

[PUBLISH]

**IN THE UNITED STATES COURT OF APPEALS**

**FOR THE ELEVENTH CIRCUIT**

FILED  
U.S. COURT OF APPEALS  
ELEVENTH CIRCUIT  
NOVEMBER 23, 2005  
THOMAS K. KAHN  
CLERK

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**No. 03-16216**  
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D. C. Docket No. 01-01029-CR-AJ

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

FRANCISCO MUNOZ,  
ALBERTO LLONA,

Defendants-Appellants.

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**Appeals from the United States District Court  
for the Southern District of Florida**  
\_\_\_\_\_

**(November 23, 2005)**

**Before HULL, MARCUS and HILL, Circuit Judges.**

**HULL, Circuit Judge:**

Appellants Francisco Munoz (“Munoz”) and Alberto Llona (“Llona”) appeal their convictions and sentences for conspiracy to violate the federal Food,

Drug & Cosmetic Act and six related counts of mail fraud. The charges stem from a scheme to sell, through telemarketing and without prescriptions, two treatments for erectile dysfunction. Appellants challenge their convictions on several grounds, including sufficiency of the evidence. Appellants also argue that their sentences were improperly enhanced on the basis of an incorrect loss calculation and in violation of United States v. Booker, 543 U.S. \_\_\_\_, 125 S. Ct. 738 (2005). After review and oral argument, we affirm Appellants' convictions and sentences.

## I. FACTS

### A. Deceptive Sales

In late 1997 and early 1998, Munoz and Llona began discussing a business proposal with Dr. Carlos Nazir (“Nazir”), a urologist specializing in the treatment of erectile dysfunction. Munoz suggested that he, Llona, and Nazir market anti-impotence treatments to the general public through telemarketing. Nazir proposed the idea of creating a gel containing the prescription drugs prostaglandin, papaverine, and phentolamine. According to Nazir, urologists frequently combined these three drugs into an prescribable “tri-mix” injected directly into the erectile tissue of the penis to treat impotence. Nazir believed that a gel form of tri-mix, applied through a urethral suppository, would be “less aggressive” than an injectable treatment. More specifically, Nazir believed a gel

would be easier for users to apply and less likely to entail serious side effects.

Without direct injection into the penis, however, Nazir was aware that tri-mix gel would be unable to achieve the roughly 70% success rate of tri-mix injections.

In 1998, Munoz and Llona, along with non-party Fernando Maurin, formed U.S. One Marketing Services Corporation (“U.S. One”), a telemarketing business. Together Munoz and Llona owned 67% of U.S. One. Meanwhile, Nazir arranged to obtain tri-mix gel, to be named “Power Gel,” from David Gaudio (“Gaudio”). Gaudio was the owner of, and pharmacist at, Prescription Specialties, a compounding pharmacy in Connecticut.

Because the components of Power Gel were prescription drugs, Gaudio insisted that Nazir provide prescriptions for any Power Gel ordered and that all Power Gel be delivered to Nazir and not to U.S. One. As such, Munoz and Llona, along with Gaudio and Nazir, agreed upon the following arrangement. Nazir wrote prescriptions using the names of his own patients without their knowledge. After Nazir faxed to Gaudio these fraudulent prescriptions, Gaudio shipped the Power Gel to Nazir’s office and billed U.S. One. Nazir provided the drugs to U.S. One and Appellants Munoz and Llona paid Gaudio for the drugs. U.S. One then sold Power Gel to end users who had no connection to Nazir. As Munoz and Llona do not dispute, both knew that Nazir was writing prescriptions in his

patients' names even though his patients were never aware of this fact and never received either the prescriptions or the tri-mix prescribed.

Appellants Munoz and Llona decided to promote Power Gel to a Spanish-speaking market. Munoz, who headed U.S. One's sales efforts, wrote scripts for radio advertisements and infomercials in which both Munoz and Nazir eventually appeared. In the advertisements, Munoz claimed that Power Gel was 100% effective as a treatment for impotence and that it had zero contraindications or side effects. Munoz also instructed Nazir to "enhance" what he said in the advertisements in order to increase sales, asking Nazir to declare that "nothing is better than Power Gel" and insisting that Nazir make no negative statements about Power Gel. The advertisements emphasized that Power Gel required no prescription and could be purchased and used with complete discretion. The advertisements also claimed that Power Gel was easy to apply, caused no pain, produced results in 10 minutes, and resulted in a complete erection lasting from 30 minutes to an hour.

Appellant Llona's responsibilities were more administrative than Munoz's, but Llona also wrote a pamphlet that U.S. One distributed with each Power Gel

shipment.<sup>1</sup> The pamphlet discussed the physical causes of erectile dysfunction and then described the use of Power Gel and how to apply it. In a section entitled “Subsequent Effects,” the pamphlet mentioned the possibility that an erection might last “a little while” after sexual relations, in which case the pamphlet instructed to “use some ice [on the penis] for a period of time no longer than ten minutes.” The pamphlet also mentioned that “You may feel some pain in the penis, testicles, and in the area between the penis and the rectum.” The “Subsequent effects” section concluded that “In general, these effects are most often experienced with the first several uses, and disappear completely in the following application.” The pamphlet later asserts that “30 percent of those who used this product did not respond to the treatment, ten percent complained of discomfort, and there has been no indication of priapism or prolonged and painful erection.”

Customers who contacted U.S. One expressing interest in Power Gel talked to U.S. One’s telephone salesmen. The scripts for the salesmen instructed them to say that there were no contraindications or side effects to Power Gel, that it would

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<sup>1</sup>Like the radio advertisements and infomercials, the pamphlet was written in Spanish, and all quotations are translated.

not cause burning or discomfort, and that it could be used by men with high blood pressure, diabetes, or who had undergone heart or prostate surgery.

Despite these representations in U.S. One's marketing and materials, Nazir had previously told Llon and Munoz that Power Gel would only help 30 to 40% of users. Nazir also knew and informed Appellants that the placebo effect for impotence treatments of all kinds is roughly 30 to 40%. Thus Nazir, in effect, communicated to Appellants that Power Gel would be no better than a placebo at treating impotence. None of U.S. One's marketing mentioned that prostaglandin, an ingredient of Power Gel, may cause harmful uterine contractions and that Power Gel users should therefore wear a condom. None of U.S. One's materials discussed in any detail the potential side effect of priapism, a dangerous and painful persistent erection that can require medical treatment to prevent permanent damage to the penis. None of the marketing stated that either Power Gel or its ingredients were prescription drugs. The advertisements and pamphlet also failed to discuss in any detail a range of other known side effects of Power Gel's ingredients.<sup>2</sup>

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<sup>2</sup>Power Gel shares some similarities with MUSE, a prescription prostaglandin administered by intraurethral suppository. MUSE has a far higher concentration of prostaglandin than does Power Gel. Even so, MUSE is effective in less than 40% of users because the prostaglandin is not injected directly into the penis, as in the more effective tri-mix treatment. Known side effects of MUSE include a drop in blood pressure, fainting and loss of consciousness, and burning and pain in the penis. These side effects are serious enough that the

Shortly after U.S. One began selling Power Gel, Appellants Munoz and Llona expressed to Nazir an interest in an oral alternative to Power Gel. Nazir proposed Vasomax, an orally-administered phentolamine, and sent Appellants literature about the product. Appellants decided to sell their own oral phentolamine under the name “Vigor,” and they established the same arrangement with Gaudio to obtain the drug. Nazir continued to write fraudulent prescriptions ostensibly for his patients and to fax these prescriptions to Gaudio. After receiving the prescriptions, Gaudio would ship the Vigor to Nazir. In turn, Nazir would hand the Vigor over to Appellants and U.S. One, and Appellants and U.S. One would pay Gaudio for the drugs.

Nazir made it clear to Appellants Munoz and Llona that Vigor was not an improvement over Power Gel, and that it could likewise be expected to show only a 30 to 40% success rate, i.e. about the same as a placebo. Moreover, both Nazir and Gaudio explained to Appellants that Vigor was another prescription drug with side effects and contraindications, posing special dangers for users with high blood pressure. Despite having been informed of the low effectiveness of Vigor and the risks involved in using it, Appellants marketed Vigor in much the same manner as they were marketing Power Gel. The advertisements for Vigor stated

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first dose of MUSE is always administered in the doctor’s office.

that Vigor required no prescription and had no contraindications or side effects. Both Appellants told U.S. One's salesmen to tell potential customers that Vigor could be used by anyone, including people who were sick or people with heart conditions.

### **B. Investigation and Arrests**

In the summer of 1998, Cesar Arias ("Arias"), a registered pharmacist working for the Florida Department of Health, heard some of the Power Gel advertisements on the radio and received an anonymous complaint about Power Gel. Arias contacted Special Agent Mitchell Tapper ("Tapper"), who worked for the Food and Drug Administration ("FDA"). Tapper and Arias approached the Miami Police Department to voice suspicions about the legality of Power Gel. Together the agents began an investigation, making several undercover purchases of Power Gel. An analysis of Power Gel informed the agents that the product contained prescription drugs.

Arias also made an undercover call to U.S. One seeking to purchase Vigor. The U.S. One salesman told Arias that Vigor was a natural product, that it had no side effects, that it would not hurt or burn, and that it was safe to take regardless of the user's medical condition, including high blood pressure. Testing of Vigor revealed that Vigor contained phentolomine, a prescription drug.



The agents obtained warrants, searched U.S. One, and arrested Appellants. During the search of U.S. One, the agents recovered videotapes, audiotapes, and scripts for the advertisements and sales pitches discussed above. The agents also recovered two complaint letters from customers. Both letters complained that Power Gel did not work, and one complained that the application of Power Gel had injured the customer's penis and had been very painful.

The government also contacted other customers of U.S. One, ten of whom eventually testified at Appellants' trial. These witnesses testified that they had purchased either Power Gel or Vigor as a result of advertisements stating that the products were safe for everyone, that they had no side effects, and that no prescription was required. During their phone calls with U.S. One, none of these ten customers was asked about his medical history and some were told that the products were safe even after informing the U.S. One salesperson that they had high blood pressure or diabetes. Several of the former customers reported serious side effects upon using the products, including irritation in the penis lasting two days after using Power Gel, burning upon urination, bleeding from the penis, anxiety, and shortness of breath.

### **C. Indictments and Proceedings in District Court**

On November 13, 2001, a federal grand jury returned a 26-count indictment against Munoz, Llona, U.S. One, Nazir, Gaudio, and Prescription Specialties, charging them with conspiracy, mail fraud, wire fraud, and crimes related to the misbranding of prescription drugs.

On January 14, 2002, Appellant Llona moved for a bill of particulars. The other defendants sought and were allowed to adopt this motion. On July 11, 2002, the district court denied Llona's motion in all but two respects, ordering the government to file a bill of particulars in reference to the following issues: "First, Mr. Llona is entitled to know whether the mail and wire fraud referenced in Count 2 is the same mail and wire fraud referenced in Counts 3-14 . . . . Second, Mr. Llona is entitled to know whether the government contends that the United States is one of the victims of the alleged scheme to defraud." On August 26, 2002, the government filed the requested bill of particulars.

On September 18, 2002, Gaudio pleaded guilty to one count of dispensing drugs without a prescription, in violation of 21 U.S.C. §§ 331(k) and 333(a)(2). Gaudio eventually was sentenced to ten months' imprisonment and was ordered to pay a \$10,000 fine.

On October 15, 2002, a grand jury returned a 26-count superseding indictment (hereinafter "the indictment") against the remaining defendants,

charging them with conspiracy to commit offenses against the United States, in violation of 18 U.S.C. § 371 (Count 1); conspiracy to commit money laundering, in violation of 18 U.S.C. § 1957 (Count 2); mail fraud, in violation of 18 U.S.C. § 1341 (Counts 3-8); wire fraud, in violation of 18 U.S.C. § 1343 (Counts 9-14); introduction into interstate commerce of a misbranded prescription drug, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) (Counts 15-20); and misbranding prescription drugs after shipment in interstate commerce, in violation of 21 U.S.C. §§331(k) and 333(a)(2)(Counts 21-26).

On November 15, 2002, Nazir pleaded guilty to Counts 1 and 2 of the indictment. Nazir eventually was sentenced to twenty-four months' imprisonment and was ordered to pay \$29,523.34 in restitution. Both Nazir and Gaudio testified at Appellants' trial.

After a three-and-a-half week trial, a jury returned guilty verdicts against Appellants Munoz and Llona on Counts 1, 3-8, and 15-20. The jury returned verdicts of not guilty on Counts 2, 9-14, and 21-24, but found Appellants guilty of the lesser-included misdemeanor charges in Counts 21-24. The jury found Munoz guilty on misdemeanor charges in Counts 25 and 26, but found Llona not guilty on those counts.

Appellants filed post-trial motions for acquittal on Counts 1, 3-8, and 15-24. The district court granted judgments of acquittal as to Counts 15-24, but denied the motions as to Count 1 and Counts 3-8. Currently both Munoz and Llona remain convicted on Count 1 and Counts 3-8, and both appeal those felony convictions. Munoz also remains convicted of Counts 25-26, but Munoz does not appeal those two misdemeanor convictions.

#### **D. Sentencing**

At sentencing, the district court assigned each Appellant a base offense level of six for crimes involving fraud and deceit. See U.S.S.G. § 2F1.1.<sup>3</sup> The district court also adopted four enhancements to Appellants' offense level: (1) a twelve-level enhancement based on the loss, caused by Appellants' offenses, being more than \$1,500,000 and less than \$2,500,000, see U.S.S.G. § 2F1.1(b)(1); (2) a two-level enhancement because the offenses involved more than minimal planning or involved defrauding more than one victim, see U.S.S.G. § 2F1.1(b)(2); (3) a two-level enhancement because the offenses were committed through mass marketing, see U.S.S.G. § 2F1.1(b)(3); and (4) a two-level enhancement because

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<sup>3</sup>Appellants were sentenced according to the Guidelines in effect in 1998; all Guidelines citations herein therefore refer to the 1998 Guidelines.

each Appellant was an organizer or leader of the conspiracy, see U.S.S.G. §3B1.1(c).

With a total offense level of twenty-four and criminal history category I, the Guidelines range for each Appellant was fifty-one to sixty-three months' imprisonment. The district court sentenced Munoz and Llona to identical sentences of fifty-one months' imprisonment, three years' supervised release, and \$29,523.34 in restitution.

## II. CONVICTIONS

### A. Count 1: Conspiracy

Count 1 charged Appellants Munoz and Llona with conspiracy to commit certain substantive offenses against the United States.<sup>4</sup> The substantive offenses were various different violations of the Food, Drug & Cosmetic Act (“FDCA”) as codified at 21 U.S.C. §§ 331 and 333. Specifically, Count 1 charged Appellants with conspiring: (1) to introduce into interstate commerce misbranded drugs with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2); and (2) to do an act with respect to prescription drugs while held for sale after shipment in interstate commerce which resulted in the drugs being misbranded, in

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<sup>4</sup>The federal conspiracy statute makes it unlawful for “two or more persons [to] conspire [] to commit any offense against the United States.” 18 U.S.C. § 371.

violation of 21 U.S.C. §§ 331(k) and 333(a)(2). Appellants argue that their convictions on Count 1 should be reversed because the indictment failed to allege criminal acts, and because the government presented insufficient evidence to support their convictions.<sup>5</sup> We address these arguments in turn.

### **1. Alleged Flaws In the Indictment and Bill of Particulars**

Appellants first argue that the allegations in the indictment and bill of particulars, even if taken as true, fail to allege criminal acts.<sup>6</sup> More specifically, Appellants contend that the bill of particulars contradicts itself in a manner that creates an absolute defense to the FDCA violations underlying Count 1.

According to Appellants, the government's theory in Count 1 and in the bill of particulars depends on the allegation that Appellants sold Power Gel and Vigor without a prescription. See 21 U.S.C. § 353(b)(1)(deeming a prescription drug misbranded if it is dispensed other than pursuant to a valid prescription). Because the bill of particulars also asserts that Nazir wrote prescriptions for Power Gel and

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<sup>5</sup>Munoz's brief adopts all arguments raised in Llona's brief. Thus, throughout the opinion we refer to Appellants together.

<sup>6</sup>See United States v. Sanchez, 269 F.3d 1250, 1314 (11th Cir. 2001) (“A grand jury indictment must set forth each essential element of the offense in order for the conviction to stand”) (quoting United States v. Outler, 659 F.2d 1306, 1310 (Former 5th Cir. Oct. 26, 1981)). Outler, a non-unit decision of the former Fifth Circuit, is binding precedent in this Circuit pursuant to our holding in Stein v. Reynolds Secur., Inc., 667 F.2d 33, 34 (11th Cir. 1982).

Vigor, and, thus, they were in fact dispensed via prescription, Appellants argue that the indictment fails to allege a violation of § 353(b)(1).

Regardless of the fact that Nazir did write prescriptions - albeit fraudulent ones - for Power Gel and Vigor, Appellants sold the drugs to members of the public without any prescriptions for them at all. This fact quite clearly was alleged in both the indictment and the bill of particulars; there is no contradiction.<sup>7</sup> More importantly, the district court granted Appellants' motion for a bill of particulars only with respect to Counts 2-14. Thus the government's bill of particulars did not alter or limit the allegations of Count 1, allegations that go far beyond the bill of particulars in alleging a conspiracy to violate 21 U.S.C. §§ 331(a) and 331(k).<sup>8</sup>

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<sup>7</sup> Contrary to Llona's assertion that Appellants were "entitled to rely on the existence of Nazir's prescriptions as identified in the Indictment," it goes without saying that a valid prescription necessarily identifies the correct end user of the prescribed drug. See DeFreese v. United States, 270 F.2d 730, 733 n.5 (5th Cir. 1959)(defining a prescription in the context of FDCA misbranding allegations as "a physician's written order to a pharmacist for medicinal substances for a patient . . . a summary of the physician's diagnosis, prognosis, and treatment of the patient's illness"); cf. 21 C.F.R. § 1300.01(35)(stating in the context of the Controlled Substances Act that "[t]he term prescription means an order for medication which is dispensed to or for an ultimate user"). The Eleventh Circuit has adopted as binding precedent all of the decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981. Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc).

<sup>8</sup>We also readily reject Appellants' argument that because the district court granted their motions for acquittal with respect to the substantive FDA offenses alleged in Counts 15-24, Appellants must also be acquitted of the Count 1 conspiracy. While the district court concluded that Gaudio, not Appellants, initially introduced the Power Gel into interstate commerce for purposes of the substantive offenses in Counts 15-24, Count 1 is a conspiracy charge, and

## 2. Insufficiency of the Evidence

Appellants also argue that the evidence presented at trial was insufficient to support a guilty verdict on Count 1. Appellants contend that the government failed to demonstrate that Power Gel and Vigor were prescription drugs under 21 U.S.C. § 353(b)(1), a necessary element of the underlying objects of the conspiracy. Alternatively, even assuming Power Gel and Vigor were prescription drugs, the Appellants argue that the government failed to prove that Appellants knew that Power Gel or Vigor could not be dispensed to customers of U.S. One without prescriptions specific to these customers. Appellants contend that the evidence showed that they relied on Nazir's representations and believed that he had met any prescription requirements. As such, Appellants argue that there was insufficient evidence of the requisite criminal intent, i.e. an "intent to defraud or mislead." 21 U.S.C. § 333(a)(2).<sup>9</sup>

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Appellants were not required personally to perform all relevant acts in order to be convicted of the conspiracy crime charged in Count 1. See United States v. Gornto, 792 F.2d 1028, 1035 (11th Cir. 1986) ("Thus, a defendant can be convicted of conspiracy but acquitted of the substantive crimes."), overruling on other grounds recognized in United States v. Shenberg, 89 F.3d 1461, 1480 (11th Cir. 1996); United States v. Dearden, 546 F.2d 622, 624 (5th Cir. 1977) (concluding that a defendant can be convicted of a conspiracy count even when he is acquitted on all substantive counts).

<sup>9</sup>Challenges to the sufficiency of the evidence are reviewed de novo. United States v. Futrell, 209 F.3d 1286, 1288 (11th Cir. 2000). The evidence must be sufficient to convince a reasonable jury that the government has proved all the essential elements of the charged offenses beyond a reasonable doubt. Jackson v. Virginia, 443 U.S. 307, 317-18, 99 S.Ct. 2781, 2788 (1979). We review the evidence in the light most favorable to the government, with all



For purposes of the FDCA, a prescription drug includes any drug which “because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1)(A). Whether a drug allegedly distributed in violation of the FDCA is a prescription drug is a question for the jury. Brown v. United States, 250 F.2d 745, 747 (5th Cir. 1958).

At trial the government presented evidence that: (1) the active ingredients of both Power Gel and Vigor were prescription drugs not permitted to be sold over the counter in any dosage; (2) the active ingredients of Power Gel and Vigor have a wide range of serious side effects; (3) numerous users of Power Gel and Vigor had experienced harmful effects caused by Power Gel and Vigor; and (4) both Gaudio and Nazir believed Power Gel and Vigor required prescriptions, according to their own testimony. Viewed in a light most favorable to the government, this evidence overwhelmingly showed that Power Gel and Vigor were prescription drugs, and Appellants’ argument to the contrary is rejected.

With respect to Appellants’ criminal intent, the government was required to prove that Appellants acted with “an intent to defraud or mislead.” 21 U.S.C. §

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reasonable inferences and credibility choices made in the government’s favor. United States v. Simpson, 228 F.3d 1294, 1299 (11th Cir. 2000).

333(a)(2); see United States v. Bradshaw, 840 F.2d 871, 872 (11th Cir. 1988) (felony violation of 21 U.S.C. § 331 requires specific intent to defraud or mislead); United States v. Simmons, 725 F.2d 641, 642-43 (11th Cir. 1984) (conviction for conspiracy requires proof of at least the degree of criminal intent necessary for the underlying substantive offenses). The government also amply met this evidentiary burden.

It is undisputed that Appellants were aware that Nazir was obtaining Power Gel and Vigor by writing fraudulent prescriptions in the names of his patients. Thus, Appellants are essentially asserting that they believed Nazir's fraudulent prescriptions in the names of total strangers to U.S. One's transactions permitted Appellants to telemarket the drugs to customers who had never met or heard of Nazir. This argument lacks credibility, and the jury was free to view it with skepticism in light of the trial testimony from people involved in all parts of the alleged conspiracy, including both Nazir and Gaudio, three U.S. One employees, and multiple U.S. One customers. Most notably, this evidence included: (1) Nazir's testimony that Appellants knew the resale of the drugs without further prescription "was not right"; and (2) Gaudio's testimony that on separate occasions he told both Munoz and Llona that users of Power Gel and Vigor were required to visit a licensed physician to obtain a prescription, and that dispensation

of Power Gel and Vigor required a prescription “for a specific patient.” This evidence gave the jury ample basis from which to infer that Appellants knew that it was unlawful to distribute Power Gel and Vigor without prescriptions beyond the fraudulent ones written by Nazir. See United States v. Parker, 839 F.2d 1473, 1478 (11th Cir. 1988) (conspiracy to defraud may be shown by circumstantial evidence).

Appellants further argue that even if the evidence was sufficient to conclude that Appellants had knowledge of the need for prescriptions, the government still failed to prove intent to defraud or mislead the customers of U.S. One, because the government failed to show any intent to misrepresent the prescription status of Power Gel and Vigor. This argument is also meritless. The undisputed evidence showed that Appellants, through the marketing materials that they wrote and distributed, represented and even trumpeted the fact that Power Gel and Vigor required no prescriptions and could be used with complete discretion. Although Munoz prepared most of the advertising materials, Llona was indisputably aware of these representations and benefited from these representations. The only reasonable inference is that Appellants knowingly misrepresented the need for prescriptions with intent to induce potential customers into purchasing Power Gel and Vigor, drugs which were less effective than advertised, which were being sold

unlawfully without prescriptions, and which induced side effects of which the customers had not been made aware.

### **B. Counts 3-8: Mail Fraud**

Counts 3 through 8 charge Appellants with participating in a scheme to defraud customers of U.S. One, in violation of the federal mail fraud statute, 18 U.S.C. § 1341. Each count specifies a single victim who purchased Power Gel or Vigor from U.S. One and received the product by either U.S. Postal Service or Federal Express. It is undisputed that these six named customers did in fact order the drugs and receive them by mail. Appellants argue, however, that the government failed to put forth evidence showing that they specifically intended to, and did, defraud these six specific customers.

Contrary to Appellant's argument, the fact that no evidence was presented showing that Appellants personally interacted with the named victims is not a barrier to their convictions on mail fraud in Counts 3-8. "The crime of mail fraud does not include an element requiring a contemplated harm to a specific, identifiable victim." United States v. Henningsen, 387 F.3d 585, 590 (7th Cir. 2004). It is irrelevant whether or not Appellants personally knew of, communicated with, or directed activities towards the six named victims. The evidence showed that Appellants participated in a scheme to defraud all buyers of

Power Gel and Vigor by misrepresenting, through U.S. One, that the drugs were safe, effective, and non-prescription. Combined with the fact that the six named victims did in fact purchase Power Gel or Vigor from U.S. One, this evidence was sufficient to prove Appellants' criminal intent and criminal culpability with respect to Counts 3-8. See United States v. Toney, 598 F.2d 1349, 1355 (5th Cir. 1979) ("It is well settled in this circuit that so long as one participant in a fraudulent scheme causes a use of the mails in execution of the fraud, all other knowing participants in the scheme are legally liable for that use of the mails."); Blachly v. United States, 380 F.2d 665, 676 (5th Cir. 1967)("[D]irect proof of willful intent to defraud is not necessary. It may be inferred from the activities of the parties involved.").

### **III. SENTENCES**

Both Appellants challenge their sentences. First, Appellants argue that the district court improperly calculated the loss caused by their criminal conspiracy and therefore miscalculated their Guidelines range. Second, Appellants argue that the district court's sentences violated Blakely v. Washington, 542 U.S. 296, 124 S. Ct. 2531 (2004), and now Booker, 543 U.S. \_\_\_, 125 S. Ct. 738.

Although the Sentencing Guidelines are no longer mandatory after Booker, district courts must continue to consult the provisions of the Sentencing

Guidelines and consider them in sentencing. United States v. Crawford, 407 F.3d 1174, 1178 (11th Cir. 2005); United States v. Jordi, 418 F.3d 1212, 1215 (11th Cir. 2005). “This consultation requirement, at a minimum, obliges the district court to calculate correctly the sentencing range prescribed by the Guidelines.” Crawford, 407 F.3d at 1178. Accordingly, whether there is Booker error or not, we still must review whether the district court properly calculated the loss amount and, in turn, Appellants’ Guidelines range. Indeed, the loss amount in this case substantially increases the offense level and in turn the Guidelines range.

Therefore, we first review whether the district court correctly calculated the loss amount and Appellants’ Guidelines range, and then consider whether Booker error occurred.

#### **A. Loss Amount**

“Section 2F1.1 [of the Sentencing Guidelines] assigns a base offense level of six to a wide variety of fraud crimes.” United States v. Bracciale, 374 F.3d 998, 1003 (11th Cir. 2004). This Court has concluded that the “‘loss’ under § 2F1.1(b) is a specific offense characteristic intended to measure the actual, attempted, or intended harm of the offense.” United States v. Orton, 73 F.3d 331, 333 (11th Cir. 1996).

Under the 1998 Sentencing Guidelines applicable to Appellants, the base offense level is increased up to eighteen levels depending on the amount of loss occasioned by the fraud. See U.S.S.G. § 2F1.1(b). In this case, the district court found that the Appellants’ loss under § 2F1.1(b)(1) was between \$1.5 million and \$2.5 million, a finding that resulted in a twelve-level increase to Appellants’ offense level.<sup>10</sup> See id. at § 2F1.1(b)(1)(M); see also United States v. Renick, 273 F.3d 1009, 1025 (11th Cir. 2001).

Generally speaking, “loss is the value of the money, property, or services unlawfully taken.” U.S.S.G. § 2F1.1 cmt. 8. “Fraudulent schemes, however, come in various forms, and we must consider the nature of the scheme in determining what method is to be used to calculate the harm caused or intended.” Orton, 73 F.3d at 333.

Furthermore, because loss is often not calculable “with precision,” the district court need only “make a reasonable estimate of the loss, given the available information.” U.S.S.G. § 2F1.1 cmt. n. 9; Orton, 73 F.3d at 335 (citation

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<sup>10</sup>The loss amount issue involves both legal and factual issues. “We review a district court’s factual findings for clear error and its application of the Sentencing Guidelines to those facts de novo.” United States v. Phillips, 413 F.3d 1288, 1292 (11th Cir. 2005). We also review the interpretation of the Sentencing Guidelines de novo. United States v. Snyder, 291 F.3d 1291, 1295 (11th Cir. 2002).

and emphasis omitted). The district court is required, however, to support its loss calculation with reliable and specific evidence. Renick, 273 F.3d at 1025.

While there are several means by which a district court may calculate loss under § 2F1.1, see U.S.S.G. § 2F1.1, cmt. n.8(a)-(e), this Court has identified two of the more commonly used forms of calculation: (1) the “loss to the losing victims” method; and (2) the defendant’s gain or “net gain” method. See Bracciale, 374 F.3d at 1003; Orton, 73 F.3d at 334 & n.6.

When precise figures are not ascertainable, the “loss to the losing victims” method generally prefers “to calculate the victims’ loss by determining the approximate number of victims and an estimate of the average loss of each victim.” United States v. Snyder, 291 F.3d 1291, 1295 (11th Cir. 2002) (internal quotation marks, ellipsis, and citations omitted). This method “focuses on the harm to the victims. The individuals who receive a ‘return’ or break even on their ‘investments’ are not victims for the purposes of § 2F.1.” Orton, 73 F.3d at 334.

In contrast, the defendant’s gain or “net gain” method, “estimates loss as the net loss to victims as a group” and measures that by what the defendant received from the group. Id. (internal footnote omitted). “Under this method, the defendant will, for sentencing purposes, receive the full benefit of all his return payments” to the victims. Id.



In determining the loss under § 2F1.1, the district court appeared to use a combination of the two methods. First, the court found that, as neither party disputed, U.S. One’s gross sales of Power Gel and Vigor totaled \$2.876 million. The court subtracted \$656,000 to account for returns and refunds, leaving \$2.21 million as “the total amount of sales to customers who actually paid any money.” The court next reasoned that this number may have overstated the loss because some customers arguably benefited from Power Gel and Vigor, and therefore could not be said to have suffered a total loss of the money they spent on the drugs. The district court concluded based on trial testimony that about 30% of customers responded positively to Power Gel and Vigor.<sup>11</sup> To account for these arguably satisfied customers, the district court reduced the \$2.21 million figure by 30% to give a final loss figure of \$1.547 million. Because the sentence enhancement would be the same for either of these amounts, the court settled on a loss figure “of between 1.5 and less than \$2.5 million.”<sup>12</sup>

While this Court has cautioned against “abandon[ing] a loss calculation in favor of a gain amount where ‘a reasonable estimate of the victims’ loss based on

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<sup>11</sup>The 30% figure was derived entirely from the estimated placebo effect of Power Gel and Vigor.

<sup>12</sup>The district court stated that “if pressed on the issue, under the facts of this case, and not going any further, I would apply that 30 percent reduction in this case. But it does not make any difference, given my calculations on the loss amounts.”

existing information is feasible,” Bracciale, 374 F.3d at 1004 (citation omitted), we have also noted that fraudulent schemes come in many forms and, thus, courts “must consider the nature of the scheme in determining what method is to be used to calculate the harm caused or intended.” Orton, 73 F.3d at 333.<sup>13</sup> Based on the unique circumstances of the fraud in this case, we readily conclude that the district court did not err in its approach to estimating loss under § 2F1.1(b)(1). Thus, the district court properly increased the Appellants’ base offense levels by twelve pursuant to § 2F1.1(b)(1)(M).

In any event, the district court in this case would have been authorized to use a straight substitution of the defendants’ gain for the loss calculation under § 2F1.1(b)(1).<sup>14</sup> In cases such as this, the number of individual victims who were satisfied was arguably difficult to determine. Even if some of the customers were happy, they did not get the products they thought they were buying. Furthermore, as the district court noted, many of the customers were elderly and may have

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<sup>13</sup>This Court also has cautioned that “substitution of defendants’ gain is not the preferred method because it ordinarily underestimates the loss.” Snyder, 291 F.3d at 1295. That is, the defendants’ gain method does not take into account losses, such as lost opportunities or medical payments, suffered by the victims of a fraud that are not paid directly to the defendants. In this case, the defendants’ monetary gain did not underestimate the loss under § 2F1.1.

<sup>14</sup>Under such a direct substitution, the district court would not have reduced the loss amount by the 30% of customers that the district court determined were satisfied with the product.

moved or passed away. Additionally, the product was partially targeted at a Spanish-speaking audience. Even if a customer felt they had been victimized, there may be some hesitation to come forward due to embarrassment over the nature of the product in this case. In cases involving such circumstances, a straight substitution would have been appropriate. See United States v. Yeager, 331 F.3d 1216, 1225-26 (11th Cir. 2003) (noting that the district court was unable to reasonably estimate the loss due to the conflicting and confusing accounts at trial and affirming the district court's finding that the amount of profit obtained by the defendant was a reasonable estimate of the loss inflicted by his fraudulent conduct).

Two other circuits have permitted district courts to substitute a defendant's monetary gain in similar FDCA conspiracy cases. See United States v. Bhutani, 266 F.3d 661 (7th Cir. 2001); United States v. Marcus, 82 F.3d 606 (4th Cir. 1996).

In Marcus, the defendant's drug company received FDA approval to market a specific drug, but later added two unapproved, inactive ingredients to the drug without informing the FDA. Marcus was convicted of conspiracy to defraud the United States. See 18 U.S.C. § 371. At sentencing, the district court used the

company's gross sales of the drug, \$10 million, as the loss amount under § 2F1.1. Marcus, 82 F.3d at 608.

In challenging this loss amount, the defendant in Marcus argued “that the district court improperly substituted [the company's] gain as a proxy for loss without any factual showing that this was an appropriate measure of some actual, probable, or intended loss to the consumers.” Marcus, 82 F.3d at 608-09.

The Fourth Circuit disagreed. The court reasoned that even if the drug in Marcus were safe and effective, the formula change nonetheless “posed the potential to affect the safety, therapeutic value, or bioequivalence of the drug.” Id. at 610. The mere potential that the defendant's actions had affected the drug's safety or effectiveness led the Fourth Circuit to conclude that for loss purposes, the drug had no value at all, because “the sale of a drug represented to possess FDA approval under those circumstances does not provide consumers with the benefit of their bargain.” Id. The court determined that “the district court correctly concluded that [the company's] gross sales were the appropriate measure of the actual loss suffered by consumers . . . .” Id.

The Seventh Circuit has also approved of the use of the defendant's gain in calculating the amount of loss under § 2F1.1 in a FDA fraud case. See United States v. Bhutani, 266 F.3d 661 (7th Cir. 2001). In Bhutani, defendants were

convicted of adding a substance to an approved drug to mask the fact that the drugs had expired. Id. at 663-64. The district court calculated loss based on the defendant's gain, and the Seventh Circuit affirmed. The court viewed it as simply irrelevant that the adulteration of the drugs likely did not reduce their effectiveness or increase their risks, reasoning that "[t]he medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the [loss] inquiry; rather, the district court was justified in determining that there was a loss because consumers did not get what they bargained for." Id. at 670. The Seventh Circuit concluded that because consumers had not gotten the FDA-approved drugs they bargained for, the defendant's entire gain was the appropriate measure of loss. Id. ("We agree with the district court's determination of what constitutes loss in this sort of case, and that the defendant's gain is the appropriate measure of that loss.").

Appellants marketed products far more deceptive than those in either Bhutani or Marcus, drugs which it was unlawful for Appellants to sell and which barely resembled Appellants' marketing claims. Consistent with Bhutani and Marcus and under these facts, the district court would not have erred in simply using U.S. One's gains as the appropriate measure of loss under § 2F1.1. Cf. U.S.S.G. § 2F1.1 cmt. 8(a) ("In a case involving a misrepresentation concerning

the quality of a consumer product, the loss is the difference between the amount paid by the victim for the product and the amount for which the victim could resell the product received.”).

We recognize that Appellants insist that U.S. One’s customers suffered no obvious loss because they got what they bargained for: a drug treatment for impotence that, like any drug, was not 100% effective. To support their argument, Appellants cite in particular United States v. Chatterji, 46 F.3d 1336 (4th Cir. 1995), where the Fourth Circuit rejected a loss calculation based on gross drug sales in an FDA fraud case.

However, the facts in Chatterji are so materially different from this case, it does not help Appellants. In Chatterji, the drugs, though technically misbranded, were “exactly what they purported to be: [specific prescription drugs], approved by the FDA, manufactured in a certain strength and dosage, and producing the specified therapeutic benefits that FDA requirements were intended to ensure.” Chatterji, 46 F.3d at 1341. It was for this reason alone that the Fourth Circuit found it unreasonable for the district court to consider the entire \$13.4 million in the company’s gross sales a “loss” for sentencing purposes. Id. at 1340-41. The Fourth Circuit reasoned that the submission of technically incorrect testing

information to the FDA did not render the drug worthless to customers. Id. at 1341-42.

In sharp contrast to Chatterji, here the drugs received by U.S. One's customers barely resembled the drugs described and marketed by Appellants. As the overwhelming evidence at trial demonstrated, Appellants conspired to mislead potential buyers by informing them that Power Gel and Vigor did not require prescriptions. Appellants also conspired to convince potential customers that Power Gel and Vigor were 100% effective and had no side effects.<sup>15</sup> In fact, no medical evidence whatsoever indicated that tri-mix gel (as opposed to tri-mix injections) or oral phentalomene were effective treatments for erectile dysfunction, and substantial medical evidence suggested that their use would entail serious risks.

Finally, Appellants argue that the district court's loss enhancement improperly failed to identify how the losses were tied to their specific criminal conduct. According to Appellants, the government presented no evidence that

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<sup>15</sup>Appellants maintain that their conspiracy was limited to misrepresentations of the need for prescriptions for Power Gel and Vigor, and that as such the only losses are those that were proved to have been caused specifically by their prescription-related misrepresentations. This is incorrect. Appellants made, participated in and sanctioned misrepresentations as to the nature of the drugs, their side effects, their efficacy, their FDA approval and their prescription status. These misrepresentations were all elements of their conspiracy to introduce into interstate commerce misbranded drugs with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

they “w[ere] personally involved in any activity that caused economic loss to any U.S. One customers.” This argument also lacks merit. The evidence presented showed that Munoz and Llona were co-owners of U.S. One and were principal players in devising and implementing the conspiracy to market misbranded drugs. More importantly, the law is quite clear that for sentencing purposes “all losses caused by fraud or deceit . . . may be imputed to a defendant who was a member of the conspiracy which caused those losses.” United States v. Rayborn, 957 F.2d 841, 844 (11th Cir.1992); see also United States v. Hunter, 323 F.3d 1314, 1319 (11th Cir. 2003)(“[T]he district court may hold participants in a conspiracy responsible for the losses resulting from the reasonably foreseeable acts of co-conspirators in furtherance of the conspiracy.”).

For all of these reasons, we conclude that the Appellants have shown no reversible error in the district court’s calculations of the loss amount and the Guidelines range applicable to Appellants.

## **B. Booker Error**

Appellants next argue that their sentences violate the Sixth Amendment pursuant to Booker, 543 U.S. \_\_\_, 125 S.Ct. 738.

Because the parties dispute what standard of review applies, we first discuss that issue. The government asserts that the plain-error standard governs because



Appellants raise their constitutional objection for the first time on appeal.

Appellants argue that de novo review applies. Although Appellants did not object explicitly on constitutional grounds in the district court, Appellants argue that their objections in the district court were still sufficient to permit de novo review on appeal.

We agree with Appellants that a defendant may preserve a constitutional Booker objection in a number of ways, and need not object explicitly on constitutional or Sixth Amendment grounds. For example, a defendant's constitutional objection is preserved where: (1) the defendant's objection at trial invoked Booker, Blakely, or their direct predecessors; (2) the defendant objected that a fact relevant to a sentencing enhancement "should go to the jury;" or (3) the defendant argued that a fact relevant to a sentencing enhancement must be proved beyond a reasonable doubt. See United States v. Dowling, 403 F.3d 1242, 1245 (11th Cir. 2005). Even so, none of the sentencing objections raised by Appellants in district court invoked such constitutional concerns.

Rather, Appellants' objection as to the loss amount in the district court was that the loss amount was not supported by sufficient evidence or caused by the charged criminal conduct, and all of Appellants' arguments in the district court

related to the sufficiency-of-the-evidence or causation-type objections.<sup>16</sup> For example, Munoz’s written objection in the district court, which Appellants now claim raised a constitutional objection, actually began with the statement “[t]here is no evidence of any \$2,876,000 loss.”<sup>17</sup> Likewise, Llona’s written objection, now cited by Appellants, opened with the statement “[t]he \$2,876,000 loss attributable to Mr. Llona is without any evidentiary basis as set forth below.” Appellants’ other citations to the sentencing hearing transcripts are the same: at the time, Appellants were making a sufficiency-of-the-evidence or causation argument, not a constitutional one. See id. at 1245.

This case is indistinguishable from Dowling, where this Court held the plain-error standard governed. As in Dowling, Appellants made “no reference to

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<sup>16</sup>Appellants cite four specific arguments made in the district court: (1) in his written objections to the Presentence Investigation Report (“PSI”), Llona argued that the district court’s loss calculation should have been limited to losses shown to have arisen from the charged conduct for which he was convicted; (2) in his written objections to the PSI, Munoz likewise argued that because he was not convicted of the substantive counts of mail and wire fraud, the government was required to prove any losses based on the conspiracy alone; (3) at sentencing, Llona argued that because the indictment’s conspiracy charge centered on the sale of Power Gel and Vigor without prescription, the loss calculation should have focused only on losses specifically proven to have been caused by depriving customers of a doctor’s care; and (4) at sentencing, Munoz argued that the jury convicted Appellants not of mail fraud or wire fraud, but only of misrepresenting the prescription status of the drugs, and that therefore “you’ve gotta connect up the loss up [sic] to the actual fraud which the jury found.”

<sup>17</sup>In the original PSI, the probation officer offered \$2,876,000 as the correct loss amount. The PSI was revised after sentencing to reflect the district court’s final determination of a loss between \$1.5 million and \$2.5 million.

the Sixth Amendment, or a right to have the issue of [loss] decided by a jury rather than the judge.” Id. at 1246. There was no citation to Apprendi or its progeny. “[T]here was no challenge to the role of the judge as fact-finder with respect to sentencing facts.” Id. Also as in Dowling, the fact that Appellants’ objections at sentencing referred to the jury verdict does not turn their sufficiency-of-the-evidence objection into a constitutional one. Id. During sentencing in Dowling, the defendant’s counsel at one point asserted that “[t]he jury verdict . . . must be respected.” Id. at 1245. This Court found this statement insufficient to preserve the constitutional objection because the objection concerned sufficiency of the evidence and not the defendant’s constitutional rights. Id. at 1246; see also United States v. Zinn, 321 F.3d 1084, 1087 (11th Cir. 2003) (defendant must “clearly state the grounds for an objection in the district court” in order to preserve it on appeal).

Thus, we conclude that Appellants raise their Booker-type objection for the first time on appeal, and therefore we review their sentences for plain error. United States v. Rodriguez, 398 F.3d 1291, 1297-98 (11th Cir. 2005). To establish plain error, Appellants must show “(1) error, (2) that is plain, and (3) that affects [Appellants’] substantial rights.” Id. (quoting United States v. Cotton, 535 U.S. 625, 631, 122 S. Ct. 1781, 1785 (2002)). “If all three conditions are

met, an appellate court may then exercise its discretion to notice a forfeited error, but only if (4) the error seriously affects the fairness, integrity, or public reputation of judicial proceedings.” Id. (quoting Cotton, 533 U.S. at 631, 122 S.Ct. at 1785).

Appellants have satisfied the first two prongs of plain-error review because a Sixth Amendment violation under Booker occurred as to the loss amount in this case, and that Booker error is plain. See id. at 1298-99. Indeed, it is undisputed that the loss amount used in determining Appellants’ sentences was found by the sentencing judge based on facts not admitted by Appellants nor proved to a jury beyond a reasonable doubt, and that this loss amount was used to enhance Appellants’ sentences under a mandatory guidelines system. The constitutional Booker error under the Sixth Amendment, however, is not that there were extra-verdict enhancements, but “that there were extra-verdict enhancements used in a mandatory guidelines system.” Id. at 1300.

Since the first two prongs are clearly shown, the government primarily argues Appellants have not carried their burden to establish the third prong. We agree that Appellants have not established that the Booker error affected their substantial rights, as required by the third prong. Indeed, the third prong of the plain-error test “almost always requires that the error must have affected the outcome of the district court proceedings.” Id. at 1299 (quotation marks and

citations omitted). “The standard for showing that is the familiar reasonable probability of a different result formulation, which means a probability sufficient to undermine confidence in the outcome.” Id. (quotation marks and citations omitted).

In this case, the sentencing record provides no basis for a conclusion that under an advisory Guidelines scheme, there is a reasonable probability that Appellants would have received a more lenient sentence. Although the district court sentenced Appellants to the low end of the Guidelines range, that fact alone “does not establish a reasonable probability that the court would have imposed a lesser sentence under an advisory regime.” United States v. Fields, 408 F.3d 1356, 1361 (11th Cir. 2005). The district court in no way implied that it was dissatisfied with the sentence or the Guidelines range, and in fact denied both Appellants’ motions for downward departure. The district court found that “I have discretion to depart on the grounds that have been raised by both Mr. Llona and by Mr. Munoz,” but explained that “I just do not think that this is a case that falls outside of the heartland, in terms of overrepresentation of criminal culpability, or overrepresentation of the loss amount, or on any of the other grounds that have been raised.”

If anything, the record shows that the district court would have imposed the same sentences under an advisory guidelines system. In any event, the Appellants clearly have not carried their burden to show a reasonable probability of a more lenient sentence under an advisory guidelines system. Thus, under plain-error review, Appellants have not established reversible error in their sentences.

#### **IV. CONCLUSION**

We conclude that substantial evidence supported Appellants' convictions, that all of Appellants' challenges to their convictions lack merit, and that their sentences entailed no reversible error. Accordingly, we affirm Appellants' convictions and sentences.

**AFFIRMED.**