Legal Backgrounder

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# FDA's REGULATORY EXTENSIONS:
## AN OVERBURDENED AGENCY ASSIGNS ITSELF NEW RESPONSIBILITIES

by

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The Food and Drug Administration (FDA) has been given far-reaching responsibilities by Congress. FDA regulates a vast array of products, including foods, drugs, devices, animal drugs, biologicals, and radiation-emitting products. The value of FDA-regulated products is estimated at around $1.5 trillion annually. The sheer scope of these oversight responsibilities would strain any organization.

Making FDA's task more difficult, Congress frequently amends the Federal Food, Drug, and Cosmetic Act (FDC Act), the basic law enforced by FDA. These amendments often add new tasks, which rarely reduce FDA's regulatory responsibilities. Most recently, in September 2007, Congress enacted the Food and Drug Administration Amendments Act, which imposed multiple new obligations on FDA. Congress is now considering another major expansion of FDA responsibilities relating to imported products. In view of the fact that these products are becoming increasingly complex, FDA's ability to keep up with the demands on its scientific and technical resources is being challenged.

Faced with ever-expanding responsibilities, a growing number of increasingly difficult tasks, and a slowly rising budget, FDA appears to have reached the breaking point. Study after study warns of the impending crisis brought on by FDA's lack of resources. Congressional hearings have highlighted how FDA has skimped on inspections of foreign manufacturers, many of which have never been examined. Senator Kennedy has decried, "these deficiencies [that] put American families at risk." FDA's Science Board has stated, "[T]he Agency suffers from serious scientific deficiencies and is not positioned to meet current or emergency regulatory responsibilities." Subcommittee on Science and Technology, FDA Science Board, FDA Science and Mission at Risk 2 (Nov. 2007). FDA Commissioner Andrew von Eschenbach has himself admitted that these strains threaten FDA's mission to protect and promote the health of Americans. In his March 26, 2008 address to the Food and Drug Law Institute's annual conference, he noted that in the face of such pressures, FDA is placed in a situation where it "has to reprioritize with existing resources and risk not meeting existing or current responsibilities."

The health impact is felt in other ways as well. FDA serves as a gatekeeper for new products. Failing to approve new life-saving or life-enhancing products – or delays in their approval – harms the patients who need access to these products. Yet drug companies that ask to meet with the agency to discuss clinical studies are now sometimes being told that FDA does not have resources to hold such a meeting. This seems penny-wise and pound-foolish; the lack of communication at an early stage is likely to force FDA to use more resources later,

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once the company submits its application. The problem of inefficiency is not contained to pharmaceuticals. For example, FDA recently took 180 days to do an initial review of a simple 510(k) premarket notification for a low-risk device, even though FDA has committed to complete its review in 90 days or less.

The politician's instinctive response to FDA's strained circumstances is to give FDA additional funds. Congress is considering substantially increasing FDA's funding. More money would help. FDA's funding has not kept up with the responsibilities thrust upon it by Congress and the workload brought on by new products and new technologies. FDA is embarking on a major hiring spree.

But throwing more money at FDA is not enough. FDA must also make better, more efficient use of resources Congress provides. For example, when meeting with industry, the agency will frequently bring staffers who make minimal or no contribution to resolving issues on the agenda. Or staffers will decline to pick up the telephone and ask clarifying questions, even if that will be more productive than writing a letter, which must go through multiple levels of review.

FDA is not a business, and it should not be held to the same standards as a for-profit enterprise. It does, however, need to derive more from available resources. Republican members of the House Energy and Commerce Committee have recently challenged FDA's use of its Office of Criminal Investigations. "[W]e question whether continued funding and staffing of OCI at current and projected levels is the best use of scarce federal dollars." Showing that this is not a partisan issue, earlier in the year Democrats challenged the wisdom of FDA's use of resources to develop a new draft policy relating to product labeling.

Given all that FDA *must* do, one would not expect that the agency would, on its own initiative, seek to expand its responsibilities. Yet FDA periodically embarks on regulating sectors that have been regulated for decades by other governmental bodies and where FDA's own jurisdictional authority is, at best, unclear.

The best known example of FDA's attempted jurisdictional expansion involves tobacco. In 1980, FDA prevailed in a lawsuit trying to compel the agency to regulate tobacco as a drug. Two decades later, after FDA changed its position and deemed tobacco products to be subject to FDA regulation, FDA lost a Supreme Court case where the tobacco industry challenged FDA's regulation subjecting tobacco products to FDA jurisdiction. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). Ruling against FDA, the Court noted many tobacco-related congressional enactments as indicating that FDA did not have the authority to regulate these products. While FDA's desire to tackle one of the country's biggest public health problems was understandable, in the end FDA diverted a significant amount of energy, dollars, and personnel to this ultimately unsuccessful venture from those tasks that Congress had actually delegated to FDA.

The battle to regulate tobacco is not the only instance where FDA has chosen to spend significant resources and efforts on products that are not clearly within its jurisdiction and for which there was no compelling need for FDA regulation. Two current illustrations of this phenomenon are FDA's regulatory initiatives involving clinical laboratories and pharmacy compounding.

***FDA and Laboratories***. In 1976, Congress passed the Medical Device Amendments (MDA). The statute gave FDA broad power to regulate medical devices, including the requirement that devices obtain premarket authorization from FDA. At the time Congress enacted the MDA, clinical laboratories were routinely developing their own tests. These laboratories were subject to federal regulation – albeit not very extensive regulation – under the Clinical Laboratory Improvement Amendments (CLIA) of 1967.

There is nothing in the legislative history of the MDA suggesting that laboratory developed tests (LDTs) were subject to the MDA. While it was settled that the manufacturers selling tests to laboratories would now need to meet FDA's device requirements, there was not a hint that FDA was expected to regulate tests that laboratories developed for their own internal use.

In 1988, Congress greatly strengthened federal regulation of laboratories through a new version of CLIA. CLIA '88 provided for a comprehensive regulatory scheme of laboratories, including registration, personnel standards, test performance, and sanctions. The responsibility for enforcing CLIA was given to the Department

of Health and Human Services (HHS). Although FDA is part of HHS, authority for overseeing CLIA went to a different component, now known as the Center for Medicare and Medicaid Services.

To the surprise of industry, in 1992 FDA stated for the first time that LDTs were subject to FDA regulatory requirements. A citizen petition was filed challenging that position. *See* Citizen Petition from Hyman, Phelps & McNamara, P.C. to FDA (Oct. 22, 1992) (No. 92P-0405). Six years later, FDA rejected the petition, albeit without much explanation. In a separate document, FDA said it would exercise "enforcement discretion" and not regulate laboratory developed tests. Matters remained quiet for nearly a decade.

That quiet has ended. With no prior warning, and without consulting with affected parties, in September 2006 FDA proposed to regulate certain laboratory tests, known as in vitro diagnostic multi-variate index analyses (IVDMIAs), as devices, subjecting them to the same requirements as tests sold by manufacturers to laboratories. The resulting brouhaha has already led to countless meetings, speeches, and discussions within FDA, between FDA and HHS, and between FDA and outside interested parties. FDA has already devoted significant time and energy to this effort to regulate laboratories. And the process of implementing a new policy is still not complete.

FDA's proposal has provoked an intensely negative reaction. Regulation of LDTs would have a significant impact on the health care system. Many diagnostic tests, including virtually all genetic tests, are introduced as LDTs. If these tests must first go through the FDA review process, many would never enter the market – the barriers to entry will be too great for a laboratory to bear. Even though FDA's proposal does not apply to all LDTs, but only a subset, it establishes a precedent that would permit regulatory expansion encompassing other kinds of tests. Furthermore, FDA's decision to by-pass the Administrative Procedure Act and commence regulation through a guidance document has proven highly controversial and would facilitate broader jurisdiction without rulemaking. *See* Petition from Washington Legal Foundation to FDA (Sept. 2006) (No. 2006P-0402) *available at* http://www.wlf.org/upload/Clinical%20Labs-%20FDA%20Citizen%20Petition.pdf.

Whatever the substantive and legal merits of having FDA regulate these new LDTs, there is another, larger policy issue: whether FDA should use its scarce resources this way. The agency has already devoted considerable assets trying to finalize the policy regulating IVDMIAs as devices. But that would be just the beginning of the resource drain on FDA. If FDA were to succeed in imposing device regulation on IVDMIAs, the expenditure to date will be dwarfed by the work necessary to actually regulate these laboratories and their tests.

Given FDA's difficulties in discharging its responsibilities for devices that it already has the clear duty to regulate, the agency should not be reaching to assume responsibility for regulating this entirely new class of tests. In public discussions, FDA has not identified specific evidence of harm that has compelled the agency to seek to regulate these IVDMIAs. Put another way, it is difficult to justify allocating resources to IVDMIAs, when laboratories are already regulated by CMS, professional societies, and state bodies, while medical device manufacturers in the U.S. and abroad are inspected infrequently, or not at all, and the existing product review workload already is taxing FDA to the breaking point.

***FDA and Pharmacies***. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act. That law required companies to get approval of "new drugs." At the time Congress passed the FDC Act, a substantial proportion of all drugs were compounded by pharmacists to fill prescriptions. There is absolutely no evidence that Congress intended for the "new drug" provision to be applied to compounded drugs. There is, however, substantial contrary evidence.

Fifty years later, FDA hatched the idea that compounded drugs were "new drugs" that needed FDA approval. An internal 1989 FDA document makes it clear that this was a brand new approach. FDA publicly unveiled that novel notion a few years later. Ever since, FDA has spent countless resources and dollars defending this position and invoking it against compounding pharmacies.

FDA's theory suffers from several serious problems; one of which is that it renders all compounding a criminal act. It would mean that every pharmacist has been trained in an illegal act, and that state legislatures

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have authorized – and even mandated – that pharmacists act illegally. Many of these pharmacists have been employees of the U.S. Government, including military and Veterans Affairs pharmacists.

After passing the FDC Act, Congress specifically authorized compounding in Washington, D.C. through a series of laws. FDA's theory means that pharmacists who compounded pursuant to this later federal legislation were committing criminal acts under the FDC Act. Not surprisingly, FDA's attack on the very legality of compounding has triggered resistance by pharmacists over the past fifteen years. There has been sparring with fluctuating intensity between FDA and industry over this issue ever since.

These disagreements culminated in a lawsuit brought by a group of pharmacists in the Western District of Texas. During discovery, FDA acknowledged the extremity of its position. While being deposed, an FDA official testified that a pharmacist who filled a prescription to add a flavor to a drug to make it palatable for a child had violated the FDC Act. The plaintiff prevailed in the district court. *Medical Center Pharmacy v. Gonzalez*, 451 F. Supp. 2d 854 (W.D. Tex. 2006). FDA appealed to the U.S. Court of Appeals for the Fifth Circuit; oral arguments were held in January.

In the meantime, FDA has been busy regulating pharmacists. The agency has inspected a number of pharmacists, written warning letters to pharmacies, and taken enforcement action against companies supplying chemicals to pharmacies for use in compounding. FDA investigators are instructed to ask for records to which they are not legally entitled, such as financial data.

All of this has taken time, money, and personnel. Agency investigators who are inspecting pharmacies are not available to inspect manufacturers in China or India. During discovery in *Medical Center*, many of these investigators acknowledged that they had not even been trained in *how* to inspect pharmacies. FDA policy personnel and lawyers who are busy defending FDA's position on compounding cannot simultaneously be working to improve the safety of manufactured drugs or accelerate the introduction of life-saving medications. FDA scientists who are examining medications compounded to fill prescriptions for individual patients are not examining samples from products manufactured for national distribution.

There may be special circumstances when FDA intervention against a pharmacy is warranted. However, pharmacies are already actively regulated by state boards of pharmacy, and it is the rare case indeed where FDA alone has the ability to protect the public from a compounding pharmacy. And if that situation arose, FDA would be able to rely upon other theories relating to safety; it would not need to invoke the "new drug" theory.

Whatever the legal merits of the interpretation FDA developed five decades after passage of the FDC Act, there can be little doubt that FDA's approach has led to the diversion of agency resources from its core mission: the regulation of drug manufacturers.

***Conclusion***. FDA plays a vital role in protecting the public health. It is an agency facing demands that are growing far faster than resources. The agency needs more money and more personnel. But giving FDA more money and people will not be sufficient. FDA also needs to use its resources wisely and effectively. Congress regularly gives FDA more work to do. FDA should not on its own initiative seek to expand jurisdiction to laboratory developed tests, pharmacy compounding, and other activities where it lacks clear congressional authorization. As Commissioner von Eschenbach has noted, FDA must "reprioritize with existing resources." Rather than trying to regulate services that are at best peripheral to FDA's responsibilities, FDA should focus on doing a better job in discharging its core responsibilities.

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