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FDA Enforcement Crackdown Requires Reforms

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In recent weeks, the new commissioner of the U.S. Food and Drug Administration, Dr. Margaret A. Hamburg, has declared that she wants to “pump up enforcement” at FDA, the federal agency responsible for regulating more than \$2 trillion in food, drugs, biological products, medical devices, cosmetics and dietary supplements (and now, tobacco).

Commissioner Hamburg explained that, under her leadership, the FDA has changed its enforcement “posture to one that is more aggressive and forward leaning.”

Commissioner Hamburg is to be commended. After all, FDA enforcement of the Food, Drug and Cosmetic Act (the Act) is one of the primary ways FDA carries out its mission of protecting the public health.

FDA inspections, seizures, injunctions and prosecutions protect the public health by preventing unsafe, ineffective, adulterated and misbranded products from entering commerce and causing injury or even death to unsuspecting consumers.

In addition, FDA enforcement benefits food and dietary supplement manufacturers, drug and device makers, biologics companies, and cosmetic firms. When FDA enforcement is limited or non-existent, law-abiding firms are at a competitive disadvantage as compared to firms that, with seeming impunity, operate in violation of FDA laws and regulations.

It’s hard for an FDA-regulated firm to compete with a business rival that doesn’t bother with FDA-mandated approvals, good manufacturing practices, labeling requirements, or marketing restrictions.

An increase in the number of FDA enforcement actions, however, will improve public health and level the commercial playing field only if the enforcement actions are tethered to the statutes and regulations that govern FDA-regulated firms.

FDA enforcement actions that rely on novel or complicated legal theories, or attempt to stretch the law in a new direction, or apply the law arbitrarily, will diminish the credibility of the agency with the public and the regulated industry, as well as in the courts. Commissioner Hamburg should be mindful of this as she seeks to prod the FDA toward more enforcement.

A recent case is illustrative. In *United States v. Farinella*, the U.S. Attorney in Chicago, at the behest of FDA’s Office of Criminal Investigations (OCI), accused Charles Farinella of “introducing into interstate commerce a misbranded food with intent to defraud or mislead.”

What was his crime? In May 2003, Mr. Farinella changed the original “best when purchased by” date on 1.6 million bottles of salad dressing, a food product considered “shelf stable” (i.e., it was

edible for decades and had no real expiration date). OCI argued that if there is a “best when purchased by” date on the label of a food product that is changed without FDA’s approval, then a crime has been committed.

The problem with OCI’s legal theory? That’s not the law. The term “misbranded food” is defined at length in the Food, Drug, and Cosmetic Act, but there is nothing in the law about “expiration” or “best when purchased by” dates on food labels.

In a scathing opinion written by Judge Richard A. Posner, the court of appeals rejected OCI’s misbranding case against Mr. Farinella. To form the basis for a criminal conviction, Judge Posner declared, any requirement about dates on food labels that FDA wanted to enforce had “to be found in some statute or regulation, or at least in some written interpretive guideline or opinion ... It is a denial of due process of law to convict a person of a crime because he violated some bureaucrat’s secret understanding of the law.”

FDA enforcement, the court held, must be tethered to the Act and FDA regulations.

The government’s prosecution of the salad dressing case destroyed FDA’s credibility with the court, and Judge Posner’s opinion excoriating the agency only diminishes its credibility with the public.

Sadly, this blow to FDA’s reputation could have been easily avoided. OCI originally presented the salad dressing case to FDA’s Office of Chief Counsel and urged that criminal charges be brought.

When that office refused to bring the case (because FDA does not regulate dates on food labels), OCI shopped it to various U.S. Attorney’s Offices unfamiliar with the Act until it found a prosecutor willing to indict Mr. Farinella.

As FDA enforcement ramps up, Commissioner Hamburg will want to ensure that an increase in enforcement actions does not mean an increase in enforcement actions like the salad dressing case. She can do so by implementing a few simple reforms:

First, require Chief Counsel approval before any criminal prosecution is initiated. FDA should enforce the requirement that OCI obtain approval from the Office of Chief Counsel before presenting any potential case based on alleged violations of the Act or FDA regulations to the Justice Department for prosecution.

This would prevent OCI from shopping weak cases to unwitting federal prosecutors. It also would ensure that possible criminal charges based on the Act are reviewed by attorneys in the Office of Chief Counsel, the office most familiar with the Act and its regulations.

Second, ensure that enforcement resources are targeted. Enforcement resources should be focused on alleged violations of the Act, the law that matters most to the FDA. Allowing limited resources to be diverted to novel cases (like the salad dressing case) or cases that are tangential to FDA’s concerns (like False Claims Act cases) means there are fewer resources for investigating actual violations of the Act.

Third, issue regulations and guidance documents that clarify the law. FDA-regulated firms face difficult choices when the law (which can be murky and subject to interpretation) appears to prohibit certain conduct, but the FDA does not enforce that prohibition.

What is a firm to do when the law arguably says one thing, but its competitors do another — and the FDA does nothing at all? In the enforcement context, FDA should clarify the law by issuing regulations and guidances, giving up-front notice to affected parties of what the law requires. The agency should not attempt to clarify the law in the context of backward-looking, fact-specific prosecutions that are binding only on the parties involved.

Fourth, focus enforcement on low-hanging fruit. Because the Act's strict standards of liability can operate harshly, or even unfairly, the FDA has long-recognized that it is expected to exercise reasonable discretion in invoking the Act's criminal sanctions.

In this vein, Dr. Hamburg should ensure that any increase in enforcement be directed at preventing or correcting conditions potentially dangerous to the public health, including where there have been ongoing violations of the law (e.g., continuing insanitary conditions in a food plant); obvious or flagrant violations (e.g., a food warehouse overrun with rodents that contains adulterated products); or intentionally false or fraudulent violations (e.g., a pharmacy compounding commercially available drug products or a dietary supplement or food manufacturer claiming its product cures cancer).

Increasing enforcement actions in these run-of-the-mill categories of cases would enhance FDA's credibility with consumers, industry, and the courts.

“Pumping up” enforcement at the FDA can protect the public health and benefit FDA-regulated firms — but only if the FDA exercises its enforcement discretion reasonably and in conformity with the Food, Drug and Cosmetic Act and FDA regulations.

By implementing a few simple reforms, FDA can ensure that the increase in enforcement Commissioner Hamburg seeks actually protects the public health.