B.

315. *See generally* Testimony of Matthew Daynard, *supra* note 221.

advertising, but rather a requirement to disclose additional information to remedy the misleading perception that the advertisement created.<sup>316</sup>

Assuming that the speech at issue was truthful, even if potentially misleading, the burden would shift to the government to demonstrate that a restriction on speech served a substantial interest.<sup>317</sup> An asserted governmental interest in protecting the public's health would almost certainly be considered substantial, and a court would likely accept as substantial the government's desire to prevent at least some of the harms that critics of DTC genetic testing have asserted.<sup>318</sup>

A finding that the asserted interest is substantial, however, does not by itself mean that government restrictions of speech protecting the public's health are warranted. The third and fourth prongs of *Central Hudson* require the government to show that speech restrictions are a direct means of protecting the public, and that such restrictions are narrowly tailored to achieve this goal.<sup>319</sup> The First Amendment requires that speech restrictions be a last resort, not a first step, in such protection. Accordingly, it is most often at this stage of the *Central Hudson* analysis that the government fails to meet its burden.

A key element of succeeding in the third and fourth steps is being able to convincingly support the connection between the interest the government seeks to achieve and the means chosen to achieve it. In the case of genetic testing, the government would need to demonstrate that restricting the advertising of genetic tests will directly prevent the asserted harms and that such restrictions are a sufficiently narrowly tailored means to achieve this objective. While it is unclear what type or degree of evidence a court would require to make such a demonstration,<sup>320</sup> achieving an adequate level of evidence would likely be difficult in the case of genetic testing. While the CDC has been monitoring consumer reaction to genetic testing,<sup>321</sup> few data have emerged to date. Furthermore, assessing the actual impact of advertising on consumer behavior is generally difficult,<sup>322</sup> and would likely be difficult with respect to genetic testing as well. A court would also likely be skeptical

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316. See, e.g., *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

317. *Central Hudson*, 447 U.S. at 564.

318. See *supra* Part III.B.

319. *Central Hudson*, 447 U.S. at 564.

320. The Court has not yet indicated the level of evidence needed to support speech restrictions. *Gostin & Javitt*, *supra* note 288, at 558 n.7.

321. See CLIAC SUMMARY REPORT, Sept. 17-18, 2003, Addendum P, at <http://www.phppo.cdc.gov/cliac/pdf/CLIAC0903.pdf> (last visited Aug. 27, 2004).

322. See *supra* notes 174-75 and accompanying text (discussing consumer impact of DTC pharmaceutical advertising).

of arguments that advertising restrictions were necessary because of consumer ignorance or difficulty in making independent decisions, and might view such arguments as reflecting unwarranted paternalism. In the absence of adequate evidence to show that restricting advertising will directly advance the government's interest and that there are not less speech-restrictive means of doing so — such as more effectively regulating the tests themselves — it would be difficult for the government to satisfy the direct advancement requirement of *Central Hudson*.

Even if the government could show a direct connection between restricting advertisements and preventing consumer harm, the government would still need to show that restricting advertising is not more restrictive than necessary to achieve its purpose.<sup>323</sup> The government would need to show that any restrictions were carefully targeted and did not sweep in more speech than necessary to avoid the asserted harms. Crafting restrictions to prohibit those claims without any merit while not unduly impinging on valid claims would be challenging. Courts would likely look for some evidence that the government had diligently endeavored to determine the consequences of any restriction on all advertising, not just the speech specifically targeted for restriction.

Requiring limited disclosures to avoid misleading consumers would be more likely to satisfy the requirements of *Central Hudson*. The government would need adequate evidence to demonstrate that restricting advertisements would directly advance its interests in protecting consumers from the asserted harms from DTC advertising, and that the restrictions did not impinge on more speech than necessary to achieve this interest.

### VIII. Conclusion

The number and type of genetic tests available continues to increase, and such tests are playing an increasingly important role in health care. These tests provide information regarding a person's current or potential future health status — information with significant consequences for both individuals and their family members.

Many critics lament both the lack of federal oversight of genetic tests and the increasing efforts by some companies to promote and sell them directly to consumers. Yet there has been little careful analysis of either the regulatory environment in which these tests are provided, or the constitutional constraints implicated when the government restricts commercial communications.

While there is no constitutional barrier to government regulation of the sale of genetic tests, currently little federal or state oversight exists, especially

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323. *Central Hudson*, 557 U.S. at 564.

when compared with medical products, such as drugs and devices. This lack of oversight of the sale of tests has arguably contributed to some critics' desire to prohibit advertising. The Constitution also does not prohibit the government from restraining clearly false or misleading advertising claims for genetic tests, but FTC has not yet undertaken a review of the claims being made for these tests.

Constitutional protections would, however, be implicated were the government to prohibit truthful, nonmisleading claims about genetic tests. The government would need to support any restrictions on speech with adequate evidence, which may not yet exist, that such restrictions will directly advance its interest and are a narrowly tailored means of doing so. Limited and more narrowly focused requirements, such as the requirement for greater disclosure of information or the use of disclaimers in advertisements, would be more likely to survive judicial scrutiny.

Clearly, the First Amendment in no way restricts the government or private parties from adding their voices to that of commercial interests in the service of protecting consumers. Indeed, the premise of the "marketplace of ideas" — that more speech is better than less and that truthful ideas will win out over false ones if all are permitted to be heard — applies to genetic testing as well. The government, through its many public health-related agencies, can educate and warn consumers about the limitations, pitfalls, and dangers of genetic testing using the same media used by advertisers of such tests. As the recent statement by the American College of Medical Genetics indicates,<sup>324</sup> professional groups can, and should, voice their concerns regarding the potential harms of DTC testing to educate providers and the public about the appropriate uses of such tests.

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324. *See supra* note 7.