In the

United States Court of Appeals

For the Seventh Circuit

No. 19-2890

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

PAUL ELMER,

Defendant-Appellant.

Appeal from the United States District Court for the
Southern District of Indiana, Indianapolis Division.
No. 1:17-cr-113 — **James R. Sweeney, II**, *Judge*.

ARGUED SEPTEMBER 16, 2020 — DECIDED NOVEMBER 19, 2020

Before EASTERBROOK, MANION, and SCUDDER, *Circuit Judges*.

SCUDDER, *Circuit Judge*. Paul Elmer owned and operated multiple healthcare-related companies including Pharmakon Pharmaceuticals. His pharmacy produced and distributed drugs that Elmer knew were dangerous. Rather than halting manufacturing or recalling past shipments, sales continued and led to the near death of an infant. Federal charges followed for Elmer's actions in preparing and selling drugs that

contained more or less of their active ingredient than advertised. A jury returned a guilty verdict on all but one count. Elmer now appeals several of the district court's rulings related to the evidence admitted at trial and his sentence. The evidence before the jury overwhelmingly proved Elmer's guilt. And the district court's imposition of a sentence of 33 months' imprisonment was more than reasonable given the gravity of Elmer's crimes. We therefore affirm.

I

Through a process known as compounding, Pharmakon mixes and distributes drugs—including potent opioids like morphine and fentanyl—to hospitals across the United States. Federal regulations require such compounding pharmacies to comply with "Good Manufacturing Practices" regarding the potency of drugs and the sterility of the mixing and manufacturing process. Potency refers to the amount of the active ingredient in the drug. By way of an everyday example, consider Tylenol. The potency of Tylenol advertised as having 500mg of its active ingredient—acetaminophen—refers to whether each pill contains that precise amount of acetaminophen. Industry standards generally require compounded drugs like the ones Pharmakon produced to be within a potency range of 90–110%. Taking our Tylenol example, a 500mg pill would need to have between 450mg and 550mg of acetaminophen to comply with federal regulations. Test results showing compounded drugs outside of the required potency range are considered "out of specification."

Pharmakon conducted its own internal potency testing and contracted with a third party to perform additional testing to evaluate whether its compounded drugs had too little of the active ingredient (called "under-potent" drugs) or too

much (called "over-potent" drugs). Between 2014 and 2016, testing showed 134 instances of under- or over-potent drugs being distributed to customers.

The sale of these out-of-specification drugs risked disastrous consequences. In March 2014 Pharmakon shipped a sedative called Midazolam to a Community Health Network hospital in Indianapolis. The drug was twice as potent as indicated on the label, and before anyone caught the error, Community Health staff gave the drug to 13 infants in the hospital's neonatal intensive care unit. The administration of the overly potent Midazolam risked causing severe respiratory distress, as the infants who received the drug were already on ventilators. Fortunately, none of the babies died or went into respiratory arrest.

Two years later, in February 2016, Pharmakon again sent Community Health an over-potent batch of drugs—this time morphine sulphate. The doses contained 25 times the amount of morphine indicated on the label. Once again unaware of Pharmakon's egregious compounding error, a Community Health nurse gave this ultra-concentrated morphine to a 12-month-old child. The infant immediately went into respiratory arrest and survived only because doctors were able to administer three different doses of Narcan, a medication for reversing the effects of opioid overdose.

These events did not go unnoticed. Community Health reported the incidents to the Food and Drug Administration. Upon receiving the first of these reports in April 2014, the FDA sent investigators to Pharmakon, despite having just completed a routine inspection the prior month. During the inspection Caprice Bearden, Pharmakon's Director of Compliance, lied to FDA officials when telling them that the

company had not received any out-of-specification test results. Bearden, in turn, told Elmer of this deception, and he too lied to the inspectors during the April investigation. Bearden and Elmer repeated the falsehoods multiple times, all as part of seeking to conceal the existence of out-of-specification results.

After Pharmakon's over-potent morphine nearly killed the infant in February 2016, the FDA once again sent inspectors to the company's Indiana campus. This time Elmer took a more active role in misleading the agency. He told Michelle Beland, a pharmacist at a related Pharmakon entity, to lie to the inspectors and pretend that she was the pharmacist at the facility under inspection. He also convinced Beland to try to prevent the actual pharmacist for that facility, Marcus Fields, from speaking to the inspectors, for Elmer worried that Fields would report Pharmakon's recurring issues with producing and shipping over- and under-potent drugs.

Elmer's efforts to hide the truth ultimately failed. After Fields came clean to the FDA inspectors, Bearden and Beland followed suit and eventually provided documentation revealing Pharmakon's misconduct, foremost the out-of-specification test results. Confronted with this evidence, Elmer still refused to recall Pharmakon's compounded drugs. The FDA responded by issuing a public safety alert and referred the case to the Department of Justice for criminal investigation.

In June 2016 a federal grand jury issued a ten-count indictment charging Elmer with conspiracy to defraud the FDA (18 U.S.C. § 371); introducing adulterated drugs into interstate commerce (21 U.S.C. §§ 331(a), 333(a)(1) & 351); and adulterating drugs being held for sale in interstate commerce (21 U.S.C. §§ 331(k), 331(a)(1) & 351). A superseding

indictment added a charge for obstructing justice (28 U.S.C. § 1505). Elmer chose to go to trial on all charges.

Several Pharmakon employees (including Bearden, Beland, and Fields) testified against him. So too did various FDA inspectors and Community Health Network medical staff testify at trial. The government also introduced emails from a Pharmakon employee who conducted internal testing. These emails showed Elmer being urged to address multiple instances of out-of-specification test results. He never did so. In short, the evidence that Elmer was aware of and directed the efforts to conceal out-of-specification test results from the FDA was overwhelming.

The trial ended with the jury returning guilty verdicts on the conspiracy count and all nine counts related to the adulterated drugs. The jury acquitted Elmer on the obstruction count. The district court later sentenced him to 33 months' imprisonment. Elmer now appeals.

II

Elmer challenges two of the district court's evidentiary rulings. First, he contends the government, as part of proving the adulteration charges alleged in counts three through eleven, should not have been allowed to introduce evidence of 73 separate instances of out-of-specification test results. Second, he argues that the district court should never have allowed the jury to learn about the personal relationship he had with Pharmakon pharmacist Michelle Beland. We disagree on both fronts and see no abuse of discretion in the district court's evidentiary rulings. See *United States v. Buncich*, 926 F.3d 361, 367 (7th Cir. 2019) (explaining that abuse of discretion review is highly deferential and requires us to defer to

the district court absent any reasonable basis supporting its view).

A

We start with Elmer's challenge to the 73 out-of-specification test results. He insists these tests were evidence of prior bad acts inadmissible under Federal Rule of Evidence 404(b) and unrelated to the nine counts of making or distributing adulterated drugs. Had Elmer been charged with only those nine counts, he might have a point. What he overlooks, however, is the indictment's conspiracy charge. The indictment alleged that Elmer's efforts to hide these out-of-specification results were an object of the conspiracy. In clear and precise terms, count one alleged that the conspiracy aimed to conceal from the public that "Pharmakon was compounding and distributing numerous drugs that were under- and over-potent." And therein lies the nexus with the evidence presented at trial: Elmer's concealment of the 73 out-of-specification test results from the FDA were overt acts taken in furtherance of the charged conspiracy.

The government stood on firm ground approaching proof of the charged conspiracy this way. Time and again we have said that "Rule 404(b) does not apply to direct evidence of the crime charged." *United States v. Ferrell*, 816 F.3d 433, 443 (7th Cir. 2015). Even more, we have noted "[s]pecifically, evidence directly pertaining to the defendant's role in a charged conspiracy is not excluded by Rule 404(b)." *United States v. Adams*, 628 F.3d 407, 414 (7th Cir. 2010). In no way were these out-of-specification test results prior bad act evidence: they constituted direct evidence of the conspiracy. The district court properly admitted this evidence.

B

Elmer fares no better in his challenge to Michelle Beland's testimony. Recall that Beland worked as a Pharmakon pharmacist and testified that Elmer instructed her to lie to FDA inspectors. Beland testified that Elmer told her to pretend to be sick so she would not have to speak to the inspectors during the March 2014 inspection. He also directed her to hide the fact that she did not work in the exact facility under inspection. Finally, Elmer implored Beland to ask Marcus Fields to also lie to the FDA—urging him to tell the inspectors that Beland was the lead pharmacist at the facility being inspected and to make no mention of the related facility where Beland actually worked.

Elmer does not challenge the admissibility of this testimony. Nor does he argue that the district court should have barred Beland from testifying altogether. He instead contends that the district court abused its discretion by allowing the government to elicit testimony of Beland's personal relationship with him. In the days leading to the February 2016 inspection, and for a few months afterwards, Beland and Elmer communicated frequently through text messages and phone calls. Some of these communications contained "sexual talk" and "dirty jokes."

Elmer moved before and during trial to exclude any reference to the nature of these communications, asking the district court to limit the government's description of his relationship with Beland to that of a mentor or father figure. The government defended the admission of this testimony on the grounds that it was necessary to show why Beland was willing to follow Elmer's instructions to lie to the authorities. The district court allowed Beland to offer limited testimony about

these personal messages with Elmer. But the court prevented her from reading the content of any particular message. The government complied with the district court's instructions and only generally referenced the personal and sexual content of some of the messages. The court likewise barred prosecutors from discussing any "salacious" details provided by Beland in a pre-trial interview.

We cannot say the district court abused its discretion in allowing but limiting Beland's testimony this way. To be sure, the safer course would have been to prohibit the government from making any reference to the sexual banter. But Beland's testimony on this topic was very general, lacking in prejudicial details and occupying less than ten pages in a 1,700-page trial transcript. See *United States v. Miller*, 688 F.3d 322, 329–30 (7th Cir. 2012) (concluding that a "brief reference" to prejudicial evidence did not amount to an abuse of discretion). Even if this was an abuse of discretion, any error was harmless in light of the overwhelming evidence of Elmer's guilt. See *United States v. Taylor*, 522 F.3d 731, 735 (7th Cir. 2008).

III

We come in closing to Elmer's challenge to his sentence. He asserts the district court, in computing the advisory sentencing range under the Sentencing Guidelines, improperly applied certain enhancements while also refusing to award him credit for accepting responsibility for his offense conduct. Elmer also argues that the sentence was substantively unreasonable given his health issues and family obligations.

The district court committed no error in applying a two-level vulnerable victim enhancement under U.S.S.G. § 3A1.1(b)(1). Elmer posits that the only victim of the charged

conspiracy was the FDA. Not so. Elmer ignores the way the Guidelines and our case law have defined "victim." The Guidelines commentary advises district courts that the enhancement applies to victims of "any conduct for which the defendant is accountable under § 1B1.3" if that victim is "unusually vulnerable due to age, physical or mental condition, or who is otherwise particularly susceptible to the criminal conduct." U.S.S.G. § 3A1.1 cmt. 2. Our case law has clarified that a person who has "experienced some actual or intended harm" from the relevant conduct qualifies as a vulnerable victim. *United States v. Johns*, 686 F.3d 438, 460 (7th Cir. 2012).

Multiple infants suffered actual harm and others faced astronomical risk as a result of Elmer's deception. It affronts reality to suggest an absence of vulnerable victims. Elmer was on notice, moreover, that infant patients could (and did) receive his company's drugs by no later than April 2014, when Community Health filed its first report of over-potency attributable to Pharmakon medications. Because these infant victims were "unusually vulnerable due to age," the district court had more than enough to impose the two-level vulnerable-victim enhancement.

Nor do we see any error with the district court's application of a two-level enhancement for Elmer's abusing a position of trust or using a special skill. See U.S.S.G. § 3B1.3. Elmer bases his objection on the view that his role in the conspiracy did not require any of the special skills he possessed as a licensed pharmacist. While that point is debatable—for example, Elmer often relied on his pharmaceutical knowledge in rebuffing inquiries from regulators and his staff—his larger problem is that the district court did not apply the two-level enhancement based on any use of a "special skill," but rather

because Elmer abused a "position of trust." Elmer entirely misses this point, even after the government pointed out this lapse in its briefing. Any challenge to the position-of-trust enhancement is therefore waived. See *United States v. Cook*, 406 F.3d 485, 487 (7th Cir. 2005) ("[A] waiver is a deliberate decision not to present a ground for relief that might be available in the law.").

The district court stood on equally sound ground in denying Elmer's request for acceptance of responsibility credit. Elmer never admitted wrongdoing or accepted responsibility for his grievous offense conduct. To the contrary, he chose to contest his guilt at trial, all along continuing to blame everyone around him, including at sentencing and indeed throughout this appeal. Refusing to find that Elmer accepted responsibility under these circumstances is not clear error and comes nowhere close, as Elmer claims, to imposing a "trial tax" in violation of the Sixth Amendment right to a speedy and public trial. See *United States v. Saunders*, 973 F.2d 1354, 1363 (7th Cir. 1992) ("As long as the leniency decision is an individualized one, not based merely on the defendant's decision to go to trial, a defendant's constitutional rights are not impaired.").

Finally, the district court's imposition of a 33-month sentence was in no way substantively unreasonable. The sentence matched the low end of the advisory range and reflected the district court's application of the mitigating factors required by 18 U.S.C. § 3553(a), including Elmer's health conditions and his role as the sole caretaker for his wife who also suffers from serious medical conditions. The law required no more of the district court. If anything, Elmer's sentence strikes us as meaningfully lower than the district court could have

imposed given the extreme risks, including to infant patients, posed by his offense conduct.

For these reasons, we AFFIRM.