

# Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug, and Cosmetic Act

ERIC M. BLUMBERG \*

## I. INTRODUCTION

This paper will focus on two matters. First, it will describe the background, major provisions, and Food and Drug Administration (FDA) rationale for the recent Consent Decree of Permanent Injunction agreed to by Abbott Laboratories (Abbott). Secondly, it will explain why FDA seeks to identify and hold individual defendants responsible in its enforcement cases, including injunctions.

## II. THE ABBOTT CONSENT DECREE

On November 2, 1999, FDA filed a Complaint for Injunction and a Consent Decree of Permanent Injunction in the U.S. District Court for the Northern District of Illinois.<sup>1</sup> The Complaint alleged that:

- An establishment inspection conducted between May and July 1999 disclosed forty-five deviations from the Quality System Regulation at Abbott's K-2 and Abbott Park facilities, which manufacture *in vitro* diagnostic devices.<sup>2</sup>
- Previous FDA inspections, conducted between 1993 and 1998, disclosed deviations similar to those found in 1999.<sup>3</sup>
- Abbott and FDA met no fewer than ten times during these years to discuss current good manufacturing practices (cGMPs) and, to avoid taking judicial action, FDA allowed the company to continue to operate under an FDA-monitored compliance plan that began in 1995.<sup>4</sup>
- FDA terminated the plan in early 1998 because, in its view, the company was not making sufficient progress.<sup>5</sup>

The 1999 inspection and court filings followed.

Three provisions make this consent decree novel and of particular interest: 1) a one-time payment by Abbott to the U.S. Department of Treasury for \$100 million;<sup>6</sup> 2) provisions requiring Abbott either to validate manufacturing processes and its corrective and preventive action system within time frames approved by FDA or pay \$15,000 per business day for each process and system not validated within the time frame;<sup>7</sup> and 3) a provision requiring Abbott to pay sixteen percent of gross revenues generated by

---

\* Mr. Blumberg is Deputy Associate General at the Office of the General Counsel, Food and Drug Division, United States Department of Health and Human Services, Rockville, MD.

<sup>1</sup> United States v. Abbott Lab., White, and Brown, No. 99 CV 7135, Complaint (N.D. Ill. filed Nov. 2, 1999) [hereinafter Complaint]; United States v. Abbott Lab., White, and Brown, No. 99 CV 7135, Consent Decree of Permanent Injunction (N.D. Ill. filed Nov. 2, 1999) [hereinafter Consent Decree].

<sup>2</sup> Complaint, *supra* note 1, at 5.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* at 6.

<sup>5</sup> *Id.*

<sup>6</sup> Consent Decree, *supra* note 1, ¶ 6.

<sup>7</sup> These payments were capped at \$10 million and cover the first year of the Decree. *Id.* ¶ 10.

the sale of any "medically necessary" product not validated within one year of entry of the Decree.<sup>8</sup> These provisions raise a number of questions which must be answered.

### A. *What Was FDA's Legal Theory For Asking Abbott to Pay Any Amount?*

FDA relied on the doctrine of disgorgement, which is a long-recognized equitable remedy developed to prevent unjust enrichment and to deprive a defendant of ill-gotten gains.<sup>9</sup> Disgorgement is not a punitive measure; rather, it is designed to be a deterrent.<sup>10</sup> Disgorgement is not the same as restitution. The latter is another equitable remedy designed to compensate victims of wrongdoing. Disgorged funds typically go to a governmental entity.<sup>11</sup> Restitution is paid to the victims.<sup>12</sup>

In FDA's view, Abbott's distribution of GMP-adulterated cGMPs adulterated diagnostic devices resulted in the generation of corporate proceeds to which the company was not entitled.

### B. *Why Did Abbott Have to Pay \$100 Million?*

This amount was not derived by precise mathematical calculation. FDA believed the amount had to be large enough to attract industry's attention to an issue FDA was trying to address, and to serve as a meaningful deterrent. The issue of concern to FDA was that industry was not taking seriously the need to bring medically necessary products into compliance with cGMPs. One hundred million dollars was judged to have a deterrent effect because it represented a significant fraction of the company's profits generated by the sale of violative products.<sup>13</sup> Finally, the amount had to be acceptable to the company in the context of the overall settlement.

### C. *Why Abbott and Why This Time?*

The roughly contemporaneous occurrence of three events resulted in Abbott being the first company to have such a Decree:

- (1.) FDA was focusing actively on what to do about medically necessary products (products that patients need for serious diseases and conditions but which would be unavailable if the major supplier was shut down). FDA's perception was that companies were not taking cGMP compliance seriously because they believed FDA would not remove medically necessary products from the market.
- (2.) On September 13, 1999, the U.S. Court of Appeals for the Sixth Circuit held that courts are empowered to order any equitable remedy not prohibited expressly by the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>14</sup> This decision thoughtfully and persuasively rejected a line of previous FDA cases in which courts had held

---

<sup>8</sup> *Id.* ¶ 6.

<sup>9</sup> *Securities & Exch. Comm. v. Commonwealth Chem. Sec.*, 574 F.2d 90, 95 (2d Cir. 1978).

<sup>10</sup> *Securities & Exch. Comm. v. Pennsylvania Cent. Co.*, 425 F. Supp. 593, 599 (E.D. Pa. 1976).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> A review of Abbott's 1998 annual report showed that Abbott's diagnostic division realized \$488 million in net operating earnings during 1998. ABBOTT LABS., 1998 ANNUAL REPORT 29 (1999).

<sup>14</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq. (1994)); *see also* *United States v. Universal Management*, 191 F.3d 750 (6th Cir. 1999).

that the FDCA does not authorize an equitable remedy unless the remedy is authorized explicitly by the statute.<sup>15</sup>

- (3.) Abbott's history of producing many medically necessary products that, in FDA's view, were not in compliance with cGMP, came to the attention of senior FDA managers.

No facts support that there was an FDA vendetta against Abbott. As for the FDA district office, it is worth recalling that Abbott was given six years to resolve its cGMP problems.<sup>16</sup> This hardly suggests a "trigger-happy" district.

#### D. Will FDA Look for Similar Terms in Other Cases?

The short answer is yes. When facts of particular cases show that disgorgement or restitution is appropriate, FDA will seek those remedies in settlements and, failing settlement, from the courts.

### III. INDIVIDUAL RESPONSIBILITY

It is necessary to shift now to the second topic regarding FDA's view of individual responsibility and, more specifically, explain why FDA names individuals as defendants in its enforcement actions, which include injunction cases and consent decrees.

Before discussing this issue, it must be made clear that the following explanation probably is not necessary for most of the persons in the industries FDA regulates. Many companies earnestly try to and effectively do meet their regulatory obligations; these companies and persons will have no occasion to be concerned about individual exposure.

Despite longstanding FDA and U.S. Department of Justice policies to hold individuals accountable in enforcement actions, company executives react with surprise and sometimes anger at personally being associated with the wrongdoing that brought their companies to court. They appeared to believe that this was a corporate problem, which would not affect them directly. To eliminate this surprise and diffuse this anger, it is necessary to make FDA's reasons more transparent. FDA's reasons for including specific individuals as defendants in its enforcement actions and consent decrees of injunction follow.

#### A. Core Value of the FDCA

Personal responsibility is a hallmark of the FDCA and reflects a core value of FDA compliance and enforcement policy. FDA has defended the doctrine of strict liability three times in the Supreme Court, and has prevailed each time.<sup>17</sup>

Congress and the courts have recognized consistently the paramount importance to society of having foods that are pure and drugs and devices that are safe and perform as they should. In *Smith v. People of California*,<sup>18</sup> a case involving the prosecution under a pornography statute that did not require wrongful intent, the Court explained the rationale for applying the strict liability standard under laws governing food and drugs:

---

<sup>15</sup> *Universal Management*, 191 F.3d at 761-62.

<sup>16</sup> Complaint, *supra* note 1, at 5-6.

<sup>17</sup> *United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 16 (1964); *United States v. Park*, 421 U.S. 658 (1975).

<sup>18</sup> 361 U.S. 147 (1960).

The rationale for such statutes is that the public interest in the purity of its food supply is so great as to warrant the imposition of the highest standard of care on distributors . . . an absolute standard which will not hear the distributors plea as to the amount of care he has used.<sup>19</sup>

More recently, in *United States v. Park*,<sup>20</sup> the Supreme Court interpreted the FDCA, saying:

*Dotterweich* and the cases which have followed reveal that in providing sanctions which reach and touch the individuals who execute the corporate mission — and this is by no means necessarily confined to a single corporate agent or employee — *the act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.* The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them.<sup>21</sup>

These cases can be read to mean that people who are responsible for making foods and medical products that are distributed to and relied on by millions of consumers occupy a virtual fiduciary relationship to the public. This relationship is not unlike that between a doctor and patient or a bank and its depositors.

To be sure, FDA shares this trustee relationship to the consumer with industry leaders; but the initial and ultimate responsibility remains with these leaders. This is true not only because the law makes it so, but also for the practical reason that FDA cannot be in every factory, much less monitor every decision that is made every day that affects the quality of our food and drugs.

## B. *Accountability*

FDA names individual defendants because ultimately people are responsible for the violations. They either actively participated in the unlawful conduct, allowed it to happen by passively tolerating violations, or failed to take steps to learn that the violations were occurring. Responsibility frequently is shared by several or many people in a company, but such diffusion should not obscure personal responsibility from individual decisions.

## C. *Deterrence*

It is a cardinal tenet of enforcement philosophy that holding people accountable for their unlawful conduct, through public and peer censure, fines, incarceration, and other sanctions, will deter others similarly situated from engaging in the same conduct. If they wish to avoid the sanction, they avoid the prohibited conduct. FDA hopes that its policy and practice of naming corporate executives and other responsible employees in its court cases and consent decrees will serve as an additional motivating force to encourage compliance.

---

<sup>19</sup> *Id.* at 152.

<sup>20</sup> 421 U.S. at 658.

<sup>21</sup> *Id.* at 672 (emphasis added).

#### D. *Effective Decree Implementation*

There is another reason why FDA names specific individuals in its consent decrees: to help ensure that the terms of the decree will be implemented faithfully after it is entered by the court. If John Doe and Mary Roe are identified as individual defendants in consent decrees, they can be counted on to actively and openly resist courses of conduct espoused by other corporate officials (who have not been named as defendants) that would delay, undermine, or frustrate implementation. If the government must bring a contempt action, the named individuals will be the first to be considered for additional sanctions.

#### IV. CONCLUSION

All of these policy reasons for including individuals — core philosophy of FDCA, accountability, deterrence, and forward implementation — are overlooked by the prospective defendants and their counsel at the settlement talks. They typically argue that it is not legally necessary to name individuals, that naming individuals is punitive, or that the act of naming individual defendants raises enough awareness so that deterrence is not necessary. Even if these arguments were valid, they do not address the foregoing policy reasons for naming individual defendants in enforcement actions and consent decrees.

In closing, it should be reiterated that the majority of people in FDA-regulated industries comply with regulatory obligations. Those who are not in the majority, however, should pay attention to the special relationship their companies owe to the public.

