

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

MAR 04 2013

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES OF AMERICA,

Plaintiff - Appellee,

v.

W. SCOTT HARKONEN, M.D.,

Defendant - Appellant.

No. 11-10209

D.C. No. 3:08-cr-00164-MHP-1

MEMORANDUM*

UNITED STATES OF AMERICA,

Plaintiff - Appellant,

v.

W. SCOTT HARKONEN, M.D.,

Defendant - Appellee.

No. 11-10242

D.C. No. 3:08-cr-00164-MHP-1

Appeal from the United States District Court
for the Northern District of California
Marilyn H. Patel, Senior District Judge, Presiding

Argued and Submitted December 6, 2012
San Francisco, California

* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

Before: D.W. NELSON, TASHIMA, and MURGUIA, Circuit Judges.

A jury convicted Defendant W. Scott Harkonen of wire fraud for issuing a fraudulent press release. The district court sentenced Harkonen to three years probation and a \$20,000 fine. Harkonen appeals his conviction, and the government cross-appeals Harkonen's sentence. We have jurisdiction pursuant to 28 U.S.C. § 1291 and affirm Harkonen's conviction and sentence.

First Amendment Challenge

We review First Amendment challenges to criminal convictions in two steps: (1) deferring to the jury's findings on historical facts, credibility determinations, and the elements of statutory liability, we ask whether sufficient evidence supports the verdict;¹ and (2) if it does, we determine whether the facts, as found by the jury, establish the core constitutional facts. *See United States v. Keyser*, 704 F.3d 631, 638 n.1 (9th Cir. 2012) (citing *Planned Parenthood of the Columbia/Willamette, Inc. v. Am. Coal. of Life Activists*, 290 F.3d 1058, 1070 (9th Cir. 2002) (en banc)).

Constitutional facts determine “the core issue of whether the challenged speech is protected by the First Amendment.” *United States v. Hanna*, 293 F.3d

¹ Accordingly, our First Amendment analysis also addresses Harkonen's distinct argument on appeal that his wire fraud conviction was not supported by sufficient evidence.

1080, 1088 (9th Cir. 2002). The First Amendment does not protect fraudulent speech, *United States v. Alvarez*, 132 S. Ct. 2537, 2544 (2012), so the core constitutional issue in Harkonen’s case is whether the facts the jury found establish that the Press Release was fraudulent.

Step One: Whether Sufficient Evidence Supports the Verdict

Wire fraud comprises three elements: (1) knowing participation in a scheme to defraud; (2) use of the wires in furtherance of the scheme; and (3) a specific intent to deceive or defraud. *United States v. Green*, 592 F.3d 1057, 1064 (9th Cir. 2010). The second element is uncontested on appeal and is irrelevant for First Amendment purposes.

Knowing Participation in a Scheme to Defraud

At trial, nearly everybody actually involved in the GIPF-001 clinical trial testified that the Press Release misrepresented GIPF-001’s results. Testimony indicated that even Harkonen himself was “very apologetic” about the Press Release’s misleading nature. Evidently, the jury credited all this testimony, and it supports the finding that the Press Release was fraudulent even if not “literally false.” *See United States v. Woods*, 335 F.3d 993, 998 (9th Cir. 2003).

In addition to his being “very apologetic” about the Press Release, further evidence supports the finding that Harkonen knew the Press Release was

misleading. Harkonen prevented Intermune’s clinical personnel from viewing the Press Release prior to its publication, even when they asked to see it, at one point becoming “visibly” upset and “castigat[ing]” the head of the communications firm that helped prepare the Press Release for permitting Intermune’s Vice President of Regulatory Affairs to view a draft of the Press Release. Harkonen also did not want the FDA to know about all his post-hoc analyses—the analyses on which the Press Release was based—because he “didn’t want to make it look like we were doing repeated analyses looking for a better result.”

Lastly, there is sufficient evidence that the Press Release was at least “capable” of influencing the decision of doctors to prescribe, or patients to seek, prescriptions of Actimmune, *United States v. Jenkins*, 633 F.3d 788, 802 n.3 (9th Cir. 2011), because the Press Release was purportedly a very effective marketing tool.

Specific Intent to Defraud

Our conclusion that the jury was justified in finding that the Press Release was misleading also strongly supports the finding that Harkonen had the specific intent to defraud. *See United States v. Sullivan*, 522 F.3d 967, 974 (9th Cir. 2008). Further circumstantial evidence, *id.*, supports the conclusion that Harkonen’s GIPF-001 analyses were conducted with fraudulent intent: Harkonen stated he

would “cut that data and slice it until [he] got the kind of results [he was] looking for,” and requested the final post-hoc analysis “simply . . . to see what that did to the p-value.” Given his clear financial incentive to find a positive result in the face of GIPF-001’s failure to meet its pre-determined goals, we conclude the evidence sufficiently supports the jury’s determination that Harkonen had the specific intent to defraud.

Step 2: Whether the Facts as Found by the Jury Establish the Core Constitutional Facts

Because they are supported by sufficient evidence, we defer to the jury’s findings that the Press Release was misleading, that Harkonen knew it was misleading, and that Harkonen had the specific intent to defraud. *Cf. Keyser*, 704 F.3d at 639 (“[W]e do not defer to the jury’s finding of intent, because, in this case, intent is not an element of statutory liability.”). Thus, upon independent review of the record,² we affirm Harkonen’s conviction. *See United States v. Stewart*, 420 F.3d 1007, 1019 (9th Cir. 2005); *cf. United States v. Bagdasarian*, 652 F.3d 1113, 1123 (9th Cir. 2011) (speech was protected “because the prosecution failed to present sufficient evidence” to convict).

² Critically, Harkonen presented the evidence that most firmly supported his case for the first time at sentencing. Because we must defer to the jury’s credibility determinations, *Keyser*, 704 F.3d at 639, we will not reverse the jury’s verdict based on evidence it never considered.

***McAnnulty* Argument**

Harkonen, relying on *American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94 (1902), argues we should reverse his conviction because “genuine debates over whether a given treatment caused a particular effect are outside the scope of the mail and wire fraud statutes.” We are unpersuaded.

First, *McAnnulty* does not categorically prohibit fraud prosecutions for statements about the efficacy of a particular drug; indeed, “[t]hat false and fraudulent representations may be made with respect to the curative effect of substances is obvious.” *Seven Cases v. United States*, 239 U.S. 510, 517 (1916). Here, the government alleged the Press Release contained “false and misleading information” about Actimmune, and the government was permitted to go to trial on that theory.

Second, Harkonen’s *McAnnulty*-based argument that his statements were fraudulent only if they were universally considered objectively false is unavailing. As used in the criminal mail fraud statutes, the term “to defraud” has its commonplace definition and includes any sort of “dishonest method[] or scheme[],” and any “trick, deceit, chicane or overreaching.” *Carpenter v. United States*, 484 U.S. 19, 27 (1987); *see also Woods*, 335 F.3d at 998 (stating a scheme’s “fraudulent” nature is measured by a “non-technical” standard).

Statements are fraudulent if “misleading or deceptive” and need not be “literally false.” *Woods*, 335 F.3d at 998.

Third, Harkonen’s request that we reverse his conviction because he was engaging in a genuine scientific debate is hardly different than arguing that he is innocent; genuine debates of any sort are, by definition, not fraudulent. Here, a jury found, beyond a reasonable doubt, that Harkonen issued the Press Release with the specific intent to defraud, and that finding is supported by the evidence presented at trial. We know of no case where, based on *McAnnulty*, a court disregarded a jury’s factual findings to overturn a criminal conviction, and we will not do so here. *See Research Labs. v. United States*, 167 F.2d 410, 414–17 (9th Cir. 1948) (limiting *McAnnulty* and stating it does not prohibit a jury from weighing conflicting scientific testimony to determine whether statements about a drug’s efficacy were misleading).

Due Process

Harkonen’s due process argument is essentially a re-dressing of his First Amendment and *McAnnulty* arguments, so it too must fail. An ordinary person would have understood, *see Skilling v. United States*, 130 S. Ct. 2896, 2927–28 (2010), that if he made misleading statements in a press release with the specific intent to defraud he would be subject to the wire fraud statute.

Jury Instructions

The district court did not abuse its discretion in formulating its jury instructions. *United States v. Hofus*, 598 F.3d 1171, 1174 (9th Cir. 2010). When the district court provides adequate instructions on the specific intent element of wire fraud, no good faith instruction is required, *United States v. Frega*, 179 F.3d 793, 804 (9th Cir. 1999), and because “puffing” “fall[s] under the umbrella of . . . good faith,” *United States v. Gay*, 967 F.2d 322, 329 (9th Cir. 1992), a specific intent instruction adequately covered Harkonen’s puffing defense.

Brady Argument

Harkonen has failed to demonstrate a reasonable probability that the government’s withholding of evidence caused prejudice, which occurs if the evidence withheld “undermines confidence in the outcome of the trial.” *United States v. Kohring*, 637 F.3d 895, 901–02 (9th Cir. 2010) (internal quotation marks omitted). The documents at issue here might demonstrate that the Press Release did not mislead some doctors, but there was other evidence that the Press Release was widely and successfully used as a marketing tool, indicating it was “capable” of misleading some addressees and was, therefore, “material.”

***Matrixx* Motion**

The district court did not abuse its discretion in denying Harkonen’s “*Matrixx* motion” for a new trial, *see United States v. Del Toro-Barboza*, 673 F.3d 1136, 1153 (9th Cir. 2012), because *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), does not undermine the thrust of the government’s theory in Harkonen’s case. Harkonen’s scientific methods were not on trial; the issue was whether he misleadingly presented his analyses in the Press Release. The distinction between these two issues was made clear at trial when, for instance, Intermune’s former Senior Director of Biostatistics testified that post-hoc analyses are “good science” in the sense that they may generate hypotheses for future study, but that he “winced” when he saw the Press Release because “the conclusiveness of the results was overstated.”

Harkonen’s Sentence

The district court did not abuse its discretion in finding that the government failed to meet its burden on the U.S.S.G. § 2B1.1(b)(1) “intended loss” enhancement. *See United States v. Yopez*, 652 F.3d 1182, 1187 (9th Cir. 2011). The district court never explicitly ruled on the government’s § 2B1.1(b)(1) intended loss argument, but the record in its entirety indicates the district court was well aware of this argument. In that context, we read the district court’s statement

that, “when it comes to the loss . . . this case is really wanting in the kind of showing that would meet the preponderance standard,” as a rejection of both the government’s actual and intended loss arguments due to the government’s failure to articulate a loss theory that made sense.

Nor did the district court erroneously require the government to prove an “actual” pecuniary loss (the U.S.S.G. § 2B1.1 definition of “victim”) for a U.S.S.G. § 3A1.1 “vulnerable victim” enhancement; rather, the district court found that the government failed to meet its burden of identifying an actual victim. This is clear from the district court’s conclusion that “we can’t even figure out who is a victim in this case, and whether the victims were benefited in some way.”

AFFIRMED.