It's the Law

Disgorgement and Restitution

By Jeffrey N. Gibbs

The Food and Drug Administration can deploy a range of familiar statutory sanctions, such as warning letters, seizures, injunctions, criminal prosecution and civil penalties, against companies that violate the law. Other enforcement tools, such as untitled letters and recalls, are also well-known by regulatory affairs professionals. However, two of the most powerful FDA sanctions, which the agency has only recently employed—disgorgement of product revenue to the government and restitution to consumers—have received relatively little attention.

This lack of awareness is striking since some of the largest and most highly publicized financial penalties levied against healthcare companies for violating the *Federal Food, Drug, and Cosmetic Act (FD&C Act)* have involved restitution or disgorgement. For example, the $100 million paid by Abbott Laboratories in 1999, the $500 million paid by Schering Plough in 2002 and the $30 million paid by Wyeth-Ayerst in 2000 were all based on FDA's new legal theory. More recently, in December 2005, Eli Lilly paid $24 million in disgorgement as a result of off-label promotion of an approved drug.

On the other hand, the lack of awareness is not surprising since FDA did not seek disgorgement or restitution until recently. From the passage of the *FD&C Act* in 1938 until 1997, no court had ever ordered disgorgement or compelled a company to provide restitution to consumers. Then, a district court in Ohio enjoined Universal Management from violating the *FD&C Act* and ordered Universal Management to provide restitution to consumers who had purchased products (basically, gas grill igniters) to treat arthritis. The company appealed, and the court of appeals agreed with FDA that the power to enjoin also included the power to compel restitution.[1] Since then, FDA has used this sanction to obtain large payments from several companies when settling cases. It has also sought this remedy in litigation against other companies.

Considerable controversy has arisen over whether restitution and disgorgement can be ordered by courts. The *FD&C Act* does not grant courts the explicit authority to impose these remedies. It does give courts the power to "restrain violations" of the *FD&C Act*.[2] This provision does not refer to disgorgement or restitution or, indeed, any monetary relief. Basically, FDA's argument is that once a court imposes an injunction against a company, it can also order restitution or disgorgement as part of the court's inherent, broad legal powers.

While the *FD&C Act* does expressly provide FDA with a variety of tools, it nowhere mentions restitution or disgorgement. Under FDA's theory, the largest financial penalty the agency can seek is based on an implicit authority. Moreover, FDA's interpretation is based upon two Supreme Court cases dealing with very different types of legislation arising out of the New Deal, where restitution to the victims was integrally related to the legislative scheme. Furthermore, there are a number of other reasons to believe federal courts that have issued an injunction cannot then order any drug, device, biologic or food company to disgorge money received for past violative products to the federal government.[3]

These arguments notwithstanding, at this point it appears likely that FDA will seek with increasing frequency precisely that sort of court order. On 21 October 2005, in United States v. Lane Labs-USA, the Third Circuit Court of Appeals concluded that "[u]nless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction."[4] According to the court, the "inherent equitable powers" of a district court that issues an injunction under the *FD&C Act* include the power to order restitution. Therefore, the court of appeals upheld a district court order requiring Lane Labs to provide restitution to consumers who had bought Lane Labs' aggressively hyped dietary supplements, which the district

court found to be illegal unapproved new drugs.

Another shoe may drop soon. In United States v. Rx Depot Inc.,[5] FDA was able to obtain an injunction against a company that imported unapproved new drugs, but the court declined to order disgorgement; FDA appealed. Oral argument was held on 16 November 2005. Although it is risky to predict outcomes based upon judges' questioning, Rx Depot's position was met with clear skepticism. If FDA does prevail, that will mean three courts of appeals will have found in FDA's favor. That would be doubly problematic for industry, for it would give FDA three straight wins and could deprive industry of any near-term opportunity to obtain Supreme Court review. If Rx Depot does win, however, that would set up a potential Supreme Court showdown over this issue.

What does this mean for regulated companies? First, they can expect FDA to push harder for monetary payments from companies that it believes have violated the *FD&C Act*. Eric M. Blumberg, FDA's Deputy Chief for Litigation, was recently quoted as saying he is "fully confident" of FDA's ability to require disgorgement.[6] By threatening to file for an injunction and then seeking restitution/disgorgement from the court, FDA will try to extract more leverage in negotiating a settlement.

Second, the possible consequences of ongoing regulatory violations could increase dramatically. The costs of warning letters, recalls and seizures pale in comparison to the cash outflow caused by restitution or disgorgement.

Third, companies that have their products seized will need to be especially wary. A seizure directly affects only the seized items and therefore has a relatively confined financial impact. However, once the owner of the seized goods seeks to enter the case to defend the products' legality, FDA sometimes will seek to amend its seizure case into an injunction. If that occurs, the financial risks dramatically escalate, because the seizure could serve as a stepping stone to a request for disgorgement or restitution.

Even if FDA wins the Rx Depot case, uncertainty will continue. It is one thing for a court to award restitution to a defined set of consumers who buy gas grill igniters to treat arthritis. It is another to try to determine how much money—if any—should be paid for drugs or devices that performed as intended but were made in violation of Good Manufacturing Practice regulations. It is unclear what criteria FDA will use in deciding how much money to request, or when to wield this potentially powerful weapon.

In agreeing with FDA, the Lane Labs court recognized there were flaws in the government's position. The court recommended "the Supreme Court should draw finer lines around a court's authority to fashion specific remedies within a broad statutory grant of equitable power."[7] However, unless and until the courts draw these finer lines, regulatory affairs professionals need to be aware that the regulatory risks of noncompliance may be increasing significantly.

References

1. Universal Management Services, 191 F. 3d. 750 (6th Cir. 1999).
2. 21 U.S.C. § 332.
3. Gibbs Jeff, Fleder John, Can FDA Seek Restitution or Disengage ment, 58 *Food and Drug Law*, 129 (2003); King Ericka and Walsh Elizabeth, The Authority of a Court to Order Disengage ment for Violations of the Current Good Manufacturing Prac tices Requirement of the Federal Food, Drug, and Cosmetic Act, 58 *Food and Drug Law Journal*, 149 (2003). *Vodra William, Levine Arthur, Anchors Away: The Food and Drug administrations's Use of disgorgement Abandons legal Moorings. 59 Food and Drug Law Journal, 1 (2004).*
4. United States v. Lane Labs-USA, Inc. 4219 F. 3d27 (3rd Cir. 2005).
5. United States v. Rx Depot, Inc., No. 03-CV-0616 (N.D. Oklo. Nov 4, 2004).
6. Drug Daily Bulletin, Dec. 8, 2005.
7. Lane Labs, 427 F. 3d at 236.

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