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Federal government says regulation of consumer genetic tests is unnecessary

Industry forecasts indicate that Canadians will soon face a marketing avalanche to persuade them to purchase personal genetic test kits. But while American officials are moving to regulate do-it-yourself genetic testing kits because of concerns that results may be erroneous or may prompt patients to alter their medications or make other unhealthy choices, Health Canada says it is open season for companies hunting for Canadian sales.

With at least 19 companies marketing personal test kits costing as little as $300, and United States government investigators reporting widespread marketing fraud, that's left several geneticists and clinicians debating whether a patient's right to have information about their individual genomes could trigger harm from misleading information obtained from do-it-yourself genomic tests.

"It's likely to cause anxiety and misunderstanding," warns Dr. Tom Hudson, president and scientific director of the Ontario Institute for Cancer Research in Toronto, Ontario. "I can see harm that can come from this."

Hudson says the ability to capture genomic data from patients has now far outstripped the capability to interpret such data and put it to valid clinical use.

In many instances, particularly cancer-related tests, tests should only be done in clinical settings, he says. "The testing technology is moving far faster than our ability to use the data from such tests."

Many observers predict a tsunami of genetic data — often of dubious quality and little practical use — is roaring towards clinicians, researchers and electronic health records managers.

"In 10 years, a routine part of patient data will be their genome and, together with other information, we'll be able to chart and predict a lot about your future health and optimalize your strategy for wellness," Leroy Hood, president of the Institute for Systems Biology in Seattle, Washington, predicted at a mid-September symposium convened by the Gairdner Foundation. "We'll have a handheld device that can make 2500 blood protein measurements from each of 50 different organs to assess longitudinal cell health. … I envision a time perhaps 10 years in the future when every single patient will be surrounded by millions of data points."

Some researchers, though, see opportunity in the explosion of genetics data. Ontario health administrators might want to "prepare for whole genome sequencing of everyone in the province," in the interest of promoting genetics research, said Lon Cardon, senior vice-president, genetics for GlaxoSmithKline.

But while geneticists salivate at the prospect of vast new data pools, many fret that the brave new world of personal genomics will create chaos for patients and clinicians, rather than improved health care.

Regulatory gaps must be closed to protect consumers from unrealistic claims and misinterpretations of complex genomic information, argued the US Secretary's Advisory Committee on Genetics, Health, and Society (http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf).

The Government Accountability Office, meanwhile, revealed in its *Direct-to-Consumer Genetics Tests* report that 10 of 15 companies that it investigated were engaged in some form of fraudulent marketing practices (www.gao.gov/new.items/d10847t.pdf). Two of the companies even suggested an individual could surreptitiously test a loved one, which is illegal in some states.

Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, says personal genetics tests are also a worry. He estimates as many as 700 laboratories currently offer such tests, and as many as 5000 different test methodologies are employed by labs. In earlier testimony to Congress, Shuren said FDA investigators observed faulty lab data analyses, exaggerated clinical claims, fraudulent data, poor clinical study design and a lack of traceability.

But Shuren says the scale of the lab-based personalized genetic testing industry is now dwarfed by the direct-to-consumer industry, which is penetrating major drug chains and the internet. "None of the genetic tests now offered directly to consumers has undergone premarket review by FDA to ensure that the test results being provided to patients are accurate, reliable, and clinically meaningful."

The FDA recently warned 19 companies that it considers genetic tests as meeting "the statutory definition of a medical device," which would make them subject to full regulatory review. The FDA is also examining standardization of direct-to-consumer tests (www.cmaj.ca/cgi/doi/10.1503/cmaj.109-3669).

In Ottawa, Health Canada is taking a far more relaxed approach. Personal test kits are "neither prohibited by law, nor subject to federal regulation," said spokesperson Christelle Legault in an email.

But the department's stance is dramatically different — and far more cautious — with regard to genetic tests employed by drug developers. All devices intended to be used for pharmacogenetic testing "are classified as Class III medical devices and require a pre-market scientific assessment of [their] safety and effectiveness," federal guidelines stipulate, (www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/pharmaco/pharmaco_guid_ld-eng.php).

Such genetic testing devices must be licensed or authorized "if the test results are to be used for diagnostic purposes, patient management, or are to be submitted to Health Canada in support of a clinical trial application or drug submission" as the devices may have "a profound impact on the safety and effectiveness of the drug for which the assay/test is performed," the guidelines add. — Paul Christopher Webster, Toronto, Ont.

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