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Tenth Circuit

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PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. THOMAS BADER, Defendant-Appellant.	No. 10-1263

Appeal from the United States District Court
for the District of Colorado
(D.C. No. 1:07-CR-00338-MSK-1)

Deborah A. Pearce, Law Offices of Deborah A. Pearce, New Orleans, Louisiana (Charles Torres and Joseph Machatton, Charles H. Torres, PC, Denver, Colorado, with her on the briefs), for Defendant-Appellant.

Jaime A. Peña, Assistant United States Attorney (John F. Walsh, United States Attorney, and Andrew A. Vogt, Assistant United States Attorney, with him on the brief), Denver, Colorado, for Plaintiff-Appellee.

Before **TYMKOVICH**, **BALDOCK**, and **HOLMES**, Circuit Judges.

HOLMES, Circuit Judge.

Defendant-Appellant Thomas Bader appeals his convictions of distribution of human growth hormone ("HGH"), conspiracy to knowingly facilitate and

knowingly facilitating the sale of HGH brought into the United States contrary to law, and conspiracy to possess with intent to distribute a controlled substance (testosterone cypionate). He asks this court to reverse his convictions or, at a minimum, to grant him a new trial. Mr. Bader also challenges the district court's forfeiture order requiring him to remit the $4.8 million in proceeds that he allegedly derived from his unlawful activity. Exercising jurisdiction pursuant to 28 U.S.C. § 1291, we affirm Mr. Bader's convictions for distribution of HGH and conspiracy to possess with intent to distribute testosterone cypionate, but reverse based upon instructional error his convictions for knowingly facilitating the sale of HGH imported into the United States contrary to law, and conspiring to do so. Further, in light of our reversals, we conclude that the forfeiture judgment cannot rest on its current statutory basis, but we leave to the district court in the first instance the task of determining the precise amount (if any) of the forfeiture judgment authorized by the remaining, upheld convictions. We remand the case to the district court with instructions to vacate the judgment and sentence and for further proceedings consistent with this opinion.

I. BACKGROUND

Mr. Bader, a licensed pharmacist in the State of Colorado, owned and operated College Pharmacy, a compounding pharmacy located in Colorado Springs, Colorado. In the context of this case, the precise definition of drug "compounding" remains in dispute. Nevertheless, the parties agree that College

Pharmacy is involved in the process of purchasing, labeling, repackaging, and distributing drugs—including HGH—in finished dosages for patient consumption.[1]

In Spring 2004, Mr. Bader instructed Kevin Henry, a College Pharmacy sales representative, to locate an economical source of HGH for purchase and distribution. Mr. Henry located three manufacturers—all of them in China—and College Pharmacy began purchasing and importing HGH from these sources. Upon learning of potential contamination and potency issues with the HGH manufactured by these Chinese suppliers, Mr. Bader asked Mr. Henry to find a new HGH source. Pursuant to Mr. Bader's instructions, Mr. Henry contacted Bradley Blum, a domestic representative for Chinese HGH manufacturer Genescience, and College Pharmacy began to order and import HGH in bulk quantities from the Genescience facility in China.

Employees of College Pharmacy were then directed to repackage the

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[1] *See generally Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002) ("Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product."); 1 James T. O'Reilly, *Food and Drug Administration* § 13:74, at 194 (Supp. 2011) [hereinafter *Food and Drug*] ("Congress could have, but did not ever affirmatively define the term 'compounding.' . . . There is no single, commonly-accepted industry or common definition of the term 'compounding,' and the definition does not necessarily exclude simple repackaging.").

imported HGH into smaller vials for distribution. Pursuant to College Pharmacy's repackaging protocol, employees copied the relevant HGH drug-instruction guides from a Food and Drug Administration ("FDA")-approved version of HGH known as Saizen and included them with College Pharmacy's own HGH drug, which they labeled and sold as Somatropin. If asked whether Somatropin was FDA-approved, College Pharmacy employees were instructed to explain that the FDA did not have jurisdiction in China, and to reassure customers that the imported HGH was manufactured in an FDA-approved Chinese facility. College Pharmacy also issued several promotional letters and advertisements which implied that Somatropin had been approved by the FDA.

Between 2003 and 2007, Mr. Bader and his employees at College Pharmacy also distributed testosterone cypionate, an anabolic steroid, to individual body-builders and to body-building and "anti-aging" clinics. Among College Pharmacy's top "clients" was Peak Physique, a large anti-aging clinic that purchased HGH and testosterone cypionate via purchase agreements that required no prescription from a licensed physician. College Pharmacy also promoted and sold the steroid, along with Somatropin, at American Academy of Anti-Aging Medicine ("A4M") conferences and trade shows, despite the fact that neither "anti-aging" nor "body-building" is a medically necessary use for these drugs.

On September 9, 2008, the government filed a Second Superseding Indictment in the District of Colorado charging Mr. Bader with a total of forty-

three counts involving: (1) conspiracy to knowingly facilitate the sale of merchandise (HGH) brought into the United States contrary to law, in violation of 18 U.S.C. § 371; (2) mail fraud, in violation of 18 U.S.C. § 1341; (3) distribution of HGH, in violation of 21 U.S.C. § 333(e); (4) knowingly facilitating the sale of merchandise (HGH) brought into the United States contrary to law, in violation of 18 U.S.C. § 545; and (5) conspiracy to possess with intent to distribute a controlled substance (testosterone cypionate), in violation of 21 U.S.C. §§ 846 and 841. The indictment also indicated that the government would seek a forfeiture judgment in the amount of $4.8 million—the estimated amount of proceeds obtained by Mr. Bader due to his unlawful conduct—as well as forfeiture of the College Pharmacy building that allegedly had facilitated these crimes. The government subsequently dismissed Mr. Bader's mail-fraud charges, and Mr. Bader was tried on the remaining thirty-three counts beginning on January 4, 2010.

On February 2, 2010, a jury convicted Mr. Bader on thirty-two of the thirty-three counts of the indictment, acquitting him on one count of receiving illegally imported goods (Count Sixteen). The jury further found that Mr. Bader had obtained a sum of $4.8 million in proceeds from his illegal activities, and that the College Pharmacy building listed in the indictment had facilitated the crimes charged. The district court entered judgment on Mr. Bader's convictions and the jury's forfeiture verdict. Mr. Bader then filed an array of post-trial motions,

pursuant to which the district court entered a judgment of acquittal on twenty-three of the HGH distribution counts; they involved prescriptions to minors, which had been validly issued by licensed physicians. Mr. Bader was subsequently sentenced to a below-Guidelines term of imprisonment of forty months and exempted from any payment of a criminal fine, the court having concluded that the forfeiture of $4.8 million and the pharmacy-building constituted an adequate financial penalty. This appeal followed.

II. DISCUSSION

Mr. Bader challenges on appeal each of his convictions and attacks the district court's forfeiture order. More specifically, Mr. Bader raises an array of arguments contesting the legal propriety of the jury instructions and the sufficiency of the evidence; alleges prosecutorial misconduct and entrapment by estoppel; and asserts violations of his Sixth Amendment rights and federal evidentiary rules. Mr. Bader asks us to reverse his convictions or, in the alternative, to grant him a new trial. We address below each of his challenges.

A. *Alleged Instructional Errors*

Mr. Bader alleges that the district court erroneously instructed the jury in three ways: (1) by including an "alternative prong on uncharged API [active pharmaceutical ingredient] importation" when it issued instructions regarding the charges of knowingly facilitating the sale of HGH imported contrary to law and conspiring to do so, Aplt. Opening Br. at 51; (2) "by telling the jury [that] all [of

the] evidence about compounding was irrelevant," *id.* at 47; and (3) by refusing to instruct the jury on applicable state pharmacy laws and his First Amendment right to advertise. The government contends that any error in the court's "alternative prong" instruction was harmless, that the district court was correct to reject Mr. Bader's compounding definition, and that the court properly refused to instruct the jury regarding state pharmacy dispensing regulations and Mr. Bader's First Amendment rights.

1. "Finished" HGH versus API

Mr. Bader's first argument pertains to two of his convictions—specifically, his convictions for knowingly facilitating the sale of HGH imported into the United States contrary to law and conspiring to do so (Counts Seventeen and One of the Second Superseding Indictment, respectively). These convictions implicate 18 U.S.C. § 545, which prohibits the smuggling of illegal goods into the United States by providing, in relevant part, that "[w]hoever fraudulently or knowingly imports or brings into the United States, any merchandise contrary to law, or receives . . . buys, [or] sells" such merchandise, "knowing the same to have been imported or brought into the United States contrary to law" shall be fined or imprisoned for a maximum of twenty years. 18 U.S.C. § 545.

In the present case, Mr. Bader was charged in Count One with conspiring to knowingly facilitate the sale of HGH after importation "knowing the same to have been imported into the United States" contrary to several identified federal

statutes: 21 U.S.C. § 331(a), which prohibits the introduction into interstate commerce of a misbranded drug; 21 U.S.C. § 352(f)(1), which relates to causing the introduction into interstate commerce of a misbranded drug that fails to bear adequate directions for use; 21 U.S.C. § 331(d), which prohibits the introduction into interstate commerce of an article that is in violation of section 355 of Title 21; and 21 U.S.C. § 355, which prohibits the introduction into interstate commerce of a "new drug" without prior application to or approval from the FDA. *See* Aplee. App., Vol. IV, at 1027–28 (Second Superseding Indictment, returned Sept. 9, 2008). At bottom, the charged conspiracy involved a scheme to import comparatively cheap HGH from China, to sell that cheap HGH in order to reap windfall proceeds, and to retain the proceeds. In Count Seventeen, Mr. Bader was charged with a specific instance of "knowingly facilitat[ing] the sale" of HGH, "knowing the same to have been imported into the United States contrary to" the federal laws cited above. *See id.* at 1039.

According to FDA documents, "finished drug products" must be approved through an "effective new drug application" ("NDA") before they can be legally imported.[2] Aplt. App., Vol. I, at 267 (Import Alert # 66-71, dated Jan. 23, 2007).

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[2] "Under the Federal Food, Drug, and Cosmetic Act (FDCA), a drug manufacturer may not market a new drug before first submitting a new drug application (NDA) to the FDA and receiving the agency's approval." *Wyeth v. Levine*, 129 S. Ct. 1187, 1219 (2009) (Breyer, J., concurring) (citing 21 U.S.C. § 355(a)).

(continued...)

Active pharmaceutical ingredients ("API"), in contrast, may be legally imported on a case-by-case basis if they are intended for use in pharmacy compounding. *Id.* at 270–71.

The government concedes that the district court significantly limited the basis upon which the jury could convict Mr. Bader under § 545, focusing upon the government's primary theory that the HGH that Mr. Bader imported from China was a "finished" drug product subject to FDA oversight and, because Mr. Bader had failed to file an NDA, he had imported HGH "contrary to" 21 U.S.C. § 355's ban on the importation of "new drugs" that lack FDA approval.

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[2](...continued)

> An NDA must contain, among other things, the labeling proposed to be used for such drug, full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use, and a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling.

Id. (alteration in original) (citations omitted) (quoting 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.50(d)(5)(viii) (2008)) (internal quotation marks omitted). In order to receive FDA approval, a new drug must be "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," there must be "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and the drug's proposed labeling must not be "false or misleading in any particular." 21 U.S.C. § 355(d); *see also* Aplee. App., Vol. I, Tr. at 17 (Test. of Jason Woo) ("The new drug approval process refers to the requirement that any article that's intended for use in the diagnosis, treatment, prevention, mitigation or cure of a disease for humans or animals has to be presented to the . . . FDA[] for review for safety and efficacy before it can be marketed legally.").

As the court later explained in its order partially granting Mr. Bader's motion for judgment of acquittal, its instruction on Count One—outlined in jury instruction number twenty ("Jury Instruction No. 20")—"[d]istilled to its essence, . . . directed the jury to resolve the 'imported contrary to law' question by first determining whether the HGH being imported was a 'finished drug' or an 'ingredient.'" Aplee. App., Vol. IV, at 1258 (Op. & Order Granting, in Part, Mot. for J. of Acquittal and Den. Remaining Mots., filed Apr. 29, 2010). The court further instructed that "[t]here is no definition under the law for the term 'finished drug'" but that "in determining whether the [HGH] was a finished drug, [the jury could] consider whether it was in a finished dosage form; for example, a tablet, capsule, or solution." Aplt. Trial Tr. App., Vol. VIII, at 2169 (Jury Instruction No. 20).

In the event that the jury determined that the Chinese HGH was in finished form, "they were instructed that a 'finished drug' must have NDA approval in order to be legally imported, and because it was undisputed at trial that the HGH here did not have such approval, a finding that the HGH was a 'finished drug' compelled the conclusion that it was 'imported contrary to law.'" Aplee. App., Vol. IV, at 1258–59; *see* Aplt. App., Vol. VIII, Tr. at 2715–16. However, significantly, the district court further instructed the jury, in the alternative, that if the jury "f[ound] that the [HGH] was *not* a finished drug but instead an active pharmaceutical ingredient," then it still was authorized to find that the HGH was

"imported contrary to federal law *if it was manufactured by a foreign entity that was not registered with the FDA*." Aplt. Trial Tr. App., Vol. VIII, at 2170 (emphases added).

Importantly, the district court incorporated the legal standards concerning the contrary-to-law component of § 545, articulated in Count One's Jury Instruction 20, into the instructions that would control the jury's finding as to Count Seventeen. Specifically, the court stated: "For purposes of determining whether the human growth hormone was imported into the United States in a manner contrary to federal law, you should use the same standards and instructions I gave you with regard to that issue in Count 1." *Id.* at 2176. Therefore, to the extent that a ground for reversal could be demonstrated regarding Count One relating to a defect in Jury Instruction 20's contrary-to-law standard, that ground for reversal would also fatally undermine Mr. Bader's conviction as to Count Seventeen because it employed the same standard.

Mr. Bader contends that there is such a ground for reversal, focusing on the final sentence of Jury Instruction 20, relating to API importation. However, Mr. Bader did not specifically object to this portion of Jury Instruction No. 20 at trial—despite the fact that the court afforded him ample opportunity to do so, *see id.* at 2145 (Jury Trial Tr., dated Jan. 28, 2010) ("Counsel, this is your second opportunity to lodge any objections to the concluding jury instructions reflected in the packet or to the verdict form."). At most, Mr. Bader's counsel made a

general "object[ion] to the [c]ourt's instruction"—with no reference to which of the enumerated instructions was put at issue in his objection—and "re-urge[d]" the court to adopt the defense's compounding instruction. *Id.* at 2148. This falls far short of Mr. Bader's obligation to lodge a timely and specific objection. *See, e.g.*, *Abuan v. Level 3 Commc'ns, Inc.*, 353 F.3d 1158, 1172 (10th Cir. 2003) ("No party may assign as error . . . the failure to give an instruction unless that party objects thereto before the jury retires to consider its verdict, stating distinctly the matter objected to and the grounds of the objection." (quoting Fed. R. Civ. P. 51) (internal quotation marks omitted)); *Medlock v. Ortho Biotech, Inc.*, 164 F.3d 545, 553 (10th Cir. 1999) ("Because the purpose of [an] objection is to give the court an opportunity to correct any mistake before the jury enters deliberations, an excessively vague or general objection to the propriety of a given instruction is insufficient to preserve the issue for appeal." (citation omitted)).

We therefore review Mr. Bader's objection to Jury Instruction No. 20 for plain error. *See, e.g.*, *United States v. Willis*, 476 F.3d 1121, 1127 (10th Cir. 2007); *see also* Aplee. App., Vol. IV, at 1261 ("In the absence of a specific objection, the [c]ourt need only review the instruction for plain error . . . .") "Plain error occurs when there is (i) error, (ii) that is plain, which (iii) affects the defendant's substantial rights, and which (iv) seriously affects the fairness, integrity, or public reputation of judicial proceedings." *United States v. Lopez-Medina*, 596 F.3d 716, 738 (10th Cir. 2010) (quoting *United States v. Ruiz-*

Terrazas, 477 F.3d 1196, 1199 (10th Cir. 2007)) (internal quotation marks omitted).

In undertaking the threshold error inquiry, we must "determine whether, as a whole, the instructions correctly state the governing law and provide the jury with an ample understanding of the issues and the applicable standards." *United States v. Visinaiz*, 428 F.3d 1300, 1308 (10th Cir. 2005) (quoting *United States v. Smith*, 413 F.3d 1253, 1273 (10th Cir. 2005)) (internal quotation marks omitted). Regarding the second prong, we have recognized that error is plain if it is "clear or obvious under current law." *United States v. Cooper*, 654 F.3d 1104, 1117 (10th Cir. 2011) (quoting *United States v. Goode*, 483 F.3d 676, 681 (10th Cir. 2007)) (internal quotation marks omitted). As for the third prong of the test, "[i]n the ordinary case," to have the requisite affect on substantial rights, an error must be "prejudicial," which means that "there must be a reasonable probability that the error affected the outcome of the trial." *United States v. Marcus*, --- U.S. ----, 130 S. Ct. 2159, 2164 (2010) (internal quotation marks omitted); *accord United States v. Thornburgh*, 645 F.3d 1197, 1212 (10th Cir. 2011); *United States v. Fishman*, 645 F.3d 1175, 1196 (10th Cir. 2011). Lastly, as to the fourth prong, it is notable that there is a relationship between that prong and the third: "[I]n most circumstances, an error that does not affect the jury's verdict [i.e., the third prong] does not significantly impugn the 'fairness,' 'integrity,' or 'public reputation' of the judicial process [i.e., the fourth prong]." *Marcus*, 130 S. Ct. at

2166 (quoting *Johnson v. United States*, 520 U.S. 461, 467 (1997)).

We are constrained to conclude that, in propounding Instruction No. 20 to the jury, the district court committed clear or obvious error; that there is a reasonable probability that the error affected the outcome of the trial; and that, under the circumstances presented here, this error significantly impugned the fairness, integrity, and public reputation of the trial. In denying Mr. Bader's post-trial motion for a judgment of acquittal, the district court concluded that the final sentence of Instruction No. 20 was "unnecessary," but that any potential error was harmless.[3] Aplee. App., Vol. IV, at 1260–61. We conclude, however, that the final paragraph of the instruction was more than "unnecessary"; it effectively allowed the jury to convict Mr. Bader under a theory upon which he was never charged—*viz.*, illegal importation of an *API*, as opposed to illegal importation of a *finished drug product*. *See id.* at 1024–50.

Under Instruction No. 20, the jury was allowed to convict Mr. Bader of illegally importing HGH if *either*: (1) the imported HGH was a *finished drug* that

[3] The district court's error may have partially derived from its misplaced reliance upon *Hedgpeth v. Pulido*, 555 U.S. 57 (2008) (per curiam). While the district court was correct that *Hedgpeth* directs courts to consider "whether [a] flaw in the [jury] instructions 'had substantial and injurious effect or influence in determining the jury's verdict,'" *id.* at 58 (quoting *Brecht v. Abrahamson*, 507 U.S. 619, 623 (1993)), its holding pertains to whether purported instructional errors are "structural" in nature for purposes of collateral review in a habeas proceeding. As Mr. Bader's case involves neither a claim of structural error nor a collateral attack in a habeas proceeding, *Hedgpeth* is inapposite.

did not receive "new drug approval" from the FDA; *or* (2) the imported product was an *API* that was "manufactured by a foreign entity that was not registered with the FDA." Aplt. Trial Tr. App., Vol. VIII, at 2170. This effectively rendered the "finished drug" versus "API" distinction—upon which the government's entire case was based—a nullity, allowing the jury to convict Mr. Bader regardless of the imported HGH's form. In particular, the instruction permitted the jury to convict Mr. Bader of a charge for which he was never indicted.[4] Therefore, in propounding Instruction No. 20 to the jury, the district court committed clear or obvious error.

We also are convinced that there is a reasonable probability that this error affected the outcome—i.e., that there is a reasonable probability that the jury would not have convicted Mr. Bader of the § 545-related counts but for this error. *See United States v. Marcus*, 628 F.3d 36, 42 (2d Cir. 2010) ("[T]he overall effect of the due process [instruction-related] error must have been sufficiently great such that there is a reasonable probability that the jury would not have convicted him absent the error."). The probable prejudicial impact of Instruction No. 20 is evident when we examine it within the context of the entire trial. *See Visinaiz*,

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[4] The Second Superseding Indictment explained that "[t]he FDA has never approved any [HGH] manufactured in or imported from China for lawful use in the United States." Aplee. App., Vol. IV, at 1025. Nowhere does the indictment suggest, however, that an individual may be held criminally liable for illegally importing an API that was manufactured at a *facility* lacking FDA registration.

428 F.3d at 1308. In his closing argument, the prosecutor invited the jury to consider several email exchanges between Mr. Bader, Mr. Henry, and Genescience representatives that "reflect[ed] a concern about whether [the Genescience facilities] [were] even registered facilities." Aplt. App., Vol. IX, Tr. at 2760. In one of those email chains, Mr. Henry asked a Genescience representative whether Genescience was "FDA registered yet," to which the representative responded that Genescience "ha[d]n't got registered in FDA yet." *Id*. at 2767 (Gov't Ex. 34). In another, Mr. Henry informed Mr. Bader that a representative from Medisca—apparently an API supply company—would be "sending a letter with information on the FDA[-]registered facility that their HGH comes from," explaining that the representative was "totally convinced that Medisca is the only place in the country that is bringing in [HGH] legally." *Id.* at 2771 (Gov't Ex. 44). In conclusion, Mr. Henry noted, College Pharmacy "need[ed] to . . . find out if anybody [was] telling the truth or if they[were] all doing it 'illegally.'" *Id.*

Dr. Jason Woo, Associate Director for Medical and Scientific Affairs with the Center for Drug Evaluation Research, testified at trial. When questioned about the FDA approval of foreign-produced HGH, Dr. Woo explained that "[t]here are no approved Chinese facilities"—more specifically, there are not "any facilities in China that are approved to make any *components* of the approved human growth hormone products." Aplee. App., Vol. I, Tr. at 18 (emphasis

added). As Dr. Woo explained, those "components"—also known as API—are "basically the precursor to an approved drug. [They are] part of the mix that goes into making the drug." *Id.*

A reasonable jury presented with this evidence—the emails exchanged by Mr. Bader, Mr. Henry, and the Genescience representative; and the testimony of Dr. Woo—could have easily concluded that, even if the imported HGH was not a "finished drug" subject to NDA oversight, it was still an API that had been imported contrary to federal law by virtue of its having been manufactured at a foreign facility that lacked FDA approval.[5] In particular, there is a reasonable probability that such a jury—considering this evidence, in conjunction with the district court's erroneous jury instruction—convicted Mr. Bader when it would not otherwise have done so, on a theory upon which he was never indicted. Consequently, we conclude that the third prong of the plain-error test is satisfied.

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[5] The district court apparently relied upon *United States v. Urbano*, 563 F.3d 1150, 1155 (10th Cir. 2009), for the proposition that we must assume that the jury "did not vote to convict on a theory for which no evidence existed." Aplee. App., Vol. IV, at 1262. In that case, however, we held only that "this court generally assumes jurors follow jury instructions." 563 F.3d at 1155. Where, as in *Urbano*, the erroneous instruction is entirely "extraneous" to the charges upon which a defendant is indicted—such that if the jury followed the erroneous instruction, a conviction would not result—any error is necessarily harmless. *See id.* Here, in contrast, the court's erroneous instruction was far from "extraneous"; on the contrary, it provided an *alternative* basis upon which the jury could convict Mr. Bader in the event that it found that he had not imported a "finished drug." Moreover, the government *did* present evidence supporting this alternative, API-based theory at trial. As such, *Urbano* offers no support for the district court's position.

And we discern nothing in the circumstances of this case that would indicate that such a prejudicial effect would not significantly impugn the fairness, integrity, and public reputation of Mr. Bader's trial. Thus, we conclude that the fourth prong of the plain-error test also is satisfied. *See Marcus*, 628 F.3d at 44 (concluding that there was "a reasonable probability that the erroneous jury charge affected the outcome of the trial and affected the fairness, integrity or public reputation of the proceedings").

This plain-error analysis indicates that because of Jury Instruction No. 20's inclusion of an erroneous theory of liability—*viz.*, a theory that permitted Mr. Bader's conviction for having imported an API, as opposed to a finished drug, so long as that API was "manufactured by a foreign entity that was not registered with the FDA," Aplt. Trial Tr. App., Vol. VIII, at 2170 (Jury Instruction No. 20)—we must reverse and remand. Specifically, we reverse Mr. Bader's conviction on Count Seventeen, for knowingly facilitating the sale of HGH imported into the United States contrary to law, and on Count One, for conspiracy to do so. Both counts rely on the erroneous liability theory set forth in Jury Instruction 20.[6]

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[6] In reaching this disposition, however, we pause to note the possibility that Mr. Bader may be re-prosecuted on these counts. Upon remand, in the event that he is re-prosecuted, it will be important for the parties to furnish the court with appropriate instructions, reflective of the applicable law, so as to provide the jury with adequate guidance regarding the "finished drug" versus

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"API" distinction. The district court was correct when it represented to the jury that "[t]here is no definition under the law for the term 'finished drug,'" Aplt. Trial Tr. App., Vol. VIII, at 2169; however, we do not operate on a blank slate. While the law is far from clear, we endeavor to outline here the relevant precedent to which the parties and the court should look in defining these terms upon remand.

As the Supreme Court has explained, "[t]he active ingredients in most prescription drugs constitute less than 10% of the product; inactive 'excipients' (such as coatings, binders, and capsules) constitute the rest." *United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983). A "complete product[]," therefore, consists of "active ingredients and excipients together." *Id.* at 461. Thus, the district court was correct when it instructed the jury that a finished drug product—as opposed to an API—is often in "finished dosage form; for example, a tablet, capsule, or solution." Aplt. Trial Tr. App., Vol. VIII, at 2169.

Much of the law concerning the finished-drug versus API distinction is grounded in the recent methamphetamine epidemic. Pursuant to 21 U.S.C. § 971(c)(1), for example, the DEA "may order the suspension of any importation or exportation of a listed chemical . . . on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance." *PDK Labs., Inc. v. DEA*, 438 F.3d 1184, 1186 (D.C. Cir. 2006) (quoting Pub. L. No. 100-690, tit. VI, § 6053(a), 102 Stat. 4312 (1988)) (internal quotation marks omitted). One of these "listed chemical[s]"—ephedrine—"is an active ingredient in over-the-counter medications for the treatment of asthma and nasal congestion. Ephedrine is also used in the illicit production of methamphetamine, a controlled substance." *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 789 (D.C. Cir. 2004). It has therefore fallen upon the courts to determine whether the DEA can act pursuant to § 971(c)(1) in order to divert a pharmacy's finished drug—as opposed to the raw API that it imports—from the hands of methamphetamine producers who seek to buy (or purchase) the medication from retail stores. In so doing, courts have offered at least a cursory explanation of the production process: pharmacies "purchase[] raw, bulk ephedrine from foreign companies, *combine*[] *the chemical with other active agents*, and produce[] a *finished product* in tablet form, packaged in bottles or blister packs." *Id.* (emphases added). Thus, at least in the methamphetamine context, an API is a raw product that is *combined* with other active ingredients to produce a "finished drug product" that is ready for public
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2. Relevancy of Compounding Law

Next, Mr. Bader challenges Jury Instruction number twelve ("Jury Instruction No. 12"), pursuant to which the court informed the jury that "evidence

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consumption. In other words, a finished drug is a final, patient-ready drug that consists of one or more APIs and, most likely, one or more "excipients." *See Generix*, 460 U.S. at 461.

Indeed, this Court has also weighed in on the API/finished-drug distinction. In *Pharmanex, Inc. v. Shalala*, 221 F.3d 1151 (10th Cir. 2000), the FDA challenged the district court's decision to enjoin an FDA administrative decision that concluded that Cholestin—a product intended to promote healthy cholesterol levels—was not a "dietary supplement" that was exempt from FDA regulation. "The district court," we explained, "based its decision on the determination that [the relevant statute] refer[ed] unambiguously to *finished drug products*, rather than their *individual constituents*." *Id.* at 1153 (emphases added). On appeal, the FDA argued that the applicable statute was "properly understood to contemplate active ingredients as well as finished drug products." *Id.* at 1154 (footnotes omitted). Our role, therefore, was to "determine whether Congress unambiguously manifested its intent to exclude only finished drug products (rather than ingredients) from the definition of dietary supplement." *Id.*

In so doing, we noted that the term "'[a]ctive ingredient' means 'any *component* that is intended to furnish pharmacological activity or other direct effect.'" *Id.* at 1154 n.3 (emphasis added) (quoting 21 C.F.R. 210.3(b)(7)), while a "'[d]rug product'"—a term that we analogized to "finished drug product"—"is defined as a 'finished dosage form . . . that contains a *drug substance*, generally, but not necessarily, *in association with one or more drug ingredients*.'" *Id.* at 1154 n.4 (emphases added) (quoting 21 C.F.R. 314.3(b)). These definitions—promulgated by the FDA itself—are certainly less than clear. At the very least, however, they provide a rudimentary foundation regarding the interrelation between the two terms: an API is a medicinally active "component" that is associated with additional "drug substance[s]" to form a "finished product" available in individual doses. *See id.* at 1154 n.3–4. These definitions, in conjunction with the aforementioned case law, should inform the district court's jury instructions in the event that Mr. Bader is retried.

concerning whether Mr. Bader's actions constituted compounding under various legal authorities[was] not relevant to the issues" that the jury was to "resolve under [the court's instructions]." *Id.* at 2164 (Jury Instruction No. 12). Though Mr. Bader represents that he "objected" at trial to the court's instruction, he did not do so on the grounds that he asserts here. *See* Aplt. App., Vol. VIII, Tr. at 2699.[7] We therefore review his claim for plain error. *See Willis*, 476 F.3d at 1127.

Mr. Bader argues that the court erroneously "told the jury that none of these meticulous and required pharmacy processing standards mattered when, in truth, they controlled the core questions: whether the [HGH] was already finished prior to College's purchase, and whether [Mr.] Bader knew this." Aplt. Opening Br. at 49; *see also* Aplt. Reply Br. at 12 (noting that "[Mr.] Bader's defense that compounding absolutely had to occur before this [HGH] was in finished form safe and ready for patient dispensing was wholly negated by the court's instruction that all evidence about compounding was *irrelevant*"). His objection to Instruction No. 12, therefore, relates exclusively to his § 545-related charges. As discussed above, however, we must reverse and vacate Mr. Bader's § 545-related convictions on account of the erroneous "alternative prong" in Instruction No. 20.

[7] Mr. Bader presented this argument for the first time in his *post-trial* motion for judgment of acquittal. *See* Aplee. App., Vol. IV, at 1257. His objection at trial, in contrast, merely sought to include a definition of the term "prescription" in Instruction No. 12. *See* Aplt. App., Vol. VIII, Tr. at 2699.

Consequently, we need not (and do not) consider whether the district court's characterization of compounding law as "irrelevant" obliges us to reverse Mr. Bader's § 545-related convictions; we have already determined that those convictions cannot stand.

3. Rejection of State Pharmacy and First Amendment Instructions

Finally, Mr. Bader argues that the district court erred with respect to the jury instructions that it did *not* give—i.e., in refusing to inform the jury of Colorado's pharmacy-dispensing laws, *see* Aplt. Opening Br. at 52–54, and in failing to instruct the jury that Mr. Bader "had a Supreme Court-recognized right to advertise" under the First Amendment, *id.* at 55. We review the district court's refusal to issue these instructions for an abuse of discretion. *See United States v. Crockett*, 435 F.3d 1305, 1314 (10th Cir. 2006). However, in determining "whether the district court exercised its discretion properly, we review the jury instructions de novo to determine whether, as a whole, they accurately state the governing law and provide the jury with an accurate understanding of the relevant legal standards and factual issues in the case." *Id.*

Applying this standard to the present case, it is patent that the district court appropriately exercised its discretion when it rejected Mr. Bader's proposed instructions. Mr. Bader first contends that the district court erred in refusing to issue several "relevant" state pharmacy instructions regarding: (1) "Colorado requirements that pharmacies maintain adequate drug inventories and provide

adequate services," Aplt. Opening Br. at 52; (2) "[s]tate laws governing ordering, dispensing[,] and requirements for valid prescriptions," *id.* at 53; (3) "[s]tate laws clarifying that pharmacists who prepare, compound, package, repackage, or dispense drug[s] are not drug wholesalers or manufacturers," *id.*; and (4) a "Colorado law providing that pharmacists may rely on a physician's professional judgment in ordering a drug for a patient," *id.* at 54. However, Mr. Bader fails to identify to which of the forty-three charged counts these state laws pertain, let alone explain how they are "relevant" to the charges upon which he was convicted. Indeed, it is clear from the record that the district court was more than generous in including "some language [from the proffered instructions] . . . where it [was] relevant to [the] explanation of a particular element of a particular count," despite its determination that Colorado's pharmacy laws generally had no bearing upon Mr. Bader's charges. *See* Aplee. App., Vol. III, Tr. at 634. As Mr. Bader offers no support for his bald allegation that this determination was somehow erroneous, we are constrained to conclude that his first argument is meritless.

Mr. Bader's undeveloped First Amendment claim, which he seeks to assert throughout his opening brief, is even less persuasive. As we discuss *infra*, the government introduced evidence of College Pharmacy advertisements in order to prove that Mr. Bader purposefully marketed HGH and testosterone cypionate for impermissible purposes. At no point, however, did the government contest, as a

general matter, College Pharmacy's right to advertise its products. In other words, Mr. Bader's First Amendment right to advertise was in no way implicated, let alone compromised, by the charges against him. Consequently, an instruction regarding Mr. Bader's First Amendment rights could not possibly have promoted an "accurate understanding of the relevant legal standards and factual issues in the case." *See Crockett*, 435 F.3d at 1314. We therefore reject Mr. Bader's unsubstantiated assertion that the district court somehow abused its discretion in refusing to issue an (irrelevant) instruction pertaining to his First Amendment right to advertise.

B. *Sufficiency of the Evidence*

Mr. Bader avers that there was insufficient evidence to support his convictions, renewing many of the unsuccessful arguments that he asserted in his Renewed Motion for Judgment of Acquittal and Alternative Motion for a New Trial that he filed post-trial. We review de novo the sufficiency of the evidence upon which Mr. Bader was convicted, "ask[ing] only whether taking the evidence—both direct and circumstantial, together with the reasonable inferences to be drawn therefrom—in the light most favorable to the government, a reasonable jury could find the defendant guilty beyond a reasonable doubt." *United States v. McCane*, 573 F.3d 1037, 1046 (10th Cir. 2009) (alteration in original) (quoting *United States v. Brown*, 400 F.3d 1242, 1247 (10th Cir. 2005)) (internal quotation marks omitted). "Rather than examining the evidence in 'bits

and pieces,' we evaluate the sufficiency of the evidence by 'consider[ing] the collective inferences to be drawn from the evidence as a whole.'" *United States v. Wilson*, 107 F.3d 774, 778 (10th Cir. 1997) (alteration in original) (quoting *United States v. Hooks*, 780 F.2d 1526, 1532 (10th Cir. 1986)), *abrogated on other grounds as recognized by United States v. King*, 632 F.3d 646, 651–52 & n.5 (10th Cir. 2011); *accord United States v. McGehee*, 672 F.3d 860, 871 (10th Cir. 2012). In so doing, "we may not assess the credibility of witnesses or weigh conflicting evidence, as these tasks are exclusively for the jury." *United States v. Bowen*, 527 F.3d 1065, 1076 (10th Cir. 2008).

1. Unlawful Distribution or Possession with Intent to Distribute HGH

In order to convict Mr. Bader of unlawful possession with intent to distribute HGH in violation of 21 U.S.C. § 333(e), the government was obligated to prove each of three elements beyond a reasonable doubt: (1) that Mr. Bader knowingly distributed HGH or possessed HGH with the intent to distribute it; (2) that Mr. Bader knew that the HGH that he possessed and intended to distribute was for use in humans; and (3) "[e]ither [that] Mr. Bader knew that the [HGH] was not being distributed for a[] use authorized by the Secretary of Health and Human Services[,] or that Mr. Bader knew that the [HGH] was not being distributed pursuant to the order of a physician[,] or was not being prescribed for a valid medical purpose." Aplt. Trial Tr. App., Vol. VIII, at 2180–81 (Jury Instruction No. 38). Mr. Bader challenges the third of these three elements on

appeal.

Mr. Bader principally argues that his conviction cannot stand because the government failed to present proof that he knowingly filled a prescription for an unauthorized use—"[i]llegal distribution," he contends, "requires proof of a prescription sale for an unapproved use *and* that a pharmacist knowingly filled it." Aplt. Opening Br. at 31. This is simply incorrect. Under 21 U.S.C. § 333(e)(1),

> whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans *other than* the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.

21 U.S.C. § 333(e)(1) (emphasis added). Thus, the plain terms of the statute belie Mr. Bader's argument—specifically, his contention that there is only one means to violate the statute involving knowingly filling a prescription for an unauthorized use.

Indeed, Jury Instruction No. 38—the instruction that outlined the elements of the unlawful distribution charge *and* to which Mr. Bader has offered no objection—was phrased in the disjunctive. According to that instruction, proof of the filling of an improper physician prescription was but one of three ways that the government could satisfy its burden. The government could demonstrate

either: (1) that "Mr. Bader knew that the [HGH] was not being distributed for a[] use authorized by the Secretary of Health and Human Services"; "*or* [(2)] that Mr. Bader knew that the [HGH] was not being distributed pursuant to the order of a physician"; "*or* [(3) that Mr. Bader knew that the HGH that he possessed] was not being prescribed for a valid medical purpose." Aplt. Trial Tr. App., Vol. VIII, at 2181 (emphases added).[8]

Throughout Mr. Bader's trial, the government introduced a series of exhibits consisting of College Pharmacy advertisements that extolled the anti-aging and muscle-building benefits of HGH, as well as related statements from Mr. Blum and various College Pharmacy employees. Several of the witnesses who testified recalled that Mr. Bader had promoted HGH at A4M trade shows as an anti-aging and body-building drug. And their testimony was corroborated by photographs depicting Mr. Bader and his advertisements at one of these trade shows. Mr. Bader apparently argues that this evidence is insufficient because it merely demonstrates promotion, as opposed to actual distribution, of HGH. However, under the plain language of the statute—as well as Mr. Bader's counts of conviction—proscribed is not only the actual distribution of HGH but also

[8] In addressing a sufficiency-of-the-evidence challenge, a panel of the Ninth Circuit construed the statute as having a similar breadth. *See United States v. Hunter*, 445 F. App'x 998, 1000–01 (9th Cir. 2011) ("Because Hunter's sales of HGH were for a use in humans that was not approved by the FDA and were *not* pursuant to a physician's prescription, those sales violated 21 U.S.C. § 333(e)." (emphasis added)).

possession with intent to distribute. 21 U.S.C. § 333(e). As it is undisputed that College Pharmacy "possessed" HGH at its Colorado Springs facility, any rational trier of fact could have concluded that these advertisements demonstrated Mr. Bader's intent to market and distribute HGH as an anti-aging and body-building drug, which were not authorized uses of HGH.[9]

In that regard, the government introduced evidence demonstrating that the FDA had not approved the use of HGH for either anti-aging or body-building purposes through the testimony of Dr. Woo. After establishing that his position as medical director had familiarized him with the process that a pharmaceutical manufacturer must undergo in order to obtain FDA approval for a drug such as HGH, Dr. Woo informed the jury that HGH had yet to be approved for *any* off-label uses due to congressional safety concerns.[10] Specifically, Dr. Woo also

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[9] Mr. Bader also avers that the government's reliance upon these advertisements runs afoul of the First Amendment in light of the Supreme Court's decision in *Western States*. In *Western States*, the Court invalidated several restrictions of the Food and Drug Administration Modernization Act of 1997 ("FDAMA") on advertising of compounded drugs on the ground that they constituted unconstitutional restrictions on commercial speech. *See* 535 U.S. at 360. As the government points out, however, Mr. Bader's First Amendment rights were not at issue in the instant case, and there is absolutely nothing in *Western States* that bars the government from relying upon a defendant's commercial advertisements as evidence that he sought to distribute HGH or any other compounded drug for an unauthorized use in violation of 21 U.S.C. § 333(e). Thus, any First Amendment argument by Mr. Bader predicated on *Western States* is without merit.

[10] Generally, a new drug must be approved by the FDA through an NDA, under which it is approved for specific uses—i.e., to treat certain

(continued...)

testified that body-building and anti-aging were *not* FDA-approved "uses" for HGH. On the basis of this evidence, a reasonable jury could have logically deduced that the College Pharmacy anti-aging and body-building advertisements introduced at trial were aimed at distributing HGH for those uses—uses which had yet to be authorized by the Secretary of Health and Human Services or recognized as valid medical conditions warranting HGH prescriptions. Accordingly, a reasonable jury could have construed this evidence as satisfying the third element of 21 U.S.C. § 333(e).

2. Facilitating the Sale of Illegally Imported HGH and Conspiracy to Facilitate the Sale of Illegally Imported HGH

While we must vacate Mr. Bader's 18 U.S.C. § 545-related convictions of facilitating the sale of illegally imported HGH and conspiracy to facilitate that sale due to the aforementioned error in Jury Instruction No. 20, standing alone, this action would not preclude the government from re-prosecuting Mr. Bader on these charges. It is the law of this circuit that the reversal of a defendant's conviction "bars retrial only where the government presents no evidence that

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[10](...continued)
conditions. Any use of the drug other than that in the approved labeling is considered an "off-label" use of the drug. Aplee. App., Vol. I, Tr. at 20–21. For most drugs, these off-label uses are entirely legal, and physicians may proceed to prescribe the drug for other purposes. As Dr. Woo explained, however, this is not the case with HGH; due to congressional concerns with HGH abuse, off-label prescriptions of HGH are uniformly illegal. *Id.* This is evident from the plain language of § 333(e), which holds a party liable for *any* use of HGH that has not been expressly "authorized by the Secretary of Health and Human Services." 21 U.S.C. § 333(e)(1).

could support [his] conviction." *United States v. Holly*, 488 F.3d 1298, 1311 n.11 (10th Cir. 2007); *accord United States v. Pearl*, 324 F.3d 1210, 1214 (10th Cir. 2003) ("Our conclusion that [defendant's] convictions on counts 2 through 5 must be reversed does not, however, preclude retrial of [defendant] on these counts . . . ."); *cf. Level 3 Commc'ns v. Liebert Corp.*, 535 F.3d 1146, 1150 (vacating the jury's verdict and remanding for a *new trial* where the court erroneously instructed the jury).

This principle is grounded in the Double Jeopardy Clause. In contrast to a second trial following an acquittal, which would "present an unacceptably high risk that the [g]overnment, with its vastly superior resources, might wear down the defendant so that 'even though innocent, he may be found guilty,'" *United States v. Scott*, 437 U.S. 82, 91 (1978) (quoting *Green v. United States*, 355 U.S. 184, 188 (1957)), the Supreme Court has held that "the successful appeal of a judgment of conviction, on any ground other than the insufficiency of the evidence to support the verdict . . . poses no bar to further prosecution on the same charge" because "to require a criminal defendant to stand trial again after he has successfully invoked a statutory right of appeal to upset his first conviction is not an act of governmental oppression of the sort against which the Double Jeopardy Clause was intended to protect," *id.* at 90–91.

Accordingly, this circuit has established a distinction between "trial error" deriving from an erroneous jury instruction and "pure insufficiency of evidence"

such that, in the former case, a defendant "may be retried without violating double jeopardy." *Pearl*, 324 F.3d at 1214; *accord United States v. Wacker*, 72 F.3d 1453, 1465 (10th Cir. 1995). Thus, Mr. Bader may be re-tried following remand to the district court *if* his case falls within this "trial error" category—in other words, so long as the government presented legally sufficient evidence. *See United States v. Nacchio*, 519 F.3d 1140, 1157 (10th Cir. 2008) ("Although we have concluded that Mr. Nacchio's conviction must be reversed on account of trial error, we cannot leave it at that. He also claims that the government failed to introduce evidence sufficient for him to be convicted. If he is right, he was entitled to a judgment of acquittal and cannot be retried without violating the Double Jeopardy Clause."), *vacated in part on other grounds*, 555 F.3d 1234, 1236 (10th Cir. 2009).

Perhaps because he is aware of this fact, Mr. Bader devotes a substantial portion of his briefs to challenging the sufficiency of the evidence supporting his § 545-related convictions. Specifically, he avers that: (1) his convictions cannot stand because they were premised upon the importation of an *API* rather than a finished drug—i.e., that a reasonable jury could not have concluded that the imported HGH was a "finished drug" on the basis of the evidence that the government produced at trial; (2) the record contains no evidence that Mr. Bader possessed the requisite *mens rea* to be convicted of the importation of HGH contrary to law; and (3) the government failed to prove that Mr. Bader knowingly

participated with a specific intent to further the conspiracy to sell contraband HGH. Aplt. Opening Br. at 21–30.[11] None of these arguments has merit.

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[11] Mr. Bader also appears to advance two related arguments: that he must be acquitted of the HGH § 545-related charges (1) because the government conceded that the imported HGH was an API, rather than "finished" drug, at pretrial proceedings; and (2) because "four-fifths of the [HGH] counts"—i.e., the twenty-three HGH distribution counts involving prescriptions to minors which were validly issued by physicians—were deemed unsupported by sufficient evidence and dismissed post-trial. Aplt. Opening Br. at 19. Mr. Bader also makes a third argument in his reply brief, asserting that his conviction for importation of HGH cannot stand because he was acquitted of "receiving contraband" lacking NDA approval in Count Sixteen, which necessitates a finding that the imported HGH was not "finished." Aplt. Reply Br. at 3. These arguments are without merit.

First, with regard to the government's allegedly inconsistent pretrial position, Mr. Bader misinterprets the government's statements. The government merely asserted pretrial that Mr. Bader had falsely "represented" that the HGH was an "ingredient" in order to import it into the United States, in accordance with its theory that Mr. Bader received smuggled HGH on the basis of false statements, *see* Aplt. App., Vol. VI, Tr. at 1778 ("That's how it [i.e., HGH] was *represented*, your Honor, for compounding purposes as an ingredient." (emphasis added)); at no point did the government indicate that the imported HGH was actually an API. Moreover, at no point did the *court* "note[]," Aplt. Opening Br. at 19, that the imported HGH was an API; on the contrary, the court observed that the Genescience API was released for importation by FDA inspectors on the basis of Mr. Bader's allegedly *false representation* that the Genescience HGH was an API as opposed to a finished drug, *see* Aplt. App., Vol. VI, Tr. at 1962. Second, the court's subsequent decision to vacate Mr. Bader's convictions for distribution of HGH to minors hinged upon the government's inability to prove that those HGH prescriptions had been *dispensed* in the United States for improper purposes; the dismissals had absolutely nothing to do with the *importation* of that HGH.

Because Mr. Bader cursorily asserts his third argument for the first time in his reply brief, we need not consider it in the first place. *See, e.g., Stump v. Gates*, 211 F.3d 527, 533 (10th Cir. 2000) ("This court does not ordinarily review issues raised for the first time in a reply brief . . . . It robs the appellee of the

(continued...)

(i) Importation of Illegally Manufactured API or Finished Drug Product Lacking NDA Approval

Mr. Bader insists that a reasonable jury could not have convicted him of the § 545-related charges because the government failed to sufficiently demonstrate that the imported HGH was a "finished" drug product rather than an API. Though as noted we find error with the dual avenues that Jury Instruction No. 20 provided for conviction, there was ample evidence upon which a reasonable jury could have convicted Mr. Bader on the proper ground specified in this instruction: that is, the imported HGH was a finished drug that was illegally imported on account of Mr. Bader's failure to garner NDA approval.[12]

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[11](...continued)
opportunity to demonstrate that the record does not support an appellant's . . . assertions . . . ."). However, even if we were to do so, we would conclude that it is without merit. Specifically, the jury's decision to acquit Mr. Bader of receiving stolen goods under Count Sixteen of the Second Superseding Indictment had no bearing upon his § 545-related convictions. Count Sixteen primarily turned upon 18 U.S.C. § 542, which relates to the entry of merchandise into the United States by means of false statements. Aplee. App., Vol. IV, at 1038–39; *see* Aplt. Trial Tr. App., Vol. VIII, at 2173 (Jury Instruction No. 26). A reasonable jury could have found that Mr. Bader was not guilty of having knowingly facilitated the importation of HGH into the United States *through false statements* to the FDA (i.e., statements indicating that the HGH was an API in order to gain import approval), yet simultaneously concluded that Mr. Bader was nevertheless guilty of knowingly facilitating the sale of an illegally imported finished drug—even if the importation of this finished drug was not facilitated through false representations.

[12] While we conclude that the government presented sufficient evidence that the imported Genescience HGH was a "finished drug," the government offered us little help in reaching this conclusion. Though the government baldly asserts that Mr. Bader "directed employees of College Pharmacy to repackage the (continued...)

Specifically, the government produced sufficient evidence upon which a reasonable jury could have concluded that the HGH that Mr. Bader imported was a "finished drug"—primarily through detailed witness testimony explaining how the imported Genescience HGH remained essentially unaltered prior to distribution. Much of this testimony pertained to the specific, step-by-step protocol that College Pharmacy employees followed in preparing the imported Chinese HGH for distribution. Stacy Griffin, one of those employees, read portions of College Pharmacy's "Somatropin prepackaged protocol" aloud from the stand as she testified. Aplee. App., Vol. I, Tr. at 131 (Test. of Stacy Griffin). That protocol was remarkably simple, requiring College Pharmacy employees to simply gather and sterilize "5 cc 20-millimeter vials," clean the requisite measuring materials, calibrate the scales used to weigh out the appropriate doses, then "[p]lace [an] empty sterile vial on the balance and begin to weigh powder into it." *Id.* at 132–34 (internal quotation marks omitted). Ms. Griffin verified that this was "essentially the process that was followed when College Pharmacy

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[12](...continued)
Genescience [HGH] into smaller vials labeled with College Pharmacy boxes and information" for sale as "Somatropin," without ever "add[ing] ingredients to, or remov[ing] anything from, the product itself," Aplee. Br. at 21–22, it fails to point to *any* excerpts from the record that support these sweeping statements. We remind counsel that is not this Court's job to "sift through the record to find support" for the government's arguments, and its failure to "direct us to the location in the voluminous record where we [might] find support for their [arguments]" has resulted in the unnecessary expenditure of valuable judicial resources. *Phillips v. James*, 422 F.3d 1075, 1081 (10th Cir. 2005).

took the Somatropin from the large bottles and put it into small vials," *id.* at 134, and confirmed that College Pharmacy "got Somatropin from" Genescience, *id.* at 131.

John Ruth, a College Pharmacy national sales representative, also told the jury that, at least initially, College Pharmacy did no more than simply "repackag[e]" the imported HGH. *Id.*, Vol. II, Tr. at 296 (Test. of John Ruth). Mr. Ruth explained that College Pharmacy employees were "told via Mr. Bader" to repackage the imported HGH, and that the College Pharmacy sales team, in turn, "told all of [its] clients and prospective clients" the same thing: College Pharmacy was "bringing in a drug, importing it from another country, and . . . repackaging [it] into [College Pharmacy's] own package and selling it to them." *Id.* Then, "in early 2005, after [College Pharmacy] had been selling the Somatropin for several months and had done well, [the sales team was] told . . . that [it was] not repackaging [the HGH] because [it] could not get a license to repackage from the . . . FDA." *Id.* The College Pharmacy sales team then simply began to inform customers that the HGH "was compounded; that it was no longer repackaged." *Id.* Any change in College Pharmacy's Genescience processes—from "repackaging" to "compounding"—was therefore illusory, and was aimed at avoiding FDA oversight rather than actually "compounding" imported ingredients.

The testimony of Ms. Griffin and Mr. Ruth was corroborated by the

testimony of Mr. Blum, who stated that he was not aware of "anything being added or taken out of the bottled version [of HGH] that [Genescience] provided [College Pharmacy] [as juxtaposed with] the vials that [College Pharmacy was] putting out." *Id.*, Vol. I, Tr. at 182 (Test. of Brad Blum). Mr. Blum consistently referred to the Genescience HGH product that he sold to Mr. Bader as "Somatropin," and even testified that he "personal[ly] use[d]" Somatropin after purchasing it directly from Genescience. *Id.* at 168–69. Upon receiving the Genescience shipment from China, Mr. Blum explained, he mixed the imported vial of HGH powder with a vial of water and injected himself with the hormone at his home, noting that HGH enables one to "recover faster from injury" and that he found it to improve his "general well being." *Id.* at 170. On the basis of testimony from the man who actually imported and dealt directly with Genescience, it would have been entirely reasonable for a jury to conclude that Genescience's HGH, to which nothing was "being added or taken out," was essentially (in substance) identical to the smaller Somatropin doses that College Pharmacy later marketed—particularly in light of Mr. Blum's testimony that he was able to personally use (as well as distribute to his friends) the "finished" HGH that he received directly from Genescience. *See id.* at 172, 182.

Having learned (1) that the imported Genescience HGH was merely repackaged into smaller vials as "Somatropin," (2) that College Pharmacy employees themselves told clients they were merely repackaging the imported

HGH, and (3) that the imported Genescience HGH was—at least in certain significant instances (e.g., the use of Mr. Blum)—patient-ready even prior to College Pharmacy's processing, a reasonable jury could have easily inferred that the imported Genescience HGH was already in its "finished" form when it arrived at College Pharmacy for repackaging and distribution. In sum, Mr. Bader's conviction was supported by a wealth of evidence.

(ii) *Mens Rea*

Mr. Bader also argues that the government failed to present sufficient evidence that he possessed the necessary *mens rea* to be convicted under 18 U.S.C. § 545. *See* Aplt. Opening Br. at 28. Neither party does a good job of developing this issue. And, in particular, the government's conclusory assertion that "[i]t was uncontroverted that [Mr. Bader] knew the [HGH] in question was not the subject of an approved NDA," Aplee. Br. at 23—with no citations to the record that support this statement—is unhelpful. Our independent review of the record, however, confirms that the government is correct: a reasonable jury could have easily concluded that Mr. Bader knew the illicit nature of his transactions on the basis of the evidence adduced at trial.

Admittedly, our own circuit has offered little in the way of guidance regarding the *mens-rea* requirement of § 545. Our sister circuits, however, have observed that "the word 'knowingly'"—as it appears in § 545—"modifies 'imports or brings into the United States, any merchandise contrary to law.'"

United States v. Garcia-Paz, 282 F.3d 1212, 1217 (9th Cir. 2002) (quoting 18 U.S.C. § 545); *accord United States v. Molt*, 615 F.2d 141, 146 (3d Cir. 1980) ("An essential element of a section 545 offense is . . . a knowing importation of merchandise contrary to law."); *see also Roseman v. United States*, 364 F.2d 18, 23 (9th Cir. 1966) (noting that an appellant's charge under 18 U.S.C. § 545 for the sale of LSD required proof "(1) that the appellants sold the LSD"; "(2) that [the] appellants had *knowingly brought this LSD into the United States contrary to law*"; "and (3) that the LSD . . . was a 'new drug' . . . for which there was no effective new drug application" (emphasis added)). Under § 545, "[i]t is not a requirement of the offense that the defendant know the type of merchandise he is importing. He need only know that he is importing or bringing in 'merchandise contrary to law.'" *Garcia-Paz*, 282 F.3d at 1217 (quoting 18 U.S.C. § 545). In the present case, therefore, the government could satisfy § 545's *mens-rea* requirement so long as it could demonstrate that Mr. Bader "knew" that he was importing a drug from Genescience illegally.

As proof that Mr. Bader possessed the requisite *mens rea* to be convicted of a § 545-related offense, the government first presented the testimony of Chris Strong, College Pharmacy's managing pharmacist at the time that Mr. Bader began importing the Chinese HGH. Mr. Strong testified that he had expressed his concerns about the importation of Chinese HGH to Mr. Bader and other College Pharmacy pharmacists at a meeting in 2004. He explained that the meeting had

centered upon whether or not College Pharmacy was "going to operate the pharmacy with the compliance policy guidelines of the FDA," and he recalled that "Mr. Bader's opinion [had been] that [the FDA's policy] was a guideline"—*not* "a rule or a regulation" that College Pharmacy was obligated to follow. Aplee. App., Vol. I, Tr. at 113 (Test. of Chris Strong); *see also id.*, Vol. II, Tr. at 293–94 ("[T]he FDA wanted in, and [Mr. Bader] wanted them out. . . . [T]hey were known as Big Pharma. They were the big enemy, and we were the good guys."). Mr. Strong further testified that he and Mr. Bader had quarreled over appropriate College Pharmacy protocol, usually in relation to Mr. Bader's continuous attempts to increase College Pharmacy's profit. Not long after Mr. Strong attempted to institute a new policy at College Pharmacy—pursuant to which pharmacists would be asked to verify that any new physician who sought to fill a prescription with College Pharmacy was adequately certified—he was fired from his position at the pharmacy.

Mr. Bader's knowing disregard of the FDA's regulatory scheme was directly confirmed by the testimony of Mr. Blum, who admitted that both he and Mr. Bader had known that the Genescience HGH was not an FDA-approved product and had also known that it was being imported from China. Mr. Ruth also told the jury that Mr. Bader had known that the imported HGH was subject to FDA approval, and recounted how Mr. Bader had directed his sales staff to inform College Pharmacy customers that the pharmacy was "compound[ing]" rather than

merely "repackaging" the imported HGH in order to avoid FDA licensing requirements. *Id.*, Vol. II, Tr. at 296.

A reasonable jury certainly could have construed the testimony of Mr. Strong, Mr. Blum, and Mr. Ruth—particularly when viewed collectively—as constituting sufficient evidence that Mr. Bader "knowingly" imported HGH from Genescience and that he knew that he was doing so "contrary to law." *See* 18 U.S.C. § 545; *see Garcia-Paz*, 282 F.3d at 1217. As such, the government presented sufficient evidence upon which a reasonable jury could have concluded that the *mens rea* element of § 545 was satisfied.

3. Conspiracy

Finally, Mr. Bader contends that the government failed to prove that he conspired with Mr. Blum and others to illegally import HGH, alleging that (1) "the [g]overnment failed to prove anything other than an equipoise buyer-seller relationship between [Mr.] Blum and the purchasing pharmacies," and (2) that the government failed to prove that he knowingly participated in the alleged conspiracy. Aplt. Opening Br. at 29. The district court here instructed the jury that, in order to convict Mr. Bader of conspiring to violate 18 U.S.C. § 545, the government was obligated to prove, beyond a reasonable doubt, that "(1) Mr. Bader entered into an agreement or understanding with one or more others to import [HGH] into the United States contrary to federal law and thereafter to sell or distribute that [HGH] within the United States"; (2) "[t]here was an

interdependence among Mr. Bader and the others involved in [the] agreement"; (3) "Mr. Bader knew that the purpose of the agreement was to import the [HGH] contrary to federal law[,]" to sell it thereafter, and that he "voluntarily entered into that agreement"; and (4) "[o]ne or more of the people who entered into the agreement performed one or more overt acts—that is, actions that constituted a substantial step towards achieving the purpose" of the illegal importation scheme.[13] Aplt. Trial Tr. App., Vol. VIII, at 2168 (Jury Instruction No. 18); *see*

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[13] In most material respects, the district court's instruction accurately reflects the elements of conspiracy under 18 U.S.C. § 371, which we have repeatedly articulated:

> To convict a defendant of conspiracy under 18 U.S.C. § 371, the government must prove that: (1) there was an agreement to violate the law, (2) the defendant knew the essential objective of the conspiracy, (3) the defendant knowingly and voluntarily participated in the conspiracy, (4) an overt act was committed in furtherance of the conspiracy, and (5) the coconspirators were interdependent.

Cooper, 654 F.3d at 1115 (quoting *United States v. Bedford*, 536 F.3d 1148, 1156 (10th Cir. 2008)) (internal quotation marks omitted). We pause, however, to observe that the district court equated the "overt act" element with the accomplishment of a "substantial step" toward the completion of the crime. Yet, as we have noted, an "overt act" and a "substantial step" are distinct concepts in the law and the latter *necessarily* contemplates a threshold or baseline action of greater magnitude than the former. *See United States v. Irving*, 665 F.3d 1184, 1198 n.14 (10th Cir. 2011) ("In conspiracy law, given the existence of an unlawful agreement, 'virtually any act will satisfy the overt act requirement.' In other words, the overt act need not necessarily be substantial." (citation omitted) (quoting Wayne R. LaFave, *Substantive Criminal Law* § 12.2(b), at 627 (4th ed. 2003))). Thus, theoretically, the district court's instruction could be interpreted as having placed a greater burden of proof on the government than mandated by § 371. However, the government did not object to any possible error in this instruction and therefore was bound by it. *See, e.g.*, *United* (continued...)

also Molt, 615 F.2d at 146 (discussing elements of crime of conspiring to violate § 545). Mr. Bader arguments implicate only the first and third elements. The government, however, presented ample evidence to support the jury's findings as to these elements.

First, on redirect, Mr. Blum clearly and unequivocally testified that he illegally imported and distributed HGH, and that he did so with Mr. Bader's knowledge and assistance. Mr. Blum acknowledged that he had "agree[d] to violate the law" when he "agreed to do business with Tom Bader," and he further admitted that this agreement amounted to a conspiracy involving "importation of [HGH] and delivery to Mr. Bader," that the "essential objective of the conspiracy" was to "distribute [HGH]," and that the "members of that conspiracy" were "[him]self and Tom [Bader]." Aplee. App., Vol. I, Tr. at 252. Mr. Blum also confirmed that Mr. Bader had "knowingly and voluntarily participated in that agreement." *Id.*; *see id.* at 189 (agreeing that "Mr. Bader . . . kn[e]w that this was not FDA[-]approved product").

Mr. Blum's statements were corroborated by the testimony of Mr. Strong, who told the jury that Mr. Bader was aware of the fact that his importation of

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[13](...continued)
States v. Williams, 376 F.3d 1048, 1051 (10th Cir. 2004) ("The law of the case is applied to hold the government to the burden of proving each element of a crime as set out in a jury instruction to which it failed to object, even if the unchallenged jury instruction goes beyond the criminal statute's requirements."). In any event, given the nature of Mr. Bader's specific challenges, we have no need to address this matter further.

Genescience HGH violated FDA protocol, as well as the testimony of Mr. Ruth, who confirmed that College Pharmacy was purchasing HGH from Mr. Blum and from Genescience in China at the direction of Mr. Bader. On the basis of this testimony, a reasonable jury could have concluded that Mr. Bader "knowingly" entered into an agreement with Mr. Blum to import and distribute HGH in a manner that Mr. Bader knew was "contrary to law"—i.e., in a way that he knew ran afoul of FDA rules and regulations. Accordingly, we conclude that the government presented sufficient evidence of Mr. Bader's involvement in a conspiracy relating to the § 545 charge.

4. Conspiracy to Distribute or Possess with Intent to Distribute Testosterone Cypionate

Finally, Mr. Bader challenges the sufficiency of the evidence that the government presented to prove Count Nineteen of the Superseding Indictment—conspiracy to distribute and to possess with the intent to distribute testosterone cypionate (an anabolic steroid), in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(D), and 21 U.S.C. § 846. Mr. Bader argues that, of the nearly four thousand doctors that College Pharmacy serviced, only two admitted that they had "secretly" prescribed testosterone through College Pharmacy for unlawful uses. Aplt. Opening Br. at 56. He also avers that he was unaware of these unlawful prescriptions.

As the jury was instructed at trial, the government bore the burden of proving, beyond a reasonable doubt, that: "(1) Mr. Bader entered into an

agreement or understanding with one or more others to unlawfully distribute or to possess . . . with the intention of unlawfully distributing a controlled substance; namely, testosterone cypionate, an anabolic steroid"; "(2) Mr. Bader knew that the purpose of the agreement" was to unlawfully distribute or to possess with intent to distribute that testosterone cypionate; and "(3) [t]here was an interdependence among Mr. Bader and the others involved in this agreement or understanding." Aplt. Trial Tr. App., Vol. VIII, at 2178 (Jury Instruction No. 34). Mr. Bader contests the government's proof of the first two of these three elements.

(i) Agreement to Unlawfully Distribute

Although Mr. Bader primarily attempts to discredit the government's evidence regarding the two doctors who prescribed testosterone cypionate for unlawful uses through prescriptions filled by College Pharmacy,[14] this was merely

[14] The government did elicit testimony from College Pharmacy pharmacists indicating that patient-prescription histories that detailed the dispensing practices of these two doctors were readily available on a College Pharmacy computer system. *See* Aplee. App., Vol. I, Tr. at 108–10 (Test. of Teresa Weisenbach); *see also id.* at 49–51 (Test. of Frieda Martin). However, Mr. Bader points to record evidence tending to establish that these physicians ceased doing business with College Pharmacy in 2003. *See* Aplt. Opening Br. at 59–60. In its answer brief, the government does not appear to dispute this fact. This is significant, because by its own admission, Mr. Bader only had access to that computer system as Pharmacy Manager beginning in July 2005. *See* Aplt. App., Vol. V, at 1421 (Gov't's Resp. to Def.'s Mot. for J. of Acquittal and in the Alternative for New Trial, filed Apr. 2, 2010). Therefore, we have difficulty seeing how the testimony of the government witnesses indicating that the two physicians' patient-prescription histories would have been available on the (continued...)

one aspect of the abundant evidence that the government presented to demonstrate that Mr. Bader knowingly agreed with other College Pharmacy sales and advertising staff to illegally distribute and to possess with the intent to distribute testosterone cypionate. First, to prove that an agreement existed, the government presented testimony from one of Mr. Bader's co-conspirators. Specifically, Mr. Ruth testified that he "always got instruction from Thomas Bader" regarding how he and fellow College Pharmacy employee, Kevin Henry, should prepare for and present information at the A4M anti-aging conferences at which College Pharmacy marketed testosterone cypionate, Aplee. App., Vol. II, Tr. at 298—despite the fact that anti-aging is not a lawful, approved use for this drug. Sometimes Mr. Bader even attended these conferences himself and, when he did, Mr. Bader was the one "running the show." *Id.*, Vol. I, Tr. at 191. Mr. Ruth also explained that College Pharmacy had enjoyed a lucrative relationship with Peak Physique, a large anti-aging clinic that purchased large volumes of prescriptions from College Pharmacy, and that Mr. Bader had supervised the Peak Physique account.

Additionally, the government introduced a series of College Pharmacy's

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[14](...continued)
College Pharmacy computer advances the government's cause. Nonetheless, as noted above, the evidence concerning the two physicians was only a small part of the inculpatory picture painted by the government concerning the charge of conspiracy to unlawfully distribute and possess with the intent to distribute testosterone cypionate.

advertisements promoting testosterone for anti-aging and body-building purposes.[15] Among these was a printout of College Pharmacy's web page, which depicted a bulging bicep and the word "TESTOSTERONE" in large, block print, accompanied, at the top of the page, by these words: "Recent headlines question the benefits of testosterone for aging men . . . To learn more, click here."[16] *Id.*, Vol. III, at 657 (Gov't Ex. 23) (some capitalization altered). Mr. Ruth testified that this advertisement was geared toward promoting "[b]ig muscles," and that Mr. Bader himself had approved it. *Id.*, Vol. II, Tr. at 318. Government Exhibit Thirteen—a College Pharmacy print advertisement encouraging consumers to "[l]ive [l]ife to the [f]ullest"—also billed "[t]estosterone for [m]en & [w]omen" as one of College Pharmacy's featured anti-aging products, and boasted that

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[15] Once again, Mr. Bader apparently objects to the government's reliance upon these advertisements on First Amendment grounds. As we explained *supra*, however, this argument is without merit.

[16] Mr. Bader contends that College Pharmacy's website advertisement contains "no discussion of body-building"; instead, he avers, it merely references a "report from a congressionally-chartered medical institute stating that testosterone is useful for men who suffer from hypogonadism," which is an "age-related medical condition." Aplt. Opening Br. at 62–63. First, to the extent that College Pharmacy's web page contains such a report reference, as best we can tell, it does not do so on the face of College Pharmacy's homepage or in the advertisement that appears at the top of that homepage. Second, Mr. Bader's contention that the advertisement was not geared toward "body building" is clearly refuted by the overtly muscular male image that the advertisement prominently displays. A reasonable jury presented with this image could have easily concluded that the advertisement was geared toward *muscle, not medicine*, particularly in light of Mr. Ruth's statement that it was developed to promote the product's use for the former.

"[a]nti-[a]ging clinics all over the United States [were] coming to College Pharmacy for solutions to their age[-]management questions." *Id.*, Vol. III, at 645 (Gov't Ex. 13). Mr. Ruth explained that Tracy Crawford, College Pharmacy's managing director of sales, had affixed a post-it note to this advertisement asking Mr. Bader whether he would like to include it as an insert in the registration bags that College Pharmacy distributed to anti-aging trade show attendees.

Indeed, Mr. Ruth confirmed that *all* of College Pharmacy marketing materials and major decisions were subject to Mr. Bader's approval. His testimony, combined with these College Pharmacy advertisements, provided more than sufficient evidence upon which a reasonable jury could have concluded that Mr. Bader "entered into an agreement" with Mr. Ruth and other members of the sales department to unlawfully distribute testosterone cypionate—in other words, the government met its burden of proof concerning element one of Count Nineteen under Jury Instruction No. 34. *See* Aplt. Trial Tr. App., Vol. VIII, at 2178; *see id.* at 2168–69 (Jury Instruction No. 19) ("In determining whether the [g]overnment has shown that Mr. Bader entered into an agreement or understanding with others, you are instructed that the [g]overnment need not show that the people involved had any formal or written agreement nor that they specifically discussed among themselves what the purpose or details of the agreement would be or the means by which it would be accomplished.").

(ii) Knowingly Unlawful Distribution

The government also established that "Mr. Bader *knew* that the purpose of the agreement was to unlawfully distribute" testosterone cypionate. *Id.* at 2178 (emphasis added). At trial, the jury was instructed that "[w]ith regard to whether any distribution or possession with intent to distribute testosterone cypionate by Mr. Bader was unlawful," it was to consider whether the government had shown "that Mr. Bader either knew that he was distributing or possessing with intent to distribute the testosterone cypionate without a valid prescription by a medical practitioner or knew that the prescription he was filling was issued without a valid medical purpose." *Id.* at 2178–79. As Mr. Ruth and others testified, Mr. Bader knew that he was distributing testosterone to Peak Physique and other clinics for anti-aging and body-building purposes. Furthermore, particularly in light of Mr. Ruth's concession that *he* knew that anti-aging was not a "valid medical purpose," *id.* at 2179, a reasonable jury could have easily inferred that "a reasonable pharmacist acting in good faith," *id.* at 2173, would have known that these were unlawful uses. Thus, the government also satisfied its burden of proof regarding element two of the testosterone-conspiracy charge. Accordingly, construing the evidence in the light most favorable to the government, a reasonable jury could have convicted Mr. Bader of conspiracy to distribute and to possess with the intent to distribute testosterone cypionate.

C. *Prosecutorial Misconduct*

Mr. Bader claims that the government committed prosecutorial misconduct

when it prosecuted him for importation of HGH contrary to law in spite of the district court's purported pretrial ruling that the imported Genescience HGH was an API as opposed to a finished drug. In so doing, he argues that the prosecution "intentionally misled th[e] jury to convict on an unfounded legal basis"—that is, he was prosecuted on the basis of "no legally cognizable evidence." Aplt. Reply Br. at 15 (emphasis removed); *see United States v. Farinella*, 558 F.3d 695, 700–01 (7th Cir. 2009) (reversing a defendant's conviction where the prosecutor committed egregious misconduct in failing to present any evidence that the defendant violated any federal law or FDA regulation).[17] Because he raises it for the first time on appeal, we review Mr. Bader's prosecutorial-misconduct

[17] Though Mr. Bader relies heavily upon *Farinella* in support of his poorly presented prosecutorial-misconduct argument, that case is largely inapposite. In *Farinella*, the Seventh Circuit reversed the defendant's convictions for wire fraud and introducing into interstate commerce a misbranded food with intent to defraud and mislead where the prosecutor failed to present *any* evidence that the defendant's changing of a product's "best when purchased by" date constituted a "misbranding" of food or otherwise violated federal law or FDA regulations. 558 F.3d at 700–01. In the present case, in contrast, Mr. Bader's § 545 illegal importation charge was predicated upon 21 U.S.C. § 355, which expressly forbids the importation of any "new drug" absent FDA approval. *See* Aplee. App., Vol. IV, at 1037–38. Thus, so long as the government presented evidence that the Genescience HGH was in all material respects a "new drug"—i.e., a finished drug as opposed to an API—it presented a theory upon which a reasonable jury could convict Mr. Bader of illegally importing HGH. And the government in fact presented ample evidence on this point. Consequently, this is a far cry from the government's failure to present *any* evidence that the defendant violated any law or regulation in *Farinella*; indeed, but for the fact that *Farinella* involved products that fall within the purview of the FDA's regulatory scheme, it bears no resemblance to the present case. *Farinella* lends no support to Mr. Bader's argument.

contention for plain error. *See, e.g.*, *United States v. Sands*, 968 F.2d 1058, 1063 (10th Cir. 1992).

"We use a two-step process when evaluating claims of prosecutorial misconduct. First, we examine whether the conduct was, in fact, improper. If we answer that question in the affirmative, we must then determine whether it warrants reversal." *United States v. Oberle*, 136 F.3d 1414, 1421 (10th Cir. 1998). "When evaluating allegedly inappropriate remarks of counsel for plain error, we must view the remarks in the context of the entire trial." *Id.* (quoting *Sands*, 968 F.2d at 1063–64) (internal quotation marks omitted). Thus, "[t]he relevant question is whether the prosecutors' comments 'so infected the trial with unfairness as to make the resulting conviction a denial of due process.'" *Darden v. Wainwright*, 477 U.S. 168, 181 (1986) (quoting *Donnelly v. DeChristoforo*, 416 U.S. 637, 643 (1974)). Applying these standards to the facts before us here, it is patent that Mr. Bader's allegations fall short.

Mr. Bader's argument fails, in part, because it is premised upon a misreading of the record. Though Mr. Bader insists that the district court concluded pretrial that "the imported [HGH] undisputedly was API," Aplt. Opening Br. at 19, actually the *court* made no such determination. As discussed above, the *government* alleged that Mr. Bader had "*represented*" to FDA officials that the Genescience HGH was an "ingredient" in order to successfully (but unlawfully) smuggle it into the United States. Aplt. App., Vol. VI, Tr. at 1778

(emphasis added). If anything, the government's allegation underscored its position that Mr. Bader had facilitated the unlawful HGH importation through the use of false statements, as charged in Count Sixteen of the Second Superseding Indictment. *See* Aplee. App., Vol. IV, at 1038. It certainly did not amount to a government concession that the imported HGH was in fact an "API" as opposed to a finished drug. Moreover, at no point did the *court* conclude that the imported HGH was API; indeed, the API/finished-drug distinction was exclusively reserved for jury determination. Consequently, because neither the court nor the government concluded or represented that the imported HGH was an API, as opposed to a finished drug, the government's argument that it was the latter (i.e., a finished drug) was entirely proper. As such, Mr. Bader cannot satisfy even the first prong of *Oberle*'s two-step analysis with regard to the government's allegedly impermissible statements pertaining to finished HGH. *See Oberle*, 136 F.3d at 1421. In sum, Mr. Bader has failed to offer any plausible argument that the prosecution's actions were in any way improper.

D. *Constitutional and Estoppel Claims*

1. Entrapment by Estoppel and Right to Due Process

Though the precise nature of Mr. Bader's claims are unclear, he appears to contend that he was "entrapped" by the prosecution and by the district court, in violation of his Fifth Amendment right to due process. Specifically, Mr. Bader alleges that: (1) he relied upon the Supreme Court's ruling in *Western States*

which held that the speech-related provisions of the FDAMA were unconstitutional, as well as on a district court's ruling that "compounded drugs" were not "new drugs" subject to inspection by the FDA in *Medical Center Pharmacy v. Gonzales*, 451 F. Supp. 2d 854 (W.D. Tex. 2006), *vacated in part by Medical Center Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008)[18]; (2) that the government nonetheless prosecuted him under the FDAMA; and (3) that the district court subsequently "used [the] FDAMA to justify [his] conviction," Aplt. Opening Br. at 37–38. Mr. Bader also suggests that confusion in the legal landscape at the time that he engaged in the conduct for which he was charged precludes his conviction on due-process grounds. These claims are meritless.

"The defense of entrapment by estoppel is implicated where an agent of the government affirmatively misleads a party as to the state of the law and that party proceeds to act on the misrepresentation so that criminal prosecution of the actor

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[18] The Fifth Circuit partially reversed the district court's decision in *Medical Center Pharmacy*, having concluded that compounded drugs were not uniformly exempt from the FDA's "new drug" approval requirements—in other words, to be exempted, compounded drugs must still comply with the conditions set forth in the FDAMA, 21 U.S.C. § 353. 536 F.3d at 405–06. Mr. Bader notes that he has not cited *Gonzales* "as a statement of current law." Rule 28(j) Resp. Ltr. at 2 (dated Mar. 18, 2011). Instead, Mr. Bader appears to rely upon the Texas district court's decision because it was issued during the time period that he allegedly committed the crimes for which he was charged. However, Mr. Bader was indicted for conduct beginning in April 2004, and the district court published *Gonzales* in August 2006. Thus, even if the court's decision in *Gonzales* could justify his conduct post-August 2006, it does not apply to Mr. Bader's conduct between 2004 and 2006. *See* Aplt. App., Vol. II, at 558–59 (Op. & Order Granting, In Part, Mot. for Reconsideration, and Reserving Remainder, dated July 23, 2009); Aplt. Opening Br. Add. 4.

implicates due process concerns under the Fifth and Fourteenth Amendments." *United States v. Nichols*, 21 F.3d 1016, 1018 (10th Cir. 1994). In order to establish an entrapment-by-estoppel defense, a defendant must prove: (1) that there was an "active misleading by a government agent"; (2) that the defendant actually relied upon the agent's representation, which was "reasonable in light of the identity of the agent, the point of law misrepresented, and the substance of the misrepresentation"; and (3) that the government agent is "one who is responsible for interpreting, administering, or enforcing the law defining the offense." *United States v. Apperson*, 441 F.3d 1162, 1204–05 (10th Cir. 2006) (quoting *United States v. Hardridge*, 379 F.3d 1188, 1192 (10th Cir. 2004)) (internal quotation marks omitted).

To the extent that Mr. Bader premises his estoppel claim upon federal court decisions, it fails at the outset. While this circuit has yet to explicitly address whether a court's *ruling* can give rise to a claim of estoppel,[19] the law is clear that

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[19] In summarily rejecting Mr. Bader's claim that the Supreme Court's decision in *Western States* had led him to believe that the "FDAMA was unconstitutional in its entirety and that College Pharmacy's operations fell outside of FDA oversight," the district court stated that "judicial findings or advisements do not typically give rise to the doctrine of entrapment by estoppel." Aplee. App., Vol. IV, at 1058 (Op. & Order Den. Remaining Mots., dated Nov. 12, 2009). However, the cases that the district court cites are specifically premised upon the notion that a *state* court judge cannot plausibly offer an interpretation of *federal* law upon which a defendant may rely. *See United States v. Stults*, 137 F. App'x 179, 184 (10th Cir. 2005) (holding that defendant did not present a plausible claim of entrapment by estoppel where it was based upon the representations of a *state* probation officer and a *state* judge pertaining to his

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the offending party must be a "government *official or agency*." *United States v. Gutierrez-Gonzalez*, 184 F.3d 1160, 1167 (10th Cir. 1999) (emphasis added). A court is neither an "official," nor for purposes of making allegedly misleading declarations of law would it customarily be understood to be an "agency." *Cf. United States v. Manning*, 526 F.3d 611, 617–18 (10th Cir. 2008) (discussing the codified "judicial function exception" to prosecution under 18 U.S.C. § 1001, which makes the statute inapplicable to false statements made to the court *in its judicial capacity*, rather than its administrative capacity). Furthermore, courts cannot be said to serve as an arm of the Executive Branch—indeed, it is beyond peradventure that the separation of powers principles embodied in our Constitution forbid them from operating as such. Accordingly, any allegation that a court, as an entity, issued a decision inducing Mr. Bader to take a particular action is not one upon which an estoppel claim may stand.

Mr. Bader's remaining estoppel claim against the prosecution fails at step

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[19](...continued)
conviction under *federal* law); *United States v. Etheridge*, 932 F.2d 318, 321 (4th Cir. 1991) (noting that no defense of entrapment by estoppel could be established where "the government that advises and the government that prosecutes are not the same") (quoting *United States v. Bruscantini*, 761 F.2d 640, 641–42 (11th Cir. 1985)) (internal quotation marks omitted)); *see also Bruscantini*, 761 F.2d at 641–42 (explaining that "the entrapment problem is different" where state officials provided the legal interpretation upon which the defendant relied, but his conviction was based upon federal law), *abrogated on other grounds by United States v. Fernandez*, 234 F.3d 1345, 1347 n.2 (11th Cir. 2000). As Mr. Bader asserts no such reliance upon a state court decision, these cases do not provide an answer for the question posed by Mr. Bader's argument.

one of the *Apperson* inquiry. *See Apperson*, 441 F.3d at 1204. Mr. Bader presents no evidence that any government official made any sort of "active[ly] misleading" statement with regard to the FDAMA; even if he had, his argument would be based upon a faulty premise. As the district court explained in its order denying Mr. Bader's motion to dismiss, the FDAMA is "material to this case only as a defense belonging to Mr. Bader." Aplee. App., Vol. IV, at 1060 (emphasis removed).

Under the FDAMA, 21 U.S.C. § 353a(a), a licensed pharmacist is *exempt* from federal liability where he compounds a drug product "for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation," provided that certain conditions are met, *id.* The FDAMA therefore presents an affirmative defense that Mr. Bader might have asserted, not a "charge" that the government impermissibly sought. Thus, if anything, the FDAMA could have worked to Mr. Bader's advantage—an advantage that was precluded by Mr. Bader's repeated averments that the FDAMA had no bearing upon his case. *See* Aplee. App., Vol. I, Tr. at 1–2. As Mr. Bader offers no evidence of "active misleading"—let alone evidence of such conduct that might have prejudiced him at trial—his entrapment-by-estoppel claim is without merit.

As for Mr. Bader's argument that "due process confusion precluded [his] conviction," Aplt. Opening Br. at 39, although it is not entirely clear, Mr. Bader appears to argue that the confusion rendered in the wake of *Western States* and

Medical Center Pharmacy failed to place him on notice that his "compounding" of HGH was subject to FDA oversight. In this regard, Mr. Bader asserts that "[t]he courts told him [that] his pharmacy was compounding legally," *id.* at 37, and, based upon his survey of the legal landscape, he "followed State law, the only law he knew to be applicable," *id.* at 39. This argument is misguided.

With regard to *Western States*, by its terms, the Court's decision merely invalidated the FDAMA's speech-related provisions as they related to advertising; it did not address the FDAMA's substantive exemptions and accompanying restrictions with respect to compounding. *See* 535 U.S. at 366, 377. Therefore, Mr. Bader could not have divined from the text of *Western States* that his compounding activities were free from substantive FDA regulation.[20]

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[20] To be sure, because of the unique procedural posture of *Western States*, the FDA suggested in certain policy guidance that the decision also effectively invalidated the FDAMA's substantive provisions. *See* Compliance Policy Guidance ("CPG") § 460.200. The FDA described the situation this way:

> The Supreme Court affirmed the 9th Circuit Court of Appeals decision that found section 503A of the [FDCA, added by the FDAMA] invalid in its entirety because it contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescriptions for and advertising specific compounded drugs). The Court did not rule on, and therefore left in place, the 9th Circuit's holding that the unconstitutional restrictions on commercial speech could not be severed from the rest of section 503A. Accordingly, all of section 503A is now invalid.

Id. However, the overarching premise of this policy guidance was that, generally, the FDA had maintained some degree of regulatory authority over pharmacy

(continued...)

[20](...continued)
compounding both before *Western States*—as ultimately defined and restricted by the FDAMA, *cf. Food and Drug*, *supra*, § 13.74, at 194 (noting that "no FDAMA-described safe harbor would have been necessary if the FDA indeed [previously] lacked the power to regulate compounded drugs")—and after *Western States*. However, following *Western States* the agency "recognize[d] the need for immediate guidance on what *types* of compounding might be subject to enforcement action under current law," and it indicated that its principal focus would be on the situation "when the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer." CPG § 460.200 (emphasis added). In that regard, among other things, the FDA would consider whether the pharmacy was involved in "[c]ompounding of drugs in anticipation of receiving prescriptions, *except in very limited quantities* in relation to the amounts of drugs compounded after receiving valid prescriptions." *Id.* (emphasis added). As the Third Circuit noted:

> [W]e agree that the FDA's reliance on the apparent volume of compounding is a reasonable means of determining whether that pharmacy is compounding in the regular course of its business of dispensing or selling drugs or devices at retail. Indeed, were we to adopt Wedgewood's view that the volume of compounding is irrelevant, much of the FDCA would become a nullity. If a pharmacy could compound an unlimited quantity of drugs, supposedly in anticipation of individual prescriptions, then it could essentially act as a commercial drug manufacturer and totally circumvent the approval requirements of the FDCA.

Wedgewood Vill. Pharmacy, Inc. v. United States, 421 F.3d 263, 274 (3d Cir. 2005) (internal quotation marks omitted); *accord Food and Drug*, *supra*, § 13:74, at 13-95 (3d ed. 2007). As we further explicate *infra*, Mr. Bader and College Pharmacy were involved in the large-scale preparation and marketing of dosages of HGH. Consequently, even taking into account the FDA's arguably broad reading of the substantive impact of *Western States*, Mr. Bader still would have had fair warning—as it related at least to his pharmacy business—of the possibility of FDA regulatory oversight.

Moreover, viewed from another perspective, Mr. Bader has repeatedly discounted the effect of this specific policy provision—CPG § 460.200—noting that it is "nonbinding" and "not law or proper for instruction." Aplt. Opening Br. (continued...)

The district court's decision in *Medical Center Pharmacy* is also unavailing. In *Medical Center Pharmacy*, the district court concluded that "any drugs *created* through the compounding process must be exempt from the new drug definitions" of the FDCA. 451 F. Supp. 2d at 864 (emphasis added). Mr. Bader's convictions on appeal, however, pertain to: (1) distribution of HGH for unauthorized use, in violation of 21 U.S.C. § 333(e); (2) knowingly importing HGH into the United States contrary to law, in violation of 18 U.S.C. § 545 and 21 U.S.C. § 355; and (3) conspiracy with intent to distribute and possess with intent to distribute testosterone cypionate, in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(D), and 21 U.S.C. § 846. Of these three groups of charges, only the second

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at 7 n.11; *see id.* at 38 (noting that "the [compliance policy guidance] CPG admittedly is not law and may not be instructed"). In this regard, he has cited *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 597, 602 (5th Cir. 1995) (holding that Compliance Guidance Manual provision relating to whether pharmacies were engaged in drug manufacturing did not establish "binding norms"). As a consequence, Mr. Bader is not well-situated now to contend that this policy guidance had placed a gloss on *Western States* that muddied the waters concerning the FDA's substantive regulatory authority over compounding. Furthermore, insofar as Mr. Bader's argument focuses on whether the FDAMA's specific substantive provisions related to compounding remained viable after *Western States*, Mr. Bader would be hard-pressed to claim prejudice resulting from any lack of notice concerning the state of the law because he has expressly declined to avail himself of a statutory FDAMA defense to justify his compounding activities. *See, e.g.*, Aplee. Supp. App., Vol. I, at 1–2. In light of his large-scale preparation and marketing of HGH doses this declination is not entirely surprising. *See* 21 U.S.C. § 353a(a)(2); Aplee Br. at 40 ("Defendant's waiver [of a FDAMA compounding defense] is consistent with the knowledge that, even if the FDAMA was viable, the evidence did not support its applicability to the instant case.").

implicates new drug approval under the FDA and, as discussed above, those charges concern only the *imported* Genescience HGH as it existed *before* it was compounded by College Pharmacy. Consequently, *Medical Center Pharmacy* is inapposite.

Moreover, as the district court correctly concluded, Mr. Bader misreads *Medical Center Pharmacy*'s actual holding. In *Medical Center Pharmacy*, the court found that subsections (a) and (c) of the FDAMA, 21 U.S.C. § 353a, were severable from the remainder of § 353a; consequently, pharmacies were still obligated to comply with subsection (b)'s requirements for "compounded drugs." 451 F. Supp. 2d at 863. In other words, the court's decision can be read as concluding that "only drugs compounded in compliance with the restrictions set forth in [the] FDAMA fall outside [of] FDA regulation and the NDA process." Aplt. App., Vol. II, at 559 (emphasis removed).

Furthermore, this "exemption for compounded drugs from the new drug definition [was] limited to compounds which are made in *reasonable quantities* upon receipt of a *valid prescription for an individual patient* from a *licensed practitioner*." 451 F. Supp. 2d. at 863 (emphases added). Indeed, the *Medical Center Pharmacy* court clarified that "[d]rugs that are compounded in large quantities before a prescription is received from a doctor do not fall within [this] narrow exemption." *Id.* It is clear from the record that Mr. Bader's large-scale HGH compilation method fell outside the protective scope of this exemption.

Specifically, Ms. Griffin's testimony regarding College Pharmacy's "Somatropin prepackaged protocol" indicated that College Pharmacy repackaged massive amounts of HGH as Somatropin long before it received individual prescriptions, and College Pharmacy's numerous advertisements extolling the anti-aging and body-building benefits of HGH—in conjunction with its promotion of the drug at trade shows for those purposes—clearly suggested that College Pharmacy prepared and actively marketed dosages of HGH on a massive scale. Thus, in sum, *Medical Center Pharmacy* is inapposite for at least two salient reasons: (1) it did not completely eviscerate the compounded drug NDA requirements as Mr. Bader suggests; and (2) its "limited exception" is not one under which Mr. Bader's charged conduct would fall. Accordingly, Mr. Bader's reliance upon *Medical Center Pharmacy* is misplaced, and the case cannot support his illusory due-process claim.

2. Sixth Amendment Claims

Mr. Bader also argues that his Sixth Amendment rights were violated: (1) when the district court purportedly limited his ability to adequately cross-examine the government's "star witness," FDA Agent Catherine Hermsen, in violation of the Confrontation Clause; and (2) by "the [g]overnment's efforts to keep out [evidence of] pharmacy practices," which prompted a ruling by the court that allegedly hindered his ability to raise a plausible *mens-rea* defense at trial. Aplt. Opening Br. at 43.

Because Mr. Bader neglected to raise a Confrontation Clause objection at trial, we review his first claim for plain error. *See United States v. Pablo*, 625 F.3d 1285, 1291 (10th Cir. 2010). In so doing, the record reveals the absurdity of his argument: the district court permitted Mr. Bader to extensively cross-examine Agent Hermsen; the cross-examination fills approximately 138 pages of transcript. Consequently, Mr. Bader Confrontation Clause argument is wholly without merit and cannot satisfy even the first prong of the plain-error standard.

Mr. Bader's second argument is equally unavailing. Apparently, Mr. Bader challenges the district court's setting of "parameters as to what questions can be asked of witnesses," seemingly in reference to a warning that the court issued to Mr. Bader's attorney: "if witnesses are repeatedly asked questions about the state of the law[,] [the court] w[ill] be compelled to admonish him before the jury." Aplt. App., Vol. VII, Tr. at 2339; *see* Aplt. Opening Br. at 43. Mr. Bader avers that this "ruling" deprived him of the ability to introduce pertinent information regarding Colorado state pharmacy regulations, consequently hindering his ability to "disprove *mens rea*," Aplt. Opening Br. at 43, pursuant to *Cheek v. United States*, 498 U.S. 192, 202 (1991). This argument is unpersuasive.

In *Cheek*, the Supreme Court noted that "forbidding the jury to consider evidence that might negate willfulness would raise a serious question under the Sixth Amendment's jury trial provision." *Id.* at 203. *Cheek*, however, was premised upon the district court's error in instructing the jury that it was

obligated to *completely disregard evidence* that the defendant had a good faith misunderstanding of the applicable tax laws. *Id.* Here, in contrast, the district court merely (and permissibly) limited the *scope of defense counsel's questioning* on account of counsel's repeated attempts to surreptitiously introduce a legal definition of "compounding" that would favor Mr. Bader. *See* Aplt. Trial Tr. App., Vol. IV, at 962 ("I'm . . . going to instruct the jury that this witness'[s] understanding of what compounding is[,] is not a legal definition of compounding and therefore they should not understand it as such."). This in no way ran afoul of the Sixth Amendment, nor did it prevent Mr. Bader from otherwise attempting to introduce a defense as to his understanding of the law at the time of the allegedly illegal conduct. Accordingly, we conclude that *Cheek* is inapposite, and that Mr. Bader's unsupported second claim is entirely without merit.

E. ***Alleged Evidentiary Errors***

Alternatively, Mr. Bader alleges that he should at least be afforded a new trial on account of various evidentiary objections that the government made and that the district court ruled upon. First, Mr. Bader asserts that the government impermissibly and excessively objected to much of the evidence that the defense offered, particularly that relating to the FDA's approval of the HGH shipments as an API, College Pharmacy employees' understanding of the meaning of "compounding," FDA import alerts distinguishing between API and finished HGH, and test results regarding the HGH that was seized from College Pharmacy.

Mr. Bader apparently claims that the government's frequent objections somehow amounted to prosecutorial misconduct. Because he failed to challenge these objections at trial, we review for plain error. *Sands*, 968 F.2d at 1063.

It is clear that there was nothing "improper" about the government's objections, nor has Mr. Bader fashioned any argument as to how we might construe them as such. *See Oberle*, 136 F.3d at 1421. Each of the objections that Mr. Bader contests was grounded in the Federal Rules of Evidence, and each was entirely consistent with the government's overarching theory of the case—*viz.*, that the imported HGH was a "finished drug," not an API. In raising these objections, the government merely upheld its obligation to zealously advocate for its position, and the district court certainly did not clearly or obviously err by permitting the objections.[21] Accordingly, we need not further consider Mr. Bader's unsubstantiated allegations regarding this matter.

Second, Mr. Bader argues that the district court erred in sustaining the

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[21] Mr. Bader concludes his evidentiary allegations against the prosecution with the assertion that the government went "so far as to intimidate witnesses not to say [that] College compounded the [HGH]." Aplt. Opening Br. at 44. Stacy Griffin, a College Pharmacy employee, did testify on cross that she "remember[ed] [the government] getting upset with [her]" when she referred to the College Pharmacy process as "compounding" HGH. Aplt. App., Vol. VII, Tr. at 2375. Her statement, however, falls far short of evidence that the government "intimidated" a witness. *Cf. United States v. Morrison*, 535 F.2d 223, 227 (3d Cir. 1976) (noting that "[t]he actions of the prosecutor in his repeated warnings [that the potential witness could be prosecuted for drug and perjury charges] which culminated in a highly intimidating personal interview were completely unnecessary" and required reversal of defendant's conviction). Accordingly, we do not credit Mr. Bader's witness-intimidation argument.

government's objections and in "refus[ing] to allow the defendant the same latitude" as the government with regard to the introduction of evidence. Aplt. Opening Br. at 44. However, Mr. Bader offers absolutely no explanation as to how the district court abused its discretion in ruling on the government's objections, nor does he establish that each of the allegedly impermissible government objections was actually sustained in the first place. *See* Aplt. Opening Br. at 42–43. Consequently, he has left us with no basis upon which we might discern error with the district court's evidentiary rulings.

Furthermore, Mr. Bader provides no meaningful support for his conclusory assertion that the court "allow[ed] the [g]overnment to offer evidence on critical issues" while depriving him of an opportunity to do the same. *Id.* at 44. Specifically, Mr. Bader contends that the court allowed the government to "impermissibl[y] use . . . its rejected compounding definition," while rejecting Mr. Bader's own compounding definition. *Id.* However, Mr. Bader points to nothing in the record evincing the government's impermissible use of a compounding definition that the court rejected. Moreover, even assuming *arguendo* that there was some foundation in the record for his assertion, Mr. Bader fails to explain how the court's alleged "rejection" of his own compounding definition was erroneous.

Mr. Bader also appears to argue that the court abused its discretion in refusing to admit the government's pretrial concession that "their case was

gutted" with regard to Mr. Bader's HGH claims if the court were to adopt the compounding definition that he proffered.[22] Aplt. App., Vol. VIII, Tr. at 2570. The government, in opposing Mr. Bader's request, argued that its prior "admission" should be excluded under Federal Rule of Evidence 403, particularly

[22] Prior to trial, the government filed a motion asking the district court to reconsider its decision to issue a jury instruction on the Colorado definition of "compounding" and, in the alternative, to dismiss counts one through fifteen, seventeen, and twenty through forty-three of the Second Superseding Indictment—i.e., those counts related to conspiracy to facilitate the sale of illegally imported HGH, distribution of HGH, facilitating the sale of illegally imported HGH, possession with intent to distribute HGH, and distribution of HGH to minors. In that motion, the government conceded that "the [c]ourt's proposed definition of compounding *substantially undermine*[*d*] the [g]overnment's theory of criminal liability in the [HGH] related counts," and therefore asked that, in the interest of judicial economy, *the HGH counts be dismissed* in the event that the court still planned to instruct the jury as to the definition of compounding under Colorado law. Aplt. App., Vol. II, at 495 (Gov't's Mot. to Reconsider & in the Alternative Mot. to Dismiss, dated Apr. 14, 2009) (emphasis added). In disposing of that motion, the court confirmed that it would instruct the jury according to Colorado law, but amended that instruction slightly such that the jury would "be instructed in two phases: (i) that 'compounding' is defined according to the terms of Colorado law as set forth in [Colo. Rev. Stat.] § 12–22–102(6); and (ii) that a drug that is otherwise 'compounded' according to that definition may still be subject to NDA requirements and other regulatory burdens if it runs afoul of the terms of the [FDA's 2002] CPG/FDAMA." *Id.* at 566. Observing that the government's position might be "different" on the basis of the court's conclusion that "both the state definition of 'compounding' and the provisions of the CPG/FDAMA can apply simultaneously," the court declined to assume that "its (re-)adoption of the Colorado definition of 'compounding' compel[led] dismissal of any Counts" at that time. *Id.* at 567. Of course, these determinations were *voided* by the court's subsequent conclusion that the definition of "compounding"—under Colorado law—had no bearing upon Mr. Bader's case. *See* Aplee. App., Vol. IV, at 1256 ("With the benefit of hindsight and a full trial record, the Court now recognizes that nearly all of the briefing, discussion and analysis of 'compounding' was an unnecessary digression.").

since the alleged admission arose out of the government's pretrial motion to dismiss—a motion that it had no occasion to pursue because the district court favorably shifted its position on the need to instruct the jury concerning Colorado's compounding laws. *Id.* at 2571. Mr. Bader presents no argument as to how the district court's decision to deny Mr. Bader's request to admit the government's statement constitutes an abuse of discretion; indeed, it was entirely possible—and, in fact, probable—that the admission of the statement would have confused the jury and proved to be unfairly prejudicial to the government. Accordingly, because Mr. Bader has provided no persuasive argument pertaining to any of the alleged evidentiary errors, he has presented no basis upon which we might grant him a new trial.

F. *Forfeiture*

Finally, Mr. Bader challenges the district court's $4.8 million forfeiture order, renewing his argument that the calculated amount was improperly based upon "aggregated [HGH] sales" rather than properly "limit[ed] . . . to proceeds 'constitut[ing]' or 'derived' from a crime." Aplt. Opening Br. at 67 (third alteration in original). Additionally, Mr. Bader argues that the court erroneously failed to reduce the forfeiture amount to account for (1) the HGH seized and retained by the government, and (2) the HGH attributable to the counts for which

Mr. Bader was acquitted.[23]

"Forfeiture is an element of the sentence imposed following conviction . . . ." *Libretti v. United States*, 516 U.S. 29, 38–39 (1995) (emphasis removed); *see United States v. Wittig*, 575 F.3d 1085, 1096 (10th Cir. 2009) ("Double jeopardy does not apply to the forfeiture findings because forfeiture is a component of a sentence rather than an offense for which the defendants were tried." (internal quotation marks omitted)). Consequently, we review the district court's forfeiture order as we would any other sentencing determination—that is, we review its legal conclusions de novo and its factual findings for clear error. *See, e.g.*, *United States v. Olguin*, 643 F.3d 384, 395 (5th Cir. 2011) (observing that, in reviewing a district court's forfeiture order, the "court reviews the district court's findings of fact under the clearly erroneous standard of review, and the question of whether those facts constitute legally proper forfeiture de novo."); *United States v. Browne*, 505 F.3d 1229, 1278 (11th Cir. 2007) ("We review *de novo* the district court's legal conclusions regarding forfeiture and the court's findings of fact for clear error." (quoting *United States v. Puche*, 350 F.3d 1137, 1153 (11th Cir. 2003)) (internal quotation marks omitted)); *cf. United States v. McGinty*, 610 F.3d 1242, 1245 (10th Cir. 2010) (concluding that we apply de

[23] In the proceedings before the district court, Mr. Bader challenged both the jury's $4.8 million forfeiture verdict and the real property forfeiture of the College Pharmacy building, which was used to facilitate the underlying crimes. However, Mr. Bader's appellate arguments pertain exclusively to the $4.8 million monetary forfeiture.

novo review to our *legal* interpretation of federal forfeiture *statutes*). A forfeiture judgment must be supported by a preponderance of the evidence. *See United States v. Dicter*, 198 F.3d 1284, 1289 (11th Cir. 1999) ("[T]he preponderance standard is most consistent with the notion that section 853(a)(2) forfeiture is a matter of sentencing."); Stefan D. Cassella, *Asset Forfeiture Law in the United States* § 15-3(d), at 480 (2007) [hereinafter *Asset Forfeiture Law*] ("Because forfeiture is part of sentencing, the Government's burden is to establish the nexus between the property and the offense by a preponderance of the evidence, not beyond a reasonable doubt.").

Mr. Bader seemingly seeks to reassert here the argument that he set forth in his post-trial motion to set aside the jury's forfeiture verdict—*viz.*, that "the calculation of proceeds based on gross HGH sales, instead of net sales, was improper." Aplee. App., Vol. IV, at 1273; *see id.* at 1189–1212 (Def.'s Mot. to Set Aside Special Forfeiture Verdict Under Rule 29(C) and Opp'n to Gov't's Mot. for Forfeiture, filed Mar. 5, 2010). In his motion before the district court, Mr. Bader relied primarily upon the Supreme Court's ruling in *United States v. Santos*, 553 U.S. 507 (2008), where he argued that only the "profits" that he derived from the allegedly illegal conduct, as opposed to the "gross receipts," could be included for purposes of the forfeiture calculation, *see* Aplee. App., Vol. IV, at 1201–02 (internal quotation marks omitted). In his opening brief, however, Mr. Bader devotes only a single sentence to this argument, baldly asserting—with

no explanation—that the forfeiture verdict was based upon improperly "aggregated [HGH] sales" rather than being restricted to "proceeds 'constitut[ing] or 'derived' from a crime." Aplt. Opening Br. at 67 (second alteration in original). That is not enough. Mr. Bader has waived this argument on appeal. *See, e.g.*, *Kabba v. Mukasey*, 530 F.3d 1239, 1248 (10th Cir. 2008) ("[B]ecause the issue was insufficiently raised in [the party's] opening brief, we agree that it has been waived."); *Becker v. Kroll*, 494 F.3d 904, 913 n.6 (10th Cir. 2007) ("An issue or argument insufficiently raised in the opening brief is deemed waived."); *Gaither v. Aetna Life Ins. Co.*, 394 F.3d 792, 810 (10th Cir. 2004) (Murphy, J., dissenting) ("It is well-settled in this Circuit that an issue listed, but not argued in the opening brief is waived.").

In any event, unlike the present case, *Santos* involved whether the term "proceeds" meant "profits"—as opposed to gross receipts—under the federal money-laundering statute. *See* 553 U.S. at 513–14; *see also* 18 U.S.C. § 1956(a)(1)(A)(i). As we recently observed, "*Santos* . . . caused considerable disagreement and confusion among the circuit courts of appeal," *Thornburgh*, 645 F.3d at 1208, with the result that "the *Santos* decision has been interpreted by lower courts in many different ways," *Fishman*, 645 F.3d at 1193. We "therefore confined it to its factual setting, and conclude[d] that 'proceeds' means 'profits' for the purpose of the money laundering statute *only* where an illegal gambling operation is involved." *Fishman*, 645 F.3d at 1193–94. Mr. Bader's reliance on

Santos is therefore misplaced, as his convictions pertain neither to the federal money-laundering statute nor to an illegal gambling operation.

Mr. Bader's remaining two claims—that the court erred in failing to exclude the amount of HGH (1) that the government seized and kept, and (2) that was attributable to the counts upon which he was acquitted—are also waived on account of his utter failure to explain or in any way substantiate his allegations, including with citation to legal authority.[24] *See, e.g.*, *United States v. Pursley*, 577 F.3d 1204, 1231 n.17 (10th Cir. 2009) ("[A]lthough Mr. Pursley alluded to the ex parte issue in his appellate brief, that skeletal reference does not present a cognizable issue for appellate review."); *Bronson v. Swensen*, 500 F.3d 1099, 1104 (10th Cir. 2007). The latter argument about acquitted counts, however, prompts us to consider a separate issue: Because we reverse Mr. Bader's convictions for knowingly facilitating the sale of illegally imported HGH and conspiring to commit that offense (i.e., Counts Seventeen and One, respectively), we must consider the impact of that action on the district court's forfeiture order.

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[24] Furthermore, the government contends that the second claim concerning the counts of acquittal was not raised before the district court. *See* Aplee. Br. at 53. Mr. Bader does not deny this contention in his reply brief, and our independent review of his district court filing supports the government's contention. Therefore, even if his second claim were not waived, Mr. Bader "could not prevail unless he could successfully run the gauntlet created by our rigorous plain-error standard of review." *McGehee*, 672 F.3d at 866. Mr. Bader does not even begin to shoulder his burden of establishing that the district court erred—much less clearly or obviously so—with respect to its treatment of his counts of acquittal.

There must be a nexus between the property forfeited and *an offense of conviction* that authorizes forfeiture. *See United States v. Bornfield*, 145 F.3d 1123, 1137 n.8 (10th Cir. 1998) (dismissing the government's suggestion that both bank accounts at issue were tied to the structuring count because if that were true, "the government would have no basis for forfeiture of either account as [defendant] was not convicted of the structuring charge"); *see also United States v. Capoccia*, 503 F.3d 103, 116 (2d Cir. 2007) ("The violation on which the forfeiture is based must be the specific violations of which Capoccia was convicted . . . ."); *United States v. Hasson*, 333 F.3d 1264, 1279 n.19 (11th Cir. 2003) ("We do not mean to imply that a court could impose a forfeiture order based on a money laundering offense with which the defendant was not charged or for which he was acquitted.").

However, because we reverse Mr. Bader's convictions of conspiring to knowingly facilitate the sale of illegally imported HGH and knowingly facilitating the sale of illegally imported HGH, the forfeiture judgment against Mr. Bader cannot rest on his violation of 18 U.S.C. § 545. *See Asset Forfeiture Law*, *supra*, § 15-3(a), at 476 ("[I]f the conviction that supported a forfeiture is reversed on appeal, the forfeiture—along with all other aspects of the defendant's sentence for that offense—must be reversed as well."). Ordinarily, such violations would trigger forfeiture under 18 U.S.C. § 981(a)(1)(C) (noting that "property is subject to forfeiture to the United States" where it "constitutes or is

derived from proceeds traceable to a violation of section . . . 545 . . . , or a conspiracy to commit such offense"). Yet, significantly, the district court's analysis focused primarily on this § 545-related path of forfeiture, in particular in rejecting Mr. Bader's contention that "the $4.8 million forfeiture verdict is inconsistent with evidence that reveals a smaller amount is attributable to illegal HGH sales." Aplee. App., Vol. IV, at 1275.

As the court's analysis revealed, there was ample evidence of unlawful HGH sales to support the $4.8 million figure by a preponderance of the evidence. Among other things, the government presented College Pharmacy's own sales records detailing a total of approximately $4.7 million in sales of imported HGH. This sales log was corroborated by Catherine Hermsen, a Special Agent ("SA") with the FDA Office of Criminal Investigations, who testified that the log detailed College Pharmacy's Somatropin sales from September 13, 2004 to March 30, 2007. SA Hermsen also explained that she verified this figure through information retrieved from College Pharmacy's computer server, as well as through her own review of checks that the FDA had subpoenaed. These records revealed that College Pharmacy also had issued additional payments to Bradley Blum, which resulted in a total of $4.8 million estimated proceeds attributable to Mr. Bader's HGH-related crimes. *See id.*, Vol. II, Tr. at 441 ("We came up with $4.8 million."). Additionally, as the district court observed in its disposition of Mr. Bader's motion to set aside the forfeiture order, SA Hermsen explicitly noted

that this "$4.8 million figure *excluded* College Pharmacy's lawful sales of commercially-produced, NDA[-]approved HGH, such as Saizen and Norditropin." *Id.*, Vol. IV, at 1275 (emphasis altered); *see id.*, Vol. II, at 440 (SA Hermsen testifying about a separate log that exclusively recorded the sales of the illegally imported HGH).

To be sure, the district court correctly suggested that the Second Superseding Indictment charged Mr. Bader with violating other statutes that, in appropriate circumstances, may support a forfeiture judgment.[25] *See id.*, Vol. IV, at 1273 (noting that "[e]ach of the counts of conviction in this case give[s] rise to a claim for forfeiture, albeit through varying statutory routes"). Furthermore, the district court's instructions and verdict form—to which Mr. Bader did not lodge an objection—did not ask the jury to attach its forfeiture finding to any particular counts of the Second Superseding Indictment. Instead, these documents only obliged the jury to determine whether Mr. Bader had "obtained [as proceeds]

[25] For example, Mr. Bader's convictions under 21 U.S.C. § 333(e) for discrete distributions of HGH on particular dates (i.e., Counts Twelve through Fifteen, and Count Twenty) trigger forfeiture under 21 U.S.C. § 853. Under § 333(e)(3), "[a]ny conviction" under § 333 "shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture." The Controlled Substances Act, *see* 21 U.S.C. § 853, in turn mandates that a person who is convicted under the statute must forfeit "any property constituting, or derived from, any proceeds the person obtained, directly or indirectly, as the result of such violation." 21 U.S.C. § 853(a)(1). As a controlled substance felony offense, Mr. Bader's conviction for conspiracy to distribute and to possess with the intent to distribute testosterone cypionate (i.e., Count Nineteen) also triggers forfeiture under § 853(a)(1).

directly or indirectly *as a result of the crime(s) for which* [it] found [him] guilty" "the sum of $4.8 million." Aplt. App., Vol. IV, at 1196. (Jury Verdict Form, dated Feb. 2, 2010) (emphasis added); *accord id.*, Vol. VIII, at 2749–50 (Jury Instruction No. 41); *cf.* Aplee. App., Vol. IV, at 1040 (seeking "[a] sum of money equal to $4,800,000 in United States Currency, representing the amount of proceeds obtained as a result of the offenses in *Counts One through Seventeen, and Nineteen*"—*viz.*, proceeds obtained pursuant to the charges of knowing facilitation of the sale of illegally imported HGH, conspiracy to do so, mail fraud, distribution of HGH, and conspiracy to distribute and to possess with the intent to distribute testosterone cypionate (emphasis added)).

Yet, given the current posture of this case—involving our reversal of the § 545-related HGH counts—we are reluctant to speak definitively regarding the precise amount (if any) of proceeds that properly may be attributed to the other (i.e., non-§ 545) counts of the Second Superseding Indictment for purposes of adjudging the forfeiture amount.[26] *Cf. Asset Forfeiture Law, supra*, § 15-3(a), at 476–77 ("[A] defendant may be acquitted on one offense and yet be convicted on

[26] A panel of our Court previously has reached such a conclusion. *See United States v. Lovett*, Nos. 92-6401, 93-6070, 1993 WL 298897, at *5 (10th Cir. July 26, 1993) (holding that the district court "did not err in ordering . . . forfeiture" where we had reversed two of the defendants convictions and vacated four other counts, because we "did not reverse or vacate his convictions" on three other counts upon which the jury's forfeiture verdict may *also* have been premised).

another that gives rise to the forfeiture of the same property. In that case, the forfeiture would survive the acquittal (or the reversal of the conviction) on the first offense because it would have an independent basis."). First, our analysis might be rendered of little or no effect, if the government elects upon remand to retry Mr. Bader on Counts One and Seventeen (i.e., the § 545-related counts) and he is convicted again. Then, § 545 would again be a viable basis on which to rest a forfeiture award.

And, second, we do not have the benefit of the parties' briefing on the implications of our reversal of the § 545-related counts with regard to the precise amount of the forfeiture judgment that is legally authorized based on the remaining convictions. Of course, that is not surprising because it is only through this opinion that we effectuate our reversals. However, the reversals do raise serious questions. As noted, the district court relied in its forfeiture analysis on the testimony of SA Hermsen concerning the aggregate amount of the HGH sales during a time period beginning shortly after the start of the charged § 545-related conspiracy and concluding at the end of the conspiracy. Agent Hermsen testified that those sales totaled $4.8 million.

Let us assume, however, that Mr. Bader *only* may be held accountable in monetary forfeiture under the Second Superseding Indictment for *all* of the unlawful HGH sales identified by the government, because of his § 545-related conspiracy charge, which sweeps broadly enough to encompasses those sales.

See, e.g., *Capoccia*, 503 F.3d at 117–18 ("Where the conviction itself is for executing a scheme, *engaging in a conspiracy*, or conducting a racketeering enterprise, the government need only establish that the forfeited assets have the 'requisite nexus' to that scheme, conspiracy, or enterprise." (emphasis added) (citation omitted) (quoting Fed. R. Crim. P. 32.2(b)(1))); *Asset Forfeiture Law*, *supra*, § 15-3(a), at 477 ("[I]f the defendant is convicted of an *over-arching conspiracy* offense, he may be ordered to forfeit all property involved in the conspiracy, including property involved in substantive conduct that is not charged in the indictment or on which the defendant was acquitted." (emphasis added)). Put another way, let us assume that proceeds from *uncharged* discrete acts of facilitating the sale of illegally imported HGH may *not* be considered in determining the total monetary proceeds subject to forfeiture. *See Asset Forfeiture Law*, *supra*, § 15-3(b), at 478 ("Because forfeiture is part of the defendant's sentence for *committing a given offense*, the criminal forfeiture is limited to the property involved in *that* offense." (emphases added)). In this event, even assuming that some of the remaining counts of conviction (e.g., involving 21 U.S.C. § 333(e) or 21 U.S.C. § 846) would yield forfeitable proceeds, what would be the proper amount of those proceeds? The district court's analysis does not offer an answer, nor have the parties addressed the matter before us.

We are disinclined to answer such complex questions without input from

the parties or the district court. The district court is better equipped to entertain the parties' arguments; if necessary, consider additional evidence; and to resolve such questions in the first instance. In sum, given our reversal of Mr. Bader's § 545-related convictions, we think it the prudent course to allow the district court in the first instance to speak to the precise amount (if any) of the forfeiture judgment that is legally authorized in this case.

III. CONCLUSION

For the foregoing reasons, we **AFFIRM** Mr. Bader's convictions for discrete distributions of HGH (Counts Twelve through Fifteen, and Count Twenty), and conspiracy to distribute and to possess with intent to distribute testosterone cypionate, i.e., anabolic steroids (Count Nineteen); **REVERSE** his convictions for knowingly facilitating the sale of illegally imported HGH and for conspiring to do so (Counts Seventeen and One, respectively); and **REMAND** Mr. Bader's case to the district court with instructions to **VACATE** its judgment and sentence, and to conduct further proceedings consistent with this opinion.