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

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