Understanding the Food and Drug Administration's Jurisdiction Over Laboratory-Developed Tests and Divisions Between Food, Drug, and Cosmetic Act–Regulated and Clinical Laboratory Improvement Amendments of 1988–Regulated Activities

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• LDT • IVD • Laboratory-developed test • FDA • Laboratory tests • CLIA

KEY POINTS

- The Food and Drug Administration has a strong case for its claims of jurisdiction over laboratory-developed tests under the Federal Food, Drug, and Cosmetic Act (FDCA).
- Developing a dividing line between regulation of laboratory-developed tests as articles under the FDCA and the analytical services provided by clinical laboratories under Clinical Laboratory Improvement Amendments of 1988 will pose a challenge to implementing an efficient and effective regulatory framework.
- Without a clear framework, any new regulatory system could be a major challenge to navigate, and could lead to duplicative regulation.

The scope of the Food and Drug Administration's (FDA's) jurisdiction over laboratory-developed tests (LDTs), and whether FDA has such jurisdiction at all, has been a heavily debated issue over the past several years. With FDA's release of draft guidance in October 2014 detailing its proposed framework for regulating many

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LDTs,[1] the issue has become even more contentious. On a basic level, there are 2 sides to the debate: (1) those who believe FDA's efforts to expand its authority to regulate LDTs are unlawful and detrimental to the practice of medicine and diagnostic innovation; and (2) those who believe FDA should step in to regulate at least a subset of LDTs due to the potential harm they may cause in the absence of regulation. The former tend to include clinical laboratories and hospitals, whereas the latter tend to include FDA, certain patient groups, and in vitro diagnostics (IVD) manufacturers.

If FDA moves forward with its guidance, or Congress takes action to reform LDT and IVD regulation, a fundamental question that needs to be answered is how to divide activities regulated by the Food, Drug, and Cosmetic Act (FDCA) from those regulated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Without a clear framework, any new regulatory system could be a major challenge to navigate, and could lead to duplicative regulation. Unfortunately, in the LDT debate, we rarely get to into these important details because both sides are entrenched in arguing generalities: FDA can do anything it wants or nothing at all with respect to LDTs. Therefore, in this article, we consider FDA's authority to regulate LDTs and the policy implications of regulation, and discuss an idea for a fact-driven framework to distinguish FDCA and CLIA activities.

FRAMING THE LEGAL ISSUES

The FDCA gives FDA jurisdiction over devices in interstate commerce for commercial distribution. In the following few pages we consider 3 questions that frame the legal issues with respect to this jurisdictional trigger, and whether it allows FDA to reach LDTs and the laboratories that make them.

Are In Vitro Diagnostic Devices Defined Narrowly as Packaged Kits or Something Broader?

A common issue of dispute in the debate over FDA's authority is over the identity of in vitro diagnostics. Often, those who argue that FDA's reach does not extend to LDTs say that the agency's authority is limited to packaged kits that are sold to the laboratories. As a starting place, we therefore consider whether FDA's authority is limited to these test kits or are more extensive.

The statutory definition of a medical "device" under the FDCA is very broad, and gives FDA the authority to regulate instruments, in vitro reagents, and other similar or related articles "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man…."[2] FDA has interpreted this statute as giving it authority over in vitro diagnostic devices, among other things. Under FDA's regulations, "In vitro *diagnostic products* are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body."[3]

Within the definition of "in vitro diagnostic devices," the terms "reagents" and "instruments" are straightforward, and refer to items used to conduct a laboratory test. However, the term "systems" is somewhat less tangible. This is because FDA regulates the collection of all those things used to conduct an in vitro diagnostic test, as specified in labeling. Therefore, the "system" is determined mostly off the written word, but to some extent based on features that reveal intent that 2 items be used together. The scope of the system is determined by the all-important "intended use" of the system.