Insight

Primer: FDA and Regulation of Laboratory Developed Tests

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Laboratory Developed Tests

Laboratory Developed Tests (LDTs) are *In Vitro* Diagnostics (IVDs) that are designed, developed, manufactured, and used entirely within a single laboratory.[1] IVDs are a broader class of tests performed on biological samples such as blood or tissue.

Confusion in Regulation of LDTs

There is quite a bit of dispute over which agency should properly regulate LDTs. The Centers for Medicare and Medicaid Services (CMS) has jurisdiction over clinical laboratories and the clinical testing process, while the Food and Drug Administration (FDA) has jurisdiction over commercial medical devices.[2]

CMS regulates LDTs under the Clinical Laboratory Improvement Amendments of 1998 (CLIA).[3] CMS oversees the laboratories themselves, as well as the process applied to tests performed in the laboratory – they regulate the quality of the outcome of the tests, not the equipment used to perform them.

The FDA regulates devices, or "articles, instruments, machines or *in vitro* reagents" used in the collection, preparation, and examination of specimens of the human body.[4] However, it has been understood that (as with off-label drug use) the FDA does not have the power to regulate how devices are used. That authority is granted to CMS under CLIA.[5]

Laboratory representatives emphasize that tests are processes, not devices.[6] Most laboratories purchase medical devices from FDA regulated device manufacturers. The manufacturer must obtain FDA approval to sell the device, and the lab must have CLIA approval to use it. However, according to historical understanding of the law, the lab does not need FDA approval to make changes to the device so long as it is not resold or used outside the CLIA approved lab.[7] This separation of CLIA and FDA approvals allows experts to adapt quickly and keep expenses relatively low.

Changing Use of LDTs

Historically, LDTs were left exclusively to CLIA because they were used in-house by medical professionals.[8] More recently, developments in technology have made direct-to-consumer testing available.[9] Unlike other at-home testing kits, such as thermometers or pregnancy tests, where results are immediately available to the consumer and therefore firmly under FDA control as medical devices, these new LDTs are sent to the consumer to provide a sample (typically a cheek swab) and then mailed back to the lab for testing. The results are produced entirely within the lab and then sent directly to the consumer.[10] Though these tests are not intended to diagnose particular symptoms or diseases, they can provide detailed genetic information.

The FDA has responded to this development by attempting to bring LDTs under its regulatory control to manage the "risks".[11] The FDA argues that individuals may use this knowledge of their personal genomic make-up when considering their health risks and when or how to seek health care. A recent Congressional Research Service report supports the FDA's decision by explaining that "the public needs assurances that LDTs are sound and reliable."[12] This position is also defended by the Government Accountability Office by arguing that direct-to-consumer LDTs are "of little or no practical use to the consumer."[13]

The American Clinical Laboratory Association has argued that LDTs approved by CMS under CLIA but exempt from FDA requirements are able to be used to help patients years sooner than if they were subject to the FDA's more stringent and duplicative controls.[14]

[1] http://fas.org/sgp/crs/misc/R43438.pdf