FDA Ignores CLIA and Moves to Regulate Clinical Laboratories

The Food and Drug Administration (FDA) is advancing a policy that could have sweeping consequences for clinical laboratories. It is unclear whether the FDA is maneuvering to expand its jurisdiction or simply ignoring the law governing clinical laboratories. Clinical laboratorians should examine the FDA’s position closely and take steps to ensure that this policy, which could thwart innovation and decrease the availability of medically useful tests, is not adopted.

The FDA has issued a draft of Chapter 24, Devices of the FDA Compliance Policy Guide, which states:

It has come to the attention of FDA that laboratories have been manufacturing, 'home brew' products, either from products already on the market, or from components, and utilizing these unapproved products for diagnostic purposes. Before FDA decides to take action against these firms at this time, FDA should focus on whether the nature of the test raises issues of safety and effectiveness of the product. The following circumstances should be taken into consideration: 1. The public health significance of the disease or condition; and 2. The significance of the test results to the individual.

In this statement, the FDA declares its authority to regulate method development in clinical laboratories for any test with clinical significance. What the FDA refers to as "home brew" products are, in reality, either verified modifications of manufacturers' test procedures or methods devised through in-house research and development. The FDA assertion that this places clinical laboratories under its jurisdiction represents a significant expansion of the agency’s authority.

The Clinical Laboratory Improvement Act of 1988 (CLIA) and its most recent regulations issued February 28, 1992, address modifications of test procedures in § 493.1213. Section 493.1213 specifically provides standards by which laboratories may make modifications to manufacturers' test procedures. CLIA regulations establish performance specifications for laboratories that either develop in-house protocols or perform a "modification of the manufacturers' test procedure." Clearly the CLIA regulations permit and sanction these procedures based on sound laboratory testing principles.

The FDA, in contrast, is taking the position that it is not sufficient for laboratories to comply only with the CLIA regulations. In the FDA's view, laboratories must obtain premarket approval from the FDA as well. This FDA policy position ignores the CLIA regulations regarding modifying test procedures and adds regulatory requirements meant for manufacturers.

The FDA bases its policy position on the fallacy that laboratories are "manufacturers" in this context, thereby extending the FDA’s limited jurisdiction to include clinical laboratories providing diagnostic services. This is not the intent of CLIA or the CLIA regulations and, from a practical standpoint, should not be the law. It is nonsensical to declare, as the FDA has done, that both the Food, Drug and Cosmetic Act and CLIA apply to the same procedures, thus subjecting clinical laboratory testing to two regulatory schemes, enforced by two regulatory agencies.

Scope of FDA Policy

The FDA's controversial "home brew" provision is not the first indicator that it believes laboratories modifying approved test kits or developing in-house procedures are violating the law unless they submit those procedures for premarket approval. For more than a year, the FDA has been advancing this policy with regard to the testing of urine and saliva for HIV-1.

Altering the "home brew" provision is not likely to change the underlying FDA policy. Despite statements by FDA officials that the FDA plans no enforcement action, enforcement is ongoing. The FDA has informed manufacturers that they cannot sell devices to any laboratory that does not precisely follow the label. According to the FDA, any "off-label" use must be reported immediately to the FDA. The manufacturer must cease sales until it obtains premarket approval for that "off-label" use or obtains certification from the laboratory that it will cease using the device in any way other than its labeled use.

The FDA's position has nothing to do with CLIA. As far as the FDA is concerned, laboratory compliance with CLIA is irrelevant. The FDA views its regulatory scheme and CLIA as coexistent and complementary. Furthermore, change in the language of the FDA draft policy will not change the underlying policy and the critical issue. Laboratories should be concerned that the FDA considers them to be manufacturers within the terms of the Food, Drug and Cosmetic Act. At issue is which agency has jurisdiction over testing performed by clinical laboratories: the Health Care Financing Administration? FDA? or both? And, more important, which law must the clinical laboratories follow: CLIA? The Food, Drug and Cosmetic Act? Or both?

The FDA says "both" on each question. FDA officials, however, cannot point to their legal authority for this position. Nor can the FDA explain why compliance with the comprehensive CLIA regulations is insufficient. The FDA's position, which requires that laboratories comply with CLIA and obtain premarket approval, goes beyond simple duplication of regulation. It renders CLIA nonsensical. Compliance with CLIA may assure a labora-
tory certification, but it will not assure a laboratory that it may use its own testing procedures for diagnostic purposes.

Critical in understanding this issue is understanding that the FDA's jurisdiction, although extensive, is not pervasive. Its jurisdiction is limited by Congress and until Congress acts to extend it, the FDA's jurisdiction is limited to authority over manufacturers and distributors. There is no legal precedent for the proposition that laboratories providing testing services are "manufacturers" within the meaning of the Food, Drug and Cosmetic Act.

Impact of the FDA Policy Position

The FDA's position places laboratories in a precarious position when it comes to developing new or modified test procedures. As long as the FDA maintains this policy position, clinical laboratorians cannot predict how the FDA will react to the test modifications or procedures they develop in-house. It is not safe to assume that because the FDA has done nothing thus far with regard to a particular modification it will not do so in the future. If the FDA can successfully attack the testing of urine or saliva for HIV-1, it may do the same with any modified or in-house test procedure. A testing protocol developed at considerable cost and in compliance with CLIA may be classified as illegal by the FDA until a laboratory obtains premarket approval. The requirement that laboratories obtain FDA premarket approval could virtually put an end to test development and modification by clinical laboratories, and could have a detrimental effect on public health by severely limiting the test menu most laboratories can offer.

Conclusion

The issue of jurisdiction over clinical laboratories must be resolved. Our nation's lawmakers have declared that clinical laboratories fall under the CLIA regulations. The FDA, without authorization by Congress, has declared that it has jurisdiction over clinical laboratories. This attempt by the FDA to expand its authority can only work to stifle the innovation that is the heart of our discipline, the innovation that has led to countless improvements in clinical laboratory science. Now is the time for us, as laboratorians, to make our voices heard and help shape the future of laboratory medicine.

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