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FDA’s Warning Letter to 23andMe: Ethical and Legal Issues

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The FDA’s warning letter to **23andMe,** the maker of mail-order genetic tests, highlights the challenging legal and ethical issues posed by such products. While the FDA’s letter focuses on charges that (a) 23andMe’s DNA collection kit is an adulterated **Class III medical device** because it has not obtained prior regulatory clearance, and (b) the product is misbranded because 23andMe has failed to provide adequate evidence that its product provides accurate results, the situation raises additional questions.

For example, should direct-to-consumer medical genetic testing (DTCMGT) be regulated as “the practice of medicine”? To date, DTCMGT, which takes place outside of the traditional medical setting, has not been subjected to state law regulatory requirements applicable to “the practice of medicine” imposed on medical providers. Such requirements could assure involvement of a genetics professional in the testing, which could reduce risks of inadequate informed consent, misinterpretation of results, lack of follow-up care, and other potentially adverse consequences.

Whether or not DTCMGT is regulated as the practice of medicine, many urge that more attention needs to be paid to assuring that consumers are fully informed about what the test can and cannot disclose about their health. Most DTCMGT genetic tests do not give a definitive answer as to whether an individual will develop a condition. They provide only a risk or probability of developing a disease—and the interpretation of such results is often highly nuanced and may need to be communicated to the consumer in an appropriate context and in an understandable fashion that is linguistically and culturally appropriate.

Finally, privacy concerns need to be adequately addressed. Prior to testing, the consumer should be told about who will have access to the test results, what security is in place to protect the test information, and what potential impact the results could have on family members.

FDA’s action opens up much-needed discussion on a number of critical issues. Let the debate begin

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