

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 07-1048

UNITED STATES OF AMERICA

v.

MARVIN GOLDBERG,

Appellant

Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Criminal Action No. 05-cr-00157)
District Judge: Honorable J. Curtis Joyner

Argued June 10, 2008

Before: AMBRO, CHAGARES and
GREENBERG, Circuit Judges

(Opinion filed: August 8, 2008)

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OPINION OF THE COURT

AMBRO, Circuit Judge

Marvin Goldberg ran an outfit called Equihealth Products that sold veterinary grade prescription drugs to horse owners so long as they affirmed that they were using the drugs to treat their own horses and that under their state's law owners treating their own horses were considered veterinarians. Because his clientele made these affirmations, Goldberg argued that Equihealth could legally dispense these drugs without proof of prescription, a proposition he supported by citation to Food, Drug, and Cosmetic Act (F.D.C.A.) provisions permitting veterinarians to transfer prescription drugs to other veterinarians without a prescription. Specifically, Goldberg argued that since Equihealth, which had a veterinarian on staff, was selling to owners who were recognized as veterinarians under their states' laws, Equihealth's activities involved a legal vet-to-vet transfer, and thus were exempt from the F.D.C.A.'s prescription requirement.

The Food and Drug Administration (F.D.A.) and its state counterparts took a dim view of Goldberg's argument, repeatedly notifying him that this explanation was nothing more than an excuse for dispensing prescription drugs illegally. Because Equihealth continued to rely on this vet-to-vet transfer rationale even after hearing from these agencies, and thus continued to dispense drugs without the required prescription, the Federal Bureau of Investigation (F.B.I.) launched an investigation that eventually led to Goldberg's indictment for

crimes related to Equihealth's operations, as well as for crimes related to his role in supplying his brother, a race horse trainer, with anabolic steroids for use in the brother's training operation. At trial, the jury rejected Goldberg's theory as to the legality of Equihealth's actions—finding instead that he was in the business of illegally dispensing prescription drugs – and further found him guilty on all the steroid-related counts.¹

On appeal, Goldberg accepts that Equihealth's activities were illegal, but argues that his conviction was nonetheless flawed and that the District Court erred in calculating his sentence. For the reasons stated below, we affirm in part, reverse in part, and vacate Goldberg's sentence.

I. Factual and Procedural Background

This case stems from the formation of Equihealth Products,² which was an operation dedicated to circumventing

¹ As a result, this opinion recounts the relevant facts in the light most favorable to the verdict. *United States v. Cartwright*, 359 F.3d 281, 285-86 (3d Cir. 2004).

² Although this entity was initially called “Equirace Health & Speed Products,” both parties refer to it exclusively as Equihealth or Equihealth Products and we follow suit. That said, references to Equihealth may include activities taken under its former name.

the F.D.C.A.'s general ban on dispensing certain drugs without a prescription and to circumventing the agreements Equihealth had with some of its suppliers not to distribute commercially the drugs that it received.

Although he never explained why it was permissible to mislead his suppliers, at trial Goldberg contended that Equihealth's activities were legal under the F.D.C.A. because "it is perfectly permissible for veterinarians to transfer drugs amongst themselves without prescriptions [and] the definition of 'veterinarian' is governed by state law, which generally permits animal owners to practice veterinarian medicine on their own animals, without the need for an educational degree or license," propositions that he took to mean that "transfers of drugs from Equihealth to animal owners, for use exclusively on their own animals, are veterinarian-to-veterinarian transactions that need not be accompanied by a prescription." Goldberg Op. Br. 7-8.

Relying on this view of the law, Goldberg repeatedly sold prescription veterinary drugs to any visitor to his website who affirmed that, where he or she lived, owners treating their own horses were considered veterinarians and that these drugs were to be used accordingly. From the outset, the F.D.A. was aware of Equihealth's operations and its purported justification – indeed, Goldberg actually called the F.D.A. to get its approval for the vet-to-vet transfer theory on which Equihealth was relying. But despite these overtures, the F.D.A. never approved

the operations of Equihealth or its view of the law; to the contrary, it told Goldberg on multiple occasions that Equihealth's activities were illegal. Indeed, the F.D.A. twice warned Equihealth that it was violating the F.D.C.A. because, as Goldberg charitably puts it, the agency "disagreed with the notion that animal owners are veterinarians with respect to their own animals, and viewed Equihealth as dispensing drugs without the requisite prescription from a veterinarian." *Id.* at 8. Various state boards of veterinary medicine also wrote Equihealth to tell it the same thing: this was not a permissible way to dispense prescription drugs. Unwilling to cede to the federal and state agencies' views, Goldberg and/or his counsel "responded in writing to each of these []administrative warnings," restating the argument that Equihealth's activities were legal under the vet-to-vet transfer exception, and thus that it would continue to sell drugs without proof of prescription. *Id.* at 8-9. While he was battling with the F.D.A. and its state counterparts, Goldberg used his position at Equihealth to obtain anabolic steroids for his brother, a race horse trainer who used them in his training operation. One such transaction involved the purchase of Stanozolol, an anabolic steroid marketed as Winstrol. According to Goldberg's version of events, Equihealth resident veterinarian Dr. Jack Wilkes ordered the drugs, had them sent to Equihealth's main office (Goldberg's home), and then, once they arrived, Goldberg sent them on to his brother. However, on a call recorded by F.B.I. Agent Greg Tremaglio, with whom Dr. Wilkes was cooperating, the veterinarian offered a very different version of events, accusing

Goldberg of stealing his (Wilkes') Drug Enforcement Administration (D.E.A.) number and placing the order without his knowledge.

A jury convicted Goldberg of: (1) wire and mail fraud based on his transactions with Luitpold Pharmaceuticals, an Equihealth supplier with whom Goldberg had an agreement not to resell commercially the drugs that he received (Counts 1-28); (2) possession with intent to distribute Stanozolol, an anabolic steroid (Counts 29-36); (3) two counts of introducing misbranded drugs into interstate commerce (Counts 37 and 39); and (4) misbranding (Counts 38 and 40). He now appeals.³

II. Merits

A. The Response to the Jury's Question

³Our Court has jurisdiction pursuant 28 U.S.C. § 1291 and 18 U.S.C. § 3742(a). On appeal, the jury's findings will not be disturbed unless no "rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt," and the District Court's factual findings will be credited unless they appear to be clearly erroneous. *United States v. Lloyd*, 469 F.3d 319, 321 (3d Cir. 2006); *United States v. Cartwright*, 359 F.3d 281, 285-86 (3d Cir. 2004). The District Court's legal conclusions are reviewed without deference. *United States v. Myers*, 308 F.3d 251, 255 (3d Cir. 2002).

We turn first to Goldberg’s claim that the District Court erred in responding to a question posed by the jury concerning the possession with intent to distribute charges. During deliberations, the jury asked if they had to find that the events recounted in the indictment’s second paragraph – namely that “Defendant Marvin Goldberg used Dr. [Wilkes’] Drug Enforcement Administration (‘DEA’) number to order and receive controlled substances from Pet Health Pharmacy in Youngstown, Arizona . . . without the knowledge and consent of Dr. [Wilkes]” – in order to convict, asking:

For counts 29 through 36 [the counts related to the Stanazolol possession], does Paragraph 2 of the indictment . . . count as an element of the charges, or do we need to only consider elements pertaining to distribution and possession? In other words, do we need to find guilty on all four elements for an overall guilty verdict on Counts 29 through 36.

Goldberg wanted the District Court to respond by instructing the jury that “it must find that [he] illegally possessed the Stanazolol” because “implied in the term possession is illegal possession.” The District Court refused, concluding that by giving Goldberg’s proposed instruction it would erroneously add another element to the crime, *illegal* possession, when under the law either legal or illegal possession would suffice. After so ruling, the District Court made the following statement to the

jury about the elements needed to convict:

One, that the defendant, Marvin Goldberg, possessed Stanazolol, the controlled substance described in the indictment.

Two, that the defendant knew that the substance charged in the indictment was a controlled substance.

And, three, that the defendant intended to distribute the controlled substance alleged in the indictment.

Those are the three essential elements for each of these offenses.

Paragraph 2 of the indictment is, as I indicated from the outset, the indictment is not evidence. It's what the government is alleging that took place. It's not an element of the offense charged.

So you have to determine whether or not the government has proven these three elements on each of these three counts. These are the most crucial factors.

On appeal, Goldberg argues that the District Court's failure to

give his proposed instruction led the jury to convict even though a critical element, illegal possession, was absent.⁴

Although we are not certain that Goldberg's proposed instruction was appropriate given its attenuated relationship with the question, we put this aside to focus on the larger issue: whether "possession," as it is used in "possession with intent to distribute," is limited to instances of illegal possession. Goldberg cites no law in support of his argument that it is, and our own survey has not found any either. That said, we have found an abundance of precedent to the contrary, generally involving pharmacists facing charges of possession with intent to distribute after being caught moonlighting as drug dealers. In this context, the earliest case where we found an argument equivalent to Goldberg's was *United States v. Goldfine*, where one such pharmacist argued that because his possession was legal, he could not be convicted of possession with the intent to distribute. 538 F.2d 815, 819-20 (9th Cir. 1976). The Court of

⁴In his reply brief, Goldberg for the first time advances an alternative argument: that he was seeking a defense instruction to the effect that his possession would have been permissible had the prescription been valid. Such an instruction would have been inappropriate because Goldberg had not produced any evidence that his possession was permissible under 21 U.S.C. § 822, which covers the limited circumstances where one can legally possess controlled substances. Accordingly, we do not deal with this argument.

Appeals for the Ninth Circuit flatly rejected this argument, explaining that possession, when used in this context, encompasses both its legal and illegal variants, a proposition that every other Court of Appeals confronting this issue over the past 30-plus years has either explicitly or implicitly agreed with. *See, e.g., United States v. Gurgiolo*, 894 F.2d 56, 58 (3d Cir. 1990) (reviewing the case of a pharmacist convicted of possession with intent to distribute after he admitted selling to individuals who lacked valid prescriptions); *United States v. Lartey*, 716 F.2d 955, 967 (2d Cir. 1983).

As a result, we believe that possession – not “illegal” possession – is all that is required to sustain a charge of possession with intent to distribute. Therefore, we conclude that the District Court’s refusal to give Goldberg’s proposed response was entirely proper.

B. Whether Hearsay Testimony Introduced at Trial Violated the Constitution’s Confrontation Clause

The irrelevance of the illegal/legal possession distinction ties directly into the next issue we consider: whether the admission of Dr. Wilkes’ hearsay testimony suggesting that Goldberg’s possession of the steroids was illegal violated the Confrontation Clause of the Constitution.

During the course of its investigation of Equihealth, the Government reached out to Dr. Wilkes, Equihealth’s then in-

house veterinarian who was weakened by illness and unable to care for himself at the time that the F.B.I. spoke with him. As a result of his circumstances, we surmise that Wilkes was more than willing to cooperate with the F.B.I.'s investigation in order to avoid arrest and/or incarceration for his role in Equihealth's operations, and accordingly view his statements made under the circumstances with a degree of suspicion.

During the course of his interview, Wilkes told the agent what he did for Equihealth on a day-to-day basis, and then disclosed an incident where Goldberg obtained Stanozolol for his brother to use on racehorses in his care. In order to prove that his story was true, Wilkes agreed to place a call to Goldberg that would be surreptitiously recorded. During that conversation, Goldberg freely admitted that he had obtained steroids for his brother after a three-way call involving Wilkes, Goldberg, and Goldberg's brother. In response, Wilkes told Goldberg that he did not remember that call, implying instead that Goldberg had actually obtained the prescription by forging his signature and D.E.A. number on the order form submitted to the wholesaler. Wilkes stated, "I don't understand . . . how you got . . . my DEA number." In response, Goldberg recounted to Wilkes the following chain of events: "You called Pet Health and gave it to them . . . I called you and told you that I wanted to use it for, uh, my brother's horses, and you said okay[;] you called [P]et [H]ealth, and you gave them the number, you never gave the number to me."

Later in the same conversation, Wilkes accused Goldberg of lying about his qualifications, saying, “you told me you had a license to practice in Pennsylvania[,] [t]o sell drugs in Pennsylvania.” Again, Goldberg responded with his version of events: “Naw, I didn’t, I am not a Vet, Doc,” and further explained that he had no license to dispense drugs at the behest of a veterinarian, saying, “I never told you I am a pharmacist, I don’t have a pharmacy.” Wilkes retorted, “Well that’s . . . what I was led to believe, that’s all.”

Although Wilkes died before trial, the Government sought to introduce the tape (and succeeded in doing so), which it relied on during its closing argument to prove that Wilkes “did not know that Marvin Goldberg had his DEA number,” that he “didn’t know that Marvin Goldberg was repeatedly using that number in order to obtain Stanozolol from Pet Health Pharmacy,” and that Goldberg had lied to Wilkes about being licensed. Put another way, the Government offered Wilkes’ self-interested, out-of-court statement to prove the matters asserted. The parties (and we) agree that this amounted to a violation of Goldberg’s rights guaranteed by the Confrontation Clause. As a result, we are only concerned with the harm visited by this event, and will reverse unless the Government proves this misstep was harmless beyond a reasonable doubt. *E.g.*, *United States v. Toliver*, 330 F.3d 607, 612 (3d Cir. 2003).

The steroids transaction that we are concerned with here is the same one that is discussed above, the Stanozolol

transaction that led to the possession with intent to distribute charges. Relevant to our analysis, we note that the elements of the offense are: (1) “knowing or intentional” (2) “possession” (3) “with intent to distribute” of (4) “a controlled substance.” *United States v. Lacy*, 446 F.3d 448, 454 (3d Cir. 2006). For the same reasons that we disagreed with Goldberg’s claim that the jury had to be told that “possession” really meant “illegal possession,” we disagree with his claim that “the salient issue” was “whether Dr. Wilkes prescribed the Stanazolol in the amounts ordered, and whether he used his DEA number to obtain it.” Goldberg Op. Br. 38. Instead, we view the key issue to be whether Goldberg possessed (legally or illegally) a controlled substance with the intent to distribute it.

The conflict between Wilkes’ statement and Goldberg’s version of events centers solely on the legality of his possession, which, as we explained above, has no bearing since a conviction for possession with intent to distribute can stand whether it is predicated on legal or illegal possession. Because Wilkes’ statements are irrelevant to whether he had committed this crime, its admission into the mix of information the jury was considering in relation to this charge was harmless. *Government of Virgin Islands v. Joseph*, 964 F.2d 1380, 1390 (3d Cir. 1992).

That said, we do consider the effect that Wilkes’ statements, which undoubtedly impugned Goldberg’s credibility, could have had on the trial as a whole. To that end, we note that Goldberg’s credibility is simply not at issue in this case – the

balance of the charges can be grouped into two categories, those based on false certifications that the drugs would not be resold and those based on dispensing prescription drugs without a veterinarian's order. At trial, the evidence supporting the jury's finding that Goldberg lied about his intention not to resell the drugs was overwhelming, so these twenty-eight convictions still stand. Further, the remaining charges stem from dispensing drugs without a prescription, which is something that Goldberg readily acknowledges that he did, meaning that there were no credibility determinations that needed to be made as to these counts. In this context, the Government's error was harmless. *See Joseph*, 964 F.2d at 1390.

C. The Felony Misbranding Convictions

Counts 37-40 deal with Goldberg's misbranding activities, and specifically Equihealth's filling of two orders submitted by F.B.I. Agent Tremaglio. While Goldberg admits selling these drugs to Tremaglio, he argues that he cannot be convicted of misbranding because the drugs were not misbranded, and in any event not misbranded before they were sold. Further, he argues that even if what he did was misbranding, it was misdemeanor misbranding because there was no evidence that he acted with any intent to defraud or mislead. Accordingly, his appeal raises two issues: (1) was there sufficient evidence for a reasonable juror to conclude that Goldberg misbranded these drugs and/or held them for sale while they were misbranded; and if so, (2) was there sufficient

evidence for a reasonable juror to conclude that he acted with an intent to defraud or mislead (so as to make the convictions felonies)? We consider each issue in turn.

1. Misbranding

Misbranding is governed by 21 U.S.C. § 331(k), which in pertinent part prohibits “the doing of any . . . act with respect to . . . a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.”

Although Goldberg admits selling these drugs without a valid prescription, he argues that he did not misbrand them, since (as a technical matter) he never “misbranded or adulterated the drugs in question.” Goldberg Op. Br. 21. In other words, Goldberg argues that misbranding prohibits “alter[ing] the product in some way – not merely dispensing to an end-user without a prescription.” *Id.* at 45 (emphasis deleted). However, Goldberg is a bit loose in his argument, because two paragraphs later he admits that “dispensing a drug without a prescription is ‘misbranding.’” *Id.* at 46. And his second instinct is the correct one: misbranding does encompass dispensing these drugs without a prescription. 21 U.S.C. § 353(b)(1); *see, e.g., United States v. Arlen*, 947 F.2d 139, 141 n.2 (5th Cir. 1991) (“Any prescription drug that is dispensed without a prescription is deemed ‘misbranded’ as a matter of law.”); *United States v.*

Bradshaw, 840 F.2d 871, 872 n.2 (11th Cir. 1988).⁵

However, Goldberg stands by his argument that “there is a temporal problem” because a drug cannot be “dispensed ‘while’ it is held for sale, because it cannot be ‘delivered’ and ‘held for sale’ at the same time.” Goldberg Op. Br. 46. This argument gets him nowhere because the statute clearly states that “[t]he act of dispensing a drug contrary to the provisions [requiring a prescription] shall be deemed to be an act which results in the drug being misbranded while held for sale.” 21 U.S.C. §353(f)(1)(C). As a result, whatever temporal confusion comes with the misbranding provision, it is resolved by the relatively straightforward declaration that dispensing drugs without a prescription means that those drugs were misbranded while they were held for sale. *Id.*

We also reject Goldberg’s argument that he cannot be properly convicted under § 331(k) because this provision “was enacted to regulate the drug distribution chain, not dispensing to the end user.” Goldberg Op. Br. 47. To the contrary, the Supreme Court’s ruling in *United States v. Sullivan* notes that

⁵Apparently, Goldberg too arrived at this conclusion, admitting that he was “properly convicted” of misbranding based on these activities. Goldberg Reply Br. 18. That said, his opening brief takes the opposite tack. We deal with this issue because we cannot find any precedent from our Court on point.

the purpose of § 331(k)'s misbranding prohibition was to "extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer." 332 U.S. 689, 696-97 (1948) (discussing H.Rep. 2139, 75th Cong., 3d Sess., 3.). Accordingly, there is no reason grounded in legislative intent not to apply § 331(k) to Goldberg's sales to end users.

Based on the analysis above, we affirm Goldberg's misbranding convictions.

2. Requisite Intent

Because we conclude that Goldberg was properly convicted of misbranding, we turn to whether the evidence shows that he acted with an intent to defraud or mislead as he conducted these misbranding activities. The presence or absence of intent is important since willful misbranding is only a misdemeanor unless there is "the intent to defraud or mislead." 21 U.S.C. § 333(a). Then it is a felony.

Although the jury found such an intent, Goldberg claims that this finding has to be wrong. There was, he contends, undisputed evidence showing that "[f]ull disclosure was given to Equihealth's customers about the drugs sold, the nature of the transaction, and Equihealth's status as a non-prescribing party," and he "was open and transparent with the FDA and the various state agencies that inquired about Equihealth." Goldberg Op.

Br. 42-43.

The Government offers three reasons to affirm on this issue. First, it claims that the “Product and Use Disclaimer,” which customers signed and supplied to Goldberg, was misleading as to, among other things, the rights of the customer to treat his or her own animal under the various state law provisions governing the practice of veterinary medicine. In making this argument, the Government overlooks that the Disclaimer is not an affirmative representation by Goldberg, but rather by the customer, meaning that any misrepresentation occasioned by the statements was caused by the customer lying about the applicable law in his or her home state, not the misbrander (Goldberg) that merely received the statement. As a result, it cannot be said that Goldberg misled anyone via the statements his customers made.

Next, the Government points to “[s]ales literature assert[ing] that the company veterinarian actually would prescribe the drugs.” Government Br. 55. This is easily dealt with, as the literature in question has no tie to the four counts of misbranding that Goldberg was charged with. Agent Tremaglio was repeatedly told that the drugs he was ordering would not be provided pursuant to a prescription, were not prescribed by a veterinarian, and that he would not be able to consult directly with one either before or after he placed his order. As a result, the only way that we could deem Goldberg’s conduct misleading would be to hold that when a vendor permits outdated sales

literature to continue to exist in some form, even though it told customers not to rely on the representations therein, the vendor has misrepresented its activities. We are not prepared to do this, and therefore we deem that this argument does not justify Goldberg's felony convictions.

Finally, the Government argues that by "having [his suppliers] believe that they were sending him drugs pursuant to valid prescriptions, and that he would not resell the drugs," Goldberg acted with deception or an intent to mislead in his misbranding activities. *Id.* at 52. Whatever the merits of this argument, there is no factual basis for it. Nothing in the record shows that Goldberg made those statements (or implied them) in relation to the drugs he sold to Tremaglio. As a result, this argument, unsupported by any evidence we found, cannot justify Goldberg's felony misbranding convictions.

This leaves the Government without any persuasive argument in favor of sustaining Goldberg's felony conviction for misbranding. Beyond that, our own independent review of the record has not yielded any trace of an intent on Goldberg's part to avoid detection or misrepresent what he was up to. Instead, the evidence demonstrates that Goldberg conducted his admittedly illegal ventures in the open, and (at least as far as the drugs that led to the misbranding counts with which he was charged) in accordance with all the agreements he made. As a result, we vacate his felony misbranding convictions, making these convictions instead misdemeanors.

*D. The Sentencing Challenges*⁶

Goldberg raises two challenges to his sentence, arguing that the District Court erred (1) in the way it calculated the losses associated with Equihealth's conduct, and (2) in imposing an enhancement based on his disregard of numerous agency letters that informed him of the illegal nature of Equihealth's activities. We address each in turn.

1. Loss Calculation

The District Court enhanced Goldberg's sentence by sixteen levels pursuant to U.S.S.G. § 2B1.1(b)(1), providing for such an enhancement when the losses associated with the conduct in question are between \$1 and \$2.5 million. While Goldberg does not contest the general applicability of § 2B1.1(b)(1) to his situation, he argues that the District Court erred when it used Equihealth's \$1.1 million in total gross profits as a proxy for the losses suffered, and thus erred in relying on those profits to calibrate the § 2B1.1(b)(1) enhancement.

⁶While we acknowledge that Goldberg will have to be resentenced based on our decision to overturn his felony convictions on the misbranding counts, we have no doubt that these same issues will arise again on remand, and thus we will address them now.

To this end, Goldberg correctly argues that § 2B1.1(b)(1) calls for a calculation based on the actual loss occasioned by his conduct, unless “there is a loss but it reasonably cannot be determined.” *Id.* cmt. 3(B). Further, he is correct insofar as he argues that the record produces scant, if any, evidence of actual harm, and further provides little reason to suspect that the losses occasioned by his fraudulent conduct “bear[] a logical relationship to Equihealth’s gross profits.” Goldberg Op. Br. 53.

That said, he fails to appreciate that these provisions are not designed for offenders like him. Instead, the way to account for his conduct is established by § 2B1.1 cmt. 3(F)(v), which reads:

(v) Certain Other Unlawful Misrepresentation Schemes.--In a case involving a scheme in which . . . (III) goods for which regulatory approval by a government agency was required but not obtained . . . [,] loss shall include the amount paid for the property, services or goods transferred, rendered, or misrepresented, with no credit provided for the value of those items or services.

As admitted by Goldberg and established by the numerous agency letters, F.D.A. approval was required for these drugs to be sold – they were prescription drugs after all. There was no such approval because the drugs were misbranded. This means

Goldberg was selling goods for which regulatory approval was required but not obtained. Therefore, under cmt. 3(F)(v), the District Court's gross profits methodology was proper.

2. Administrative Order Enhancement

Turning to Goldberg's alternative sentencing objection, we agree that the two-level enhancement pursuant to U.S.S.G. § 2B1.1(b)(8) – violating a “prior, specific judicial or administrative order, injunction, decree, or process not addressed elsewhere in the guidelines” – was unwarranted.

As a general rule, federal courts of appeals considering the issue have been willing to impose the enhancement after a meaningful negotiation or interaction led the agency to issue a directive that the defendant subsequently violated. For example, the Second Circuit held that a defendant who failed to abide by a negotiated consent decree was subject to the enhancement, a proposition that the Seventh Circuit also agreed with. *See United States v. Mantas*, 274 F.3d 1127, 1132-33 (7th Cir. 2001); *United States v. Spencer*, 129 F.3d 246, 252 (2d Cir. 1997). Going even further, the Seventh Circuit in *United States v. Mantas* held that the enhancement was merited after the Illinois Department of Agriculture (the U.S.D.A.'s state counterpart) *inspected* a meat packing plant, *discussed* the situation with the owner face to face, *proposed* a possible remedy, and then officially *seized* the meat products at issue (the owner then sold the meat in question nonetheless).

That said, no court of appeals has held that a mere warning letter, without more, can justify the enhancement. To the contrary, the Seventh Circuit, in *United States v. Wallace*, a post-*Mantas* decision, held that the enhancement should not be applied “to every situation where a defendant knew or was told by someone in authority that what she was doing was illegal.” 355 F.3d 1095, 1097-1098 (7th Cir. 2004). The Ninth Circuit also adopted this view in *United States v. Linville*, saying, “[T]he Guideline speaks of ‘violations.’ That is a perfectly intelligible usage as it applies to an ‘order, injunction [or] decree’ It is considerably less intelligible if process is taken to mean a mere letter or . . . warning.” 10 F.3d 630, 633 (9th Cir. 1993).

We agree with the analysis of our sister circuit courts to the extent that they deem administrative orders, injunctions, decrees, and processes as flexible concepts. *Cf. Morrissey v. Brewer*, 408 U.S. 471, 481 (1972) (“[D]ue process is flexible and calls for such procedural protections as the particular situation demands.”). We also agree that even this flexible approach cannot permit a district court to impose the enhancement for no other reason than that the defendant continued to engage in certain conduct after the agency questioned its legality. As a result, we hold that imposing the two-level enhancement requires an interaction between the agency and defendant that allowed the defendant to participate in some meaningful way (if he elected to do so), and that led to a definite result, like a consent decree or a seizure. *See Wallace*,

355 F.3d at 1097-1098; *United States v. Thayer*, 201 F.3d 214, 227-28 (3d Cir. 1999).

The question then is whether this happened here. The Government argues that the F.D.A.'s repeated dealings with Goldberg were sufficient because it notified Goldberg (by a so-called "Section 305 Notice") that he had engaged in prohibited conduct, that he had the opportunity to attend a meeting with agency officials where he could "present [his] views on this matter," and that the next step was to refer the matter to the Department of Justice for possible criminal prosecution. This, the Government contends, represented "the final agency action, a precursor to criminal proceedings." Government Br. 89. In doing so, it equates § 2B1.1(b)(8)'s "prior, specific . . . administrative order, injunction, decree, or process" language with any "final agency action," citing 21 U.S.C. § 335, governing the F.D.C.A., which provides that "[b]efore any violation of this chapter is [referred] for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."

We disagree. Just because the agency believes it has enough information to act – and thus believes itself finished with this part of the process – it has not *a fortiori* issued a "specific . . . administrative order, injunction, decree, or process" sufficient to trigger § 2B1.1(b)(8). Instead,

§ 2B1.1(b)(8) requires some specific directive that the defendant can defy. In other words, like the defendant in *Mantas* whose meat products were seized (and thus who had the option of either respecting the seizure or defying it), or the defendant in the Second Circuit's *Spencer* case who entered into a consent decree, in order to subject Goldberg to this enhancement, he had to be ordered to stop. To that end, there is no dispute that the F.D.A. never issued any definitive order telling Goldberg that he had to stop. This makes the F.D.A.'s notice insufficient for these purposes.⁷

In the alternative, the Government argues that the enhancement is proper in light of the letter Goldberg received from the Kentucky Board of Veterinary Examiners stating that he should "CEASE AND DESIST from engaging in the practice of veterinary medicine (emphasis in original)."⁸ While this

⁷We acknowledge that this is a highly formalistic interpretation. As the District Court observed, the F.D.A.'s notice said "you are dispensing illegal drugs. Does a person have to say the word 'desist' on that same line to tell him to stop?" Our answer is yes: if we are going to enhance a sentence based on a failure to comply with a directive, we do not think that it is too much to ask the directive be definitive in nature.

⁸While the Government argues that a similar letter was sent by California authorities, the record does not show that Goldberg did any further business in California after receiving it. As a result, there is no evidence that Goldberg violated the

contains the explicit directive that we are looking for, it fails because the other required element is missing – Goldberg was not offered the chance to participate in the process in any meaningful way. The Kentucky letter starts out by stating that the Board has already “referred the . . . matter to the Office of the Attorney General” for possible enforcement proceedings (*e.g.*, injunctive relief and/or criminal sanctions), and threatens to “pursue all available legal remedies” *unless* Goldberg “CEASE[S] AND DESIST[S] from engaging in the practice of veterinary medicine or consulting with unlicensed animal owners in the Commonwealth.” There is no invitation for Goldberg to state his case, or to come to a resolution with the Board. Instead, he has two choices, stop or be subject to further proceedings. This is the quintessential warning letter saying nothing more than stop or else. As a result, it cannot provide the basis for the two-level enhancement pursuant to § 2B1.1(b)(8).

terms of the California letter, whatever its characterization may be. *See* App. at 327-29. Therefore, it cannot serve as the basis of the enhancement. By the same token, we set aside the more general warnings issued by remaining states because none of them contains sufficiently explicit language (*e.g.*, cease and desist) to merit consideration of the enhancement. *See, e.g.*, App. at 285 (letter from the Pennsylvania Department of Health); 289-90 (letter from the Maryland State Board of Veterinary Medical Examiners); 315-16 (letter from the Texas Board of Veterinary Medical Examiners); 317-18 (letter from the Texas State Board of Pharmacy).

Therefore, we find nothing in the record justifying the two-level enhancement.

VI.

For the reasons stated above, we affirm Goldberg's convictions in all respects except that we reverse his convictions for felony misbranding, as set forth in counts 37-40, and vacate his sentence. As a result, we remand to the District Court with instructions to enter a judgment of conviction for the misdemeanors corresponding to each of the felony misbranding convictions in counts 37-40 and for resentencing consistent with this opinion.