The Task Force on Genetic Testing was created to review genetic testing in the United States and, when necessary, to make recommendations to ensure the development of safe and effective genetic tests. A survey to explore the state of genetic testing was undertaken for the Task Force and completed in early 1995. The survey, as well as literature reports and other information collected for the Task Force, showed problems affecting safety and effectiveness, as defined by the Task Force: validity and utility of predictive tests, laboratory quality, and appropriate use by healthcare providers and consumers. On the basis of these findings, the Task Force made several recommendations to ensure safe and effective genetic testing. The Secretary of Health and Human Services followed up one recommendation by creating the Secretary’s Advisory Committee on Genetic Testing. One of its functions will be to implement other recommendations of the Task Force.

Since I spoke at this Forum in 1993 (1), the emphasis in human genetics research has shifted from rare Mendelian disorders to common, complex diseases, but “Issues of benefits and risks of genetic testing”, the title of my earlier presentation, have, if anything, become more important. The growing interest of clinical researchers in the role of genes in common diseases and of commercial firms in genetic testing lends new urgency to establishing benefits and risks. Large collaborative projects have been undertaken to look for gene loci at which the presence of specific alleles increase the risk of asthma, bipolar affective disorder, diabetes, hypertension, schizophrenia, and other disorders. The last 5 years have seen the marketing of commercial tests for predicting risks of breast and colon cancer despite warnings of the Advisory Council of the National Human Genome Research Institute and, separately, the American Society of Human Genetics that testing for susceptibility to common cancers should be conducted on a research basis only (2, 3). A commercially available test for the apolipoprotein E ε4 allele was available to predict the risk of Alzheimer disease until professional statements criticized its use in clinically unaffected individuals (4, 5). It remains on the market for diagnostic testing. A survey completed for the Task Force on Genetic Testing early in 1995 found that 53 biotechnology companies were developing or performing tests for genetic disorders. The companies were much more likely to be developing tests for common complex disorders than for relatively rare single gene disorders (Table 1) (6).

Reflecting concern about the rapid proliferation of genetic tests before their safety and effectiveness had been demonstrated, the NIH-Department of Energy (NIH-DOE) Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI) convened the Task Force on Genetic Testing in 1995. The ELSI Working Group asked the Task Force to review genetic testing in the United States and, when necessary, to make recommendations to ensure the development of safe and effective genetic tests. Part of the review was accomplished by the survey already mentioned. The Task Force defined safety and effectiveness “to encompass not only the validity and utility of genetic tests, but their delivery in laboratories of assured quality, and their appropriate use by healthcare providers and consumers” [Ref. (7), p. 4]. I will discuss these components, and the recommendations of the Task Force for ensuring safety and effectiveness of newly developed genetic tests.
Table 1. Organizations developing or providing genetic tests for certain disorders.

<table>
<thead>
<tr>
<th>Disorders</th>
<th>BTCs n</th>
<th>%</th>
<th>Nonprofit clinical laboratories n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any of 44(^a)</td>
<td>53</td>
<td>100.0</td>
<td>212</td>
<td>100.0</td>
</tr>
<tr>
<td>3 complex(^c) (not 3 single-gene)</td>
<td>18</td>
<td>34.0</td>
<td>9</td>
<td>4.2</td>
</tr>
<tr>
<td>3 single-gene(^d) (not 3 complex)</td>
<td>9</td>
<td>17.0</td>
<td>99</td>
<td>46.7</td>
</tr>
<tr>
<td>Both</td>
<td>16</td>
<td>30.2</td>
<td>38</td>
<td>17.9</td>
</tr>
<tr>
<td>Neither</td>
<td>10</td>
<td>18.8</td>
<td>66</td>
<td>31.2</td>
</tr>
</tbody>
</table>

\(\chi^2, P <0.0001.\)

\(^a\) Percentage of all organizations engaged in testing for any of 44 disorders. Modified from Holtzman and Hilgartner (6), p. 120.

\(^b\) Most of the 44 disorders were rare single-gene disorders. The remainder were common, complex disorders for which tests were available or under development.

\(^c\) Complex: Alzheimer disease, breast cancer, colon cancer (HNPCC).


The need for new policies concerning genetic testing has been recognized by the Secretary of Health and Human Services. Secretary Shalala asked to be briefed about the progress of the Task Force, and when its report was submitted, she created an interagency working group in the Department of Health and Human Services to review the recommendations of the Task Force and to consider their implementation. One reason the Report gained such attention was that it represented the consensus of multiple stakeholders in genetic testing (Table 2). There were no dissenting votes for any of the recommendations. Another reason was the effort of the Task Force to solicit public and professional input. The Task Force had public hearings, and published its preliminary recommendations in the Federal Register (8). Eighty-two people responded at least once. On the basis of those comments, the Task Force drastically modified a number of its recommendations before issuing its final report [(7), Appendix 1].

During the summer of 1998, Secretary Shalala implemented one recommendation of the Task Force (Table 3) by creating the Secretary’s Advisory Committee on Genetic Testing. As of January 1999, the members of this committee, which is being administered from the Office of the Director, NIH, had not been appointed. Over 200 nominations were received.

 Validity

The Task Force divided the validity of genetic tests into analytical validity, the ability of the test to detect correctly the presence or absence of the analyte it was designed to detect, and clinical validity, the probability that a person with a negative test result is, and will remain, free of the disease, as well as the probability that a person with a positive test result has, or will develop, the disease. Analytical validity depends in part on the capabilities of the laboratory performing the test, which I will discuss briefly in the section on laboratory quality.
disease-related alleles exist at either one gene locus (allele diversity), which is often the case, or at several loci (locus heterogeneity), current technology sometimes fails to detect all of them. Heterogeneity occurs frequently for both Mendelian and common, complex disorders. Sensitivity is further lowered for the latter because the vast majority of cases are not attributable to alleles at any gene locus, but to a combination of genetic and environmental factors, which will not be detected by any genetic test.

When penetrance is incomplete, the chance that a person with a positive test result will develop the disease [positive predictive value (PPV)] is lower than when penetrance is complete. Complete penetrance is usual for Mendelian disorders for which, consequently, we can speak of disease-causing rather than susceptibility-conferring genotypes. Penetrance is incomplete when other genetic or environmental factors must be present before disease manifests. Despite the strong association of certain BRCA1 or BRCA2 alleles with breast cancer in certain families (PPV ≥85%), fewer than 60% of Ashkenazi Jewish women found by a population-based search to have any one of three such alleles developed breast cancer by age 70 (9). Alleles at other gene loci and similar environments are more likely to be shared by relatives than by people in the general population.

The Task Force was concerned that genetic tests intended to predict risk of future disease in apparently healthy people were becoming available before adequate data on sensitivity and PPV had been collected. It first established the three criteria shown in Table 4, requiring an investigational stage and defining in broad terms the types of studies that were needed.

<table>
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<th>Table 4. Criteria of the Task Force to help ensure collection of data on clinical validity of genetic tests.</th>
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<td>• Data to establish the clinical validity of genetic tests (clinical sensitivity, specificity, and predictive value) must be collected under investigative protocols.</td>
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<tr>
<td>• In clinical validation, the study sample must be drawn from a group of subjects representative of the population for whom the test is intended.</td>
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<tr>
<td>• Formal validation for each intended use of a genetic test is needed.</td>
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Reprinted from Holtzman and Watson (7), p. 28.

clinical validity or having an approved IRB protocol. On the other hand, organizations marketing tests as kits must submit data to the FDA. They are, therefore, much more likely to comply with FDA requirements, including submission of protocols to an IRB.

In the survey of biotechnology companies (BTCs) and nonprofit organizations (NPOs) completed in 1995, only 23 of 37 BTCs (62%) and 97 of 127 NPOs (76%) that were developing genetic tests had ever submitted protocols to an IRB. Only 8 of 14 BTCs (57%) and 72 of 95 NPOs (76%) using home brews for genetic tests had ever submitted protocols to an IRB (6).

To give an example of the problem: When a polymorphic mutation in Ashkenazi Jews (10) was reported to increase the risk of colon cancer, the availability of a clinical laboratory test for the mutation was announced simultaneously. The work received considerable publicity, and in the following weeks, >1000 people called the center from which the report emanated to find out about getting the test. At that point, the work had not been independently replicated. Moreover, in the original research report, the risk of colon cancer in those with the mutation (PPV) was only ~30%, twofold higher than in Ashkenazi Jews without the mutation. In subsequent studies on other Ashkenazi Jewish populations, the risk has been reported to be either nonexistent (11) or lower (12). Thus, under existing regulations, the test could be made available as a clinical laboratory service before clinical validity or utility were established.

The Task Force went even further to assure that an investigative stage would precede marketing (Table 5). It made explicit that tests developed commercially (as well as those developed in state and local health departments) should submit protocols to IRBs although companies without Federal support were under no legal obligation to do so [Ref. (7), pp. 30, 33–4]. That IRBs have the authority to assess protocols for scientific merit as well as protection of human subjects is made clear by the Office of Protection of Human Subjects from Research Risks, which governs IRBs: “(I)f a research project is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study (emphasis added) [Ref. (13), p. 4–1]. The Task Force maintained that a protocol for genetic test development

<table>
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<th>Table 5. Recommendation of the Task Force on IRB approval of protocols for genetic tests.</th>
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<td>Protocols for the development of genetic tests that can be used predictively must receive the approval of an institutional review board (IRB) when subject identifiers are retained and when the intention is to make the test readily available for clinical use, i.e., to market the test. IRB review should consider the adequacy of the protocol for: (a) the protection of human subjects involved in the study, and (b) the collection of data on analytic and clinical validity, and data on the test’s utility for individuals who are tested.</td>
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would be flawed if it did not collect data on clinical validity and utility in an appropriate manner.

Utility
Let me turn to "collection of data . . . on the test’s utility" (Table 5). A test will not have clinical utility if neither the provider nor the patient will do anything differently after obtaining the test result, except worry. Unfortunately, there may be little else to do. The development of tests to predict future disease often precedes the development of interventions to prevent, ameliorate, or cure that disease in those born with genotypes that increase its risk. In this gap phase, people with negative results may be spared frequent monitoring for signs of disease or prophylactic surgery, and insurance or employment discrimination—situations they might face if their family history placed them at high risk in the absence of a predictive test. There may, however, be little to offer people with positive test results. For early-onset, severe Mendelian disease, families or individuals identified as heterozygotes by carrier screening could use testing to avoid the conception or birth of an affected child. For common, adult-onset diseases, however, therapies either have not been developed or their benefit to those with susceptibility-conferring genotypes have not been established. Thus, we do not know whether young, healthy women who have BRCA1 or BRCA2 mutations will benefit from mammography. Women with a family history of breast cancer (but not necessarily with BRCA1 or BRCA2 mutations) do have a reduced incidence of breast cancer following prophylactic mastectomy for as long as they have been followed (14). Consider the polymorphic mutation that was reported to double the risk of colon cancer in Ashkenazi Jews (10). How many 40-year-olds would undergo frequent colonoscopy, or have their colons removed, because their risk had gone from 15% to 30%? We need to know how people will respond to genetic tests for which positive results increase their risks, but to levels considerably below certainty of future disease. One can envision psychological harm as well as possible therapeutic benefit. Thus, the Task Force recommended: “Before a genetic test can be generally accepted in clinical practice, data must be collected to demonstrate the benefits and risks that accrue from both positive and negative results” [Ref. (7), p. 29].

External Review of Data Collected under Protocols
IRBs have no responsibility to assess the quality of the data collected under protocols approved by them. Consequently, the Task Force recommended that “test developers must submit their validation and clinical utility data to internal as well as independent external review. In addition, test developers should provide information to professional organizations in order to permit informed decisions about routine use” [Ref. (7), p. 36]. By “internal review,” the Task Force meant a review within the same organization that had developed the test but “conducted by those not actually involved in developing the test and collecting the data” [Ref. (7), p.37]. For instance, a test developed within an academic medical center could be reviewed by the standing hospital committee that reviews tests that the clinical laboratory wants to add to its repertoire.

With the exception of genetic tests marketed as kits, for which the FDA reviews data on clinical validity (but not utility as the Task Force defines it), no regulations exist for external review of genetic tests. External review can have a marked influence on providers’ decisions to use, or not use, new medical technologies. Examples include statements of professional societies, consensus development panels, and ratings by the US Preventive Services Task Force (15). The decision of health insurers on whether a specific genetic test will be included in their benefits or reimbursement packages can also influence use. The Task Force called on the FDA to consider the need for new policies on genetic tests [Ref. (7), p. 38].

Two problems need to be addressed regarding external review: the lengthy time needed to obtain data on utility as well as, occasionally, validity; and the large number of new genetic tests that might be developed, which could overwhelm any review system. To remedy the first problem, the Task Force presented several alternatives that could be used “when preliminary data indicate a test is likely to have validity and utility” [Table 6 and Ref. (7), p. 36]. The first option, voluntary postmarket collection of data by test developers, leaves unanswered the question of whether anyone external to the developing organization will decide when sufficient data have been collected and when to definitively review the data to decide on safety and effectiveness. The second option, reimbursement by health insurers while the test is still in an investigative stage, will greatly facilitate data collection because many providers will be reluctant to order a test under development if patients must pay for it out of pocket. The insurers themselves could make the final determination of a test’s validity and utility, although their decision might be unduly influenced by whether the test will lower their costs (M. Schoonmaker, submitted for publication).

Unless the FDA decides to regulate genetic tests marketed as services as it does kits, which it acknowledges it has the authority to do [Ref. (7), pp. 29–30], the third option, conditional premarket approval by the FDA, applies only to genetic test kits. The Task Force recom-

<table>
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<th>Table 6. Task Force options for assuring adequate data collection for external review of new tests.</th>
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<td>(1) Voluntary collection of data by developers after their tests enter clinical use.</td>
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<tr>
<td>(2) Reimbursement for, or coverage of, tests by third-party payers, including government programs, such as Medicare, Medicaid, CHAMPUS, and managed care organizations, during investigative stages in which data are being collected.</td>
</tr>
<tr>
<td>(3) Conditional premarket approval by the FDA of genetic test kits. Modified from Holtzman and Martin (7), p. 36.</td>
</tr>
</tbody>
</table>
mended that “(w)hen FDA considers it likely that a test kit will prove to make an important contribution to the prevention or management of the disorder, it should grant conditional premarket approval when a developer requests it. (FDA frequently clears or approves products for a limited-indication use with the requirement for postmarket studies or the expectation that claims may be extended as sufficient evidence accumulates.)” [Ref. (7), p. 36]. In return for conditional approval, developers could include a profit markup in the price of their test. They could promote the test, but would have to indicate that its safety and effectiveness were still under investigation. Informed consent would be needed, but the Task Force also recommends it for many predictive genetic tests fully approved for marketing (see below). Developers of kits would continue to collect and periodically present data to the FDA until such time as the agency either gave unconditional approval for marketing or denied it.

The Task Force dealt with the second problem by recommending that tests defined by the proposed advisory committee on genetic testing (Table 3) as requiring “stringent scrutiny” be given priority for review. “Stringent scrutiny,” the Task Force report said, “is indicated when a test has the ability to predict future inherited disease in healthy or apparently healthy people, is likely to be used for that purpose, and when no confirmatory test is available” [Ref. (7), p. 11]. It called on the proposed advisory committee on genetic testing, perhaps in conjunction with the Office of Protection of Human Subjects from Research Risks or the FDA, to define additional indications.

Review panels could become enmeshed in endless debate if they attempt to set cutpoints for sensitivity and PPV; these should vary depending on the particular test, its use, options for treatment, and other factors. Even for a particular test, reasonable people will differ on how much test uncertainty they can tolerate. The Task Force maintained that it was more important for external reviewers to ensure that the data have been collected and analyzed appropriately than to attempt to set cutpoints. That way individual users (providers and patients) could decide whether a test was suited to their needs. Review panels could suggest intended uses, e.g., the target f groups for specific tests [Ref. (7), p. 17].

Laboratory Quality
Respondents to the survey completed for the Task Force in 1995 were asked whether they personally agreed with the statement, “Current policies under the Clinical Laboratory Improvement Act assure the quality of genetic test services”. Of the 81 BTCs that responded, 53% agreed. Of the 245 NPOs responding, only 39% agreed [Ref. (6), Table 7, p. 124]. Thus, many of those providing tests acknowledged that the CLIA requirements were inadequate. To improve the situation, the Task Force urged the Clinical Laboratory Improvement Advisory Subcommittee on Genetics, whose parent Committee operates under CLIA 1988, “to consider the creation of a specialty of genetics that would encompass all predictive genetic tests that satisfy criteria for stringent scrutiny” [Ref. (7), p. 46]. The Subcommittee was formed in part to address the Task Force’s concerns. The Task Force also recommended that “(p)articipation [of laboratories performing genetic tests] in well-established proficiency testing programs for genetic tests must be required under CLIA once a genetic specialty is established. When no relevant proficiency testing programs exist, laboratories must, whenever possible, participate in interlaboratory comparison programs and help develop them if none exist in their particular area of testing” [Ref. (7), p. 50]. Although most BTCs and NPOs participated in formal proficiency testing programs or shared unknown samples informally, 3 of 27 BTCs (11%) that offered genetic test services and 16 of 97 (16.5%) NPOs that performed molecular testing reported in the 1995 survey that they participated in neither [Ref. (6), Table 5, p. 122]. The response of the Subcommittee to these and other recommendations regarding laboratory quality is described in this Forum by Schwartz (16).

The Task Force was also concerned with the quality of information provided to practitioners or patients by clinical laboratories. Drawing on data from the 1995 survey, Cho et al. (17,18) collected pamphlets that BTCs and NPOs gave to practitioners, patients, or both and determined how many of 10 elements each pamphlet included. Of the 115 pamphlets reviewed, only three elements were mentioned in a majority of pamphlets: who the candidates for testing were; a description of the condition; and availability of, or need for, genetic counseling. Only 10% included a statement on risks, limitations, or benefits of testing, and fewer than one-third contained a statement regarding confidentiality or need for informed consent. Although almost one-half made some statement about test performance these were usually vague, often using the term “accuracy” without indicating sensitivity, specificity, or predictive value (17). Pamphlets from NPOs were significantly more likely than those from BTCs to include information on patient rights and the need for or availability of counseling. They were significantly less likely than those from BTCs to indicate the intended purpose of the test (18).

In late 1996, the Task Force collected informational material from four laboratories—three BTCs and one NPO—offering testing for inherited susceptibility mutations in the BRCA1 and BRCA2 genes. They differed markedly in content. One commercial brochure said, “population screening should be offered where feasible” (19), but the brochure from the University of Pennsylvania maintained that systematic monitoring was still “essential . . . so that one day we will be able to offer appropriate screening guidelines based on firm clinical data” (20). Myriad’s brochure said, “Early [breast] cancer detection provides the best opportunity for reducing mortality from cancer” (21), but OncorMed’s brochure pointed out, “There is no surveillance or prevention
strategy which is proven to decrease the mortality associated with carrying a [BRCA] mutation” (22). Myriad’s brochure also stated that, “prophylactic mastectomy does not completely eliminate the risk of breast cancer. . . . However, the procedure substantially reduces the risk of breast cancer”. The University of Pennsylvania’s brochure accurately pointed out that, “there is very little data available as to how effective prophylactic surgery is at reducing breast cancer risk” (20).

The Task Force called for external review of proposed informational material to make sure the data were interpreted correctly and that test limitations (such as imperfect sensitivity and PPV) were indicated. It also encouraged the College of American Pathologists and the American College of Medical Genetics, which have programs for evaluating clinical laboratories performing genetic tests, to place greater emphasis on the pre- and postanalytic phases of testing in their programs for evaluating laboratories and to seek greater input from consumers and genetic counselors on educational, psychological, and counseling issues [Ref. (7), p. 55].

**Provider Education**

A number of studies performed in the last few years have documented deficiencies in the knowledge of genetics of primary care providers and other non-genetics specialists (23, 24). Without a better understanding of genetics, healthcare practitioners may not order genetics tests for the appropriate indications and may interpret the results incorrectly. Giardiello et al. (25) showed that 32% of physicians misinterpreted the results of a test for familial adenomatous polyposis. In a 1998 survey, Teresa Doksum in my group found that only 43% and 48%, respectively, of internists and obstetrician/gynecologists recognized that inherited mutations for breast cancer account for <10% of all breast cancers. Only 40% of internists and 30% of obstetrician/gynecologists knew that a woman could inherit a BRCA1 mutation from either parent, and only 53% and 54%, respectively, knew that the healthy sister of a woman with an inherited BRCA1 mutation had a 50% chance of inheriting the same mutation. Doksum also found that except for oncologists, physicians’ knowledge of genetic susceptibility to breast cancer was not associated with their ordering a test for inherited susceptibility mutations (T. Doksum, work in preparation).

The Task Force made several recommendations to rectify the problem of inappropriate ordering of, and counseling about, tests. One of its principles was that “People being offered testing must understand that testing is voluntary. Their informed consent should be obtained”. To accomplish informed consent, “healthcare providers must describe the features of the genetic test, including potential consequences, to potential test recipients” [Ref. (7), p. 12]. The Task Force emphasized this point: “The responsibility for providing information to the individual lies with the referring provider, not with the laboratory performing the test” [Ref. (7), p. 12]. To improve the chance that physicians will convey accurate information the Task Force recommended that, “Hospitals and managed care organizations . . . should request evidence of competence before permitting providers to order predictive genetic tests defined as needing stringent scrutiny or to counsel about them. Periodic, systematic medical record review, with feedback to providers, should also be used to ensure appropriate use of genetic tests” [Ref. (7), p. 67]. To improve the chances that physicians of the future would have a better grasp of genetics, the Task Force commented, “It will improve the likelihood that genetics will be covered in [medical school and specialty training] curricula if relevant genetics questions are included in general licensure and specialty board certification examinations, and if correctly answering a proportion of the genetics questions is needed to attain a passing score” [Ref. (7), p. 66].

**Appropriate Use of Genetic Tests by Consumers**

The state of the public’s knowledge of genetics was beyond the scope of the Task Force and this report. Suffice it to say that the Task Force had reservations about consumers obtaining genetic tests without the involvement of knowledgeable healthcare practitioners. It recommended that, “Consumers should discuss testing options with a healthcare provider competent in genetics before having specimens collected for analysis . . . The Task Force discourages advertising or marketing of predictive genetic tests to the public” [Ref. (7), p. 56].

**Conclusions**

At each stage in the transition between discovery of a gene and the clinical application as a predictive test, problems exist. Associations between genes and disease are not always replicated. Tests may become available to practitioners with insufficient data on their sensitivity and positive predictive value. Laboratories are not yet required to demonstrate their proficiency in performing molecular tests or the comprehensiveness or accuracy of the information they make available to practitioners or the public. Providers who order new genetic tests do not always know the proper indications. Nor are they always capable of interpreting the results correctly. In its report, the Task Force on Genetic Testing identified many of the problems in this transition and recommended solutions. Improvements are being made in laboratory quality. The creation of the Secretary’s Advisory Committee on Genetic Testing may lead to other improvements.

For obvious reasons, commercial test developers will resist government regulations that might impede the speed with which their products reach the market or restrict the size of those markets. From the problems encountered thus far, I cannot conclude that the public is well-served by a laissez-faire policy. In one area in particular, a simple change in Federal policy could correct many of the problems: the FDA could regulate tests marketed as services the way it markets other medical devices, including tests marketed as kits. The Task Force
could not reach consensus on this recommendation, but a majority agreed that the FDA’s proposed regulation on analyte specific reagents (since issued)—requiring manufacturers of such reagents to register with the FDA and to follow good manufacturing practices—did not address the problem (26).

Despite the publicity given to new tests, it is not evident that the FDA would immediately be flooded by a host of applications or that it would have to deal with a tremendous backlog. If this were to happen, the Agency could set priorities for review by using criteria for “stringent scrutiny” as suggested by the Task Force. I do not think there will be a deluge. Because of the difficulties of establishing new genetic tests with current technology; relatively few companies are investing in it (6). With the development of oligonucleotide chips and other advances, the technology is likely to change, and more manufacturers may be drawn in. One could argue that the FDA could wait until then, particularly because chip technology lends itself to kit development more than the current technology, which often involves some sequencing. If chips were marketed as kits, they would be covered by current FDA policy. However, many people are being exposed to genetic tests marketed as services, and even chips may be marketed that way. If the FDA is to live up to its commitment to assure that medical devices, which include genetic tests whether marketed as services or kits, are safe and effective it will need to extend its regulatory authority. If this policy change were to be made, commercial developers will discover, I believe, that the market for their tests will expand as the doubts that consumers and providers have about their benefits and risks are removed.

References