

ENFORCEMENT CORNER



Courts Rule that Confronting FDA Has Costs

by John R. Fleder

It is generally thought that companies have constitutional and other rights to disagree with the Food and Drug Administration (FDA). However, a recently-decided appeals court decision shows the potential perils faced by a company and its officers who aggressively defend their position.

FDA has prioritized potential enforcement actions concerning unapproved drugs.¹ The prosecution of Marilyn Coleman, owner of Ovimmune, Inc., and her business partner, Mitchell Kaminski, appears to be somewhat of an anomaly, in that the prosecution may have largely been based on what FDA considered was an intransigent group of defendants who clearly played “hard ball” during an FDA investigation.² Moreover, this prosecution demonstrates that while many companies regulated by FDA may believe that they have a right to contest FDA, the price for doing so may be quite high and potentially unfair to those persons who identify concerns with FDA’s actions.

Ms. Coleman, a former assistant professor of poultry science at Ohio State University, patented a process for making “hyperimmunized” eggs and launched Ovimmune, Inc. in 1993. The egg products were manufactured by “vaccinating” chickens with specific antigens (disease agents) that could result in eggs creating antibodies against these diseases. Ms. Coleman believed that the eggs were foods, not drugs; the chickens were vaccinated like other chickens, and she did not add anything to the eggs. In 1998, the U.S. Department of Agriculture (USDA) notified her that Ovimmune’s hyperimmunized eggs were “Generally Recognized as Safe” for human consumption and could be marketed as food products. From 1998 through 2002, Ms. Coleman marketed the eggs to allegedly protect people from a wide range of diseases.³

FDA’s Investigation and Prosecution of Defendants

As a result of health claims that a distributor used in marketing Ovimmune’s product, and a complaint made by a school nurse,⁴ FDA became aware of Ovimmune eggs and the agency started an investigation. In 2001, FDA sent Ms. Coleman a Warning Letter telling her to stop making health claims for her egg products, because the claims caused the eggs to be unapproved new drugs.⁵ Shortly thereafter, FDA investigators conducted a search at Ovimmune’s farm. Apparently still not understanding (or agreeing with) FDA’s view of the law, Ms. Coleman notified FDA of her intent to market the egg powder as a dietary supplement.⁶ Although FDA again informed Ms. Coleman that the egg product was a drug because of the implied claims that it treated diseases, Ms. Coleman continued to market the product.⁷

In 2002, a federal grand jury in Columbus, Ohio returned a 23 count *felony* criminal indictment against Ms. Coleman, Mr. Kaminski and Ovimmune, Inc., charging them with running a criminal conspiracy, engaging in mail fraud, and violations of the Federal Food, Drug, and Cosmetic Act (FDCA). The government charged them with illegally marketing the egg powder as a cure for various physical ailments, including cancer, fibromyalgia, candida, toenail fungus and rheumatoid arthritis. The indictment alleged that Ovimmune’s egg product was an adulterated drug that was produced under insanitary conditions, without adequate testing and approvals.⁸

The jury rejected all the conspiracy and mail fraud counts, but did find that the egg product was unapproved, adulterated and misbranded. The defendants were found guilty of five counts of

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introducing unapproved new drugs into interstate commerce, four counts of introducing misbranded drugs into interstate commerce, failure to register a drug manufacturing facility, three counts of misbranding drugs while held for sale after shipment in interstate commerce, and two counts of producing adulterated drugs.⁹ Each violation constituted a misdemeanor only, because the jury found that the defendants did not act with the intent to defraud or mislead, thereby finding them not guilty of the more serious felony charges. The District Court found that the government had failed to produce any convincing evidence that the defendants lacked faith in their product.¹⁰ Nevertheless, the government subsequently sought sentences of 30-37 months imprisonment for the two individuals, based on their convictions for *misdemeanor* violations of the FDCA.

The Court grouped the counts into one count because they all involved substantially the same harm; all counts were based on one product being marketed as an unapproved drug harming one “victim,” society.

Court’s Sentencing of Defendants

The district judge who presided over the trial then determined the sentences to be imposed. Employing the federal Sentencing Guidelines, he began by referring to “the offense level” applicable to a violation of the FDCA (which is 6).¹¹ The Court had the authority to determine sentences by adjusting this base offense level upward or downward based on various factors such as the knowledge and intent of a defendant.

The Court grouped the counts into one count because they all involved substantially the same harm; all counts were based on one product being marketed as an unapproved drug harming one “victim,” society. The government advocated a rather heavy-handed application of proposed upward adjustments, including enhancements and consecutive sentencing provisions. Although Ms. Coleman had been acquitted of fraud charges, the government argued that her fraudulent intentions should nevertheless be used to enhance her sentence. The Court, however, held that such an

enhancement could not be based on behavior for which the defendants had been acquitted because such enhancement would ignore the jury verdict.¹²

Allegations of Obstruction of Justice

The court rulings contain an extensive discussion of whether the sentences to be imposed should be increased if the defendants obstructed justice in the government’s investigation. It was determined that after the FDA, led by Office of Criminal Investigations (OCI) Special Agent Douglas Loveland, executed a search warrant of Ms. Coleman’s home, she and several associates began inquiring into Special Agent Loveland’s background, seeking his Social Security number, his credit reports, and information concerning his military

service.¹³ Ms. Coleman’s customers and associates mounted what the appeals court later referred to as a letter-writing campaign directed to the Secretary of Health and Human Services, the FDA Commissioner, and a Congresswoman, complaining about FDA’s alleged poor treatment of the defendants.¹⁴

The District Court ruled that both individual defendants had obstructed justice, which caused the Court to enhance their criminal sentences. The Court cited the following “facts” as

evidence of the defendants’ obstruction of justice:

- The defendants filed a defamation suit against a person who allegedly provided information and documents to FDA during its investigation of the defendants. Special Agent Loveland testified that this lawsuit prompted potential witnesses to decline to be interviewed by OCI;
- The defendants filed a complaint with FDA’s Internal Affairs Division against Special Agent Loveland;
- Ms. Coleman sent an email to friends, complaining that she had been “raided at gunpoint and warning that the FDA would be interviewing others at gunpoint”;
- Ms. Coleman asked an acquaintance “to ask people in his internet chat group to obtain personal information about [Special Agent] Loveland”;
- She also filed reports with a Sheriff’s Department alleging that FDA had “prevented her receipt of mail and email” and that FDA had engaged in other allegedly improper activity;

- Special Agent Loveland testified that the “accusations had harmed his career” and that the defendants’ actions caused him to have another agent “accompany him on all work related matters” pertaining to the case; and
- Mr. Kaminski “participated in petitions to the Acting [FDA] Commissioner, . . . the Secretary of Health and Human Services, and [a] Congresswoman,” in an effort to “throw [] up roadblocks” to FDA’s investigation.¹⁵

What is most noteworthy about these findings is that the District Court based its obstruction finding on activity which, in some of the cited instances, is similar to conduct routinely undertaken by companies (or more likely their legal counsel) that have disputes with FDA. The determination that each of the above cited actions was evidence of obstruction of justice will surely have a chilling effect on many persons and entities who believe that they have a right to question FDA’s decisions.

Eventually, the judge sentenced Ms. Coleman to six months of community confinement, six months of house arrest, and five years probation. In addition, the defendants were required to provide restitution.¹⁶ The total proceeds from the defendants’ sale of eggs did not amount to more than \$89,000. About \$55,000 resulted from sales to the distributor. Because the distributor had been convicted of a felony associated with the sale (at a profit) of Ovimmune products, the District Court ruled that restitution of the \$55,000 was inappropriate. The remaining \$33,000, however, needed to be returned to the other purchasers of Ovimmune’s egg product.¹⁷

The Appeal

The U.S. Court of Appeals for the Sixth Circuit affirmed in part, and reversed in part, the District Court’s rulings. It initially rejected Ms. Coleman’s argument that the District Court could not enhance her sentence based on her “abuse of trust,” because (as Ms. Coleman claimed) such an enhancement could not be applied where she had merely been convicted of strict liability offenses.¹⁸ However, the Court reversed the District Court’s sentencing enhancement for obstruction of justice as to Mr. Kaminski. The Court ruled that there was insufficient evidence to support that enhancement, based on its finding that Special Agent Loveland acknowledged that the letter Mr. Kaminski had caused to be

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sent to FDA complaining about the FDA investigation had not impacted FDA’s investigation.¹⁹

Conclusion

A lesson to be learned from *Coleman* is that FDA may pursue criminal prosecution for a seemingly minor regulatory violation. Ovimmune was a small corporation and the sale of the hyperimmunized eggs, although found to be adulterated and misbranded, did not apparently cause any physical harm. Nevertheless, the hostilities that developed during the government’s investigation may well have caused the prosecution to be initiated, and surely increased the sentences that were imposed after conviction. ▲

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- 1 FDA, Guidance for FDA Staff and Industry, Marketed Unapproved Drugs - Compliance Policy Guide Sec. 440.100, at 3 (June 2006) (Unapproved Drugs Guidance) available at <http://www.fda.gov/cder/guidance/6911fml.pdf>.
- 2 United States v. Coleman, 370 F. Supp. 2d 661 (S.D. Ohio 2005), *aff’d in part, vacated in part and remanded sub nom.*, United States v. Kaminski, 501 F.3d 655 (6th Cir. 2007).
- 3 501 F.3d at 657-58.
- 4 Hoping that the hyperimmunized eggs would help students with attention deficit disorder, Coleman had contacted a school about using her eggs in the school lunch program.
- 5 FDA Warning Letter to M.A. Coleman (July 24, 2001).
- 6 Letter M.A. Coleman to FDA (Oct. 19, 2001).
- 7 FDA Courtesy Letter to M.A. Coleman (Nov. 16, 2001).
- 8 370 F. Supp. 2d at 662-64.
- 9 *Id.* at 664.
- 10 *Id.* at 669-70.
- 11 U.S. Sentencing Guidelines Manual § 2N2.1 (2007).
- 12 370 F. Supp. 2d at 668-72.
- 13 501 F.3d at 660.
- 14 *Id.* at 661.
- 15 370 F. Supp. 2d at 674-76.
- 16 *Id.* at 681; *see also* 501 F.3d at 664-69.
- 17 501 F.3d at 664-69.
- 18 *Id.* at 665-69.
- 19 *Id.* at 673.