Comments on the DRAFT Resolution on Direct-to-Consumer Marketing of Genetic Tests
Presented to the Secretary's Advisory Committee on Genetics Health and Society

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By
Gail Javitt
Policy Analyst
Genetics and Public Policy Center
Johns Hopkins University[1]

The analysis of DTC marketing of genetic testing must clearly distinguish between advertising of genetic tests on the one hand and commercial availability of these tests on the other. Each of these activities is subject to distinct systems of regulation and amenable to different possible policy solutions.

With respect to advertising, the Draft Resolution rightly identifies the FTC as potentially playing a key role in preventing companies from making misleading claims about genetic tests. But, while FTC has a broad statutory mandate to protect consumers, this mandate is circumscribed by two factors. First, FTC may prohibit only advertising that is false or misleading. While establishing the falsity of some genetic test ads would likely be neither difficult nor a matter of debate, as to others both ambiguity and disagreement can be expected. Concerns about the impact of DTC ads on consumers unrelated to their truth or falsity would not likely provide a basis for FTC intervention. Indeed, the government is significantly constrained by the First Amendment in regulating truthful commercial speech.

Second, FTC must choose its enforcement actions carefully, based on the nature and magnitude of the harm caused by the advertising in question. Evidence of this nature does not currently exist with respect to DTC genetic testing. We therefore recommend that the Committee consider ways to foster data gathering concerning the harms – and benefits – of DTC advertising to consumers -- data which then could be provided to the FTC and used as a basis for that agency's involvement.

With respect to commercial distribution, the Draft Resolution recommends that "genetic tests should not be sold directly to consumers without the informed guidance of an appropriately trained health care professional." Some will view this position as unduly restricting patient choice. Others may feel that such guidance should be required only for certain types of tests, such as those that predict serious disease. Some will also question whether health care professionals are adequately prepared to provide guidance and interpretation of genetic tests.

These are all important issues for the Committee to consider, but these comments are intended to address whether, as a practical matter, there is a means of effectively

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implementing the Committee's recommendation. Currently no federal or state entity regulates when or under what circumstances genetic testing services may be commercially offered to consumers or to health care providers. It is therefore unclear from the Draft Resolution what entity would now have the authority to implement this recommendation.

The Draft Resolution recommends that FDA enhance oversight of genetic tests while acknowledging FDA's currently limited oversight of most genetic testing. FDA regulates genetic test kits that are sold as freestanding products, and not genetic testing services provided in-house by clinical laboratories. FDA has therefore had the opportunity to review only a few DNA-based genetic tests, even though genetic tests are available for more than 700 genetic diseases. This is not the first committee to identify FDA as an appropriate body to provide more substantial oversight for genetic testing, and we do not disagree that FDA involvement could be both beneficial and consistent with the agency's broad public health mission. But we question FDA's willingness to step into this arena without a clear mandate to do so, particularly in the absence of more concrete evidence of consumer harm.

The Draft Resolution fails to mention another key player in genetic test oversight. The Center for Medicare and Medicaid Services administers the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that provide commercial genetic testing services are covered by this statute. Despite recommendations from advisory groups, CMS has not yet issued any proficiency testing standards for most genetic tests. In enacting CLIA, Congress recognized the crucial public health role played by clinical laboratories. More rigorous oversight of genetic testing laboratories under CLIA could enhance public health protection.

The federal government has not invested in any entity the ability to serve as a "gatekeeper," meaning to decide when and whether genetic tests possess sufficient validity or utility to be used in the clinical setting. This is in contrast to the situation for many other clinical tools used by health care providers to diagnose and treat patients. Some argue that increased government involvement in genetic testing is neither necessary nor desirable. Others believe that, given the increasing importance that genetic testing is assuming in health care, this gap in oversight is a threat to public health. This Committee could play an important role in identifying the benefits and drawbacks of a more rigorous system of oversight.

The Draft Resolution rightly identifies several areas of potential concern related to DTC genetic testing. At the same time, much remains unknown about the DTC enterprise. Is this a trend that will continue to grow? What is the impact of DTC testing today and what can we predict about its future impact on consumers? Sound policy formulation in the months and years ahead on this issue will be greatly facilitated by sound empirical evidence. Thus, it is important that this Committee identify the entities best equipped to gather such data and foster a mechanism for gathering these data and studying these issues.

In summary, we recommend that attention be given not only to the dubious claims made for some genetic tests but to preventing genetic tests of dubious value from getting on the market in the first place. To that end, we offer the following suggestions. First, the Committee should foster data collection concerning consumer impact of DTC genetic testing, including whether and to what extent consumers are obtaining genetic testing through DTC means, whether such tests are causing harms or providing benefits to consumers, and the nature and magnitude of such harms and benefits. Second, the Committee should consider how CLIA could be harnessed to provide greater oversight of laboratories providing genetic testing services. Third, the Committee should identify the current barriers to greater FDA involvement in genetic testing oversight and consider means to overcome these barriers. Finally, the Committee should consider the merits and drawbacks of a federal oversight entity that would set standards that genetic tests must meet before they are made commercially available.