FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Appellee*, v. MICHAEL STANLEY KAPLAN, MD, *Defendant-Appellant.*	No. 15-10241 D.C. No. 2:13-cr-00377- GMN-CWH-1 OPINION

Appeal from the United States District Court
for the District of Nevada
Philip M. Pro, District Judge, and
Gloria M. Navarro, Chief District Judge, Presiding

Argued and Submitted July 19, 2016
San Francisco, California

Filed September 9, 2016

Before: Susan P. Graber and Richard C. Tallman, Circuit Judges, and Nancy G. Edmunds,[*] Senior District Judge.

Opinion by Judge Tallman

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[*] The Honorable Nancy G. Edmunds, Senior United States District Judge for the Eastern District of Michigan, sitting by designation.

SUMMARY[**]

Criminal Law

The panel affirmed a conviction for conspiracy to commit adulteration in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), with the intent to defraud or mislead, in a case in which the defendant, a urologist, reused single-use plastic needle guides during prostate biopsy exams.

The panel held that a physician's use of a consumable, single-use device on a paying patient satisfies the "held for sale" element under § 331(k), and that the district court, in denying the defendant's motion to dismiss the indictment, did not err in determining that the defendant's use of the needle guides in the course of treating his urology patients constituted a "sale" under § 331(k).

The panel held that there was sufficient evidence to support the conviction that the defendant conspired to commit adulteration in violation of § 331(k) and to support the special finding that he intended to defraud his patients, the public, the FDA, and the Nevada State Medical Board.

The panel held that the district court did not err in rejecting the defendant's requested jury instruction stating that off-label use of an unadulterated device is not unlawful, where the theory was already covered by the instructions. The panel held that the district court did not plainly err in

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

refusing to give a "practice of medicine" exemption instruction.

The panel held that because the indictment contained the elements of the defendant's fraud in adequate detail, he was fairly informed of the charges against him, and that any error in omitting the materiality element from the indictment was, on this record, harmless.

The panel held that the defendant waived any challenge to the jury instructions and special verdict form regarding how the jury distinguished between a misdemeanor and a felony conviction.

COUNSEL

Dennis P. Riordan (argued) and Donald M. Horgan, Riordan & Horgan, San Francisco, California, for Defendant-Appellant.

Elizabeth O. White (argued), Appellate Chief and Assistant United States Attorney; Daniel G. Bogden, United States Attorney; United States Attorney's Office, Reno, Nevada; for Plaintiff-Appellee.

OPINION

TALLMAN, Circuit Judge:

It is axiomatic that physicians are expected to do no harm. When a physician breaches that duty and puts his own interests above those of his patients, great harm can occur. Though the regulation of the practice of medicine is delegated to the states, when a physician misuses medical devices and threatens public health, the physician may run afoul of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Doctor Michael Kaplan, a Nevada urologist, entered that domain when he decided to start reusing single-use plastic needle guides during prostate biopsy exams.

Kaplan appeals his felony conviction for conspiracy to commit adulteration in violation of 21 U.S.C. § 331(k) with the intent to defraud or mislead. Kaplan challenges the statute under which he was charged, the sufficiency of the evidence, the denial of his proposed jury instructions, the sufficiency of the indictment, and his enhanced sentence. For all the reasons set forth below, we affirm.

I

In December 2010, Kaplan owned and operated two urology clinics located in Henderson and Las Vegas, Nevada. Kaplan worked at the clinic in Henderson, while his associate Dr. Brian Golden worked out of the Las Vegas clinic. At both offices the physicians regularly performed prostate needle biopsies, a surgical procedure in which prostate tissue is removed and examined for disease.

During a prostate biopsy, an ultrasound probe is inserted into the patient's rectum to locate the prostate. A hollow needle is then injected through the rectal wall into the prostate to gather the tissue sample. A needle guide, housing the collection needle, stabilizes the needle throughout the biopsy procedure. During the biopsy procedure, both the inside and outside of the needle are contaminated with various biological debris, including tissue, blood, and fecal matter, along with any bacteria and viruses. When the procedure is complete, the needle is pulled back into the channel of the needle guide, bringing debris with it. Because the procedure is bloody and dirty, patients take antibiotics at the time of the biopsy to prevent infection.

Needle guides come in both single-use and reusable forms. Reusable guides are made of stainless steel and can be disinfected after every use. Single-use guides, however, are made of plastic, which is prone to scratching by the needle, creating crevices that can trap debris. The plastic guides come in distinctive packaging and are accompanied by a booklet clearly stating that they are sterile only for a single use and are not to be reused. Before the conduct at issue, Kaplan's office used a reusable stainless-steel guide and Golden's office used single-use plastic guides.

Circumstances changed in December 2010, when Kaplan's ultrasound machine broke and a new one was ordered. Kaplan was in a "tight crunch" and quickly ordered a refurbished machine and requested another reusable stainless-steel guide. Because a reusable stainless-steel guide was not available for the new machine and the old stainless-steel guide did not fit, sales representative Timothy Brandt arranged to send single-use plastic guides to Kaplan's office.

Office manager Mary Taylor called Brandt after the Kaplan office received the plastic guides, because she was concerned and upset that the guides were not reusable. Brandt told Taylor he had heard from a physician in California that, with appropriate sterilization, the single-use guides could be used two to three times before the guides disintegrate. Brandt, however, testified that he was relying only on the California physician's information because he was a lay person and "naive." Brandt further testified that he never advised Taylor to reuse the single-use guides, he did not believe he was qualified to give such advice, and he never instructed her on how to sterilize the guides.

By January 2011, because both clinics were using the plastic guides, supplies were running short and additional plastic guides were on backorder with the manufacturer. Kaplan told Taylor and the medical assistant supervisor, Martha Cortez, to tell the medical assistants to reuse the plastic guides by cleaning them in the same manner as the reusable stainless-steel guides. Taylor told a medical assistant, in Kaplan's presence, that because the single-use guides were expensive, it would be "ridiculous" not to reuse them. Kaplan and Taylor insisted on reusing the guides even after the medical assistants pointed out that the packaging for the plastic guides clearly stated that they were for single use only.

No formal procedures for cleaning the single-use plastic guides were ever provided, other than Kaplan's instruction to clean them with the same Cidex[1] cleaning protocol used to clean the stainless-steel guide. Using that protocol, the

[1] Cidex is a liquid chemical sterilant, primarily composed of glutaraldehyde, used to disinfect reusable medical devices.

medical assistants would first hold a guide under the sink to rinse it with water and then use a wire with bristles, like a pipe cleaner, or thin needle to clean the inside of the guide. The guides were then submerged in Cidex for a period of time. After transferring the guides to sterile water for some time, the guides were placed on a sterile tray, ready to use in the next biopsy.

There were many inconsistencies and safety issues surrounding the Cidex cleaning protocol as implemented in Kaplan's office. The temperature of the water and the length of time a guide spent in the initial rinse varied from medical assistant to medical assistant. The amount of time the guides spent in the Cidex also varied. Though Cortez, the supervisor, testified that the Cidex was refreshed and replaced "religiously," the medical assistants did not know how often the Cidex was replaced or whether the logs were updated; they had never replaced the Cidex and had never checked the Cidex with test strips or checked the temperature. Cortez herself testified that she did not know that Cidex came with test strips. The sterile water in which the guides were placed at the end of the protocol was not changed frequently enough to maintain sterility.

Finally, Kaplan's office kept no record of how many times a particular guide was reused. But all employees estimated that the guides were reused three to five times. Neither Kaplan, Taylor, Cortez, nor the medical assistants informed patients that the guides were being reused.

During the time the medical assistants were instructed to reuse the plastic guides, they observed blood and pinkish water left in the guides. The pipe cleaner that the assistants used to clean the stainless-steel guide was not designed to

clean the plastic guides and therefore did not reach fully inside the plastic guides. Additionally, the pipe cleaner could not reach into the scratches in the plastic created by the needle during the biopsy procedure, and blood and fecal matter became trapped in the guides. Assistants observed brown scratches that did not come clean during the disinfecting process. Cortez testified that she could tell the difference between a new and used plastic guide because the used guides were discolored.[2]

A month after Kaplan began reusing the single-use plastic guides, Dr. Golden discovered the reuse. Golden immediately contacted Taylor to tell her to stop the practice. Taylor informed Golden that "if this was ever happening at this office it's not happening anymore." Golden assumed that the practice stopped. And Golden himself, who had always used the plastic guides, never reused them.

At this time, Kaplan's wife, Michelle Darquea Kaplan, an attorney and the office administrator, learned that the plastic guides were being reused. Mrs. Kaplan spoke to her husband, who told her they reused the plastic needle guides just like any other medical equipment in the office. After doing some research and calling the company that made the disposable guides, Mrs. Kaplan again spoke to Kaplan because she was still confused as to whether the guides were reusable and why Golden had contacted Taylor. Kaplan replied that he didn't know and that Golden was "always mad at me for something. . . . He's probably just trying to give me a hard

[2] The medical assistants never reported to Kaplan, Taylor, or Cortez that they were having trouble cleaning the plastic guides. One assistant stated that she did not go to Kaplan or Taylor because she was afraid she might get in trouble because "they already knew it was wrong."

time or whatever." Mrs. Kaplan then told her husband that they should stop reusing the plastic guides, he agreed, and Mrs. Kaplan told Taylor, the office manager, to instruct everyone to stop using the guides. As of January 6, 2011, Mrs. Kaplan believed that reuse had stopped.

The practice of reusing the needle guides, however, did not stop. The medical assistants all testified that they were never told by Kaplan or Taylor to stop reusing the plastic guides. Reuse continued until March 2011, when Kaplan's own medical assistants reported him to the Nevada State Medical Board ("Medical Board"). The Medical Board immediately notified federal investigators and commenced its own inquiry in response.

When Food and Drug Administration ("FDA") Office of Criminal Investigations special agents arrived on March 11, 2011, Kaplan readily admitted to reusing the guides. However, Kaplan inconsistently claimed to the agents how long reuse had lasted. First he insisted that reuse had ended as early as January, when Dr. Golden called, then later stated that it had lasted not beyond late February. When asked why he reused the devices, Kaplan would say only that "he was practicing cost-effective medicine and good patient care." The agents spoke to the medical staff the same day, and the staff all reported that reuse was still ongoing at that time. When agents spoke again to Kaplan later that same day, Kaplan then stated that reuse had lasted only from December 21, 2010, to January 21, 2011.

A Medical Board representative also attended the FDA agents' interviews at Kaplan's office. Kaplan's medical license was suspended by the Nevada State Medical Board on

March 14, 2011.[3] In his representations to the Medical Board in April 2011, Kaplan maintained that reuse had stopped in January of 2011.

Kaplan then hired a law firm and put together a public relations team. The public relations team decided to publish an advertisement in the Las Vegas Review-Journal, explaining Kaplan's conduct. To do so they interviewed everyone involved in Kaplan's medical practice. Kaplan told the team that he had ordered his staff to stop reuse on January 6, 2011. But all the staff interviewed told the team that they were never ordered to stop reusing the plastic guides. The one staff member who stated that reuse lasted only one to two weeks later testified that she was pressured to do so by Taylor.

Despite the results of the medical assistants' interviews, the advertisement that the public relations team ultimately published asserted that reuse of the plastic guides ended on January 6, 2011, less than three weeks after the new ultrasound machine was put into service. It was established at trial, however, that, based on their investigation, the FDA agents estimated that between January 7, 2011, the date that the reuse was alleged to have stopped, and March 11, 2011, Kaplan used 67 guides for 94 procedures.[4] Kaplan's

[3] In its original administrative complaint, the Medical Board alleged several charges, including malpractice. Later, the Medical Board reinstated Kaplan's license, and then amended the complaint to drop the malpractice count and add a count alleging failure to properly supervise medical assistants.

[4] For the period between December 10, 2010, the date the new machine was purchased, and March 11, 2011, the agents estimated that Kaplan used 51 guides for 123 procedures.

published advertisement further asserted that he reused the guides because he had been instructed that "it was perfectly safe to do so."

On October 2, 2013, a grand jury in Nevada returned a two-count indictment; the one count relevant to this appeal charged Kaplan with conspiracy under 18 U.S.C. § 371 to commit adulteration in violation of 21 U.S.C. §§ 331(k), 333(a)(2), and 351(a)(2)(A).[5] In addition to the relevant testimony recounted above, at trial both sides offered expert testimony regarding whether the guides were adulterated; that is, whether the guides were held under insanitary conditions such that they may have become contaminated. *See* 21 U.S.C. § 351(a)(2)(A). The government established that there were no data on whether the single-use plastic guides were reusable, and that the Cidex label clearly indicated that it was not to be used to reprocess single-use devices. Furthermore, the government expert testified that, without testing, it was not possible to determine whether cleaning and sterilization of a single-use device was effective.

The defense expert acknowledged that the cleaning procedure was imperfect, but speculated that the risk of infection in Kaplan's patients was between one in one trillion and one in one hundred trillion. The defense expert nonetheless admitted that he was the primary author of an article that advised "do not reuse items labeled for single use," had conducted no experiments to determine if the plastic guides could safely be reused, and was not actually advocating for reuse of the single-use plastic guides.

[5] The other count charged Kaplan with making a false statement to a government agency, on which the petit jury found him not guilty. That count is not before us on appeal.

On September 25, 2014, after a nine-day jury trial presided over by now-retired District Judge Philip M. Pro, Kaplan was found guilty of conspiring to commit adulteration. The jury expressly found that Kaplan acted with the intent to defraud or mislead, thereby convicting Kaplan of a felony. At sentencing on May 5, 2015, Chief District Judge Gloria Navarro calculated an advisory guidelines sentencing range of 31–41 months' imprisonment based on the felony conviction and varied upward from that range to impose 48 months' imprisonment. Final judgment was entered on May 7, 2015, and this timely appeal followed. We have jurisdiction under 28 U.S.C. § 1291.

II

Before we can decide whether there was sufficient evidence to convict Kaplan of the conspiracy, we must first determine whether his conduct can be criminally prosecuted under the FDCA. Section 331(k) prohibits "the doing of any . . . act with respect to . . . [a] drug [or] device . . . if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated." 21 U.S.C. § 331(k). A device is adulterated if it is "held under insanitary conditions whereby it may have been contaminated with filth, or . . . rendered injurious to health." *Id.* § 351(a)(2)(A). This case turns on the interpretation of "held for sale" in § 331(k); can a doctor's use of a device in the course of treating a patient be considered a "sale" under the statute? Before trial, Kaplan moved to dismiss the indictment on the ground that his use of the guides in treating patients was not covered by the "held for sale" provision of § 331(k). Based on the report and recommendation of the magistrate judge, the district court

held otherwise and ruled that "held for sale" included a physician's use of a device in treating patients. We agree.

This is an issue of first impression and requires us to interpret § 331(k) of the FDCA. We review questions of statutory construction de novo, *J & G Sales Ltd. v. Truscott*, 473 F.3d 1043, 1047 (9th Cir. 2007), and hold that the district court did not err in determining that Kaplan's use of the guides in the course of treating his urology patients constituted a "sale" under § 331(k).

A

To interpret a statute, "we look first to the plain meaning of the text." *Transwestern Pipeline Co. v. 17.19 Acres of Prop. Located in Maricopa Cty.*, 627 F.3d 1268, 1270 (9th Cir. 2010). When words in a statute are not defined, they "will be interpreted as taking their ordinary, contemporary, common meaning." *Id.* (quoting *Perrin v. United States*, 444 U.S. 37, 42 (1979)). Courts examine "not only the specific provision at issue, but also the structure of the statute as a whole, including its object and policy." *United States v. Williams*, 659 F.3d 1223, 1225 (9th Cir. 2011) (quoting *Children's Hosp. & Health Ctr. v. Belshe*, 188 F.3d 1090, 1096 (9th Cir. 1999)). The FDCA is to be interpreted broadly in order to protect public health. *See United States v. Article of Drug* (*Bacto-Unidisk*), 394 U.S. 784, 798 (1969) ("Congress fully intended that the Act's coverage be as broad as its literal language indicates . . . .").

The FDCA's overall purpose is to protect consumers from dangerous products. *United States v. Sullivan*, 332 U.S. 689, 696 (1948). Congress's specific intent in enacting § 331(k) was "to extend the Act's coverage to every article" in

interstate commerce until it reaches "the ultimate consumer," the patient. *Id*. at 697; *see also United States v. Evers*, 643 F.2d 1043, 1049 (5th Cir. 1981) ("The flow of commerce begins with the manufacturer of the drug and ends with the consumer, that is, the patient.").

In construing the meaning of "held for sale" under § 331(k), several courts have held that the phrase extends to physicians using both drugs and devices in the treatment of patients. *See United States v. Rhody Dairy, L.L.C.*, 812 F. Supp. 2d 1239, 1244 (W.D. Wash. 2011) ("[S]everal cases have held that drugs and devices used in the treatment of patients are 'held for sale' by doctors as part of the distribution process."); *see also Evers*, 643 F.2d at 1050 ("Doctors holding drugs for use in their practice are clearly one part of the distribution process, and doctors may therefore hold drugs for sale within the meaning of section 301(k) of the Act."); *United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975) (per curiam) ("Such devices, used in the treatment of patients, may properly be considered 'held for sale' within the meaning of the [FDCA], 21 U.S.C. § 331(k)."); *United States v. Device Labeled "Cameron Spitler Amblyo-Syntonizer"*, 261 F. Supp. 243, 246 (D. Neb. 1966) (holding that a physician was not exempt from the requirements of the FDCA when he used misbranded devices in the treatment of his patients even though he did not sell the devices in the commercial sense). The statements made in these cases, however, are quite conclusory and offer little guidance.

In the only case from our circuit addressing the "held for sale" provision, we concluded that "held for sale" does not reach homemade products distributed in a noncommercial setting at no cost to the recipients. *United States v. Geborde*,

278 F.3d 926, 928 (9th Cir. 2002). Geborde, who was not a physician, made his own recreational drugs and distributed them free of charge. *Id.* at 927. The government charged Geborde under § 331(k), alleging that "held for sale" included this type of distribution because it covered any conduct in which a drug is not held for personal consumption. *Id.* at 931. In rejecting that argument, we emphasized "that the phrase 'held for sale' plainly contemplates a sale." *Id.* at 932. Notably, in construing the term "held for sale" we focused on "commercial transactions, commercial actors, and commercial products" but did not define the term more specifically. *Id.* at 931. Geborde's conduct was not a sale under this definition because Geborde was a noncommercial actor, in a noncommercial setting, distributing homemade drugs completely free of charge. *Id.* at 931–32; *see also Rhody Dairy*, 812 F. Supp. 2d at 1244 (noting that the distinguishing factor in *Geborde* was the noncommercial nature of the transaction).

B

In applying § 331(k) to Kaplan's conduct, Kaplan argues that the phrase "held for sale" must be interpreted narrowly and cannot be read to mean "held for use." Because title and possession of the guides were not transferred to patients, Kaplan argues that there was no sale and thus that his use of the guides during prostate biopsies falls outside the scope of the statute. Such an argument, however, is in direct contravention to out-of-circuit caselaw stating that a physician's use of a device on a patient is covered by the statutory phrase "held for sale." *See Evers*, 643 F.2d at 1050; *Diapulse Corp.*, 514 F.2d at 1098; *Rhody Dairy*, 812 F. Supp. 2d at 1244; *Cameron Spitler*, 261 F. Supp. at 246.

Kaplan's reliance on *Geborde* to distinguish these cases is misplaced. We did not hold that a sale in the strict sense must occur. Rather, we focused more generally on the commercial nature of the transaction, actors, and products. *Geborde*, 278 F.3d at 931. The district court in this case, therefore, properly focused on the commercial nature of Kaplan's business, a medical practice operated for profit, reasoning that patients who paid Kaplan for the medical services he performed were also paying for the cost of products used in the course of treatment, including biopsies, and that the patients were therefore the ultimate consumers of the guides. Kaplan is a physician engaged in the business of providing medical services in exchange for payment: a commercial actor in a commercial setting, using a commercial product. We hold that his use of the plastic guides is covered by the "held for sale" provision of § 331(k).[6]

The single-use nature of the guides is particularly critical to our decision. A single-use device is meant to be "consumed" in the course of treating a patient—just like a drug. Once the single-use device is used or consumed there is nothing left to be done with the device. It no longer possesses a functional purpose in the medical practice and, rather than giving the used device to the patient, the doctor disposes of it. Therefore, when a physician uses a disposable device on a patient, the device is "held for sale" within the meaning of the FDCA provided that there is a commercial

[6] Contrary to Kaplan's argument, the rule of lenity is inapplicable. *See Warren v. Crabtree*, 185 F.3d 1018, 1023 (9th Cir. 1999) ("The simple existence of some statutory ambiguity is not sufficient to warrant application of that rule, for most statutes are ambiguous to some degree." (internal quotation marks and ellipsis omitted)).

relationship between the doctor and the patient and that the device is one that is meant to be "consumed" in the process.[7] This interpretation of "held for sale" comports with Congress's intent that the FDCA be interpreted broadly, *see Bacto-Unidisk*, 394 U.S. at 798, and the intent of § 331(k) to protect the ultimate consumer, the patient, from dangerous products, *see Sullivan*, 332 U.S. at 696. Even a physician can make a product dangerous for a patient if the product is utilized improperly.

The argument that defining "held for sale" in this manner impermissibly interferes with a physician's ability to treat patients is foreclosed by *United States v. Regenerative Scis., LLC*, 741 F.3d 1314 (D.C. Cir. 2014). There, physicians removed stem cells from patients, cultured them in a mixture with antibiotics, and then reinjected them into the patients to treat orthopedic conditions. *Id.* at 1318. In the suit alleging that the stem cell mixture was misbranded and adulterated under the FDCA, the physicians argued that the FDA was improperly attempting to regulate the practice of medicine by regulating the stem cell procedure. *Id.* at 1319. The court noted, however, that "the FDA does not claim that the procedures used to administer the Mixture are unsafe; it claims that the Mixture itself is unsafe." *Id.* Similarly, in Kaplan's case the government is not alleging that the biopsy procedure is unsafe, but rather that the guides themselves are

[7] We need not decide at this time whether "held for sale" encompasses services donated free of charge or devices that are part of a physician's general office equipment, such as an MRI machine or examination table. Additionally, we also decline to consider here whether the reusable stainless-steel guide, an item that can be properly and safely reused, could be considered "held for sale" under § 331(k). We leave those questions for another day.

unsafe. Kaplan's "arguments about the practice-of-medicine exemption are therefore wide of the mark." *Id.*

Finally, Kaplan's claim that his reuse of the single-use guides is merely off-label use is similarly unavailing. Off-label use allows a physician to use drugs or devices regulated by the FDCA for a purpose not approved by the FDA. *See Evers*, 643 F.2d at 1049 (holding that a physician's off-label use of chelating agents to treat circulatory disorders in patients, though potentially dangerous, was permissible off-label use). The purpose of this exception is to allow physicians the freedom to manage the care of their patients. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (noting that off-label use is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine" and the FDA cannot interfere with a physician's off-label use of a device in a "legitimate health care practitioner-patient relationship." (quoting 21 U.S.C. § 396)).

Kaplan's argument that his reuse of the single-use guides was merely a permissible off-label use that cannot be criminally prosecuted fails for two reasons: the allegations of adulteration and the purpose of the off-label use. First, off-label use does not immunize a physician who uses adulterated products. Though off-label use "allow[s] physicians to prescribe . . . lawful drugs for unapproved uses," *Evers*, 643 F.2d at 1049, off-label use of *adulterated* products is beyond the scope of the privilege. While a physician may exercise professional judgment in the off-label use of unadulterated products, nothing in the FDCA or caselaw

suggests that the use of adulterated products is ever permissible.[8]

Second, Kaplan's stated purpose for reusing the guides was "cost-effective medicine," and there is no evidence in the record to suggest that this cost savings was passed on to the patients or that the practice in any way benefitted the patients. The benefits, if any, of reusing the single-use guides seem to be confined to cost savings for Kaplan and had nothing to do with Kaplan's management of patient care. The argument that Kaplan used professional judgment for some legitimate off-label purpose fails.

Therefore, we hold that a physician's use of a consumable, single-use device on a paying patient satisfies the "held for sale" element under 21 U.S.C. § 331(k). The district court did not err in denying the motion to dismiss the indictment.

III

Though we have established that Kaplan's conduct is covered by the element "held for sale" under 21 U.S.C.

[8] In upholding the determination that Kaplan's conduct is covered by § 331(k), it is appropriate to highlight briefly the difference between malpractice and criminal behavior. While criminal acts by a physician against a patient nearly always constitute malpractice, only a fraction of malpractice acts rise to the level of a crime. Evers' patients may have been able to bring a malpractice action against him because his care fell below prevailing professional standards, *see Evers*, 643 F.2d at 1045, 1053, but a criminal charge could not be sustained because he used unadulterated products in a permissible way. By contrast, not only could Kaplan's patients bring a putative malpractice action, Kaplan's alleged conduct can also be criminally charged under § 331(k).

§ 331(k), he was not charged with the substantive offense. The government instead charged Kaplan with conspiracy to commit adulteration in violation of § 331(k), and Kaplan challenges the sufficiency of the evidence convicting him of that crime. We review the sufficiency of the evidence de novo. *United States v. Sullivan*, 522 F.3d 967, 974 (9th Cir. 2008) (per curiam).

A

"There is sufficient evidence to support a conviction if, 'viewing the evidence in the light most favorable to the prosecution, *any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt.'" *Id.* (quoting *Jackson v. Virginia*, 443 U.S. 307, 319 (1979)). In reviewing the sufficiency of the evidence, "[t]he test is whether the evidence and all reasonable inferences which may be drawn from it, when viewed in the light most favorable to the government, sustain the verdict." *United States v. Terry*, 911 F.2d 272, 278 (9th Cir. 1990) (quoting *United States v. Soto*, 779 F.2d 558, 560 (9th Cir. 1986)). "[A]ny conflicts in the evidence are to be resolved in favor of the jury's verdict." *United States v. Alvarez-Valenzuela*, 231 F.3d 1198, 1201–02 (9th Cir. 2000).

To prove a conspiracy under 18 U.S.C. § 371, the government must establish three elements: "(1) an agreement to engage in criminal activity, (2) one or more overt acts taken to implement the agreement, and (3) the requisite intent to commit the substantive crime." *Sullivan*, 522 F.3d at 976 (quoting *United States v. Montgomery*, 384 F.3d 1050, 1062 (9th Cir. 2004)). An agreement to commit a crime "can be explicit or tacit, and can be proved by direct or circumstantial evidence, including inferences from circumstantial evidence."

United States v. Loveland, 825 F.3d 555, 557 (9th Cir. 2016). Proof of the underlying substantive crime, however, does not, without more, prove the existence of a conspiracy. *United States v. Lennick*, 18 F.3d 814, 819 (9th Cir. 1994).

In this case, the government must show that (1) Kaplan agreed with others to hold the single-use plastic guides in an adulterated state in violation of 21 U.S.C. § 331(k)—that is, in insanitary conditions such that the guides may have been contaminated, *see id.* § 351(a)(2)(A); (2) Kaplan and others took acts in furtherance of that agreement; and (3) Kaplan and others had the intent to adulterate the guides. In order to sustain the felony conviction, the government also had to show that Kaplan acted with the intent to defraud or mislead. *See id.* § 333(a)(2). Evidence of intent to defraud can be circumstantial and may be inferred from misrepresentations and omissions. *United States v. Rogers*, 321 F.3d 1226, 1230 (9th Cir. 2003). Considering the evidence in the light most favorable to the government and the jury's verdict, there was sufficient evidence to convict Kaplan of the felony of conspiracy to violate 21 U.S.C. § 331(k) with the intent to defraud.

B

First, the government provided sufficient evidence that Kaplan and Taylor agreed to reuse the guides in an adulterated state. When the clinic noticed that it was running short of guides, Kaplan explicitly told Taylor and Cortez to instruct the medical assistants to reuse the single-use guides and to employ the Cidex cleaning protocol. Taylor told a medical assistant, in Kaplan's presence, that it would be "ridiculous" not to reuse the guides considering the cost. Kaplan, Taylor, and Cortez instructed the medical assistants

to clean and reuse the devices despite the medical assistants' protests that the packaging for the devices labeled them for single use. Finally, after being notified by Golden that reuse had to stop, Taylor spoke with Kaplan but neither of them decided to stop. Taking the evidence in the light most favorable to the government, there was sufficient evidence for a rational trier of fact to determine that Kaplan agreed with others to nonetheless reuse the devices after employing the Cidex cleaning protocol.

Second, the evidence clearly established, and Kaplan does not dispute, that after he and Taylor told the medical assistants to clean and reuse the guides the medical assistants did so. Therefore, Kaplan caused an act to be committed in furtherance of the agreement.

Third, there was sufficient evidence to show that Kaplan and others intended to hold the devices in an adulterated state. This is a closer question because, as Kaplan notes, the difficulty with the intent element is that an agreement to intend to reuse the devices is not the same as an agreement to intend to hold the devices in an adulterated state. Additionally, proof of actual adulteration is not relevant to showing that Kaplan intended to adulterate the devices. *See Lennick*, 18 F.3d at 819.

According to Kaplan, the government must show that he intended to adulterate the devices but cannot do so because Kaplan thought that the disinfection protocol was working and that the guides were not insanitary or contaminated. Kaplan urges us to declare that the government must show that the guides were in fact contaminated and that Kaplan intended to use them in that state. The argument proves too much. The record established that Kaplan intended to reuse

the guides following the Cidex cleaning protocol, though he possessed no evidence that such a protocol would actually work, based apparently on Brandt's hearsay statement that a California physician said it would work, and with no guidance to the medical assistants on how to clean the guides properly.[9] And there was sufficient evidence—testimony of actual blood, stains, scratches, discoloration, and expert testimony—to show that, after the lax Cidex cleaning protocol, the devices were being held under insanitary conditions and may have been contaminated.[10] The guides' packaging clearly declared they were not to be reused and the Cidex label clearly warned that it was not to be used to clean disposable devices.

Kaplan may not have intended the guides to be contaminated when he reused them, but he intended to put them through the Cidex cleaning protocol that had never been tested on single-use guides. There is a reasonable probability that the Cidex cleaning protocol as actually employed left the single-use guides in an insanitary condition that may have contaminated them, leaving them adulterated. Therefore, because Kaplan intended to put the guides through an

[9] Kaplan argues that his reuse of a single-use device cannot be adulteration because the "FDA does not know if [the guides] can be cleaned and disinfected effectively because no data exist." However, this argument works against Kaplan as well. Because there are no data to show that the guides can be cleaned, there is a possibility the guides were adulterated; that is to say, they may have been kept in insanitary conditions. Given the known risk of infection from the biopsy procedure, proceeding in this manner exposed his patients to a much greater risk of harm with no notice to them of this increased danger.

[10] That no patient contracted an acute infection is not dispositive. The patients were, after all, already taking antibiotics at the time of the procedure.

inappropriate cleaning protocol, he intended to put the guides through a procedure that left them adulterated. That is sufficient to constitute criminal intent to support the conspiracy conviction.

Moreover, Kaplan's claim of ignorance as to the adulterated state of the guides is unavailing. The evidence showed that he ordered reuse despite the protest of his medical assistants. In January, Dr. Golden called Taylor to tell the Kaplan clinic to stop reusing the guides, and Dr. Kaplan was aware of that conversation. When questioned by his wife regarding reuse, Kaplan stated that Golden was "just trying to give me a hard time." Her research confirmed the risk. But after that, no medical assistant was ever instructed to stop reusing the guides. Kaplan was repeatedly made aware of the problems with reusing the guides, knew that the guides should not be reused, and persisted in reusing the guides anyway for several weeks thereafter. His continued reuse of potentially adulterated guides was unquestionably intentional, and the jury reasonably concluded that Kaplan possessed the sufficient intent to support a conspiracy conviction.

Finally, in order to constitute a felony offense rather than simply a misdemeanor, the government had to prove that Kaplan intended to defraud or mislead. The government provided evidence that clearly established that Kaplan and his staff did not disclose reuse to his patients, and that Kaplan and his public relations team attempted to conceal the truth from the public, the Nevada State Medical Board, and the FDA, by stating that reuse ended in January 2011, when in fact reuse continued into March. Those misrepresentations about when reuse stopped are indicative of his consciousness of guilt. Office Manager Taylor even pressured an employee

to lie about the extent of reuse. Though the evidence that Kaplan and his public relations team were attempting to hide his tracks is circumstantial evidence of his intent, a reasonable jury could find on this record that he was acting with the intent to defraud and mislead.

Additionally, the government offered sufficient evidence to support the contention that this was done in an effort to enrich Kaplan and save him money. As Taylor stated, the expense of the reusable guides was "ridiculous." And the only reason Kaplan offered to FDA agents to explain reuse was that he was practicing "cost-effective medicine."

Viewing the evidence in the light most favorable to the government and in support of the jury's verdict, there was sufficient evidence to support the conviction that Kaplan conspired to commit adulteration in violation of 21 U.S.C. § 331(k) and to support the special finding that Kaplan intended to defraud his patients, the public, the FDA, and the Medical Board. We will not overturn the jury's verdict.

IV

Kaplan also appeals the exclusion of two proposed jury instructions: one on "off-label use" and the other on the "practice of medicine."[11] In the course of drafting the jury instructions, Kaplan attempted to introduce these instructions

[11] The two instructions proposed the following: (1) that off-label use is approved by the FDA, a physician is not required to follow the manufacturer's label, and therefore reuse of a single-use device is not per se unlawful; and (2) that the FDA does not have the authority to interfere with a physician's health care practices within a legitimate physician-patient relationship.

because he feared that the jury would determine that reuse of a single-use device was a per se violation of the law. The trial judge rejected these arguments because the court believed that the jury instructions as they were written sufficiently advised the jury that this was not a strict liability offense. Kaplan contends that the absence of the requested instruction allowed the government to improperly suggest at closing argument that reuse of the single-use guides was per se adulteration.

We review the wording of jury instructions for an abuse of discretion, but review de novo "[w]hether jury instructions omit or misstate elements of a statutory crime or adequately cover a defendant's proffered defense." *United States v. Christensen*, No. 08-50531, 2015 WL 11120665, at *13 (9th Cir. July 8, 2016). Because Kaplan's instructions were offered to cover his preferred defense, we review them de novo. *See id.*

We must determine whether the instructions, viewed as a whole, "were misleading or inadequate to guide the jury's deliberation." *United States v. Moore*, 109 F.3d 1456, 1465 (9th Cir. 1997) (en banc) (quoting *United States v. Perez*, 989 F.2d 1111, 1114 (9th Cir. 1993)). "Jury instructions, even if imperfect, are not a basis for overturning a conviction absent a showing that they prejudiced the defendant." *Christensen*, 2015 WL 11120665, at *13. "A defendant is not entitled to any particular form of instruction, nor is he entitled to an instruction that merely duplicates what the jury has already been told." *United States v. Lopez-Alvarez*, 970 F.2d 583, 597 (9th Cir. 1992). A judge need not include proposed instructions that are "not necessary to explain to the jury the legal effect of the theory of the defense." *Id.*

First, as Kaplan himself states, the "theory of the case was . . . that he never agreed to use, and did not use, adulterated devices in his treatment of patients." Kaplan further argues that the "cornerstone" of this defense was that off-label use of a single-use device was not illegal. However, the district court properly noted that the instructions did not improperly permit the jury to find that reuse of the guides was a per se violation of § 331(k). Kaplan's legal theory was ultimately that the devices were not adulterated, and the instructions state explicitly that the jury had to determine whether the devices were adulterated. Therefore, there is no need for a jury instruction stating that off-label use of an unadulterated device is not unlawful, the theory was already covered by the instructions, and the district court did not err in rejecting Kaplan's "off-label use" instruction.[12]

Second, Kaplan did not object when the district court rejected his "practice of medicine" instruction. Whether we review for plain error, Fed. R. Crim. P. 30(d) and 52(b), or whether we consider the argument to have been litigated adequately, *see, e.g.*, *United States v. Chhun*, 744 F.3d 1110, 1119 (9th Cir. 2014), the result is the same. The district court declined to give this instruction, noting "there could not be a

[12] Kaplan highlights a brief statement in the government's closing argument that implied that reuse is equivalent to adulteration and attributes it to the court's failure to accept his jury instruction. However, the government repeatedly agreed that this was not a strict liability offense. The government's theory actually relied heavily on the manner in which Kaplan cleaned and reused the guides and the fact that these particular guides were not suited to reuse because they would become adulterated—not the mere fact that they were reused. This brief statement during closing arguments by the government therefore did not prejudice Kaplan.

practice of medicine exemption which provided that he could use . . . adulterated stuff."

We hold that the district court properly rejected Kaplan's proposed jury instructions because his proposed "theory of the case" instructions merely duplicated what the jury was already told, and there was no plain error in the district court's refusal to give the "practice of medicine" instruction.

V

Before trial, Kaplan moved to dismiss count one of the indictment for failure to allege that he acted with the intent to defraud or mislead. The district court denied the motion and adopted the magistrate judge's recommendation noting that, because the indictment cited to the specific provision, 21 U.S.C. § 333(a)(2), and contained enough factual allegations, Kaplan was sufficiently notified that he was charged with a felony. Kaplan continues to argue here that the indictment was insufficient. We review the sufficiency of an indictment de novo. *United States v. Enslin*, 327 F.3d 788, 793 (9th Cir. 2003).

"An indictment is sufficient if it contains the elements of the charged crime in adequate detail to inform the defendant of the charge . . . ." *United States v. Buckley*, 689 F.2d 893, 896 (9th Cir. 1982). In judging the sufficiency of the indictment we look to "whether the indictment adequately alleges the elements of the offense and fairly informs the defendant of the charge, not whether the Government can prove its case." *Id.* at 897. The court must look at the indictment as a whole, include facts which are necessarily implied, and construe it according to common sense. *Id.* at 899.

That the indictment referred to the particular statute, 21 U.S.C. § 333(a)(2), rather than explicitly stating that Kaplan was being charged with the felony of intent to defraud, does not render the indictment invalid. Common sense dictates that Kaplan was adequately informed of the charge against him where the indictment alleged the specific conduct that constituted fraud: that Kaplan concealed reuse from patients and made false representations to the FDA, the public, and the Medical Board regarding the extent of reuse of the guides for his own enrichment.

Kaplan further argues that the indictment failed to allege the element of materiality in charging him with the intent to defraud and that the government failed to argue materiality at trial. Kaplan is correct; an allegation in the indictment stating that the facts concealed from patients were material omissions may have been necessary. *See Neder v. United States*, 527 U.S. 1, 20 (1999). "[T]he well-settled meaning of 'fraud' require[s] a misrepresentation or concealment of *material* fact." *Id.* at 22.

But Kaplan seems only to be arguing that the words "and it was material" had to appear in the indictment and be presented to the jury. Such an "omission of an element is an error that is subject to harmless-error analysis." *Id.* at 15. And an error is harmless when an omitted element is supported by uncontroverted evidence. *Id.* at 18. We therefore must ask "whether the record contains evidence that could rationally lead to a contrary finding with respect to the omitted element." *Id.* at 19. Kaplan does not argue, nor could he, that failing to inform patients that he was reusing single-use plastic devices in their prostate biopsies was not material. Therefore, omitting the element of "materiality" in the indictment was harmless error.

Because the indictment contained the elements of Kaplan's fraud in adequate detail, he was fairly informed of the charges against him. Additionally, any error in omitting the materiality element from the indictment, on this record, was harmless. The district court did not err in refusing to dismiss the indictment.

VI

Finally, Kaplan contends that the jury instructions and verdict form defined the offense as a misdemeanor, and not a felony, and he was therefore improperly sentenced for a felony conviction under 21 U.S.C. § 333(a)(2). However, Kaplan waived any challenge to the jury instructions and special verdict form regarding how the jury distinguished between a misdemeanor and a felony conviction. A party forfeits a right when it fails to make a timely assertion of that right and waives a right when it is intentionally relinquished or abandoned. *United States v. Olano*, 507 U.S. 725, 733 (1993). "Forfeited rights are reviewable for plain error, while waived rights are not." *United States v. Perez*, 116 F.3d 840, 845 (9th Cir. 1997) (en banc). Waiver of a jury instruction occurs when a party considers "the controlling law, or omitted element, and, in spite of being aware of the applicable law, proposed or accepted a flawed instruction." *Id.* ("If [a party] has both invited the error, and relinquished a known right, then the error is waived and therefore unreviewable.").

The trial judge specifically asked both parties during the instruction conference to take a hard look at how the jury instructions distinguished between a misdemeanor conviction and a felony conviction. The judge separated the jury instructions into two parts: (1) an instruction on what was

required to convict Kaplan of the conspiracy to commit adulteration, and (2) a separate instruction on the intent to defraud element necessary to make the offense a felony. The judge particularly noted that he did not explicitly use the terms "misdemeanor" and "felony" because he felt that they were not helpful to the jury and that the instructions were self-explanatory. The intent to defraud instruction was also included on the jury verdict form as a separate special finding to be made by the jury.

Objections during the editing process were few, and Kaplan affirmatively approved the instructions on several occasions. At a key point in the discussions, Kaplan's attorney explicitly stated, "I think the verdict form handles the intent to defraud." Furthermore, in asking the court to modify the intent to defraud instruction to add the term "beyond a reasonable doubt," which the court did, Kaplan affirmatively approved the instruction: "[W]hen I took a look at the verdict form I didn't have a problem with it, except that I think it needs to say . . . beyond a reasonable doubt . . . ."

Kaplan characterizes what happened at trial as the submission of "the conspiracy charge to the jury on instructions defining the offense as a misdemeanor." At sentencing, Kaplan's newly retained counsel objected to a felony sentence for a misdemeanor conviction. However, the contention that the instructions submitted to the jury defined the offense only as a misdemeanor is belied by the judge's own explanation of the instructions to "look . . . carefully as to how I dealt with . . . distinguishing . . . what we would call a felony and misdemeanor." Kaplan's sentencing counsel cannot rewrite the record to avoid what is clearly a well-supported felony conviction by the jury based on proper jury

instructions and a verdict form affirmatively approved by Kaplan's trial counsel.

Because the arguments now pressed on appeal do not change the fact that Kaplan's trial counsel waived any objection to the jury instructions and verdict form as they relate to the felony conviction, we find the claim waived and decline to reach the issue.

VII

At one point, Kaplan bragged that the volume of his successful medical practice made him the "McDonald's of Urology." But the evidence showed that, instead of protecting the safety of his patients, Kaplan took shortcuts to keep pumping patients through his clinic. Greed overcame his concern for patient care. And his practice of reusing single-use plastic needle guides on prostate biopsy patients brought them into contact with dangerous products, threatened public health, and breached § 331(k) of the FDCA. A physician's use of a consumable device on a patient is covered by the "held for sale" provision of 21 U.S.C. § 331(k), and there was sufficient evidence to support the jury's verdict that Kaplan engaged in a conspiracy to violate § 331(k). The district court did not err in denying Kaplan's proposed jury instructions or in holding that the indictment sufficiently charged him with a felony. Finally, Kaplan waived any objection to how the jury instruction and special verdict form distinguished between a misdemeanor and felony conviction.

AFFIRMED.