

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2010N0274]

Oversight of Laboratory Developed Tests; Public Meeting; Request for Comments

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice of public meeting; request for comments.

Summary: The Food and Drug Administration (FDA) is announcing the following public meeting: Oversight of Laboratory Developed Tests. The purpose of the public meeting is to create a forum for interested stakeholders to discuss the agency's oversight of laboratory developed tests (LDTs). FDA is seeking input and requesting comments on this topic.

Date and Time: The public meeting will be held on July 19 and 20, 2010, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at Crowne Plaza Washington, DC - Rockville, 3 Research Court, Rockville, MD 20850. For directions, please contact the hotel 3018400200 or refer to the meeting web page at <http://www.fda.gov/Medical&fxsp0;Devices/News&fxsp0;Events/WorkshopsConferences/default.htm>.

Contact: Katherine Serrano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5613, Silver Spring MD 209930002, 3017966652, e-mail: Katherine.Serrano@fda.hhs.gov.

Registration and Requests for Oral Presentations: There is no registration fee to attend the public meeting. Registration can be completed online at <http://www.fda.gov/Medical&fxsp0;Devices/News&fxsp0;Events/WorkshopsConferences/default.htm>. Online registration is available until 5 p.m. on July 12, 2010. Persons without Internet access may call Katherine Serrano at 3017966652 by July 12, 2010, to register for the meeting. Early registration is recommended because seating is limited. If space permits, onsite registration will be permitted on a first-come, first-served basis.

Interested persons who would like to make a presentation during the meeting will be given 10 minutes to do so if they submit their request (either electronic or written) to the contact person at the address shown in the Contact section of this document, and to the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 (including name, title, firm name, address, telephone, and fax number). All requests should indicate in which of the four sessions of the meeting the person would like to

present. Persons who would like to present in multiple sessions should indicate this in their request as well as provide a prioritization of the sessions in which they would like to present. A copy of the material to be presented may also be submitted with requests. Depending upon the number of individuals and organizations that submit requests to present, the allotted time may be expanded or shortened to provide all interested parties an opportunity to present. Requests to present are to be identified with the docket number found in brackets in the heading of this document.

If you need special accommodations due to a disability, please contact Katherine Serrano (see Contact) at least 7 days in advance of the meeting.

Comments: FDA is holding this public meeting to provide a public forum in which it will hear presentations and comments from interested stakeholders regarding reasonable and effective regulation of LDTs. The comment period for this public meeting closes on August 15, 2010.

Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

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

Initially, laboratories manufactured LDTs that were generally relatively simple, well-understood pathology tests or that diagnosed rare diseases and conditions that were intended to be used by physicians and pathologists within a single institution in which both were actively part of patient care. These tests were ordinarily either well-characterized, low-risk diagnostics or for rare diseases for which adequate validation would not be feasible and the tests were being used to serve the needs of the local patient population. In addition, the components of traditional LDTs were regulated individually by FDA as analyte specific reagents or other specific or general reagents, and the tests were developed and offered in laboratories with certificates to perform high complexity tests under the Clinical Laboratory Improvement Amendments of 1988, which are laboratories that have extensive experience in complex laboratory testing. Today, while these tests are still performed in laboratories with high complexity certificates, they often use components that are not regulated individually by FDA, and they 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, or may be marketed directly to consumers. In addition, even when FDA-approved tests are available for a disease or condition,

laboratories often continue to use LDTs that have not been reviewed by the agency. Finally, an increasing number of LDT manufacturers are corporations rather than hospitals or public health laboratories, which represent a significant shift in the types of tests developed and the business model for developing them.

At the same time as LDTs are becoming more complex, diagnostic tests are playing an increasingly important role in clinical decisionmaking and disease management, particularly in the context of personalized medicine. However, LDTs that have not been properly validated for their intended use put patients at risk. Risks include missed diagnosis, wrong diagnosis, and failure to receive appropriate treatment. In April of 2008, the Secretary's Advisory Committee on Genetics, Health, and Society, in its report entitled U.S. System of Oversight of Genetic Testing, recommended that FDA should address all laboratory tests in a manner that takes advantage of its current experience in evaluating laboratory tests.

FDA also recognizes that while the absence of FDA oversight may make it easier for laboratories to develop and offer tests on a rapid timeline, the absence of a level playing field creates a competitive disadvantage and potential disincentive to innovation by other manufacturers whose tests are approved or cleared by the agency for similar indications. In addition, as set out above, it means that some diagnostics critical for patient care may not be developed in a manner that provides a reasonable assurance of safety and effectiveness.

In response to these public health concerns, the agency believes it is time to reconsider its policy of enforcement discretion over LDTs. The public must be assured that the tests used in the provision of health care, whether developed by a laboratory or other manufacturer, are safe and effective. However, The FDA recognizes that there are issues unique to the laboratory community that should be taken into consideration so that patients will receive the desired benefits of innovative, yet safe and effective, diagnostic tests. FDA recognizes the importance of implementing an oversight framework that fosters innovation in this area while assuring that such tests are safe and effective. For example, the field of genomics and genetic testing has the potential to revolutionize patient care. As a second example, fostering innovation in tests for rare diseases and conditions is another important public health concern. In these and other categories, it is important that FDA provide a reasonable, predictable, and consistent regulatory policy for ensuring the safety and effectiveness of LDTs and provide sufficient time for implementation. Therefore, this policy should encourage innovation, improve patient outcomes, strengthen patient confidence in the reliability of these products, and help reduce health care costs.

At this time, FDA believes that a risk-based application of oversight to LDTs is the appropriate approach to achieve the desired public health goals and would like to hear from stakeholders, including laboratory professionals, clinicians, patients, and industry, as we develop our draft oversight framework, to define the issues that pose the greatest concern to the public health. The public meeting announced in this notice will serve as a forum to discuss issues and stakeholder concerns surrounding LDT oversight. Following the public meeting and the close of the public docket the FDA will move forward expeditiously to develop a draft oversight framework for public comment to provide predictability as quickly as possible. The FDA also intends to phase in such a framework over time based on the level of risk of the test.

II. Agenda

FDA will start the public meeting with a series of presentations introducing the history and current regulatory status of LDTs. The remainder of the meeting will be divided into four sessions highlighting areas in which FDA hopes to gain public input from critical perspectives in response to its proposal to develop an oversight framework, as well as to hear stakeholder opinions on which issues around laboratory developed testing present the greatest concern to the public health. These sessions include the following: (1) Patient Considerations, (2) Challenges for Laboratories, (3) Direct to Consumer Marketing of Testing, and (4) Education and Outreach. Each session will consist of approximately 2 hours of public presentations focused on the session topic followed by an expert panel discussion and a question-and-answer period. This public meeting agenda will be available on the Internet at <http://www.fda.gov/Medical&fxsp0;Devices/News&fxsp0;Events/WorkshopsConferences/default.htm>.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/Medical&fxsp0;Devices/News&fxsp0;Events/Workshops&fxsp0;Conferences/default.htm> approximately 45 days after the meeting. The transcript may be viewed at the Division of Dockets Management (HFA305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CDROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 630, Rockville, MD 20857.

Dated: June 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 10????? Filed ?????10; 8:45 am]BILLING CODE 416001S

[FR Doc. 2010-14654 Filed 06/16/2010 at 8:45 am; Publication Date: 06/17/2010]