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RECENT FDA ACTIONS ON LDTs AND GENETIC TESTING: Where Have We Been and Where Are We Heading?

BY PETER M. KAZON

On June 17 of this year, the Food and Drug Administration (FDA) announced it was going to hold a two day meeting on July 19-20, the subject of which would be ''Oversight of Laboratory Developed Tests (LDTs).''[1] That announcement was the latest in a series of actions focusing on the rapidly expanding area of LDTs, a type of laboratory test that often includes genetic tests and some ''direct to consumer'' (DTC) tests. While no one can say for sure where the FDA is heading, this announcement and the meeting that followed, may suggest the beginning of a new chapter in FDA's oversight of an important form of laboratory testing in this new age of ''personalized medicine.'' Set out below, we discuss some background on the FDA's past efforts, what has happened more recently, and where we may be heading.

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FDA's Past Efforts With Regard to LDTs

To understand the significance of recent events, it is important to understand how laboratory tests are developed and used today. Currently, clinical laboratory tests are offered through two different pathways. In some cases, a medical device manufacturer may create a ''test kit,'' which includes the reagents, supplies, and a

[1] 75 *Fed. Reg.* 34463 (June 17, 2010).

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''package insert'' that describes the intended use of the test and how to perform it. These test kits are usually considered to be medical devices, subject to the FDA's oversight under the Food Drug and Cosmetic Act (FDCA).[2] If not otherwise exempt, they will either be cleared through FDA's 510(k) process or approved under a Pre-Market Approval.

Clinical laboratories can also develop tests for their own use ''in house.'' While the laboratory performs tests using these LDTs, it does not sell an actual test kit. It simply uses the LDT when performing the test in-house. Because the LDTs are only used ''in-house,'' and are not sold in commerce, there has always been a question of whether LDTs are subject to FDA jurisdiction. While FDA has noted at times that laboratories developing LDTs were, in fact, subject to FDA oversight, it also stated it would exercise its ''enforcement discretion'' with regard to such tests.[3] In announcing the June meeting on LDTs, the FDA described its past policy this way:

> Since the implementation of the 1976 Medical Device Amendments, the FDA has generally exercised enforcement discretion and not enforced applicable regulations with respect to LDTs, a class of *in vitro* diagnostics (IVDs) that are manufactured, including being developed and validated, and offered within a single laboratory. Thus, the FDA has not actively regulated most LDTs.[4]

The laboratories offering LDTs were still subject to regulation under the Clinical Laboratory Improvement Amendments (CLIA), a separate regulatory scheme that applies to virtually all clinical laboratories, but which is enforced by the Centers for Medicare & Medicaid Services (CMS), rather than FDA. Under CLIA, clinical laboratories must comply with a broad set of regulatory requirements, applicable to certification, personnel, quality control, proficiency testing and other quality assurance regulations.[5]

After the mapping of the human genome was completed in 2003, new genetic tests began to be developed, many of which were initially developed as LDTs. The growth of this testing led to increasing attention, both from FDA itself and industry stakeholders. For example, in 2006, the FDA issued a draft guidance document in which it noted a concern about a new type of LDT, which it termed ''*In Vitro* Diagnostic Multivariate Index Assays'' (IVDMIAs), a sophisticated test that analyzed numerous pieces of genetic information and then determined a particular result for a patient.[6] After receiving comment, it issued a revised draft of the Guidance in July 2007 (1 MELR 328, 8/1/07).[7] In describing IVDMIAs, FDA used the example of gene expression profiling tests for breast cancer prognosis – a test that analyzes tumor tissue to determine the likelihood of a patient's breast cancer recurring. FDA noted that physicians (and patients) might be unclear about the uses and limitations of IVDMIAs; therefore, they might use the results to make critical health care decisions, even though FDA had not assured their accuracy or validity.

The IVDMIA Guidance evoked numerous comments and has never been issued as a final Guidance. While the FDA has not specifically withdrawn the Guidance, recent statements by FDA officials have focused on a broader, risk-based approach. Jeff Shuren, Director of FDA's Center for Devices and Radiological Health (CDRH), was quoted recently that the agency did not intend to proceed ''subset by subset,'' but would instead address all LDTs, a statement that suggests it was taking a different approach than was demonstrated by the Draft IVDMIA Guidance.[8]

In addition to FDA's action, other industry stakeholders also weighed in on the need for FDA regulation. For example, in December 2008, a major biotechnology company, Genentech, Inc., filed a Citizen Petition (3 MELR 53, 1/28/09) in which it urged FDA to exercise jurisdiction over LDTs, just as it did with other forms of in vitro diagnostic products.[9] To date, FDA has taken no action on the petition, however.

With the arrival of the Obama Administration and new leadership at the FDA, it was widely expected that LDTs and genetic testing could be the subject of even greater FDA interest.

The Pathway to Personalized Medicine

One of the first signals that the FDA might take a new look at LDTs occurred earlier this year when FDA Commissioner Margaret A. Hamburg, M.D., and the Director of the National Institutes of Health, Francis S. Collins, M.D., Ph.D., published a ''Perspective'' column in the *New England Journal of Medicine*, entitled ''The Path to Personalized Medicine.''[10] In that article, Dr. Hamburg and Dr. Collins acknowledged the great opportunities in clinical medicine resulting from the growth of personalized medicine and noted the importance of accurate diagnostic testing to identify patients who can benefit from new targeted therapies. However, they also expressed concern about the way in which some of these new tests were being used and marketed. For example, they stated that ''many laboratories have begun performing and broadly marketing laboratory-developed tests, including complicated genetic tests.'' The results of these tests were quite challenging to interpret, according to the article, which also noted the importance of ensuring the accuracy of the results in the first instance. Drs. Hamburg and Collins also

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[2] 21 U.S.C. § 321(h).

[3] E.g., 62 *Fed. Reg.* 62243, 62249 (Nov. 21, 1997) (FDA Regulation on Analyte Specific Reagents); *see Draft Guidance for Industry, Clinical Laboratories, and FDA Staff*, In Vitro Diagnostic Multivariate Index Assays (July 26, 2007), at 2, *available at* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071455.htm (hereinafter ''IVDMIA Guidance'').

[4] FDA, Notice of Public Meeting: Oversight of Laboratory-Developed Tests (LDTs), http://www.FDA.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm (hereinafter ''FDA Meeting Announcement'').

[5] 42 U.S.C. § 263a; 42 C.F.R. 493.1 *et seq.*

[6] 71 *Fed. Reg.* at 52800.

[7] The 2007 version of the Guidance is available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071455.htm.

[8] A. Bouchle, ''PGx: Back to the Drawing Board,'' *BioCentury: The Bernstein Report on BioBusiness*, A10 (June 28, 2010).

[9] Citizen Petition filed by Genentech, Inc., Dkt. No. FDA-2008-P-0638-001 (filed Dec. 8, 2008), *available at* http://op.bna.com/hl.nsf/r?Open=bbrk-7nnne2 or http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064807d4a7e.

[10] The original version appeared online; however, the published version is: M. A. Hamburg & F. S. Collins ''The Path to Personalized Medicine,'' 363 *The New England Journal of Medicine* 301 (July 22, 2010).

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pointed out that in many instances FDA had not reviewed the scientific justification for the claims made, even though physicians might use the test to guide therapy.

The article also highlighted that there was no single public source of comprehensive information about the more than 2,000 genetic tests currently available through clinical laboratories. It stated that NIH, with the assistance of FDA and HHS, was planning on creating a voluntary genetic test registry to address some of these key information gaps. Increased information about this testing, including whether or not the tests were approved or cleared by the FDA would, according to Drs. Hamburg and Collins, help clinicians and consumers make informed decisions about using these tests.

As noted in the *New England Journal* article, the NIH had announced its plans to begin a voluntary genetic test registry, which would compile information about the various genetic tests that were available, including FDA cleared and approved tests and LDTs.[11] In that Notice, the NIH stated that it believed that transparent access to information on genetic tests was vital to facilitate research and allow informed decision-making by health care providers and patients. Therefore, NIH stated it planned to develop a test registry, to which researchers, developers and manufacturers could voluntarily submit test information. In its request for information (RFI), the NIH sought input from key stakeholders on the various data that should be included, and its potential uses. A week after the RFI was published in the *Federal Register*, the FDA announced its plans for the July meeting on LDTs.[12]

Direct to Consumer Genetics

About the same time, however, a separate development had occurred, which changed the focus of the discussion. On May 11, 2010, the *Washington Post* carried a front page story reporting that Pathway Genomics, a clinical laboratory in San Diego, planned to sell a genetics test directly to consumers through Walgreen's drugstores.[13] According to the article, the test would offer patients a chance to scan their genes to determine ''the chances of becoming obese, developing psoriasis and going blind. For those thinking of starting a family, it could alert them to their risk of having a baby with cystic fibrosis, Tay-Sachs and other genetic disorders.'' The test also promises users insights into how caffeine, cholesterol-lowering drugs, and blood-thinners might affect them.

The announcement was met by concern from numerous sources, including the FDA. The *Washington Post* article quoted Dr. Alberto Gutierrez, Director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, who said there were questions about the lawfulness of Pathway's plans. Company officials, on the other hand, stated that it was their understanding that the test did not have to have FDA approval because the test was done in its own laboratory. Shortly thereafter, however, the FDA sent a letter to Pathway, suggesting that the marketing for the test was a violation of FDA requirements, and Walgreens and Pathways subsequently announced that they were withdrawing plans to offer the test.[14]

Shortly thereafter (4 MELR 417, 6/16/10), FDA also announced that it had sent letters to other companies who offered DTC genetic testing, including 23andMe, Navigenics, deCODE Genetics, Knome and Illumina.[15] In the letters, FDA took particular note of the types of testing claims that were made by the companies. For example, the letter to Navigenics noted that the Company's test purported to offer patients personalized medicine information detailing which medications might work best for someone with the individual's genetic make-up. The letter to 23andMe noted a similar claim and the patient's risk for certain diseases. In the letter to Knome, FDA concluded that the company's tests did not qualify as LDTs because they were not developed by or used within a single laboratory. The letter to Illumina, a maker of a microarray chip that permits the analysis of a large amount of genetic information, raised other issues. While Illumina did not perform testing, it sold its chip to laboratories like 23andMe and deCODE Genetics, for their use. Even though the chip was labeled ''RUO'' or ''Research Use Only,'' the FDA alleged that Illumina was providing the chip to these laboratories knowing that it would be used for their patient testing. Subsequently, the FDA sent out a second set of letters in July to other makers of genetic tests, which were also sold directly to consumers.[16] All of the companies involved offered tests that were supposed to help consumers learn about their genetic predispositions to particular diseases and health conditions.

The FDA was particularly public about its position with regard to the DTC testing. Dr. Gutierrez spoke to the press about the decision of the FDA to send letters to the DTC companies. He noted that the claims being made for the DTC tests had become of far greater concern in the past year, pointing to the claims about how different drugs were metabolized as a particular reason for concern. According to Dr. Gutierrez, such claims were far more significant—and more of a risk to patient safety—that the vague claims that had been made in the past. Second, he made a clear distinction between testing offered directly to consumers and other types of LDTs. In an interview with *The Gray Sheet*, Gutierrez stated ''once a patient, rather a physician's office is tasked with taking the sample, all arguments that a product is not an FDA-regulated IVD go out the window.''[17]

The FDA's concern about direct-to-consumer testing was echoed in Congress as well. The Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, chaired by Rep. Bart Stupak (D-Mich.), held a hearing related to DTC testing on July 22 (4 MELR 529, 7/28/10). Virtually all members of the Subcommittee expressed concerns about the accuracy

[11] 75 *Fed. Reg.* at 33317 (June 11, 2010).

[12] 75 *Fed. Reg.* at 34463 (June 17, 2010).

[13] ''Company Plans to Sell Genetic Testing at Drugstores,'' *Washington Post* (May 11, 2010).

[14] ''Walgreens won't sell over-the-counter genetic test after FDA raises questions,'' *Washington Post*, May 13, 2010.

[15] The letters are available at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default.htm.

[16] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm219582.htm.

[17] ''FDA Cites Long-Term Precedent in Blocking Retail Genetic Screening Plans,'' *The Gray Sheet*, May 14, 2010; ''Why the FDA is Cracking Down on Do-It-Yourself Genetic Tests: An Exclusive Q&A,'' *available at* http://tinyurl.com/24ndvha.

of these DTC genetic tests and the types of claims being made for them.

Among those testifying at the hearing were representatives of the Government Accountability Office (GAO), which reported on an informal investigation it had performed of companies offering DTC genetic testing. It purchased tests from four companies offering this information, and then sent two DNA samples from five different people to each company. One person's submission used factual information and the other used fictitious information, such as incorrect age, race or ethnicity. Representatives then made calls to the companies seeking health care advice based on the test results. The results received and the information provided varied widely, causing GAO to conclude that consumers received ''test results that are misleading and of little or no practical use.''[18] Representatives of the testing companies also testified at the hearing but had difficulty responding to GAO, as they had not been provided the GAO report before the hearing. Subsequently, they responded that they found the report ''deeply flawed,'' but acknowledged the importance of working with the FDA going forward.[19]

The road ahead for DTC genetics looks particularly unsettled, based on this recent history. The questions related to accuracy are certainly disturbing; however, more significant from a legal standpoint may be the clear distinction that FDA is now making between direct-to-consumer tests and other types of LDTs.

FDA Meeting on LDTs

The FDA's July meeting on LDTs was a wide-ranging discussion, designed to review numerous issues involving LDTs (4 MELR 530, 7/28/10). In its initial meeting announcement, FDA had stated that LDTs had changed significantly over the past few years. Today, according to FDA, LDTs used complex elements that were not FDA regulated, but ''are often used to assess high-risk but relatively common diseases and conditions and to inform critical treatment decisions and are often performed in geographically distant commercial laboratories instead of within the patient's health care setting under the supervision of a patient's pathologist and treating physician.''[20] While FDA recognized that the lack of FDA oversight makes it easier for laboratories to develop and offer tests on a rapid timeline, it expressed concern that it may also have created an unlevel playing field with other device manufacturers. As a result, FDA stated that it had concluded that ''it should exercise its authority over LDTs.'' However, it noted that the implementation of oversight required careful consideration so that patients would receive the benefits of innovative, yet safe and effective, diagnostic tests. This policy, according to the FDA, should ''encourage innovation, improve patient outcomes, strengthen patient confidence in the reliability of these products and may help reduce health care costs.''

The agenda for the meeting provided some insight into the types of issues that were likely to concern the agency. The morning of the first day was devoted to statements and explanations from key FDA officials, who had been active in the issues involved. Then, four different panels were planned for the next day and a half, focusing on the following four areas:

- Patient and clinical considerations
- Clinical laboratory challenges
- DTC testing
- Education and outreach

All of the panels were moderated by a government official outside of FDA and included key industry and public interest representatives. While the meeting did not resolve the key issues that are likely to face the FDA if it determines to move into this area, it did at least highlight the scope and difficulty of the FDA's task.

Not surprisingly, the statements from the FDA that began and ended the meeting have been the subject of the most scrutiny and analysis. At the meeting, Dr. Shuren welcomed attendees and noted that while the FDA had decided to exercise its oversight of LDTs, no decision had been made as to how that should move forward. He assured attendees that there would be ample opportunity for public review and comment before the FDA acted, and he noted that the opportunity for written comment would continue until August 15. (The comment due date was extended until September 15 in an August 19 *Federal Register* notice.)

Dr. Shuren was followed by other FDA staff. First, Courtney C. Harper, Ph.D. of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, presented an overview of the FDA's history with LDTs. She outlined the evolution of the FDA's position beginning with the 1976 Medical Device Amendments. As with other FDA members, she also emphasized the changes that occurred with LDTs, noting that the volume of such tests had grown significantly and that LDTs were now frequently the mechanism by which new tests came to market. According to Dr. Harper, the tests are often broadly advertised and aggressively marketed to clinicians. They often require complex software, use automated interpretation and rely on complex statistical methods or algorithms for the results. In addition, she noted ''LDT'' was a self-determined term; that is, laboratories decided whether they qualified and they did not always apply the term in the same way. Finally, she commented that in the current landscape, laboratory tests were increasingly important tools, because they were often used in connection with personalized medicine and companion diagnostics.

Also speaking on behalf of the FDA was Dr. Elizabeth Mansfield, head of the Office of Personalized Medicine at FDA. She pointed out that testing has entered a new era of molecular diagnostics and personalized care, and that the public needs assurances that diagnostics were sound and reliable. Dr. Mansfield acknowledged that LDTs provided value, especially in creating tests for unmet needs, but she offered that FDA oversight could also add value, by providing greater assurances of predictability and uniformity. The current meeting was, she noted, part of a reassessment of FDA's ''bifurcated regulatory strategy in this area.'' According to Dr. Mansfield, there is little difference today between LDTs and traditionally commercially distributed IVDs; how-

[18] GAO, ''Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices,'' Rep. No. GAO-10-847T (July 22, 2010).

[19] *See* ''Working with Regulators—the Road Ahead,'' http://blog.Navigenics.com/articles/new_form_navigenics_genetic_insights_to_help_you_understand_which_medications_work_best_for_you (last visited Aug. 9, 2010).

[20] FDA Meeting Announcement.

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ever, under the current approach, FDA believes there is an ''unlevel playing field where laboratories and manufacturers are subject to different requirements.'' She emphasized that FDA had not made any final decision concerning how to proceed in this area, but they were sensitive to the need to assure that LDTs were safe and effective, while at the same time, facilitating innovation. She acknowledged the importance of avoiding duplication with CLIA, and opined it may make sense to use CLIA as part of the FDA process.

Like other speakers, Dr. Mansfield emphasized that FDA should use a risk-based classification system, which it uses for other medical devices. In making such assessments, she noted the most important question would be: How would an undetected or a false result affect the patient? She gave a broad outline of how FDA might classify the risks involved. If there were a risk of serious injury or death from a false result, or if it was difficult to detect a false result, then the test might be considered high risk. As examples, she gave companion diagnostics (i.e., where a test is used to predict who will benefit from a particular drug), cancer diagnosis tests, tests that direct or very strongly influence patient management of serious diseases, and tests for serious or fatal communicable diseases. Tests that would pose a lower risk would be those where false results would result in non-serious injuries; tests for which it would be relatively easy to detect a false result; or those tests that were adjunctive to other diagnostics. As examples of this category, she listed tests where the characteristics of the genetic marker were already well-known, tests where multiple findings are used to direct clinical management, and tests used to monitor already detected disease. Finally, she said the lowest risk was presented by those tests where there is little potential for injury; where it is easy to detect a false result; or those that were highly adjunctive. This lowest category would include those tests that identify one among several defining characteristics of the tissue or cell, or tests that have little clinical impact.

Generally, Dr. Mansfield noted that a risk-based framework would be appropriate for all manufacturers and add value. Dr. Mansfield emphasized that although the decision had been made to move forward with some sort of review, what type of review had not actually been determined. Among the questions that needed to be addressed were: Who is offering what types of tests? What is the appropriate type of risk stratification? What would be the deadlines? What would be the inspection needs? She also recognized that FDA itself faced significant resource limitations that would have to be taken into account, and suggested FDA might consider using some type of third-party review to assist in this effort.

Following the FDA's presentations, there were four panel discussions and over 65 public comments from organizations representing laboratory organizations, physician groups, manufacturers, patient groups, and others. These comments touched on a wide variety of issues and ran the gamut of concerns. While some comments noted support for the FDA's action, there was equal support for a cautious approach, lest innovation and patients' needs be adversely affected. The breadth and number of comments only emphasized the enormity of the FDA's task.

What's Next?

While it is difficult to come up with any definitive conclusions about where the FDA is heading on LDTs, the meeting clearly identified some key issues that the FDA will have to face during the next steps in the process. Some of these include the following:

The Scope of the Task

Everyone seems to agree that it would be a huge undertaking if the FDA decided to approve or clear all LDTs on the market. Drs. Hamburg and Collins noted in their article that there are over 2,000 different types of genetic tests in use today.[21] Just regulating those tests would be a tremendous undertaking; however, even that underestimates what is involved. Because each laboratory develops its own LDT, FDA would have to review each laboratory's version of a particular test, even if many laboratories used similar methods and processes. That requirement could significantly expand the number of tests FDA has to look at.

Thus, FDA may have to exempt or ''grandfather'' certain tests currently on the market in order to streamline the process. Dr. Mansfield acknowledged in her presentation, for example, that FDA might ''down-classify'' certain devices that have already been approved, a process that presumably would also reduce the standards for any LDT that were similar. Alternatively, FDA might also use third-party reviewers to assist in the review effort. At least one organization, the College of American Pathologists (CAP), has suggested that the accrediting organizations that currently inspect laboratories could be part of that process.

Process

In the past, the FDA has always used guidance documents as the way to address these concerns, as it did with the IVDMIA guidance. Dr. Shuren was very specific at the July meeting that FDA did not believe that a notice-and-comment rulemaking was required because FDA was simply interpreting its current requirements and deciding how those rules applied to particular circumstances. Notwithstanding the FDA's objections, many in the industry may prefer a more formal rulemaking process than the FDA Guidance process.

Risk Stratification

All agreed that tests should be regulated based on the risks that they presented; however, defining risk in this context has always been extremely difficult. When the Secretary's Advisory Committee on Genetic Testing (SACGT) tried such an exercise, it could not do it, noting that ''Fundamental, unresolvable questions had been raised about the feasibility of categorizing tests for oversight purposes. . .''[22] In her presentation, Dr. Mansfield set out the most detailed analysis of the considerations that might be applied to stratify risk, but clearly applying these broad principles to specific fact situations will be extremely difficult.

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[21] Hamburg and Collins, at 303.

[22] Sec'y's Advisory Comm. On Genetic Testing (SACGT), Development of a Classification Methodology for Genetic Tests: Conclusions and Recommendations of the Secretary's Advisory Committee on Genetic Testing 11 (Sept. 2001), *available at* http://oba.od.nih.gov/oba/sacgt/reports/Addendum_final.pdf.

It also remains to be seen how FDA's current 510(k) clearance process and Pre-Market Approval process can be adapted to the LDT context. For example, LDTs are often modified over time to reflect new information that is learned. It is unclear how such modifications could be handled by FDA. In his testimony before the Energy and Commerce Committee on DTC testing, Dr. Shuren stated FDA understood these challenges and would consider an approach that would allow laboratories to respond quickly to new information.

Types of Evidence

Another key issue, which was frequently addressed at the meeting, was what type of evidence would FDA require to show the test actually worked. While the ''gold standard'' for evidence is usually considered randomized clinical trials, such trials are often time-consuming and expensive, and may not be appropriate for many diagnostic tests. As a result, stakeholders will likely watch carefully to see what FDA says about this issue and, in particular, what other types of evidence it will be willing to accept and credit.

Direct-to-Consumer Testing

Given the events of the past few months, it seems likely that direct-to-consumer testing will likely be the subject of increased scrutiny and potential regulation. The issues raised by the GAO in its report concerning the value of the tests performed and the inconsistency of results could be especially problematic for DTC providers.

CLIA

Laboratory representatives frequently noted in the course of the meeting that they were already subject to numerous inspections from outside organizations. The FDA appeared to recognize this fact, as well, and even suggested there might be a way to integrate the FDA inspection process with the CLIA process. One key question that went largely unexplored is the difference between the two regularly regimes: while the CLIA inspection process is designed to review the entire laboratory operation to ensure appropriate quality assurance and quality control, FDA inspection is really supposed to be a process focused specifically on the production of the LDT. Thus, even if the processes are integrated, as some suggested, it will still be important to distinguish between the different goals involved.

Timing

Whatever FDA does, it will take a great deal of time for FDA to establish its own apparatus to review these various tests and time for those currently marketing LDTs to come into compliance with whatever is suggested. Under the draft IVDMIA Guidance, FDA had proposed a one-year grace period for those IVDMIAs that were currently being marketed with another six months for FDA to review submissions. Even this period may be insufficient for an initiative as large as the one FDA appears to be considering.

The NIH Registry

While the NIH's Genetic Test Registry, discussed above, is supposed to be voluntary, it certainly seems possible that such a registry could become more important if FDA moves to regulate LTDs. In her presentation, Dr. Mansfield specifically pointed to the NIH's proposed registry as an element that would be helpful to FDA by identifying what tests were being offered and by whom.

Possible Legislative Action

It is also possible that the FDA will not be the final word on this matter. It has been reported that Sen. Orrin Hatch (R-Utah) has been working on legislation dealing with the appropriate regulation of genetic tests in this area, although nothing has been introduced. Reps. Patrick Kennedy (D-R.I.) and Anna Eshoo (D-Calif.) have introduced H.R. 5440, the Genomics and Personalized Medicine Act of 2010, which would, among other things, require FDA and CMS to establish a committee to review their respective requirements and determine ways to reduce duplication and regulatory burdens. Such legislation, if it were to become a reality, could overtake many of the FDA's activities in this area.

Conclusion

Clearly, FDA is looking at a new role in the rapidly developing area of personalized medicine. As FDA notes, its entry into this area promises both potential benefits and risks. While greater oversight could create greater certainty about the value of this testing, it could also reduce access to such tests, hinder innovation, and drive up costs. It remains to be seen how adept FDA is at walking that line.

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