Legal Backgrounder

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# FDA LACKS AUTHORITY TO IMPOSE CIVIL MONETARY FINES

by

Marc J. Scheineson and Robert J. Kaufman

On November 2, 1999, the Food and Drug Administration (FDA) announced an agreement with a major manufacturer of reagents to temporarily stop manufacturing in-vitro medical devices and to pay a $100 million fine. Just eleven months later, the FDA announced a similar arrangement with a major pharmaceutical manufacturer in which the company agreed to $30 million in fines as an "equitable remedy of disgorgement." In May 2002, the FDA and the maker of asthma inhalers signed a consent decree detailing a record $500 million payment to the U.S. Treasury for alleged "significant violations of good manufacturing practice regulations." Finally, on April 11, 2003, the FDA announced a settlement with a national non-profit blood banking organization in which the two parties agreed to modify an older consent decree. The revised understanding included provisions for financial penalties if the organization violated the agreement in the future.

These four arrangements offer an increasingly typical example of the FDA's efforts to augment its traditional enforcement powers with civil monetary penalties expressly not authorized by Congress. Relying on a U.S. Court of Appeals for the Sixth Circuit case with very unusual facts, the FDA has reinterpreted the Food, Drug, and Cosmetic Act (FDCA) to impose civil monetary penalties (CMPs) on all regulated organizations using the equitable powers of the court which reviews injunctive proceedings. This LEGAL BACKGROUNDER offers an analysis of the legal accuracy of this conclusion. The FDA's stance, while understandable, is unwise and likely illegal. Congress, concerned about over-regulating industry, chose not to give the FDA broad CMP power. The very power that Congress rejected years ago cannot be claimed today based on a creative new reading of the FDCA.

To carry out its mission of protecting the public health, the FDA relies primarily on three powerful enforcement tools. Injunctions are used when the Agency believes that a company's operating procedures violate the FDCA. Civil seizures bring questionable goods within the jurisdiction and control of federal courts. Finally, criminal prosecutions are used when violations are not corrected or appear to be intentional or flagrant. *See* 21 U.S.C. § 331-333. In addition to these traditional remedies, the FDA issues "warning letters" and conducts

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**Marc J. Scheineson** is a partner in the law firm of Reed Smith, LLP in Washington, D.C., where he heads the firm's food and drug practice. Mr. Scheineson is a former FDA Associate Commissioner for Legislative Affairs and is Chair of the American Bar Association Business Law Section Committee on Food Drug and Cosmetic Law. **Robert J. Kaufman** is a third-year law student at Harvard Law School in Cambridge, MA.

inspections of factories and warehouses where "food, drugs, devices or cosmetics are manufactured, processed, packed or held for introduction into interstate commerce." *Id.* at §§ 336, 374. Finally, the FDA is permitted to use adverse publicity or simply the threat of negative publicity as an enforcement tool. *See id.* at § 375.

In recent years, Congress authorized greater and more flexible enforcement powers in certain, limited situations. Significantly, none of these additions has been an across-the-board grant of new power to the Agency. For example, a FDA agent may "detain" a medical device for twenty days if there is "reason to believe" such a device is adulterated or misbranded. *See Id.* at §334(g). This allows the Agency time to either seize the device or process an injunction. Additionally, Congress passed seven statutes that authorize limited civil monetary penalties.[1] In the situations specified by these seven laws, the FDA may impose financial penalties for violations of the FDCA. Each statute specifies in detail the severity of the penalty and the possibility of mitigation.

The FDA, however, used a single judgment obtained from the Sixth Circuit in 1999 to justify imposing CMPs beyond its express statutory authority. In that single case, *United States v. Universal Management Services, Inc.*, a seller of electric gas grill igniters was enjoined from marketing the product as an unapproved medical device to relieve pain. *See* 191 F.3d 750 (1999). An ancillary issue reviewed by the appeals court, in addition to the unapproved product and an inadequate assistance of counsel claim, was whether the company could be forced to pay equitable restitution. The court held that "absent a clear command by Congress that a statute providing for equitable relief excludes certain forms of such relief, this court will presume the full scope of equitable powers may be exercised by the courts." *Id.* at 761.

Shortly after the *Universal Management* decision, the FDA Deputy Chief Counsel for Litigation wrote that the Sixth Circuit's decision permits the agency to seek "any equitable remedy not expressly prohibited by the Food, Drug, and Cosmetic Act." Eric M. Blumberg, *Abbott Laboratories Consent Decree and Individual Responsibility under the Federal Food, Drug, and Cosmetic Act,* 55 FOOD & DRUG L.J 145, 146 (2000). Thus, Mr. Blumberg explained, the Agency will now pursue disgorgement and restitution in settlement negotiations and court proceedings. *Id.* at 147. Indeed, this policy change has been widely accepted at the FDA. In the official press release announcing the $500 million consent decree against the asthma inhaler maker, Dr. Lester Crawford, the FDA's Deputy Commissioner commented, "This action is another clear sign that FDA will continue to enforce the rules and regulations requiring companies to carefully control and monitor their processes.... Manufacturers who choose to wait until FDA investigators find violations rather than policing themselves will find that they have made a poor and *costly* decision." *Schering-Plough Signs Consent Decree with FDA,* at http://www.fda.gov/bbs/topics/NEWS/2002/NEW00809.html (last visited July 1, 2003) (emphasis supplied).

The *Universal Management* decision is an example of the maxim "bad facts make bad law." The defendants were charlatans who intentionally ignored FDA approval requirements in order to market a dangerous and ineffective product. Moreover, consumers were injured and defrauded. Based on these facts, and the potentially inadequate assistance of counsel who may not have been aware of instances where Congress expressly denied monetary penalties, the court was moved to use its equitable powers to effect a just remedy.

Refunds in restitution were ordered to be made to customers who requested them in writing. Although no other court in any other jurisdiction adopted this line of reasoning[2], the FDA used the decision to extract hundreds

[1]The seven statutes are: (1) The Radiation Control for Health and Safety Act of 1968 (21 U.S.C. § 360pp); (2) The National Childhood Vaccine Injury Act of 1986 (42 U.S.C. § 262(d)(2) and 42 U.S.C. 300aa-28); (3) The Prescription Drug Marketing Act of 1987 (21 U.S.C. § 333(b)); (4) The Safe Medical Devices Act of 1990 (21 U.S.C. § 333(f)); (5) The Mammography Quality Standards Act of 1992 (42 U.S.C. § 263b(h)); (6) The Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335b); and (7) The Food Quality Protection Act of 1996 (21 U.S.C. § 333(f)).

[2]In a recent unpublished decision concerning tax law, the Sixth Circuit quoted from its previous decision in *Universal*

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of millions of dollars from corporations that are unable, or unwilling, to invest the time and resources needed to challenge the FDA's new enforcement power.

There is ample reason to believe that such a challenge would be successful. The Supreme Court recently affirmed that "no matter how serious the problem an administrative agency seeks to address, ... it may not exercise its authority in a manner that is inconsistent" with the intent of Congress. *Food and Drug Admin. v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 125 (2000) (internal citations omitted). Yet, the FDA's demand that these companies and non-profit organizations pay substantial civil monetary penalties is beyond the statutory and regulatory authority of the Agency as established by Congress. Furthermore, an appeal to a court to use its own equitable powers to impose such penalties is equally inappropriate.

*FDA v. Brown & Williamson Tobacco Corp*., in fact, closely resembles the current debate over civil monetary penalties. In that case, the Supreme Court rejected a FDA attempt to regulate tobacco because the Agency had surpassed its congressionally imposed regulatory authority. 529 U.S. at 161. The Court began its analysis by noting that when evaluating instances where the FDA may have exceeded its legal authority, a two-part analysis should be employed. *Id.* at 132. *See also Chevron U.S.A. Inc. v. National Resources Defense Council*, 467 U.S. 837 (1984). The first question is whether Congress has spoken to the very issue at hand. If it has and if "the intent of Congress is clear," then both the court and the agency "must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. However, if Congress has not addressed the issue, a court should defer to the agency's construction of the statute so long as it is reasonable. *Id.* In the instant case, there is no need to reach this second step because Congress has repeatedly spoken clearly. It declined to give the FDA broad powers to seek civil monetary penalties. In the specific cases where Congress did determine that CMPs were appropriate, it was careful to limit the FDA's authority to those particular circumstances.

Furthermore, Congress considered and then rejected several bills that would have expanded FDA authority to assess CMPs in additional circumstances. For example, in 1991 and 1992 the House Energy and Commerce Committee considered augmenting FDA's enforcement powers by adding, among other tools, broad authority to levy CMPs. *See* H.R. 3642, 102nd Cong. (1991). Representative Henry Waxman proposed the legislation because, at the time, the FDA did "*not* have ... administrative civil penalty authority, except in the case of medical devices." 137 Cong. Rec. E2122 (1991). While the bill was voted out of Committee, the first Bush Administration opposed the legislation. It was never debated on the House floor. 1992 *CQ Almanac* 436-437. Echoing the sentiments of many of the bill's opponents, Secretary of Health and Human Services, Louis Sullivan, argued that "at a time when government has imposed significant burdens on the economy ... unnecessary regulatory burdens should be avoided." *Congressional Quarterly,* July 11, 1992, p.2046. Other opponents complained that "enforcement tools appropriate for one class of products are not appropriate for others" and were reluctant to give the FDA broad power to levy civil penalties. *Congressional Quarterly,* October 12, 1991, at 2963.

Congress contemplated broader CMP power and then rejected the idea. In *Brown & Williamson,* the Court similarly found that both the plain language of the FDCA and subsequent legislation indicated that the FDA exceeded its authority.

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*Management* for the notion that courts are presumed to have equitable powers unless Congress clearly excludes certain forms of relief. *United States v. Ford,* No. 01-5781, 2003 WL 21212547 at *5 (6th Cir. May 22, 2003.)

529 U.S. at 161. Congress chose to regulate tobacco in carefully delineated ways, the Court decided. Both the House and the Senate repeatedly rejected bills that would have awarded the FDA broad power over tobacco but passed legislation that created a "distinct regulatory scheme for cigarettes and smokeless tobacco." *Id.* at 144. Writing for the majority, Justice O'Connor noted that "the classic judicial task of reconciling many laws enacted over time ... necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *Id.* at 143 (internal citations omitted). Likewise, in the case of CMPs, Congress rejected a broad grant of authority to the FDA but created a distinct regulatory scheme for the specific circumstances when CMPs can be used.

Furthermore, until the FDA received the fortuitous *Universal Management* decision, the Agency itself believed it lacked authority under the FDCA to impose CMPs. For instance, in announcing its final debarment policy for generic drug makers in 1991, the FDA addressed several public comments. One comment suggested that "FDA redouble its efforts to obtain authority from Congress to levy civil penalties against applicants for willful misconduct." The FDA's response noted that "HHS proposed legislation last year that would establish broad authority to assess administrative civil penalties.... HHS currently is considering whether to propose similar legislation in the future." 56 Fed. Reg. 46191, (September 10, 1991), Question 8. Even former Secretary of Health and Human Services, Donna Shalala, acknowledged that the FDA does not have CMP authority. Writing shortly before leaving office but after the *Universal Management* decision, she wrote that HHS ought to pursue "legislation to enable the FDA to levy civil monetary penalties for violations of informed consent and other important research practices." Donna Shalala, *Protecting Research Subjects – What Must Be Done,* 343 NEW ENGLAND J. MED. 808 (2000). While "an agency's interpretation of a statute that it is charged with administering is not carved in stone," that interpretation provides "important context to Congress's enactment" of subsequent legislation. *Brown & Williamson* 529 U.S. at 157-158 (internal citations omitted). The FDA has long asserted that it does not have sweeping CMP power and branches of government have responded accordingly. The Agency can not change the commonly understood meaning of the FDCA without Congressional approval.

Finally, the *Brown & Williamson* Court noted that the judiciary should employ a "degree [of] common sense [when determining whether] ... Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency." 529 U.S. at 133. The mere threat of civil monetary penalties has already caused four organizations to sign consent decrees worth hundreds of millions of dollars with the FDA rather than risk litigation. Surely, authority that a President deemed unnecessary and Congress deemed unwise would not be delegated to the FDA without debate and the passage of legislation.

A court's equitable power cannot override the language or intent of a congressionally enacted statute. *See Miller v. French,* 530 U.S. 327, 336 (2000). The plain language of the FDCA, combined with Congress' later rejection of broad CMP authority and its endorsement of targeted penalties in seven different pieces of legislation are clear indications of Congressional intent. The Food and Drug Administration exceeds its authority when negotiating with regulated entities for financial penalties. As the Supreme Court recently cautioned, "[I]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *Brown & Williamson* at 161 citing *U.S. v. Article of Drug...Bacto-Unidisk,* 394 U.S. 784, 800 (1969) quoting *62 Cases, More or Less Each Containing 6 Jars of Jam v. U.S.*, 340 U.S. 593 (1951).

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