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File Name: 07a0356p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff - Appellee,

v.

MITCHELL V. KAMINSKI (05-3823); MARILYN A. COLEMAN (05-3826); and OVIMMUNE, INC. (05-4509),
Defendants-Appellants.

Nos. 05-3823/3826/4509

Appeal from the United States District Court
for the Southern District of Ohio at Columbus.
No. 02-00130—Algenon L. Marbley, District Judge.

Argued: July 27, 2007

Decided and Filed: August 31, 2007

Before: KEITH, MOORE, and COLE, Circuit Judges.

COUNSEL

ARGUED: Dana M. Pesha, Chicago, Illinois, Ronald E. Laymon, LAW OFFICE, Columbus, Ohio, for Appellants. Deborah A. Solove, ASSISTANT UNITED STATES ATTORNEY, Columbus, Ohio, for Appellee. **ON BRIEF:** William J. Harte, WILLIAM J. HARTE, LTD., Chicago, Illinois, Ronald E. Laymon, LAW OFFICE, Columbus, Ohio, Mark A. Whitt, JONES DAY, Columbus, Ohio, for Appellants. Deborah A. Solove, ASSISTANT UNITED STATES ATTORNEY, Columbus, Ohio, for Appellee.

OPINION

KAREN NELSON MOORE, Circuit Judge. Defendants-Appellants Mitchell V. Kaminski ("Kaminski"); Marilyn A. Coleman ("Coleman"); and Ovimmune, Inc. ("Ovimmune") (collectively, "Appellants") were each convicted under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321 et seq., on fifteen misdemeanor counts of introduction into interstate commerce of unapproved new drugs without intent to defraud or mislead; introduction into interstate commerce of misbranded drugs without intent to defraud or mislead; failure to register a drug manufacturing facility without intent to defraud or mislead; misbranding drugs while held for sale after shipment in interstate commerce without intent to defraud or mislead; and adulterating drugs while held for sale after

shipment in interstate commerce. Kaminski and Ovimmune appeal their convictions, and Coleman and Kaminski appeal the district court's calculation of their sentences. For the reasons set forth below, we **VACATE** Kaminski's sentence and **REMAND** his case for resentencing, and in all other respects **AFFIRM** the judgment of the district court.

I. BACKGROUND

A. Factual Background

Coleman and Kaminski were the sole owners and operators of Ovimmune, a for-profit corporation. Kaminski is a medical doctor and board-certified surgeon, while Coleman has a Bachelor of Science ("B.S.") degree in Biology from the University of South Carolina and a Doctor of Philosophy ("Ph.D.") degree in an unspecified subject from Auburn University, but is not a medical doctor. Coleman and Kaminski theorized that chickens immunized against various diseases would produce antibodies to those diseases, that those antibodies would be transmitted to the yolks of the chickens' eggs, and that humans could then treat or prevent the diseases by eating the egg yolks. Accordingly, they formed Ovimmune for the purpose of "produc[ing] antibodies from hyperimmune hens for administration to man and animals to modify gut/organism or act as biologic response modifiers for the prevention and/or treatment of disease." Joint Appendix ("J.A.") at 1047 (Articles of Incorporation at 1).

On March 17, 1998, Coleman requested a ruling from the United States Department of Agriculture ("USDA") regarding whether "hyperimmune" eggs are approved for human consumption. On March 25, 1998, the USDA notified Coleman that such eggs are "generally recognized as safe (GRAS)" for human consumption when produced in accordance with relevant regulations and, therefore, may be freely marketed as food products in the United States. J.A. at 1075 (USDA Letter).

Coleman and Kaminski then proceeded to acquire a brood of hens, which they inoculated for various diseases, including chlamydia and candida (a type of yeast that causes, inter alia, thrush). The eggs from the candida-inoculated hens were shipped to a processing plant, where their yolks were pasteurized and reduced to powder. The yolks of the eggs obtained from the chlamydia-immunized hens were collected in Coleman's basement and shipped to Ohio State University ("OSU"), where they were freeze-dried.

Ovimmune sold the candida powder to retailer For Your Health, Inc. ("FYH"), which was owned by Ray Suen ("Suen"), for resale as a treatment for yeast infections.[1] Coleman gave away and sold the chlamydia eggs and chlamydia and candida egg powders to individuals for treatment of various diseases and infections, including rheumatoid arthritis and toenail fungus.

On January 17, 2001, The Richwood (Ohio) Gazette published a front-page article about Coleman, titled "World-Famous Doctor Conducts Avian Antibody Research." J.A. at 1094. The article quoted Coleman as stating, "Immunized chickens produce eggs rich in antibodies which can cure mastitis, toenail fungus, rheumatoid arthritis, etc. We've also had proven success with patients suffering from Chronic Fatigue Syndrome, Fibromyalgia and similar chronic ailments." *Id.* (internal quotation marks omitted). The article reported that Coleman's and Kaminski's research was sponsored by the American Medical Association ("AMA"). It continued:

> The doctors have been involved in medical research for a number of years. Many of their current products can be found on the shelves of health[-]food stores

[1] Suen and FYH subsequently pleaded guilty, in a related case, to felony conspiracy to distribute unapproved new and misbranded drugs.

> throughout the world. One specific formula, CandidaTx, is an affordable, very effective formula which controls vaginitis, toenail fungus and candidiasis.
>
> These older successes help underwrite the expense of the new technology, allowing the doctors to serve patients at a more affordable level.
>
> Ovimmune is planning clinical trials for Lupus, Multiple Sclerosis and patients suffering from Khrone's [sic] Disease. According to Coleman, at least 13 volunteers will be needed per disease. Their treatment will be conducted in cooperation with each person's general physician. "We'll be ready as soon as we have the people lined up," she commented. In all their studies, Coleman and Kaminski work closely with hospitals, universities, medical schools and physicians.
>
> As Coleman explained, the treatment is fairly simple. The only "medication" involved is eating an egg or even a portion of an egg.

Id.

Another published article,[2] titled "Researcher Offers Hope to ADD Patients/Parents," asserted that Coleman and Kaminski had treated "a good number of patients suffering from Fibromyalgia, Chronic Fatigue Syndrome, Crohn's Disease, Lupus and MS" and that the hyperimmune egg products were also effective in treating "systemic candidiasis, candida vaginitis, toe nail fungus, athlete's food, 'jock' itch, etc.," as well as "behavioral disorders in children such as ADD [attention deficit disorder], ADHD [attention deficit-hyperactivity disorder] and in one case, autism." J.A. at 1133. The author noted Coleman's insistence "that the products produced are considered food and not a drug. The egg products are approved by the USDA and FDA as GRAS (generally regarded as safe)." *Id.* The article provided details concerning an upcoming meeting at which individuals could volunteer to participate in a clinical trial to determine whether the egg yolks could alleviate the symptoms of ADD.

During the early part of 2001, Coleman also contacted Sally Wiley ("Wiley"), a school nurse who worked for the Union County, Ohio, schools, and inquired about the possibility of using the district's students as subjects in a study to determine the effectiveness of the egg products in treating yeast-caused and other ailments. Coleman invited Wiley to attend the volunteer meeting.

On March 30, 2001, a teleconference took place among Coleman and Kaminski, representing Ovimmune, and officials of the FDA. During that teleconference, the FDA officials informed Coleman and Kaminski that FDA authorization was required before Ovimmune could conduct clinical trials involving human subjects or administer the egg products to humans for the purpose of treating diseases. Coleman and Kaminski agreed not to conduct any clinical trials and represented that they had given the eggs only to Kaminski's family members (though they also conceded that they had contracted with FYH for distribution of the candida product and that they had no control over the advertising of that product).

Notwithstanding the FDA's instructions and her own representations during the teleconference, Coleman went ahead the very next day with the previously arranged volunteer meeting, at which she passed out egg samples and suggested that participants collect data for her concerning the eggs' efficacy. Wiley, the school nurse, attended the meeting and took notes. She later provided the FDA with those notes and signed a sworn affidavit describing the meeting.

In May 2001, Coleman and Kaminski submitted an article to the American College of Nutrition in which they represented that they had distributed candida eggs free of charge to local

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[2] Though a copy of this article appears in the Joint Appendix, there is no indication on that copy of where or when it was published. *See* J.A. at 1133. Other evidence suggests that it appeared in the Richwood Gazette. J.A. at 1077 (FDA Teleconference Summary at 1).

residents over a seven-month period and collected data that suggested that consumption of the eggs lowered the incidence of toenail fungus. During a June 25, 2001, interview on the show "Well Being With Cindy Bryant," Coleman again described the Ovimmune egg products as effective in treating various human ailments, including "mastitis, toenail fungus, rheumatoid arthritis, CFS or chronic fatigue syndrome, fibromyalgia, . . . ADD, ADHD and autism" as well as "vaginitis . . . and candidiasis." J.A. at 363-64 (Trial Tr. at II79-II80), 1092-93 (Broadcast Recording Labels). At trial, the interviewer for the program testified that she knew that medical claims could only be made by a licensed physician and that she had asked Coleman on-air questions that she would only have asked of a physician.

On July 23, 2001, Coleman sold eight plastic bags of the chlamydia product and one bag of the candida product to an undercover FDA case agent, who covertly made an audio recording of the transaction. During that transaction, Coleman stated that she possessed one M.D. and two Ph.D. degrees and that the egg products that the agent purchased had been tested and proven to be effective in treating rheumatoid arthritis and toenail fungus. She also told the agent that the candida powder would cure toenail fungus.

Coleman gave the agent a tour of her office, which was located in her home. In her basement "research lab," she showed the agent boxes of unrefrigerated eggs. Gov't Ex. 21.2 (July 23, 2001 Tape Tr.) at 16. When volunteers began arriving to open the eggs and collect the yolks, the agent agreed to help them. The tape transcript reveals that all of the participants, including Coleman, were aware that many of the eggs were rotten and contaminated with mold. Coleman twice admitted that "[i]f we weren't so desperate for eggs, we'd throw out the whole thing, but we don't have any." *Id.* at 47. Upon leaving the Coleman residence, the undercover agent stated into the tape recorder:

> I can't believe they're shelling rotten eggs for the yolks are disintegrated black mold in them. Some of them are dried all clumped up it['s] like they're almost dehydrated. It's absolutely disgusting. To think they're freeze-drying that stuff and feeding it to people. I wouldn't feed rotten eggs to my chickens, cooked or otherwise.

Id. at 49.

The agent went on to describe the process by and circumstances under which the egg yolks were collected:

> Right in that room were I would suggest a dozen pieces of 96 dozen eggs. There were insects, weevils, I saw a centipede, dozens of small spiders[,] several different varieties of species crawling all over the room. In it she's got the final product which she gave me some stuff from the egg for my wife for her toenail fungus which is stuff that she sells commercially to other people. It comes out of the dehydrating plant in Zanesville. The other bag is from the stuff we were shucking eggs on tonight. Those eggs[,] you break them open the egg yolks were either already broken or as soon as you jarred them in the least they fractured unless they had started to dehydrate. They looked like they were partially soft[-]cooked even though the yolk and the egg white was fully intact. So I don't know[,] it could have been fungus. A lot of the eggs had black spots from bacteria growing in them and if they weren't solid or if they didn't stick to the shell they went in the stuff to go to Ohio State to make the stuff for pain with my arthritis and all the other problems. That is the product she was desperate for.

Id. at 50.

On July 31, 2001, a team led by FDA Special Agent Douglas Loveland ("Loveland") executed a search warrant at Coleman's home, where they seized egg products. Loveland also seized egg products, belonging to Coleman, that were stored at OSU. The products were subsequently tested and found to contain yeast, mold, and bacteria, including several forms of staphylococcus and at least one bacterium that produced a diarrheal endotoxin. Coleman sent a mass e-mail message following the raid, telling her friends and customers that the FDA had searched her house at gunpoint and intended to do the same to anyone who had purchased her egg products. Several of her associates began inquiring into Loveland's background, seeking his Social Security number, credit report, and information concerning his military service.

On November 30, 2001, Coleman filed a report with the Union County Sheriff's Office, alleging that the FDA was somehow preventing her e-mail and postal mail from reaching her. Coleman filed a second report on January 28, 2002, this time claiming that she had received several telephone calls from an anonymous caller who threatened her with bodily harm if she were to file "that suit." J.A. at 1266-71 (Jan. 28, 2002 Police Report & Attachments).

Coleman did in fact file a civil suit in the Union County Court of Common Pleas on February 21, 2002, naming Wiley (the Union County school nurse), John Doe, and Jane Doe as defendants. The complaint alleged that Wiley had made false statements to Loveland about the informed-consent form that Coleman had distributed at the March 31, 2001 volunteer meeting. Coleman sought damages in the amount of $15 million. The lawsuit was the subject of a front-page article in the local newspaper.

One week after Coleman filed her suit, Loveland tried to interview Connie Davis ("Davis"), a participant in the volunteer meeting held by Coleman on March 31, 2001. According to Loveland, Davis was nervous about assisting in the investigation and agreed only to answer very general questions. Wiley testified at the sentencing hearing that at least one other person who had attended the meeting had expressed reluctance to speak to authorities for fear of becoming a subject of publicity relating to the lawsuit.

On March 8, 2002, Coleman called the FDA's Office of Internal Affairs ("OIA") to complain that Loveland had purposely delayed her receipt of the warning letter that would otherwise have informed her in advance of the raid on her home; that the search warrant authorizing that raid was comprised of "38 pages of lies": that Loveland "pistol whipped" people to get them to tell those lies about Coleman in order "to harm her personally and professionally"; and that Loveland had refused to return some of the seized items despite a court order commanding him to do so. J.A. at 1283-84 (Mar. 8, 2002 Mem.) (internal quotation marks omitted). The OIA advised Coleman that "she and/or her attorney have recourse through the courts if she feels that the FDA is acting inappropriately" and decided to take no further action regarding the matter. J.A. at 1284 (Mar. 8, 2002 Mem. at 2).

On March 13, 2002, Coleman forwarded to the OIA a copy of a document purporting to be a motion to hold the FDA in contempt of court for refusing to return the seized items. J.A. at 1286-1311 (Mar. 13, 2002 Letter & Attachments). Coleman's letter mentioned that an OIA official had discussed the motion with Kaminski the previous week. The letter noted that the motion was only a draft and promised to "fax you the court[-]stamped copy when it is available." J.A. at 1286 (Mar. 13, 2002 Letter). It is undisputed that the motion was never filed.

Coleman filed a third report with the Union County Sheriff's Office on May 6, 2002, this time alleging that Loveland had poisoned Coleman's well with magnesium. Eight days later, Coleman reported a break-in at her home and a gas leak that she suspected was the result of deliberate tampering. A report completed by Detective Jeff Stiers ("Stiers") the following month

reflects that the case arising from the alleged well contamination and gas leak was closed due to insufficient evidence of any wrongdoing.

In July and August 2002, Coleman's customers and associates mounted a letter-writing campaign directed to Tommy Thompson ("Thompson"), the Secretary of the United States Department of Health and Human Services, which oversees the FDA. The letters were nearly identical in tone and content, each complaining of the FDA's poor treatment of Coleman and warning that such actions were likely to result in scandal and embarrassment for the administration. One individual sent a similar letter to Lester Crawford ("Crawford"), the Director of the FDA; another wrote to United States Representative Deborah Pryce. Several of these letters mentioned Loveland by name and speculated that he was acting in collusion with Coleman's competitors or was otherwise corrupt. In September 2002, Kaminski sent a similar letter to the OIA.

Coleman filed yet another police report on September 3, 2002, alleging that someone had broken into her home, removed paper and computer files, and deactivated her computer firewall while she was attending court proceedings. She told the police that "the only people that knew she was going to be away from home and at court were her attorney and the Federal Government." J.A. at 1374 (Sept. 3, 2002 Narrative Supplement). The following week, at Coleman's request, Detective Stiers swept her house for electronic listening devices but found nothing. Stiers noted that this case, too, was closed for a lack of evidence.

B. Procedural Background

On July 31, 2002, Appellants were indicted in the United States District Court for the Southern District of Ohio and charged with conspiracy to introduce into interstate commerce an unapproved and misbranded drug and to defraud (one count per defendant); mail fraud (seven counts per defendant); introduction into interstate commerce of unapproved new drugs (five counts per defendant); introduction of misbranded drugs into interstate commerce (four counts per defendant); failure to register a drug manufacturing facility (one count per defendant); misbranding drugs while held for sale after shipment in interstate commerce (three counts per defendant); and holding and causing to be held for sale adulterated drugs (two counts per defendant). Appellants' trial began on June 23, 2003, and lasted a month. On July 23, 2003, the jury found each of the Appellants guilty on five counts of introduction into interstate commerce of unapproved new drugs; four counts each of introduction of misbranded drugs into interstate commerce; one count each of failure to register a drug manufacturing facility; three counts each of misbranding drugs while held for sale after shipment in interstate commerce; and two counts of holding and causing to be held for sale adulterated drugs.

The district court pronounced sentences for Coleman and Kaminski on April 29, 2005[3] and issued a supplementary sentencing memorandum as to them on May 24, 2005.[4] The court grouped each of the two individual Appellants' convictions into a single count for purposes of sentencing, "because all of the crimes . . . are strict liability and had the same victim: society at large." J.A. at 316-17 (Sentencing Mem. at 27-28); *see also* U.S. SENTENCING GUIDELINES ("U.S.S.G.") § 3D1.2(b). The court applied the preponderance-of-the-evidence standard to facts regarding enhancements suggested by the probation office, except to the extent that an enhancement was

[3] The district court's docket sheet reflects that each of the Appellants moved for a new trial and a judgment of acquittal following the verdict. The district court denied the motions on December 15, 2003. The Appellants subsequently moved for additional time to respond to the Presentence Investigation Report ("PSR") and for an extension of the sentencing date. This procedural history accounts for the unusually long period that elapsed between the verdict and the sentencing hearing.

[4] On June 30, 2005, the district court sentenced Ovimmune, which does not appeal its sentence.

premised upon conduct of which Coleman or Kaminski was acquitted, which conduct the court required to be proven beyond a reasonable doubt.[5]

The district court found that Coleman had abused a position of trust to facilitate the commission of the underlying offenses "by portraying herself as a physician in addition to a Ph.D.," rejecting Coleman's contention that an enhancement of her offense level on this ground was not appropriate "because posing as a physician does not by itself mean that she occupied a position of trust, which is defined as a position 'characterized by professional or managerial discretion (i.e., substantial discretionary judgment that is ordinarily given considerable deference).'" J.A. at 309 (Sentencing Mem. at 20) (quoting *United States v. McCollister*, 96 F. App'x 974, 976 (6th Cir. 2004) (per curiam) (internal quotation marks omitted)). The court concluded that Coleman need not actually *be* a medical doctor to avail herself of the discretion normally afforded one.

Similarly, the district court found that Kaminski, as "a medical doctor, occupied a position of trust." J.A. at 310 (Sentencing Mem. at 21) (citing *McCollister*, 94 F. App'x at 976 ("A practicing physician enjoys perhaps the highest level of discretion afforded any professional.")). Kaminski abused that position, according to the court, by providing patients (several of whom testified at trial) with Ovimmune egg products for the treatment of ailments. Accordingly, the government enhanced Coleman's and Kaminski's offense levels by two points each.

The court went on to find, pursuant to § 3C1.1 of the Guidelines, that both Coleman and Kaminski had obstructed justice. Although "the primary foundation of its finding [was the district court's] recollection of the facts set forth at trial," the court also enumerated several specific findings. J.A. at 311 (Sentencing Mem. at 22). First, the court found that Coleman's suit against Wiley and complaints (and solicitation of the complaints of others) concerning Loveland constituted attempts to impede the investigation and prosecution of Coleman's crimes. Coleman does not appeal that determination.

The court also found that Kaminski had obstructed justice, a finding that Kaminski appeals. At the sentencing hearing, the district court initially indicated that it would impose the obstruction enhancement against Kaminski on the basis of Coleman's actions:

> Based on the testimony, the Court's review of the documents, but more importantly and most importantly, the Court's recollection of the testimony and knowledge of the facts adduced at trial, the Court finds that under all of these circumstances present in this case that there was an obstruction, including the lawsuit filed against Sally Wiley, the complaint filed against Agent Loveland and the reports filed with the Union County Sheriff's Office.
>
> With respect to Dr. Kaminski, the same essentially holds true and the Court agrees with the probation officer's analysis under 3C1.1 and finds that Dr. Kaminski is equally culpable as far as obstruction is concerned.

J.A. at 1011 (Sentencing Tr. at S161). Both the prosecution and Kaminski's defense counsel, however, indicated to the district court that they wished to present additional evidence regarding the proposed obstruction enhancement as it applied to Kaminski, and the court accordingly withdrew its finding. J.A. at 1012 (Sentencing Tr. at S162).

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[5] The district court went on to explain at length its conclusion that acquitted conduct may never be considered at all for sentencing purposes. Because, however, the district court determined as a threshold matter that the government's evidence satisfied neither of the potentially applicable standards, we do not address its broader pronouncement concerning acquitted conduct.

Later in the course of the same hearing, the parties addressed the issue more fully, with counsel for Kaminski arguing that the evidence presented at trial established that Kaminski had not obstructed justice. In particular, Kaminski's counsel argued that Suen had conceded having knowledge of the negative results of efficacy tests conducted on the egg powders, thus proving that Kaminski had testified truthfully in stating that he had told Suen's agent about the test results. J.A. at 1020-24 (Sentencing Tr. at S170-S174). Kaminski's attorney went on to argue that Kaminski could not be found to have obstructed justice by sending the September 10, 2002 letter to the FDA, because Loveland had testified that the letter had no impact on the investigation. J.A. at 1023 (Sentencing Tr. at S173). The prosecution, however, contended that Suen's testimony that he himself had known of the results of the efficacy tests was irrelevant to the truthfulness, or lack thereof, of Kaminski's testimony that he (Kaminski) had informed not Suen but Suen's *agent* of the test results. J.A. at 1025-26 (Sentencing Tr. at S174-S175). At the conclusion of this argument, the district court imposed the obstruction enhancement upon Kaminski on the basis of a finding of perjury: "The Court has heard the evidence at trial. I agree with the probation officer, I agree with the government that Dr. Kaminski did obstruct justice *by providing false testimony*. Therefore, I am going to overrule Kaminski Objection No. 5." J.A. at 1026 (Sentencing Tr. at S175) (emphasis added).

In its subsequently issued sentencing memorandum, however, the court did not mention the perjury question. Instead, after engaging in a lengthy discussion of Coleman's actions (including her defamation suit against Wiley, her complaint to the FDA concerning Loveland's activities, and her solicitation of others to investigate and complain to authorities about Loveland), the court issued the following finding regarding Kaminski's alleged obstruction:

> This Court also finds that the government proved by a preponderance of the evidence that Defendant Kaminski obstructed justice. First, on September 10, 2002, Defendant Kaminski attempted to impede the FDA's investigation by sending a report to Internal Affairs, titled: "OCI Special Agent Douglas Loveland . . . This addendum reports subsequent break-ins, attempted murder and computer crimes." *See* Ex. 23 of government Binder DL-1. Defendant Kaminski participated in petitions to the Acting Commissioner of the FDA, the Secretary of Health and Human Services, and Congresswoman Deborah Pryce. [Presentence Report ("PSR")] at ¶ 39. The Court finds that the government proved by a preponderance of the evidence that Dr. Kaminski's actions were performed in a willful attempt to impede the FDA's investigation by throwing up roadblocks, including leveling malicious personal attacks against SA Loveland. Accordingly, the actions of both Defendants warrant a two-point enhancement for obstruction of justice.

J.A. at 314 (Sentencing Mem. at 25).

After the application of the various enhancements, both Coleman and Kaminski fell into Criminal History Category I, and each had a total offense level of 10, giving rise to an advisory Guidelines range of six to twelve months' imprisonment. After noting that the Guidelines dictate a sentence of imprisonment or of probation with conditions of intermittent or community confinement or home probation, the court imposed a sentence of five years' probation, "substituting imprisonment with six months of 'community confinement' and six months of 'home detention'" for both Coleman and Kaminski. J.A. at 321-22 (Sentencing Mem. at 32-33) (quoting U.S.S.G. § 5C1.1(c)(3)).

In explaining its choice of sentence, the court stated as follows:

> The Court finds that the nature and circumstances of the offense and the history and characteristics of Defendants are such that five years of probation, with

> special conditions of community confinement and home detention, are appropriate. It appears to the Court that profit was exhorted over science and that Ovimmune products were distributed to the public without proper regard for any ensuing negative health effects. It is compelling to the Court that notwithstanding the March 30, 2001 conference call with the Food and Drug Administration, during which FDA representatives told Coleman and Kaminski that they needed an investigational new drug application ("IND") in effect before beginning human testing, Defendant Coleman, the very next day, held a meeting in a local church and gave away Ovimmune products. Indeed, the evidence showed that Defendants consistently circulated this product, touting it as a talisman for whatever ails one. Yet, while Defendants may have believed in their products' effectiveness as an immune booster and healer, evidence at trial, including corroborating photographs, demonstrated that the conditions in which at least some of the eggs were kept were unsanitary. The evidence included such details as rotten, moldy eggs; a dead cat stored less than three feet from raw eggs; live cats running around the basement; egg residue on surfaces; raw eggs remaining unrefrigerated for long periods; and raw eggs covered with blood and manure. This sentence balances the nature and circumstances of the offense with the Defendants' lack of any prior criminal history. Moreover, it allows Defendants, who are well-educated and very connected to their communities and families, to maintain these bonds throughout the period of confinement.

J.A. at 322-23 (Sentencing Mem. at 33-34). The district court further stated that the confinement component of the sentences "reflects the seriousness of the offenses and accomplishes the goals associated with both specific and general deterrence." J.A. at 323 (Sentencing Mem. at 34).

Pursuant to 18 U.S.C. § 3563(b)(2), the district court imposed restitution as a condition of both defendants' probation. "Although Defendants' strict liability offenses victimized society at large, the Court [found that] restitution to purchasers of Ovimmune products [would] compensate for any harm wrought on the consuming public." J.A. at 319 (Sentencing Mem. at 30). At the sentencing hearing, counsel for Coleman argued that the maximum amount of restitution that could be awarded (assuming, arguendo, that restitution was permissible at all) was $20,138, the sum total of all retail sales made by the defendants except for sales to retail distributors and sales to Suen and FYH. In the sentencing memorandum, however, the court ordered restitution in the amount of $33,604.12, the total retail sales less sales to Suen (but including sales to other retailers).

Ovimmune and Kaminski now appeal their convictions. Coleman and Kaminski appeal their sentences.

II. JURISDICTION

The district court possessed subject matter jurisdiction over this federal criminal prosecution pursuant to 18 U.S.C. § 3231. We possess appellate jurisdiction pursuant to 28 U.S.C. § 1291 and 18 U.S.C. § 3742.

III. ANALYSIS

A. Standard of Review

"We review 'a district court's legal conclusions regarding the Sentencing Guidelines *de novo*' and 'a district court's factual findings in applying the Sentencing Guidelines for clear error.'" *United States v. Galvan*, 453 F.3d 738, 739 (6th Cir. 2006) (quoting *United States v. Galloway*, 439 F.3d 320, 322 (6th Cir. 2006)). "We apply de novo review to the district court's interpretation of the Guidelines." *Id.*

B. Appellant Coleman

1. The Abuse-of-Trust Enhancement

The Guidelines provide for a two-level upward adjustment, or enhancement, of the offense level of a defendant who has abused a position of trust. U.S.S.G. § 3B1.3. Coleman claims that the district court erred in applying this enhancement to her sentence, because she was convicted only of strict-liability offenses, none of which required proof of mens rea. She argues that the erroneous offense-level enhancement, in turn, resulted in the district court's improperly calculating the applicable Guidelines range. "Even though the Supreme Court declared the guidelines advisory in *United States v. Booker*, 543 U.S. 220, 125 S. Ct. 738, 160 L. Ed. 2d 621 (2005), we are still required to remand for resentencing if the district court misapplies the guidelines." *United States v. Davist*, 481 F.3d 425, 427 (6th Cir. 2007).

In the PSR that it submitted in advance of Coleman's sentencing, the probation office recommended the abuse-of-trust enhancement on the ground that Coleman falsely portrayed herself as a medical doctor in order to promote the egg products as medical cures. J.A. at 1502 (Coleman PSR at 11 ¶ 54). In response, Coleman filed a sentencing memorandum in which she argued, inter alia, that the fact that she posed as a physician did not mean that she occupied a position of trust vis-a-vis the victims. J.A. at 247-49 (Coleman Sentencing Mem. II at 15-17). Her memorandum asserts that the jury, in acquitting Coleman of the fraud charge, implicitly found that she had not abused a position of trust. *Id.* Coleman argued that the strict-liability nature of the offense of which she was convicted precluded the application of the enhancement. *Id.*

While Coleman's counsel did once state, during the sentencing hearing, that Coleman did not occupy a position of trust,[6] that statement was supported by no argument and was not the thrust of Coleman's objection. The true gravamen of Coleman's challenge to the enhancement, as set forth in her sentencing brief in the district court, was that the only issue determined at trial—that the egg powder is a drug under federal law—did not support an application of the enhancement, particularly in light of the fact that the jury acquitted Coleman of fraud. J.A. at 248 (Coleman Sentencing Mem. II at 16).

In its Sentencing Memorandum, the district court rejected Coleman's argument, ruling that Coleman had, by holding herself out as a physician, assumed a position of trust that significantly facilitated her offense. J.A. at 309-11 (Sentencing Mem. at 20-22). The district court noted specifically that Coleman made the false representations in the course of convincing the undercover agent to purchase the chlamydia and candida products. J.A. at 310 (Sentencing Mem. at 21). The district court expressly stated that Coleman's belief in the efficacy of her product (i.e., her innocence of fraud) did not alter that finding. *Id.*

On appeal, Coleman reiterates her contention that the abuse-of-trust enhancement is inapplicable to strict-liability crimes. She points out that, according to the Commentary to the Guidelines, "[f]or this [abuse-of-trust] enhancement to apply, the position of public or private trust must have contributed in some significant way to facilitating the commission or concealment of the offense (e.g., by making the detection of the offense or the defendant's responsibility for the offense more difficult)." U.S.S.G. § 3B1.3 cmt. n.1 (2000).[7] The note provides the following illustrations:

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[6] Counsel's verbatim statement was, "To the extent that someone understood Dr. Coleman as a physician rather than a Ph.D. did not significantly facilitate the offense nor did she occupy a position of trust of physicians." J.A. at 958-59 (Sentencing Tr. at S66-S67).

[7] Appellants were sentenced under the 2000 edition of the United States Sentencing Guidelines Manual.

> This adjustment, for example, applies in the case of an embezzlement of a client's funds by an attorney serving as a guardian, a bank executive's fraudulent loan scheme, or the criminal sexual abuse of a patient by a physician under the guise of an examination. This adjustment does not apply in the case of an embezzlement or theft by an ordinary bank teller or hotel clerk because such positions are not characterized by the above-described factors.

Id. Coleman relies on the fact that all of the enumerated examples are specific-intent crimes requiring proof of mens rea.

Neither party has submitted, and we have been unable to find, any decision by any federal court precisely on point. Perhaps the most analogous case is the Ninth Circuit's unpublished opinion in *United States v. Merz*, No. 97-30176, 1999 WL 50880 (9th Cir. 1999) (unpublished). In *Merz*, the defendant "did not argue at sentencing whether he occupied a position of trust. He argued instead that he lacked the mens rea to abuse the position of trust that he enjoyed." *Id.* at *2. The Ninth Circuit affirmed the district court's application of the enhancement, holding that "the record shows that Merz abused a position of trust. He created a business and placed himself into a position of trust that provided him the freedom to commit a difficult-to-detect wrong." *Id.* (internal quotation marks omitted). Merz's business was that of a car courier to whom clients entrusted money with which he was to procure cars for them. And while Merz, unlike Coleman, was convicted of fraud, the Ninth Circuit's rationale for applying the enhancement was not the nature of the crime but, rather, the nature of the relationship between the defendant and his victims, which—consistent with the Guidelines language—significantly facilitated the offense.

Indeed, the cases cited by Coleman herself support the application of the enhancement, as they indicate that it is appropriately imposed where the *conduct on which the enhancement is based* (rather than the underlying offense conduct) is of a similar character as the examples given in the Application Notes. *See United States v. Peters*, 394 F.3d 1103, 1106-07 (8th Cir. 2005) ("Application Note 4 to U.S.S.G. § 3C1.1 lists examples of conduct that may constitute obstruction of justice. Each example represents conduct substantially more egregious than that of Peters."); *United States v. Strachan*, 5 F. App'x 169, 173 (4th Cir.) ("Although these examples are not exhaustive, they do provide insight into the nature of the activity by the defendant contemplated by [§ 3C1.1]. In reviewing them we find these illustrations to involve conduct actually much more egregious in character than [that engaged in by the defendant]."), *cert. denied*, 534 U.S. 931 (2001).

In this case, Coleman assumed the mantle of trust accorded to a medical doctor—and there is no question that she did so deliberately—by affirmatively misrepresenting her professional credentials. Moreover, the evidence indicates that she did so in connection with her marketing and sale of the egg powders, as the misrepresentations were invariably made to consumers of the powders or during interviews about the products. This conduct is similar in nature to the examples in the Application Notes: misconduct by an attorney, a bank executive, or a physician while serving in the role of a trusted fiduciary. In short, Coleman violated the law, and she assumed a position of trust in relation to her victims while doing so. This behavior was not substantially less egregious than that contemplated by the enhancement provision.

Coleman next argues that her assumption of a position of trust did not significantly facilitate her crime. In support of this contention, she asserts that her action in claiming to be a medical doctor was irrelevant to the only issue that the jury decided in convicting her—namely, whether or not the egg powders were drugs. While the proper characterization of the powders was the only

undecided issue, however, it is not the only element of the *offense*.[8] Coleman was convicted, inter alia, of introducing unapproved new drugs and misbranded drugs into interstate commerce, and holding and causing to be held for sale adulterated drugs. These crimes—the marketing and selling[9] of the egg powders—were, in turn, significantly facilitated by the consumers' belief that Coleman was a physician.

Indeed, Coleman's desire to persuade others to consume her products was obviously the very reason that she made the misrepresentations, the efficacy of which was shown at the sentencing hearing via the testimony of Rebecca Keller ("Keller"), which demonstrated conclusively that consumers of the powder consulted Coleman for medical advice. After becoming ill upon taking the egg powder, Keller called Coleman for instructions, which Coleman gave and Keller followed. J.A. at 960 (Sentencing Tr. at S74).

As we held in *United States v. Gilliam*, a "position of trust arises almost as if by implication when a person or organization intentionally makes himself or itself vulnerable to someone in a particular position, ceding to the other's presumed better judgment some control over their affairs." 315 F.3d 614, 618 (6th Cir.) (internal quotation marks omitted), *cert. denied*, 540 U.S. 1155 (2004). We stated, in *Gilliam*, that the Guidelines' examples of situations in which the enhancement is properly applied "translate directly to the types of relationships where a 'fiduciary duty' exists by implication (e.g., physician-patient, lawyer-client, officer-organization, etc.)." *Id.* Coleman created such relationships when she held herself out to be a medical doctor in connection with her offering of the egg powders as treatments for disease, and her customers relied on those relationships in consuming the powders.

Coleman's final argument on this point is that an enhancement under these circumstances is inconsistent with the rule that a court, when imposing a sentence for a strict-liability crime, may not depart downward from the Guidelines range on the ground that the defendant lacked mens rea. The cases that she cites for this proposition, however, all involve "lesser-harm" departures, which a district court may utilize to impose a below-Guidelines sentence upon a defendant who inflicted less harm on his or her victims than that sought to be prevented by the statute. Each of these immigration cases did involve the strict-liability offense of illegal reentry after deportation, but our sister circuits held lesser-harm departures impermissible not due to the strict-liability nature of the crimes but, rather, because the defendants had not actually perpetrated less harm than that contemplated by the statute prohibiting such reentry; because the statute prohibited illegal reentry, the motives of the defendants for their illegal reentry were irrelevant. *See United States v. Hernandez-Baide*, 392 F.3d 1153, 1155-56 (10th Cir. 2004), *vacated & remanded*, 544 U.S. 1015 (2005); *United States v. Saucedo-Patino*, 358 F.3d 790, 794-95 (11th Cir. 2004); *United States v. Dyck*, 334 F.3d 736, 741-42 (8th Cir. 2003); *United States v. Carrasco*, 313 F.3d 750, 755-56 (2d Cir. 2002).

In this case, the district court imposed the enhancement not because Coleman had committed a more egregious harm than that sought to be prevented by the statute but, instead, because the offenses that she did commit were facilitated by the trust that she enjoyed as a putative doctor. *See* U.S.S.G. § 3B1.3. In other words, the victims of Coleman's crime were individuals who were rendered particularly vulnerable by the trust that they reposed in Coleman. Accordingly, we hold that the district court did not err in finding that Coleman occupied a position of trust and concluding that her abuse of that position significantly facilitated the commission of the offense.

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[8] Again, we refer to a single "offense" because the district court grouped Coleman's convictions for purposes of sentencing.

[9] The Supreme Court has characterized the FDCA as regulating "drug manufacturing, marketing, and distribution." *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 361 (2002).

2. Restitution

When the law authorizes a restitution order, "we . . . review the amount ordered under the abuse of discretion standard." *United States v. Comer*, 93 F.3d 1271, 1278 (6th Cir.) (internal quotation marks omitted), *cert. denied*, 519 U.S. 1033 (1996). The district court ordered restitution pursuant to 18 U.S.C. § 3563(b)(2), which provides a sentencing court with discretion to order restitution to victims as a condition of probation. Coleman concedes that the district court possessed such discretion under § 3563(b)(2), but contends on appeal that the court erroneously failed, in calculating the amount of the restitution award, to account for the benefits received by retailers and consumers of the egg products.

Coleman did not, however, make this argument before the trial court. Rather, she contended in her sentencing memorandum and at the sentencing hearing that the distributors and individual recipients of the egg products were not properly characterized as victims, because all had indicated satisfaction with the products and requested more. Coleman did not, in other words, dispute the *amount* of restitution awarded or argue that that amount should be calculated with reference to benefits gained by the victims. Instead, she focused on the *identities* of the victims, as determined by ascertaining whether any of the egg-powder recipients had suffered a financial loss.[10] Because her contention that the district court improperly calculated the amount of restitution owed to each victim is raised for the first time on appeal, we decline to consider that argument. *See, e.g., Pinney Dock & Transp. Co. v. Penn Cent. Corp.*, 838 F.2d 1445, 1461 (6th Cir.), *cert. denied*, 488 U.S. 880 (1988).[11]

Coleman also contends that the district court erred in finding that society at large was the victim of her crimes. The statute defines a "victim," for the purposes of restitution, as "a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered . . . ." 18 U.S.C. § 3663(a)(2).[12] In arguing that society suffered no direct and proximate harm, Coleman again reiterates her contention that recipients of her products experienced benefits.

We rejected a similar argument in *United States v. Universal Management Services, Inc.*, 191 F.3d 750 (6th Cir. 1999), *cert. denied*, 530 U.S. 1274 (2000). In *Universal*, the defendants appealed the district court's award of restitution on the ground that the FDA charge against them was based only upon their failure to secure approval of their product and not upon any allegation that it was ineffective, and thus no detriment to consumers had been shown. *Id.* at 763. We held, however, that restitution to consumers of the product was an appropriate remedy for the harm to the general public, because the purpose of the approval requirement is "to protect consumers' health *and their pocketbooks*." *Id.* (emphasis added). Consumers purchase such products upon the mistaken assumption that the products are produced in compliance with federal regulations; the "economic

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[10] To the extent that Coleman means to argue on appeal that there is no evidence to support the amounts attributed to each recipient by the district court, that objection has been waived.

[11] In any event, Coleman offers no evidence that might prove useful in quantifying the benefits, if any, conferred upon the victims.

[12] The district court ordered restitution as a condition of probation, pursuant to 18 U.S.C. § 3563(b)(2), which provides for restitution to the victim of the offense "under section 3556." Section 3556, in turn, states that the sentencing court "may order restitution in accordance with section 3663."

harm to consumers contemplated by the FDCA" is, thus, that consumers who are deceived in this manner do not get what they pay for. *Id.*[13]

Here, as in *Universal*, Appellants sold unapproved drugs to members of the public even after being notified that FDA approval was required. In so doing, they inflicted economic harm on the consumers of their products. Accordingly, the district court did not abuse its discretion by ordering restitution.

C. Appellant Kaminski

1. The Conviction[14]

a. The FDA's Compliance With Its Own Rule

Kaminski contends that his prosecution was impermissible due to the FDA's failure (1) to abide by its own final rule[15] providing manufacturers of dietary supplements an eighteen-month grace period within which to comply with new labeling requirements and (2) to provide Kaminski with notice and an opportunity to correct his alleged violation. As the United States points out, however, Kaminski never raised these arguments before the district court, and they are accordingly forfeited unless this court finds plain error. *See* FED. R. CRIM. P. 52(b) ("A plain error that affects substantial rights may be considered even though it was not brought to the court's attention."); *United States v. Young*, 470 U.S. 1, 15 (1985) (holding that Rule 52(b) "authorizes the Courts of Appeals to correct only particularly egregious errors, those errors that seriously affect the fairness, integrity or public reputation of judicial proceedings" (internal quotation marks and citation omitted)).

Moreover, Kaminski's argument appears to be completely irrelevant to this case, both because (as the jury found) the egg powders are not dietary supplements but drugs and because the charges against him were not based solely on labeling violations. In any event, Kaminski cites no case law to support his assertion that the FDA's alleged failure to follow its own rule or to provide him with notice and an opportunity to be heard by an agency official precluded the United States from prosecuting him for violations of the FDCA. Moreover, he concedes that (1) the notice provision contains several exceptions, and (2) the FDA did not begin enforcement procedures against him or any other Appellant until after the eighteen-month period had undisputedly expired. *See* 21 C.F.R. § 7.84(a). Accordingly, Kaminski has failed to show that the district court's judgment constituted plain error.

b. Sufficiency of the Evidence

Kaminski also contends that the egg products constituted foods, not drugs, under applicable FDA regulations. The United States correctly characterizes this argument as a challenge to the sufficiency of the evidence supporting Kaminski's convictions, as a finding that the egg products were drugs was a necessary element of each crime with which he was charged. Pursuant to long-

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[13] *Universal* arose, in fact, from violations of one of the very FDCA provisions at issue here, which prohibits the introduction into interstate commerce of misbranded foods, drugs, or devices. 21 U.S.C. § 331.

[14] Because the resolution of Ovimmune's challenge to its conviction turns on precisely the same issues implicated by Kaminski's appeal on the issue, both challenges are resolved in this section, in which, for the sake of brevity, we refer only to Kaminski.

[15] Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, 65 Fed. Reg. 1000-01 (Jan. 6, 2000) (codified at 21 C.F.R. pt. 101).

standing Supreme Court precedent, we determine "whether, after viewing the evidence in the light most favorable to the prosecution, *any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt." *Jackson v. Virginia*, 443 U.S. at 319.

The relevant provision of the FDCA defines the term "drug" as

> (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) *articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man* or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1) (emphasis added).

Kaminski contends that the egg products are more accurately characterized as dietary supplements. He points to language in § 321(g) providing that a "dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement." Section 343(r)(6), in turn, sets forth the circumstances under which a dietary supplement may bear a label that (1) "claims a benefit related to a classical nutrient deficiency disease"; (2) "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans"; or (3) "describes general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A). The statute requires that any such label include a disclaimer of any intent "to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(C). Moreover, § 343(r)(6) requires the supplement's manufacturer to notify the FDA, within thirty days, of the placement of any such statement on the label of a marketed product. 21 U.S.C. § 343(r)(6).

Kaminski's reliance upon this statutory scheme is unavailing. The egg powders are drugs not because their labels state that they ameliorate nutrient deficiencies, "affect the structure or function in humans," or promote general health but, rather, because Kaminski and Coleman distributed them to consumers for the express purpose of treating and/or preventing diseases. The pattern of statements made by the defendants, and particularly by Coleman, along with the methods of sale and distribution of the products, conclusively demonstrate this fact. Contrary to Kaminski's contentions, the FDA's investigation and the United States's prosecution were not based solely on "newspaper articles that generally discussed Dr. Coleman's research and the language of the label," Kaminski Br. at 26; as explained above, the evidence in this case included not only newspaper articles and labeling materials but also the testimony of consumers who purchased the products for the express purpose of curing illnesses. Accordingly, the evidence was sufficient to lead a reasonable jury to find that the egg products were drugs.

2. The Sentencing Enhancement

Finally, Kaminski argues that the district court erred in enhancing his base offense level by two levels pursuant to § 3C1.1 of the Guidelines, on the ground that his conduct impeded the investigation and prosecution of Appellants' crimes. "We review for clear error a district court's factual findings underlying its decision to impose an obstruction-of-justice enhancement under § 3C1.1. Conclusions as to what facts constitute obstruction of justice are then reviewed de novo." *Davist*, 481 F.3d at 427 (internal citation omitted).

At the sentencing hearing, the district court found that Kaminski had perjured himself at trial. As noted above, however, the subsequently issued sentencing memorandum does not reflect the perjury finding, and so the district court presumably did not rely upon that finding. In the sentencing

memorandum, the district court concluded that Kaminski "attempted to impede the FDA's investigation" by sending the September 10, 2002 letter to the OIA and by "participat[ing] in petitions to the Acting Commissioner of the FDA, the Secretary of Health and Human Services, and Congresswoman Deborah Pryce." J.A. at 314 (Sentencing Mem. at 25).

As an initial matter, we note that we cannot find support in the record for the district court's finding that Kaminski participated in any petitions to the government entities listed in the memorandum. The only source cited for that finding is paragraph 39 of Kaminski's PSR, which mentions only Kaminski's trial testimony and the September 2002 letter to the FDA. J.A. at 1453 (Kaminski PSR at 9 ¶ 39). Accordingly, we cannot accept the finding that Kaminski impeded the investigation through communications to the Commissioner, Secretary, or Congresswoman, based upon our review of the record. *See, e.g.*, *United States v. Stubbs*, 11 F.3d 632, 638-39 (6th Cir. 1993). The only evidence properly considered by the district court in imposing the enhancement, then, is Kaminski's September 10, 2002, letter to the FDA.[16]

The Application Notes to § 3C1.1 of the Guidelines, pursuant to which the district court imposed the obstruction enhancement, provide examples of the types of conduct ordinarily covered by § 3C1.1. Note 5(b) provides that "making false statements, not under oath, to law enforcement officers" generally does *not* constitute obstruction, unless Note 4(g) applies.[17] U.S.S.G. § 3C1.1 cmt. n.5(b). Note 4(g), in turn, states that "providing a *materially false* statement to a law enforcement officer *that significantly obstructed or impeded the official investigation or prosecution of the instant offense*" will usually be considered obstruction of justice.[18] *Id.* cmt. n.4(g) (emphases added).

Thus, although the language of § 3C1.1 authorizes the imposition of the enhancement for attempts to obstruct justice as well as obstruction itself, the Notes, which describe with greater specificity types of conduct that do and do not fall within the ambit of § 3C1.1, indicate that an attempt that takes the form of a false but unsworn statement to a law-enforcement officer does not suffice to trigger the enhancement—or, phrased in another way, that an unsworn statement to a law-enforcement officer cannot constitute obstruction of justice under § 3C1.1 unless it significantly obstructs or impedes the investigation or prosecution of the offense. *See United States v. Jarman*, 144 F.3d 912, 914 (6th Cir. 1998) (noting that "the Application Notes to the Sentencing Guidelines are accorded controlling weight"); *United States v. Williams*, 952 F.2d 1504, 1516 (6th Cir. 1991) (reversing, as clearly erroneous, the district court's imposition of a § 3C1.1 enhancement, on the ground that the defendant's unsworn lies to law-enforcement officials did not actually impede the investigation), *cited in United States v. Obi*, 195 F. App'x 335, 339 (6th Cir. 2006).

The question, then, is whether Kaminski's September 10, 2002, letter to the FDA contained false statements that significantly obstructed the investigation. At the sentencing hearing, Loveland testified unequivocally that the letter had no impact whatsoever on the investigation. J.A. at 1009 (Sentencing Tr. at S159). Indeed, the district court made no finding to the contrary; instead, it

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[16] As Loveland noted during the sentencing hearing, the indictment had already been returned by the time the September 10, 2002, letter was sent. J.A. at 1008 (Sentencing Tr. at S158). Loveland testified, however, that the investigation continued even after the indictment was handed down. J.A. at 1010 (Sentencing Tr. at S160).

[17] In the 2000 edition of the Guidelines Manual, Note 5(b) refers to Note 3(g) instead of 4(g). There is, however, no Note 3(g). In the 2004 Manual Note 5(b) was corrected to refer to Note 4(g), and the corrected version appears in all subsequent editions.

[18] "'Material' evidence, fact, statement, or information, as used in this section, means evidence, fact, statement, or information that, if believed, would tend to influence or affect the issue under determination." U.S.S.G. § 3C1.1 cmt. n.6.

imposed the enhancement on the basis of Kaminski's "willful *attempt* to impede the FDA's investigation."[19] J.A. at 314 (Sentencing Mem. at 25) (emphasis added). Because the district court's characterization of the September 10 letter as an *attempt* at obstruction—and, thus, the district court's application of the § 3C1.1 enhancement *on this basis*—was erroneous, resulting in an improperly calculated Guidelines range, we **VACATE** Kaminski's sentence and **REMAND** his case to the district court for resentencing consistent with this opinion. On remand, the district court may consider all relevant record evidence in determining whether an application of the § 3C1.1 enhancement is warranted.

IV. CONCLUSION

For the aforementioned reasons, we **VACATE** Kaminski's sentence and **REMAND** his case for resentencing, and in all other respects we **AFFIRM** the judgment of the district court.

[19] The district court also referred to "malicious personal attacks on SA Loveland," J.A. at 314 (Sentencing Mem. at 25), but provided no citation to the record to support a finding that Kaminski had participated in any such attack other than by sending the September 10 letter.