

United States Court of Appeals
For the Eighth Circuit

No. 22-2864

United States of America

Plaintiff - Appellee

v.

Abdul Naushad, M.D.

Defendant - Appellant

No. 22-2865

United States of America

Plaintiff - Appellee

v.

Wajiha Naushad

Defendant - Appellant

Appeal from United States District Court
for the Eastern District of Missouri - St. Louis

Submitted: April 12, 2023

Filed: May 17, 2023

Before BENTON, GRASZ, and STRAS, Circuit Judges.

BENTON, Circuit Judge.

Dr. Abdul Naushad and Wajiha A. Naushad injected their patients with Orthovisc that was not approved by the Food and Drug Administration, while falsely representing it as FDA-approved. A jury convicted them of healthcare fraud and conspiracy to commit offenses against the United States. The Naushads appeal. Having jurisdiction under 28 U.S.C. § 1291, this court affirms.

I.

Dr. Abdul Naushad and Wajiha A. Naushad operate a collection of affiliated pain clinics. From 2010 to 2017, they injected non-FDA-approved Orthovisc into their patients while representing to Medicare and Medicaid that it was FDA-approved Orthovisc. The non-approved Orthovisc costs less than half of FDA-approved Orthovisc. The FDA and the Naushads' own employees cautioned them not to use the non-approved Orthovisc. Still, they continued to use it and submit reimbursement claims for it.

A jury convicted the Naushads of two counts: Count 1 (conspiracy to commit offenses against the United States in violation of 18 U.S.C. § 371), and Count 24 (health care fraud in violation of 18 U.S.C. §§ 1347(a)(1) and (2)). The Naushads appeal, alleging that the district court¹ erred by denying motions for judgment of acquittal on both counts and committing several reversible errors that warrant a new trial.

¹The Honorable E. Richard Webber, United States District Judge for the Eastern District of Missouri.

II.

The Naushads argue that the district court erred by denying their motions for judgment of acquittal on both the conspiracy and fraud convictions. “In reviewing a denial of a motion for a judgment of acquittal, we review the sufficiency of the evidence *de novo*, evaluating the evidence in the light most favorable to the verdict and drawing all reasonable inferences in its favor.” *United States v. Almeida-Olivas*, 865 F.3d 1060, 1062 (8th Cir. 2017).

The Naushads do not contest that the evidence establishes each statutory element for each offense. *See United States v. Golding*, 972 F.3d 1002, 1005-06 (8th Cir. 2020) (reciting the elements of conspiracy to commit an offense against the United States under 18 U.S.C. § 371 and the elements of health care fraud under 18 U.S.C. § 1347(a) the government must prove beyond a reasonable doubt). They do argue that the jury instructions and the indictment required the government to prove that non-approved Orthovisc is a “device” under the Federal Food, Drug, and Cosmetic Act. *See 21 U.S.C. § 321(h)* (2023).

The government counters that the classification of non-approved Orthovisc as a device was not an element of either statute under which the Naushads were charged. This court does not “assess sufficiency under the instructions given to the jury. The Supreme Court has recently held that ‘a sufficiency challenge should be assessed against the elements of the charged crime, not against the erroneously heightened jury instructions.’” *United States v. Ramos*, 814 F.3d 910, 916 (8th Cir. 2016), *quoting Musacchio v. United States*, 577 U.S. 237, 243 (2016). “A reviewing court’s limited determination on sufficiency review thus does not rest on how the jury was instructed.” *Musacchio*, 577 U.S. at 243.

The *Musacchio* case forecloses the Naushads’ argument that the jury instructions added another element that the government was required to prove beyond a reasonable doubt. *See id.* *See also United States v. Gross*, 23 F.4th 1048, 1053 (8th Cir. 2022) (“[W]here jury instructions ask the jury to find something not

required by the statutory elements of an offense, we review the sufficiency of the evidence based only on the statutory elements of the charged crime.”), *citing Musacchio*, 577 U.S. at 243. “A defendant has no due process right . . . to proof beyond a reasonable doubt of elements *not* necessary to constitute the crime charged, including elements erroneously or unnecessarily charged to the jury.” *United States v. Inman*, 558 F.3d 742, 748 (8th Cir. 2009). “If, for example, a jury is charged that it must find three statutory elements and a fourth element not required by applicable law, that the evidence is insufficient to prove the fourth non-statutory element does not mean that a conviction that is properly supported under the applicable law deprives the defendant of his right to due process.” *Id.*

Musacchio left open the question “whether sufficiency of the evidence at trial must be judged by reference to the elements charged in the indictment, even if the indictment charges one or more elements not required by statute.” *Musacchio*, 577 U.S. at 244 n.2. And even though *Gross* and *Inman* focused on non-statutory elements in the jury instructions, the Naushads may not be able to rely on non-statutory elements in an indictment. *Cf. Gross*, 23 F.4th at 1053 (reviewing “the sufficiency of the evidence based *only on the statutory elements* of the charged crime” (emphasis added)); *Inman*, 558 F.3d at 748 (“A defendant has no due process right . . . to proof beyond a reasonable doubt of elements *not* necessary to constitute the crime charged”); *United States v. Dennis*, 19 F.4th 656, 671 (4th Cir. 2021) (assessing sufficiency of the evidence against the elements of the underlying statute, not the conjunctive indictment); *United States v. Iverson*, 818 F.3d 1015, 1026 (10th Cir. 2016) (same). The Naushads offer no authority that the indictment may require the government to prove elements of an offense beyond those required by the statute. It is doubtful that sufficiency review exceeds the statutory elements of the offenses.

Regardless, even if the non-statutory “device” element were an essential element to each offense, the government presented sufficient evidence, viewed in the light most favorable to the verdict, that non-approved Orthovisc is a device under the FDCA. Two witnesses—Dr. Laurence Coyne, an FDA expert, and Mira Leiwant, vice president of the non-approved Orthovisc manufacturer—testified that

non-approved Orthovisc is a device. This expert testimony was sufficient to show that non-approved Orthovisc meets the FDCA definition of device:

The term “device” . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man

21 U.S.C. § 321(h) (2023).

Dr. Coyne testified about a 2018 FDA Notice. *See* **Notice of Intent to Consider the Appropriate Classification of Hyaluronic Acid Intra-Articular Products**, 83 Fed. Reg. 64844 (Dec. 18, 2018). According to the Naushads, Dr. Coyne’s testimony establishes that non-approved Orthovisc is a “drug,” rather than a “device,” under the FDCA because it achieves its primary intended purpose through chemical action. But Dr. Coyne testified that the Notice created only

room for debate about the actual action by which hyaluronic acid injectables² achieve their effect. It did not state forthrightly that they act by chemical effect. If the agency had come to that conclusion, then these—then hyaluronic acid injectables would be—there would have been a proposed change to have these classified as drugs rather than devices.

²Orthovisc is a hyaluronic acid injectable.

What the [Notice] actually stated was that, for new indications for use or new formulations of hyaluronic acid injectables, that the applicant is recommended to submit a request for a designation or a pre-request for designation to the Office of Combination Products. So it's not a decision terming these products to be drugs.

The Notice did not definitively conclude that Orthovisc achieves its primary intended purpose of the treatment of pain through chemical action. The Notice, in fact, reflects uncertainty about how hyaluronic acid products like Orthovisc work:

Because the current published scientific literature *supports* that [hyaluronic acid] achieves its primary intended purpose of the treatment of pain in [osteoarthritis] of the knee through chemical action, and therefore, [hyaluronic acid] for this use *may not* meet the definition of a device, sponsors of [hyaluronic acid] products who intend to submit a [premarket approval application] or a supplement to a [premarket approval application] for a change in indications for use, formulation, or route of administration *are encouraged* to obtain an informal or formal classification and jurisdictional determination through a Pre-[Request for Designation] or Request for Designation, respectively, from FDA prior to submission.

Notice, 83 Fed. Reg. at 64845 (emphases added). The Notice thus shows that “scientific literature *supports*” the finding that hyaluronic acid “achieves its primary intended purpose . . . through *multiple mechanisms . . .*” *Id.* at 64844 (emphases added). Dr. Coyne’s uncontradicted testimony confirms this. The Naushads misread the Notice and misunderstand Dr. Coyne’s testimony.

The district court properly denied the motions for judgment of acquittal.

III.

The Naushads believe a new trial is needed as a result of four other errors by the district court that denied: FDCA-device evidence; their theory-of-defense jury instruction; their FDCA-device argument; and their advice-of-counsel instruction.

First, the Naushads generally requested to present expert testimony that non-approved Orthovisc achieves its primary intended purpose through chemical action. They, however, cannot cite any specific attempt to introduce such testimony. They say only: “The court emphasized this ruling throughout the trial.” But Federal Rule of Evidence 103(a) requires the district court to make a definitive ruling. *See United States v. Morales*, 684 F.3d 749, 755 (8th Cir. 2012) (“The district court in this case made no such definite ruling. . . . [Defendant’s] failure to seek a final ruling at trial waived the issue.”). The Naushads waived this issue.

Even if the Naushads had not waived this first issue by failing to secure a definitive ruling, the district court did not abuse its discretion. *See Davis v. White*, 858 F.3d 1155, 1159 (8th Cir. 2017) (“The admission or exclusion of evidence is reviewed for abuse of discretion; evidentiary rulings are reversed only for a clear and prejudicial abuse of discretion.”). The district court found, as discussed in Part II, that the Naushads had misunderstood the Notice to definitively conclude that Orthovisc achieves its primary intended purpose through chemical action. The district court concluded that these arguments about the Notice could mislead the jury. *See id.* (“Federal Rule of Evidence 403 allows a district court to exclude evidence ‘if its probative value is substantially outweighed by a danger of . . . confusing the issues, misleading the jury’”). The Naushads fail to identify any probative value in communicating to the jury their misunderstanding of the Notice. *See United States v. Wilcox*, 487 F.3d 1163, 1173 (8th Cir. 2007) (District courts “may prohibit arguments that misrepresent the evidence or the law . . . or otherwise tend to confuse the jury.”).

Second, the Naushads allege that the district court improperly struck one sentence from their theory-of-defense instruction: “The Orthovisc delivered to [the pain clinics] was not a ‘device.’” The district court rejected this sentence fearing it would mislead the jury to believe it included FDA-approved Orthovisc, rather than only the non-approved Orthovisc. This court reverses only “if the failure to properly instruct the jury was prejudicial.” *United States v. Leon*, 924 F.3d 1021, 1026 (8th Cir. 2019). See *United States v. Cornelison*, 717 F.3d 623, 629 (8th Cir. 2013) (An instruction “is not necessary if it is merely duplicative of the district court’s other instructions.”). If, as the Naushads argue in Part II, the jury instructions and indictment required the government to prove that the non-approved Orthovisc is a device, then this sentence from the theory-of-defense instruction duplicates other instructions submitted to the jury. The Naushads cannot identify any prejudice in excluding this misleading, duplicative sentence.

Third, the Naushads argue that district court precluded them from arguing that non-approved Orthovisc is not a device under the FDCA. To the contrary, the district court allowed them to argue and present evidence about it (including the Notice). The district court expressly allowed the Naushads to argue to the jury that Dr. Coyne testified that hyaluronic acid operates through chemical action. Counsel for the Naushads said, “We have no issue, Your Honor. As long as we can make that argument, then we’re fine.”

The district court did not abuse its discretion by prohibiting further argument that misrepresents the Notice. The Naushads repeatedly claim the district court erred by preventing them from arguing that the Notice definitively concluded that Orthovisc is a “drug” under the FDCA. But that is not what the Notice said, and the district court found that Orthovisc remained a “device” under the FDCA. The district court properly “prohibit[ed] arguments that misrepresent the evidence or the law” *Wilcox*, 487 F.3d at 1173.

Fourth, the Naushads allege that the district court abused its discretion by rejecting their advice-of-counsel instruction. “[T]o rely upon the advice of counsel

in his defense, a defendant must show that he: (i) fully disclosed all material facts to his attorney before seeking advice; and (ii) actually relied on his counsel's advice in the good faith belief that his conduct was legal." *United States v. Wolfe*, 781 Fed. Appx. 566, 568 (8th Cir. 2019) (alteration in original), *quoting United States v. Rice*, 449 F.3d 887, 897 (8th Cir. 2006). "[A] defendant is not immunized from criminal prosecution merely because he consulted an attorney in connection with a particular transaction." *United States v. Petters*, 663 F.3d 375, 384 (8th Cir. 2011) (alteration in original), *quoting Rice*, 449 F.3d at 896-97. "A district court need not give any defense instruction where the facts do not support the defense." *Rice*, 449 F.3d at 897.

As the district court found, the Naushads did not fully disclose all material facts to their attorney. According to testimony of that attorney, the Naushads did not disclose:

- their compliance officer told them to stop using the non-approved Orthovisc;
- the FDA had previously seized a shipment of foreign hyaluronic acid injections destined for their pain clinic because they were unapproved;
- the FDA sent them a "seizure" letter explaining the seizure;
- their chief of purchasing told them not to use non-approved injections; and
- the non-approved Orthovisc included on its labeling indications for use that were not approved by the FDA.

The Naushads rely on *United States v. DeFries*, 129 F.3d 1293 (D.C. Cir. 1997), but it is not persuasive. The district court there "obviously believed that there was at least the requisite 'foundation' for appellant's advice-of-counsel defense but was under the incorrect understanding that appellants instead were obliged to satisfy a preponderance of the evidence standard in order to be entitled to the instruction." *Id.* at 1308. In contrast, the district court here denied the instruction *because* the Naushads lacked the requisite foundation. By failing to disclose all material facts to their attorney, the Naushads "failed to establish a factual basis necessary to support

such an instruction” *Rice*, 449 F.3d at 897. The district court properly denied the advice-of-counsel instruction.

None of these claims warrant reversal or a new trial.

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The judgment is affirmed.
