PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 19-4656

UNITED STATES OF AMERICA,

Plaintiff – Appellee,

v.

FELIX BRIZUELA, JR.,

Defendant – Appellant.

Appeal from the United States District Court for the Northern District of West Virginia, at Clarksburg. Irene M. Keeley, Senior District Judge. (1:18-cr−00001-IMK-MJA-1)

Submitted: March 26, 2020 Decided: June 19, 2020

Before MOTZ, HARRIS, and QUATTLEBAUM, Circuit Judges.

Reversed and remanded for a new trial by published opinion. Judge Quattlebaum wrote the opinion in which Judge Motz and Judge Harris joined.

Philip Urofsky, Washington, D.C., Shaina L. Schwartz, Sahand Farahati, SHEARMAN & STERLING LLP, New York, New York, for Appellant. William J. Powell, United States Attorney, Martinsburg, West Virginia, Sarah E. Wagner, OFFICE OF THE UNITED STATES ATTORNEY, Clarksburg, West Virginia, for Appellee.

QUATTLEBAUM, Circuit Judge:

Dr. Felix Brizuela operated a medical practice in West Virginia. Following complaints about his opioid prescription-writing practices, Brizuela was investigated by the United States Drug Enforcement Administration ("DEA") and ultimately convicted of 15 counts of unlawfully distributing controlled substances, in violation of 21 U.S.C. § 841(a)(1), (b)(1)(C). He now appeals his conviction.

Although Brizuela raises a host of arguments, we focus on his contention that, under *United States v. Kennedy*, 32 F.3d 876 (4th Cir. 1994) and Federal Rule of Evidence 404(b), the district court improperly admitted the testimony of patients whose treatment by Brizuela was not the basis for any of the charges in the indictment.[1] For the reasons set forth below, we agree with Brizuela that the testimony of the patients whose treatment was not included in the indictment was not necessary to "complete the story" of the charged offenses under Kennedy, and was not otherwise admissible under Rule 404(b). And

[1] Brizuela also argues that allowing the government's expert witness to testify that each of the 21 prescriptions cited in the unlawful distribution charges were written "outside the bounds of professional medical practice" violated Federal Rule of Evidence 704(b) because the testimony constituted an inadmissible legal conclusion; that the district court imposed an impermissible mandatory presumption by instructing the jury that "assisting another in the maintenance of a drug habit is conduct that is not for a legitimate medical purpose or is outside the bounds of professional medical practice." J.A. 1684; that the district court erred by not instructing the jury that, in order to convict him of unlawful distribution under 21 U.S.C. § 841(a)(1), it must find that he knowingly or intentionally acted outside the bounds of professional practice by writing the charged prescriptions; and that there was not sufficient evidence to support his convictions under § 841(a)(1) because no reasonable jury could find that the prescriptions cited in each charge were written outside the bounds of professional medical practice. In light of our decision today, we need not address these additional challenges to the verdict.

because the government did not carry its burden of establishing that this error was harmless, we vacate Brizuela's conviction and remand for a new trial in accordance with this decision.

We do not lightly overturn the verdict of a federal jury whose members gave substantial time and effort performing their civic duty during Brizuela's trial. But compliance with the Federal Rules of Evidence is important to ensure that trials are conducted fairly. When, as here, evidence introduced in a trial deviates from those Rules and causes prejudice, we are compelled to order a new trial.

I.

Brizuela is a Doctor of Osteopathic Medicine[2] and a board-certified neurologist who operated a medical practice in Morgantown, West Virginia. He offered pain management services, including prescribing patients opioid pain killers such as oxycodone and oxymorphone. These drugs are Schedule II controlled substances under the Controlled Substances Act ("CSA"), 21 C.F.R. § 1308.12(b)(1). Brizuela also worked at Advance

[2] A doctor of osteopathic medicine (D.O.) is a licensed doctor who has graduated from an American osteopathic medical school. Like a doctor of medicine (M.D.) who has attended a conventional medical school, D.O.s complete residency training in their chosen specialties and must pass the same licensing examination before they can treat patients and prescribe medications. However, D.O. training emphasizes holistic patient treatment that focuses on the musculoskeletal system—the body's interconnected system of nerves, muscles and bones. PATRICK WU & JONATHAN SIU, A BRIEF GUIDE TO OSTEOPATHIC MEDICINE: FOR STUDENTS, BY STUDENTS 3 (American Association of Colleges of Osteopathic Medicine 2d ed.) (2015).

Healthcare, a clinic in Weirton, West Virginia that treated patients for opioid addiction by prescribing them Suboxone, a medication designed to reduce opioid withdrawal symptoms and the desire to use opioids. Suboxone is a Class III controlled substance because it contains buprenorphine, another habit-forming opioid. *See* 21 C.F.R. § 1308.13(e)(2).[3]

Under federal law, every doctor who wishes to dispense controlled substances must apply for and obtain a unique registration number ("DEA number"). *See* 21 U.S.C. § 822(a)(2). If a registered practitioner fails to comply with the CSA or the terms of registration, their ability to prescribe certain classes of controlled substances can be revoked or suspended. *See* 21 U.S.C. § 824.

The DEA began investigating Brizuela after it received complaints from a pharmacist, the West Virginia Board of Pharmacy and the mother of one of Brizuela's patients about Brizuela's opioid prescription-writing practices. To corroborate these claims, the DEA used the West Virginia Controlled Substances Monitoring Program, a

[3] While currently regulated, opioids have been in the United States since its early days, with Benjamin Franklin taking them to deal with bladder stones and Alexander Hamilton receiving them after his fatal duel with Aaron Burr. Letter from Benjamin Franklin to M. Le Veillard (Sept. 5, 1789), *in* 3 THE LIFE OF BENJAMIN FRANKLIN, WRITTEN BY HIMSELF, 438 (John Bigelow ed., 1902); DAVID COURTWRIGHT, DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA 40, 44 (2009). The first documentation of widespread opioid addiction in the United States occurred during the Civil War. During that period, the administration of morphine—an opioid—to injured soldiers led to an addiction known as "the Army disease." Nat Hentoff, *The Treatment of Patients*, THE NEW YORKER 45 (June 26, 1965). In 1914, Congress passed the first federal law aimed at curbing the distribution of opioids for non-medical or non-scientific uses. *Id.* at 46. Although additional restrictions were placed on the use and prescribing of opioids over the next century, opioid use and abuse continued. Currently, opioids account for more than half of all overdose deaths in the United States. NATIONAL INSTITUTE ON DRUG ABUSE, WEST VIRGINIA: OPIOID-INVOLVED DEATHS AND RELATED HARMS 2 (2020).

database that records prescriptions for controlled substances. Upon reviewing the prescriptions associated with Brizuela's DEA number, agents confirmed that Brizuela was prescribing "very unusual . . . dangerous cocktails" of opioids and other drugs. J.A. 215–16.

As a result, federal and state investigators executed a search warrant to obtain patient files, medical charts, insurance documents and other materials from Brizuela's Morgantown practice. Among the items seized were pre-signed, blank prescriptions from Brizuela's prescription pad as well as sheets from his prescription pad that had been dated and filled out with the type of controlled substance to be prescribed, but not signed. On the day of the raid, Brizuela voluntarily surrendered his authority to prescribe Schedule II controlled substances, including oxycodone. Notably, Brizuela told investigators that he was relieved to give up his Schedule II prescribing authority because the patients receiving Schedule II drugs from him were "pill-seekers and addicts" that he no longer wished to treat. J.A. 223–24.

Federal investigators also reviewed 404 patient files seized from the Morgantown office to evaluate whether Brizuela subjected his opioid-prescribed patients to regular urine drug tests. Such tests help ensure that patients are taking the prescribed opioids, abstaining from illegal drugs or other illicit substances and not diverting opioids to other users. An "inconsistent" urine test—a test showing the presence of street drugs, drugs not prescribed by the doctor or such a low level of the prescribed opioid as to suggest that it is being diverted to another person—alerts a doctor to at least reconsider, or possibly stop, prescribing that patient opioids. When federal investigators reviewed Brizuela's patient

files, they found that 253—or about 63%—contained at least one inconsistent urine drug screen test, and 170—or about 42%—contained multiple inconsistent urine drug screens. Moreover, emails between Brizuela and the testing lab showed that he prescribed opioids to his patients prior to, and sometimes without ever, receiving the results of urine drug screens tests. In one email, Brizuela warned the lab that that the lack of timely test results "is going to get us in trouble . . . ." J.A. 762.

A federal grand jury indicted Brizuela on 21 counts of distributing controlled substances outside the bounds of professional medical practice, each related to specific prescriptions written for five of Brizuela's patients, in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(C);[4] one count of conspiracy to distribute controlled substances outside the bounds of professional medical practice, in violation of 21 U.S.C. §§ 841(a)(1), (b)(1)(E)(i), (b)(1)(E)(iii), 846; and 16 counts of illegal remuneration in violation of the federal anti-kickback statute, in violation of 42 U.S.C. §§ 1320a-7b(b)(1)(B).[5] The conspiracy charge was later dismissed at the government's request.

The case proceeded to trial. The government called two of the five patients whose treatments were the subject of the indictment to testify about the prescriptions they received

[4] *See United States v. Moore*, 423 U.S. 122, 124 (1975) (holding "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice"); *see also United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) ("[A] licensed physician who prescribes controlled substances outside the bounds of his professional medical practice is subject to prosecution and is no different than a large-scale pusher.")

[5] Because the jury acquitted Brizuela of the kickback charges, we have not described the evidence related to the prosecution or defense of those charges.

from Brizuela. It also called four of Brizuela's other patients to testify, although none of Brizuela's charges related to their treatment.

The government also called Robin Price and Louis Tennant, two of Brizuela's former receptionists, to testify about the operation of the Morgantown office. They testified that, although opioid prescriptions are usually not supposed to be refilled without regular in-person evaluations, Brizuela often went months without seeing patients to whom he was prescribing controlled substances. Tennant also stated that she routinely took Brizuela's prescription pad home, filled out patients' refill prescriptions and brought the prescriptions to the office for Brizuela to sign. According to Tennant, she completed around 500 prescriptions a month under this process, but never observed Brizuela comparing the prescriptions she completed with patients' medical charts.

Tennant and Price said that Brizuela's patients travelled from as far away as Virginia, Maryland and Ohio to receive opioid prescriptions. They described how some patients who came into the office looked "stoned," "high" or "glassy-eye[d]," and how they could become hostile if they did not quickly receive their refill prescriptions. J.A. 503, 573. Tennant also testified that she overheard patients discuss selling their prescriptions and that Brizuela was aware of such information. And Price noted that urine drug test results would often sit unreviewed on Brizuela's desk, while patients continued to receive opioid prescriptions. Price also stated that as far as she knew, those urine tests were the only way that Brizuela monitored whether his patients were using their controlled substances properly.

In addition, the government called Debbie Shepard, the Executive Director of the West Virginia Board of Osteopathic Medicine. Testifying not as an expert but as head of the state governing body, Shepard explained that the Board received a complaint from the mother of one of the patients whose treatment was included in the charges against Brizuela. She also explained that in West Virginia, osteopathic doctors are prohibited from either pre-signing prescription pads or prescribing controlled substances if the doctor knows or has reason to know that a patient is abusing or diverting controlled substances. Shepard also testified that physicians are required to properly document patient treatment—including the in-person examination and other justifications for prescribing a controlled substance—and to self-report any violations of the rules. She stated that Brizuela did not self-report any violations to the West Virginia Board of Osteopathic Medicine relating to the charged activity.

The government also called Dr. Patrick Marshalek, a specialist in psychiatry and addiction medicine. As the medical director of West Virginia University's Chestnut Ridge Center, he treats patients with opioid use disorders and has experience treating patients with chronic pain. Marshalek was admitted as an expert in pain management without objection.

Marshalek described the medical standards for doctors prescribing controlled substances. He stated that doctors must thoroughly assess patients by exploring their history and performing in-person, physical evaluations to identify whether they have legitimate pain or are simply seeking drugs. They must, Marshalek opined, also assess whether the medical benefits of prescribing a patient opioids outweigh the patient's unique

risk factors, and must then discuss those risks with patients to receive informed consent for a course of treatment.

Marshalek testified that doctors must closely monitor patients' use of controlled substances by utilizing options such as urine drug tests and pill counts to ensure patients are using the correct amount of medication. He also told the jury that doctors who become aware that their patients are abusing or misusing opioid prescriptions must intervene and alter the patient's treatment. For example, according to Marshalek, a doctor could stop administering the drug and refer the patient to addiction treatment or could continue prescribing the drug with increased monitoring. Marshalek testified that, if patients continue to abuse the drugs, doctors should stop prescribing them because the patient is a danger to themselves and others.

Marshalek reviewed the files of the five patients who received the prescriptions charged in Brizuela's 21 unlawful distribution counts. He also reviewed each patient's prescription data on the West Virginia Board of Pharmacy's Prescription Monitoring Program database and memoranda of interviews with the patients and their families. After discussing Brizuela's treatment of each patient, he opined that each of the charged prescriptions were issued outside the bounds of professional medical practice.

In response, Brizuela called Dr. Bruce Nicholson, an anesthesiologist with a specialty in chronic and acute pain management, and the Director of the Division of Pain Medicine for the Lehigh Valley Health Network. Nicholson testified that upon reviewing the files of the five patients who received the prescriptions charged in the indictment, all 21 of the prescriptions listed in the unlawful distribution charges were issued within the

bounds of professional medical practice. Nicholson said that while there is no standard, "concrete way" to treat a patient's chronic pain, J.A. 1157, Brizuela "adhered to the standard of care" in issuing the charged prescriptions, and "practiced within the guidelines of his medical professional competency and capabilities." J.A. 1160. Brizuela also testified, largely consistent with the opinions offered by Dr. Nicholson.

After a seven-day trial, the jury found Brizuela guilty of fifteen counts of distribution of controlled substances outside the bounds of professional medical practice, but acquitted him of six distribution counts and all sixteen counts of illegal remuneration in violation of the federal anti-kickback statute. Later, the district court sentenced Brizuela to 48 months in prison and 3 years of supervised release.

Brizuela timely filed his notice of appeal. This Court has jurisdiction under 28 U.S.C. § 1291.

II.

Brizuela argues the district court erred by admitting the testimony of patients who Brizuela treated, but whose treatment was not the basis for his criminal charges. Because this is a challenge to an evidentiary ruling, we review for an abuse of discretion. *United States v. Faulls*, 821 F.3d 502, 508 (4th Cir. 2016). "A court has abused its discretion if its decision is guided by erroneous legal principles or rests upon a clearly erroneous factual finding." *United States v. Johnson*, 617 F.3d 286, 292 (4th Cir. 2010) (internal quotation marks omitted).

With that standard of review in mind, we turn to the testimony of the patients whose treatment was not included in the indictment. The 21 prescriptions charged in Brizuela's indictment were written for five patients. Only two of these patients testified at trial. However, the government also called four other patients who Brizuela treated, but whose prescriptions were not the basis for any of the charges in the indictment, to testify at trial.

Before trial, the government filed a notice under Federal Rule of Evidence 404(b), alerting the district court and Brizuela of its intent to introduce the testimony of those four other patients. It argued that this evidence was admissible under *Kennedy* because it was "necessary to complete the story of the crime on trial." J.A. 91 (quoting *Kennedy*, 32 F.3d at 886). Specifically, the government argued that this testimony provides "[e]vidence that [Brizuela] consistently failed to follow generally recognized procedures," which "tends to show that in prescribing drugs he was not acting as a healer but a seller of wares." J.A. 91 (quoting *United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005)). It claimed that this testimony could be used "[t]o prove the criminal violation" because it "show[ed] the extent and severity of [Brizuela's] violation of a professional norm." J.A. 91. Alternatively, the government also argued that the testimony was admissible under Rule 404(b)(2) because it showed that Brizuela did not issue the 21 prescriptions charged in the indictment due to a mistake or accident.[6] The district court overruled Brizuela's objection and allowed the government to introduce the testimony.

[6] On appeal, the government makes two additional admissibility arguments for the first time. First, it argues that the testimony of McCabe, Haraczy, Lively and Walker was necessary because Brizuela asserted at trial that the government "cherry-picked" the five

Amy McCabe was the first patient whose treatment was not part of the indictment to testify. She stated that both she and her husband are recovering opioid addicts and former patients of Brizuela. She testified that when she started seeing Brizuela for her migraine headaches, he never asked for medical records or conducted any tests to determine their cause. Despite this, and her history with opioid addiction, Brizuela prescribed McCabe and her husband opioid pain medication. She testified that she twice failed her urine drug tests and, on one of her failed screenings, Brizuela wrote that she was at risk for sudden death. However, she said that Brizuela neither directly discussed her failed drug screens nor warned her of her risk of death. Instead, he continued to prescribe her the same opioids.

Next, Brennan Haraczy testified about his treatment by Brizuela. Like McCabe, his treatment was not the basis for any of Brizuela's charges. Haraczy said Brizuela prescribed him oxycodone, an opioid pain medication, for a pinched nerve in his shoulder. Haraczy testified that Brizuela did not warn him of the addiction risk posed by taking opioids or the dangers of mixing oxycodone with other types of drugs. Within the first month, Haraczy became physically dependent on the medication. He testified that he sometimes took up to

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patients and 21 prescriptions cited in the indictment to make their case J.A. 196, 1744. Second, the government argues that their testimony is also admissible under Rule 404(b) to rebut Brizuela's good-faith defense. *See United States v. Hurwitz*, 459 F.3d 463, 476 (4th Cir. 2006) ("[A] doctor's good faith generally is relevant to a jury's determination of whether the doctor acted outside the bounds of medical practice or with a legitimate medical purpose when prescribing narcotics."). Because these arguments were not presented to or considered by the district court, we do not consider them now. *Hodges v. Thompson*, 311 F.3d 316, 320 n. 3 (4th Cir. 2002) (citation omitted); *see also Wratchford v. S. J. Groves & Sons Co.*, 405 F.2d 1061, 1063 (4th Cir. 1969) ("Ordinarily, of course, a party should not be allowed to change the theory of his case after trial . . . .").

15 pills at once, at times mixing the oxycodone with marijuana, Xanax, Ativan and anxiety medication that he got off the street. Even so, Brizuela never, according to Haraczy, indicated that there was a problem with his urine drug screen tests. Haraczy also explained that his monthly in-person evaluations only lasted "[a] couple of minutes, at tops." J.A. 612. He stated that it took him three years after he stopped seeing Brizuela to get clean of opioids, and that he "lost everything" because of his addiction. J.A. 615.

The government also questioned Haraczy about Brizuela's treatment of his deceased mother. When Brizuela objected, the government argued that Haraczy's testimony about Brizuela's treatment of his mother was "part of the picture" of the crimes on trial because his mother was "[a]nother patient dependent." J.A. 611. The district court allowed this testimony as "background information concerning the course of [Brizuela's medical] practice . . . ." J.A. 611. Haraczy then testified that his mother was so physically dependent on the opioids that Brizuela prescribed that "[s]he would be sick" if she did not take them. J.A. 610.

Finally, Jennifer Lively and her wife, Donna Walker, testified about the treatment they received from Brizuela. Like McCabe and Haraczy, their treatment was not the basis for any of the charges in the indictment. Although Brizuela prescribed both Lively and Walker a combination of opioids and Xanax, they each stated that Brizuela did not warn them about the risk of addiction or discuss what drug combinations could be dangerous. Lively testified that she became so physically dependent on her oxycodone that she would get "deathly sick" if she did not take it. J.A. 661. On one occasion, her withdrawal symptoms were so bad that she had to be put on life support. Walker said that when she

called Brizuela from the hospital to talk about Lively's condition, he "cussed [her] out several times." J.A. 681. Lively and Walker testified that they witnessed a doctor from the hospital tell Brizuela over the telephone that Lively "was in withdrawals due to the medication" Brizuela prescribed her. J.A. 668. Upon Lively's release, she said Brizuela continued to prescribe her oxycodone and Xanax without ever mentioning her time in the hospital or discussing her addiction.

Lively and Walker also testified more generally about their interactions with Brizuela. Lively testified that Brizuela told her about internet posts claiming that he was "a bad physician" and that "if anybody wanted pills to go to him." J.A. 669, 680. Walker also noted that Brizuela once "threw a temper tantrum" and "stomped his feet in the middle of his . . . office" when she asked to change prescriptions because of the way it made her feel. J.A. 678. She also told the jury that she once witnessed him "cuss[] out" a nurse. J.A. 679.

On appeal, Brizuela argues that the district court erred in admitting the testimony of these four patients under the "*Kennedy* doctrine," which allows courts to admit evidence of uncharged acts or crimes if they are "necessary to complete the story of the crime on trial." *Kennedy*, 32 F.3d at 885 (internal alteration and citation omitted). He claims that the admission of this evidence constituted an "unduly expansive interpretation of *Kennedy*" that "eviscerates the protections intended to be conferred through Rule 404(b)'s general prohibition on the introduction of other crimes, wrongs, or acts." Appellant's Opening Brief at 14. Brizuela argues that the government introduced the testimony as propensity evidence because it "did not relate in any way to his treatment of those patients charged in

the indictment," and was "introduced solely to create an impression before the jury that [he] had a gaggle of allegedly pill-addicted patients." Appellant's Opening Brief at 18.

After considering these arguments and the government's responses, we agree with Brizuela that the district court abused its discretion in admitting the challenged testimony under *Kennedy*'s "complete the story" doctrine. We also reject the government's alternative argument that the evidence was properly admitted under Fed. R. Evid. 404(b)(2) to show that Brizuela's violations were not the result of accident or mistake. Last, we conclude that the government did not meet its burden of establishing that the district court's error was harmless.

A.

Federal Rule of Evidence 404(b) prohibits admitting evidence of another "crime, wrong, or other act . . . to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). Such "propensity evidence is excluded because it might 'overpersuade' a jury and cause them to 'prejudge one with a bad general record.'" *United States v. Queen*, 132 F.3d 991, 995 (4th Cir. 1997) (quoting *Michelson v. United States*, 335 U.S. 469, 475–76 (1948)). But the Rule allows the admission of evidence of other acts or crimes if used to prove "motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed. R. Evid. 404(b)(2).

Critically, however, "not all prior 'bad act' evidence is encompassed by Rule 404(b)." *United States v. McBride*, 676 F.3d 385, 396 (4th Cir. 2012). Instead, the rule is "only applicable when the challenged evidence is extrinsic, that is, separate from or

unrelated to the charged offense." *United States v. Bush*, 944 F.3d 189, 195 (4th Cir. 2019) (internal quotations omitted). In contrast, acts that are a part of, or "intrinsic to, the alleged crime do not fall under Rule 404(b)'s limitations on admissible evidence." *Id.* at 195–96. (quoting *United States v. Chin*, 83 F.3d 83, 87–88 (4th Cir. 1996)).

When, as here, we are tasked with determining whether uncharged conduct is intrinsic to the charged offenses, we have consistently held that such conduct is intrinsic, and not barred by Rule 404(b), when it "arose out of the same . . . series of transactions as the charged offense, . . . or is necessary to complete the story of the crime on trial."[7] *Kennedy*, 32 F.3d at 886 (quoting *United States v. Towne*, 870 F.2d 880, 886 (2d Cir. 1989) (internal alteration omitted); *United States v. Sutherland*, 921 F.3d 421, 430 (4th Cir. 2019), cert. denied, 140 S. Ct. 1106 (2020); *McBride*, 676 F.3d at 396; *United States v. Palacios*, 677 F.3d 234, 245 (4th Cir. 2012); *United States v. Basham*, 561 F.3d 302, 326 (4th Cir. 2009); *United States v. Siegel*, 536 F.3d 306, 316 (4th Cir. 2008); *United States v. Stitt*, 250 F.3d 878, 887 (4th Cir. 2001); *see also United States v. Denton*, 944 F.3d 170, 186 (4th Cir. 2019); *United States v. Lipford*, 203 F.3d 259, 265 (4th Cir. 2000).[8] Our "complete the

[7] Although not argued here, we have also held that that evidence of uncharged acts is "intrinsic," and not prohibited by Rule 404(b), when the charged and uncharged conduct "are inextricably intertwined." *Bush*, 944 F.3d at 196 (citation omitted). But because neither the district court's decision, nor Brizuela's appeal, raise the related "inextricably intertwined" doctrine, we need not address its applicability to the challenged testimony.

[8] These holdings are consistent with the approach embraced by a number of our sister circuits. S*ee, e.g.*, *United States v. Quinones*, 511 F.3d 289, 309 (2d Cir. 2007); *United States v. Price*, 329 F.3d 903, 906 (6th Cir. 2003); *Lockett v. Anderson*, 230 F.3d 695, 709 n. 24 (5th Cir. 2000); *United States v. Ramsdale*, 61 F.3d 825, 830 (11th Cir. 1995). However, as Brizuela notes, other circuits have criticized or done away with similar

story" decisions reflect case-by-case, fact-based analyses. But to illustrate how uncharged conduct may or may not "complete the story" of charged offenses, we describe two of our prior decisions.

In *Kennedy*—this Court's seminal case on the "complete the story" doctrine— the defendant was charged with conspiracy to distribute, and possession with the intent to distribute, cocaine. *Kennedy*, 32 F.3d at 881. At trial, the district court admitted testimony describing Kennedy's drug distribution activities with suppliers not named in his federal indictment. *Id.* at 885. On appeal, Kennedy argued that the testimony constituted impermissible "other crimes" evidence under Fed. R. Evid. 404(b) because it described a separate conspiracy that involved different people and fell outside the conspiracy time period charged in the indictment. *Id.* We rejected this argument, holding that the testimony "constituted predicate evidence necessary to provide context to the [federally charged] drug distribution scheme . . . " because it "proved Kennedy's participation in drug distribution activities, and addressed Kennedy's sources for the cocaine that he supplied . . . during the charged conspiracy period." *Id.* at 885–86. Additionally, we held that the testimony "served as evidence of a subset of the charged conspiracy—Kennedy's own distribution network—that helped the jury to understand how Kennedy's group obtained its cocaine and how that group related to and became part of the bigger [drug] conspiracy." *Id.* at 886. As a result,

"completes the story" or "inextricably intertwined" theories of intrinsic evidence. *See, e.g.*, *United States v. Bowie*, 232 F.3d 923, 929 (D.C. Cir. 2000); *United States v. Gorman*, 613 F.3d 711, 719 (7th Cir. 2010); *United States v. Green*, 617 F.3d 233, 248 (3rd Cir. 2010).

we held that the testimony "did not constitute 'other crimes' evidence under Rule 404(b)" because it "served to complete the story of the crime on trial." *Id.* at 886 (citation omitted).

In contrast, in *United States v. McBride*, 676 F.3d 385, 389–90 (4th Cir. 2012), McBride was charged with possession of cocaine with the intent to distribute, stemming from a 2009 drug sale at the Nu Vibe Club in Clarendon County, South Carolina. At trial, the government elicited testimony—over McBride's Rule 404(b) objection—describing a 2008 encounter during which a confidential police informant attempted to purchase crack cocaine from McBride at his residence. *See id.* at 390–91. On appeal, we rejected the argument that the 2008 encounter arose out of the same series of transactions as, or completed the story of, his possession of cocaine at the club in 2009. *Id.* at 396. We explained "nothing that occurred at McBride's residence in January 2008 was necessary to 'complete the story' of the crimes alleged at the club." *Id.* Instead, the evidence was "relevant primarily to establish McBride's character as a 'drug dealer'" and constituted "the very type of evidence that the limitation imposed by Rule 404(b) was designed to exclude." *Id.* at 398.

While there are other cases in which we have applied this principle, these two decisions illustrate that for evidence of uncharged conduct to be admissible to "complete the story" of a charged offense, the evidence must be probative of an integral component of the crime on trial or provide information without which the factfinder would have an incomplete or inaccurate view of other evidence or of the story of the crime itself. For example, in *Kennedy*, the evidence proved the defendant's involvement with the charged conspiracy, explained to the jury where the conspiracy sourced its cocaine and

demonstrated how Kennedy's network fit into the larger drug distribution operation. *Kennedy*, 32 F.3d at 885–86. In contrast, the challenged evidence in *McBride* was simply another drug deal that was never connected, and did not add any information to, the drug crimes for which McBride was charged. *McBride*, 676 F. 3d at 396.

And importantly, these decisions also make clear that evidence must be "necessary" to "complete the story" of the charged offense. *Kennedy*, 32 F.3d at 885. This requires a hard look to ensure that there is a clear link or nexus between the evidence and the story of the charged offense, and that the purpose for which the evidence is offered is actually essential. Otherwise, the "complete the story" doctrine might be used to disguise the type of propensity evidence that Rule 404(b) is meant to exclude.

B.

With this background in mind, we turn to the testimony of McCabe, Haraczy, Lively and Walker. From our review of the record, their testimony was not necessary to "complete the story" of the charged offenses and, therefore, described conduct that was extrinsic to the offenses for which Brizuela was charged. First, the testimony does not describe acts that "arose out of the same . . . series of transactions as the charged offense[s] . . . ." *Kennedy*, 32 F.3d at 885 (citation omitted). Under the CSA and accompanying regulations, registered doctors are prohibited from writing a prescription for controlled substances if the prescription is not "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (quoting 21 C.F.R. § 1306.04(a) (2006)). Accordingly, a doctor "knowingly . . . issuing *such a purported prescription* shall be subject to the penalties

provided for violations" of § 841. *See id.* (emphasis added, internal alterations omitted). An unlawful distribution violation under § 841 is, therefore, charged by citing a specific prescription. Each of Brizuela's § 841 charges properly identified a different prescription that he wrote for one of five patients.

For each of these charges, the "transaction" in question was Brizuela writing the specific prescription listed in that count of the indictment. Significantly, the challenged testimony of the four other patients did not reference or encompass any of the 21 prescriptions listed in the indictment. Thus, none of the acts they described arose from the same transaction, series of transactions or single criminal episode as the charged offenses. The district court indicated as much when, for example, it allowed Haraczy to testify about Brizuela's treatment of his mother. In that instance, it warned the jury that "there's been no charge in this indictment" related to Brizuela's treatment of her, and that it was only to serve as "background information concerning the course of [Brizuela's medical] practice . . . ." J.A. 611. Importantly, the warning did not connect the testimony to the charged offenses.

Second, none of the conduct described by these four patients was "necessary to complete the story of the crime[s] on trial." *Kennedy*, 32 F.3d at 885 (internal alteration and citation omitted). The testimony did not, for example, offer facts that were necessary to prove a specific element of a charged offense or provide information that was essential to understanding how the offense was committed. Instead, the testimony offered *new* patient stories that were neither the basis for, nor necessary to prove, any of Brizuela's charges. These new stories constituted "overkill" or "piling-on" by the prosecution, which

invited the jury "to find guilt by association or as result of a pattern," rather than examining whether sufficient evidence supported a conviction under each count in the indictment. *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1142 (4th Cir. 1994).

The government insists—as it did below—that the challenged testimony completed the story of Brizuela's § 841 charges by providing "evidence that [Brizuela] consistently failed to follow generally recognized procedures," which "tends to show that in prescribing drugs he was not acting as a healer but a seller of wares." J.A. 91 (quoting *United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005)). Therefore, it claims that the testimony was necessary "[t]o prove the criminal violation" because it "showed the extent and severity of [Brizuela's] violation of a professional norm." J.A. 91.

It is certainly true that in prosecuting doctors for unlawfully distributing controlled substances under § 841, the government must prove "beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice." *Alerre*, 430 F.3d at 690 (internal quotation marks omitted). And we have previously allowed "evidence that a physician consistently failed to follow generally recognized procedures [] to show that in prescribing drugs he was not acting as a healer but as a seller of wares." *Id.* at 691. But neither *Alerre* nor any other case identified by the government allow admitting the testimony of patients whose treatment was not the basis for a defendant's § 841 charges, or permit admitting uncharged acts that are not necessary to the stories of the prescriptions

cited in a § 841 charge.[9] *See Alerre*, 430 F.3d at 691; *United States v. McIver*, 470 F.3d 550, 561 (4th Cir. 2006).

As stated above, a doctor's violation of § 841 is prescription specific, and writing a prescription only violates § 841 if, in doing so, the doctor strays from bounds of professional medical practices *in treating that specific patient*. *See Tran Trong Cuong*, 18 F.3d at 1142; *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995). Therefore, the relevant "story" for a § 841 offense is whether in writing the cited prescription, the defendant doctor was treating *the patient receiving the prescription* within the bounds of professional medical practices.

Here, the government did not sufficiently connect the treatment of McCabe, Haraczy, Lively and Walker to the stories of the 21 prescriptions charged in the indictment. It simply claimed that their testimony "shows the extent and severity of [Brizuela's] violation of a professional norm." J.A. 91. This is not enough. *Kennedy* and our subsequent "complete the story" decisions require that the context provided by uncharged acts do more than simply show the "extent" and "severity," of alleged violations. Instead, they must "complete the story *of the crime[s] on trial*." *Kennedy*, 32 F.3d at 885 (emphasis added).

[9] In *Alerre*, the defendants were charged with conspiring to unlawfully distribute controlled substances, and the government's expert witness was permitted to review 88 randomly selected patient charts and opine that the defendants did not adhere to generally accepted medical standards in treating those patients. *Alerre*, 430 F.3d at 686. While "[i]t is well established that when seeking to prove a conspiracy, the government is permitted to present evidence of acts committed in furtherance of the conspiracy even though they are not all specifically described in the indictment," *see, e.g. United States v. Palacios*, 677 F.3d 234, 245 (4th Cir. 2012) (citation omitted); *United States v. Janati*, 374 F.3d 263, 270 (4th Cir. 2004), Brizuela did not face a conspiracy charge at trial.

To hold otherwise would not only misapply *Kennedy*, but would also render Rule 404(b) virtually toothless. In the absence of a clear link between other-acts testimony and the stories of the specific crimes on trial, the evidence cannot be admitted under *Kennedy*'s "complete the story" doctrine.

Finally, our precedent requires that uncharged acts must be "necessary" to complete the stories of the charged offenses. *See e.g. Kennedy*, 32 F.3d at 885. The government failed to directly address this necessity requirement below or on appeal. It certainly did not establish the testimony of McCabe, Haraczy, Lively and Walker was probative to an integral component of the crimes on trial or provided information without which the jury would have an incomplete or inaccurate view of other evidence or of the story of the charged crimes. Accordingly, for all of these reasons, the challenged testimony does not fall within *Kennedy*'s "complete the story" doctrine and is not otherwise intrinsic to Brizuela's § 841 offenses.

C.

We turn now to the government's alternative admissibility argument. In its pretrial Rule 404(b) notice, the government argued that if the challenged testimony was not admissible as intrinsic evidence under *Kennedy*, it was otherwise admissible under Rule 404(b)(2) because it showed that Brizuela did not issue the 21 charged prescriptions due to a mistake or accident. While the district court did not directly address the merits of this alternative argument, the government reiterates it on appeal.

Rule 404(b)(1) prohibits the admission of extrinsic evidence of a defendant's other crimes or bad acts to show that the defendant acted in conformity to those prior actions.

But other-acts evidence may be admitted if offered for a permissible purpose under Rule 404(b)(2). That subsection provides a non-exhaustive list of permitted purposes, which allow evidence of other acts or crimes to be admitted to prove "motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake or accident." *Queen*, 132 F.3d at 994 (quoting Fed. R. Evid. 404(b)(2)).

"The government bears the burden of establishing that evidence of a defendant's prior bad acts is admissible for a proper purpose." *United States v. Hall*, 858 F.3d 254, 266 (4th Cir. 2017). To meet this burden, the government must satisfy a four-prong test:

> First, [t]he evidence must be relevant to an issue, such as an element of an offense, and must not be offered to establish the general character of the defendant. Second, [t]he act must be necessary in the sense that it is probative of an essential claim or an element of the offense. Third, [t]he evidence must be reliable. And fourth, the evidence's probative value must not be substantially outweighed by confusion or unfair prejudice in the sense that it tends to subordinate reason to emotion in the factfinding process.

Hall, 858 F.3d at 266 (internal quotation marks and citations omitted). Here, the government cannot carry this burden.

To begin with, the government did not explain why the absence of a mistake or accident was probative of an essential element of the charged offenses. Moreover, at trial, Brizuela never asserted he wrote any of the 21 prescriptions charged in the indictment due to a mistake or an accident. To the contrary, he argued his conduct was appropriate and in the best interest of his patients. Since neither mistake nor accident was an issue below, evidence purportedly speaking to those issues is not relevant to or probative of an essential element of the charged offenses.

With good reason, we defer to the evidentiary judgments of district court judges who work on the front lines of trials like the one before us now. But despite this deference, it is our responsibility to ensure that evidentiary judgments are not based on erroneous legal principles. In that regard, our review of this record reveals that the testimony about uncharged conduct was neither necessary to complete the story of the charged offenses, nor proper to show mistake or accident under Rule 404(b)(2). Consequently, we conclude that the district court abused its discretion in admitting the testimony of McCabe, Haraczy, Lively and Walker at trial.

D.

However, our determination that the district court abused its discretion in admitting the challenged testimony does not end our inquiry. Under Federal Rule of Criminal Procedure 52(a), once we determine that the district court erred, we will not vacate the conviction if the error was harmless. An error is harmless if "we can say with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the error." *McBride*, 676 F.3d at 400 (internal quotation marks and citation omitted). In making this determination, the question is not "whether we believe that irrespective of the error there was sufficient untainted evidence to convict but, more stringently, whether we believe it highly probable that the error did not affect the judgment." *Id.* (quoting *United States v. Ince*, 21 F.3d 576, 583 (4th Cir. 1994)).

Critically, the government—as the beneficiary of the error—bears the burden of establishing that the error was harmless. *United States. v. Curbelo*, 343 F.3d 273 (4th Cir.

2003). Despite that, the government did not even argue in its brief that the admission of the testimony about uncharged conduct, if in error, was harmless. While we may address the issue on our own initiative, *United States v. Peay*, 972 F. 2d 71, n* (4th Cir. 1992) (Luttig, J. concurring),[10] we should avoid doing so when, as here, the question of harmless error is close. *See United States v. Pryce*, 938 F. 2d 1343, 1348 (D.C. Cir. 1991) (addressing harmless error despite government's failure to argue the issue in its brief because the record was straightforward and its harmlessness was beyond reasonable debate).

To be sure, there was significant evidence of Brizuela's guilt aside from the evidence of uncharged conduct. Among that evidence was the fact that, although only two of the five patients whose treatment was the subject of the indictment testified, the government's expert detailed the treatment of all five patients. Further, the government

[10] A different, but related, question is whether the government's failure to argue harmless error waives the issue. While this Court has not addressed this issue head on, we have indicated, albeit in dicta, that such a failure may waive harmless error review. *See United States v. Hall*, 858 F.3d 254, 280 n. 8 (4th Cir. 2017) and *Thomas v. Berryhill*, 916 F.3d 307, 314 n. 7 (4th Cir. 2019). But we have also explained that harmless error, under Rule 52, is a standard of review. *United States v. Massenburg*, 564 F.3d 337, 345 & n. 3 (4th Cir. 2009) (discussing the "plain error standard of review" and the "harmless error standard of review"). And "[o]ur case law is clear that 'parties cannot waive the proper standard of review by failing to argue it' or by consenting to an incorrect standard." *United States v. Venable*, 943 F.3d 187, 192 (4th Cir. 2019) (quoting *Sierra Club v. United States Dep't of the Interior*, 899 F.3d 260, 286 (4th Cir. 2018)); *see also United States v. Williams*, 641 F.3d 758, 770–773 (6th Cir. 2011) (Thapar, J., concurring) (stating that "courts of appeals, . . . routinely hold that standards of review are not waivable," and compiling cases from various circuits). These cases, along with *Peay*, suggest that, since a standard of review determines how an appellate court reviews an issue and not whether it reviews it, it cannot be waived. Because we resolve the question of harmless review on the government's failure to carry its burden of showing harmless error, we need not resolve this waiver issue today.

offered compelling testimony from an expert, the head of the state regulatory body and Brizuela's former employees supporting its theory that Brizuela's treatment of those five patients was outside the bounds of professional medical practice. Finally, the district court issued a limiting instruction concerning the uncharged conduct which, the jury's split verdict suggests, minimized the prejudice of the court's error.

But the record also supports the argument that the error was not harmless. From a sheer numerical standpoint, twice as many patients testified about uncharged conduct as those who testified about charged conduct. And aside from the numbers, the testimony of the patients whose treatment was not charged was sympathetic and dramatic. Also, the fundamental issue presented by each § 841 charge—whether Brizuela's conduct was outside the bounds of medical practice—is not, by its very nature, subject to a clear-cut answer. Thus, because there was conflicting expert witness testimony on this fundamental issue, the evidence of uncharged conduct could have tipped the scales in favor of the government on the counts of conviction. Finally, the split verdict indicates the case was close, perhaps so much so that the erroneously admitted evidence was the deciding factor in securing Brizuela's convictions.

On this record, reasonable minds could differ on the question of harmless error. Facing that close question, we decline to find the error was harmless on our own initiative and will not "relieve the government from the consequences of its failure to raise the issue of harmlessness on appeal." *United States v. Giovannetti*, 928 F.2d 225, 227 (7th Cir. 1991). Instead, we conclude that the government did not carry its burden of establishing

that the district court's error was harmless and Brizuela's convictions must, therefore, be vacated.

III.

We dispense with oral argument because the facts and legal contentions are adequately presented in the materials before this Court and argument would not aid the decisional process. For the foregoing reasons, the decision of the district court is

REVERSED AND REMANDED FOR A NEW TRIAL.