

United States Court of Appeals For the First Circuit

No. 04-2316

UNITED STATES OF AMERICA,

Appellee,

v.

WALLACE E. GONSALVES, JR.,

Defendant, Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

[Hon. Ronald R. Lagueux, Senior U.S. District Judge]

Before

Boudin, Chief Judge,

Stahl, Senior Circuit Judge,

and Lynch, Circuit Judge.

Anthony M. Traini with whom Richard M. Egbert was on brief for appellant.

Donald C. Lockhart, Assistant United States Attorney, with whom Robert Clark Corrente, United States Attorney, Luis M. Matos and Lisa Dinerman, Assistant United States Attorneys, were on brief for appellee.

January 20, 2006

BOUDIN, Chief Judge. Wallace Gonsalves, Jr., an osteopathic doctor, conducted a solo medical practice in Cranston, Rhode Island. In 1971, he was certified as a "civil surgeon" with the former Immigration and Naturalization Service ("INS"), performing blood tests and administering immunizations to immigrants seeking permanent residence in the United States. Gonsalves, like most doctors, kept drugs in his office premises, including vaccines needed for immunizations.

In June 2002, Catherine Cordy, Chief of the Board of Pharmacy of the Rhode Island Department of Health ("DOH"), received an anonymous complaint about Gonsalves' medical practice, later determined to have come from Kelly Walsh. Walsh, a former employee, reported that Gonsalves was engaged in workers' compensation fraud and was illegally selling drug samples to a local pharmacist. Cordy referred this complaint to the Attorney General and the DOH's Board of Medical Licensure, and Walsh was interviewed on July 8, 2002.

Walsh told investigators that Gonsalves had instructed employees to immunize immigrant patients with diluted vaccines and to administer to those patients only a half-dose of the already-diluted vaccines. She also reported that Gonsalves was falsely certifying to the INS that patients had been tested for various diseases when no such tests had been performed and requiring payments of \$150-\$300 in cash (which he did not record in his

books) for the INS examination, even though the examinations were covered by the patients' insurance.

On August 16, 2002, the Rhode Island Attorney General's office executed a search warrant in Gonsalves' office for general patient and business records, the DOH executed an administrative subpoena for twelve specific patient records, and Cordy, relying on her statutory authority to inspect without a warrant locations where drugs are held, R.I. Gen. Laws § 21-31-21 (2004), conducted an inspection for misbranded or adulterated drugs. Cordy seized various drugs as misbranded or adulterated--evaluations later confirmed in testing by the Food and Drug Administration.

In due course, Gonsalves was indicted in federal court for drug adulteration and tampering, 18 U.S.C. § 1365(a) (2000) and 21 U.S.C. §§ 331(k), 333(a)(2) (2000), making false statements to the government, 18 U.S.C. § 1001 (2000), and tax violations, 26 U.S.C. §§ 7201, 7206(1) (2000). At trial, the government's evidence permitted a jury to conclude that Gonsalves was criminally responsible for, among other things, the dilution and improper storage of vaccines, false certifications to the INS that patients had been tested for HIV and syphilis, falsely reporting that patients had been properly immunized, and the failure to report over \$400,000 in income. The jury convicted Gonsalves on all submitted counts.

For these offenses, the district court sentenced Gonsalves to ten years in prison and fined him heavily. In the appeal now before us, Gonsalves does not dispute the adequacy of the evidence (save in one limited respect discussed below) but contests the refusal of the district court to suppress evidence against him, certain of the jury instructions, and alleged errors in his sentencing. The principal assault is on Cordy's search of Gonsalves' office and her seizure of vaccine samples, which provided much of the evidence against Gonsalves.

Prior to trial, Gonsalves moved to suppress the drugs thus seized on the basis that Cordy had conducted the search and seizure without a warrant. The district court denied the motion on the ground that the search and seizure fell within the "administrative exception" to the warrant requirement. Such an exception to the normal requirement--a warrant based on probable cause--applies where certain conditions are met. New York v. Burger, 482 U.S. 691, 702-03 (1987). See also United States v. Biswell, 406 U.S. 311, 317 (1972); Colonnade Catering Corp. v. United States, 397 U.S. 72, 76-77 (1970).

Ordinarily, administrative searches are permitted in highly regulated industries where authorized by a statutory scheme and where, in addition, the scheme furthers a substantial government interest, warrantless inspections are necessary to further this interest, and the scheme provides a constitutionally

adequate substitute for a warrant in terms of notice to those regulated and restrictions on the administrator's discretion. Burger, 482 U.S. at 702-03. In simplest terms, a pharmaceutical factory need not be treated as if it were someone's home.

Gonsalves' first objection to Cordy's administrative search of his office is that the medical profession should not be treated as a highly regulated enterprise. Whatever the status of the profession in the abstract, the statute in this case permits administrative searches of "establishments" where drugs are manufactured or stored, R.I. Gen. Laws § 21-31-21, and the seizure at issue is solely of drugs reasonably believed to have been misbranded or adulterated. Our focus, therefore, is on the regulation of drugs--not the practice of medicine in general.

In Rhode Island, as under federal law and in other states, drugs are heavily regulated in storage and dispensation and have been for many years. Mann v. Cannon, 731 F.2d 54, 59-60 (1st Cir. 1984); see also United States ex rel. Terraciano v. Montanye, 493 F.2d 682 (2d Cir.) (Friendly, J.), cert. denied, 419 U.S. 875 (1974) (pharmacy operations in New York). Rhode Island's Food, Drugs, and Cosmetics Act has been in effect for a half-century, 1956 R.I. Pub. Laws ch. 56 § 1 (codified at R.I. Gen. Laws §§ 21-31-1 to -23), and the pertinent provisions are numerous,

longstanding and pervasive.¹ The scheme readily passes the "closely regulated" test of Burger. 482 U.S. at 701.

Whether the practice of medicine in general meets this test is a different question that we need not decide. Compare Tucson Woman's Clinic v. Eden, 379 F.3d 531, 549-51 (9th Cir. 2004). Nor are we concerned on this appeal with patient records; Cordy's search and seizure was solely directed to misbranded and adulterated drugs held at large in Gonsalves' office. Given the variations in fact patterns and the sensitivity of the subject area, there is good reason to keep our focus narrow and, for the time being, to let the law develop case by case.

The other three conditions for an administrative search are that the scheme serve a substantial government interest, that administrative (warrantless) searches be "necessary," and that the scheme impose alternative safeguards. Burger, 482 U.S. at 702-03. The first is obviously satisfied and the second is adequately covered by case law explaining the need for random and surprise inspections, United States v. Maldonado, 356 F.3d 130, 135-36 (1st

¹See R.I. Gen. Laws §§ 21-28-3.12 (requiring practitioners who administer controlled substances to keep records of receipt and dispensation); 21-28-3.13 (requiring manufacturers and wholesalers to keep records of controlled substances received and disposed of); 21-28-3.17 (requiring these records to be open for inspection); 21-31-3(1) (prohibiting the "holding . . . for sale" of any misbranded or adulterated drug). See also 21 U.S.C. § 374(a)(1) (providing for inspections "[f]or purposes of enforcement of this chapter").

Cir. 2004). Gonsalves does not make a frontal attack on either of these two conditions.

Instead, Gonsalves claims that the third condition--the "constitutionally adequate substitute for a warrant," Burger, 482 U.S. at 703--is not satisfied because neither the statute nor regulations under it (there are none) limit Cordy's discretion as to such searches. This overstates the matter: Cordy's authority was limited to entry "at all reasonable hours" to determine whether "any of the provisions of this chapter are being violated," and to "secure samples or specimens." R.I. Gen. Laws § 21-31-21. These are adequately specific limits on the timing and scope of the activity. Compare Burger, 482 U.S. at 711 ("during regular and usual business hours"); Biswell, 406 U.S. at 312 n.1 ("at all reasonable times").

Of course, the statute does not impose a probable cause or even a reasonable suspicion test as to when such inspections should be undertaken. As it happens, Walsh's complaint and follow-up interview arguably provided ample cause for the search. But the broader point is that administrative searches are allowed without probable cause precisely because of the character of the activity being regulated and the need for randomness and surprise to make such schemes effective. See Burger, 482 U.S. at 710; Maldonado, 356 F.3d at 135-36.

Ironically, Gonsalves' other main attack on Cordy's search and seizure of the vaccines stems from the fact that this search was not random but grew out of a specific charge of misconduct and was coordinated as to timing with the Attorney General's search.

Patently, the Attorney General did not use Cordy as a proxy to conduct his own warrantless search; the Attorney General secured a warrant and had probable cause. That Cordy coordinated the timing of her search with law enforcement authorities, so that neither side tipped off Gonsalves by acting alone, was not an evasion of the limits on either of them.

The question, then, is whether Cordy should be prevented from making a warrantless search because in this case it was not random and because she in fact had good cause to suppose a violation. To us the answer is self-evident: Gonsalves already had notice from the statute that his office was subject to administrative search for misbranded or adulterated drugs; and Cordy's administrative search was not more intrusive, or less justifiable, because she actually had suspicion or probable cause.

There is a 25-year-old Ninth Circuit decision that could be read as holding the contrary where specific cause exists for an administrative search. United States v. One Device Labeled Theramatic, 641 F.2d 1289, 1294 (9th Cir. 1981), cert. denied, 465 U.S. 1025 (1984). But that decision is pre-Burger, offers no

explanation for the surprising result, and conflicts with contrary rulings in the Ninth Circuit, United States v. Argent Chem. Labs., Inc., 93 F.3d 572, 577-78 (9th Cir. 1996), cert. denied, 520 U.S. 1115 (1997); United States v. Goldfine, 538 F.2d 815, 819 (9th Cir. 1976), and elsewhere, including this circuit. As we said in United States v. Wilbur, 545 F.2d 764, 766 (1st Cir. 1976):

A rule allowing federal agents to conduct a warrantless search of a [firearms] dealer's premises only until their suspicions were aroused, or, as here, the facts established probable cause, would make little sense.

Gonsalves points to language in Whren v. United States, 517 U.S. 806, 811-12 (1996), to the effect that the exemption from the warrant requirement for an administrative search extends only to searches made for administrative purposes. But Cordy's search did satisfy the administrative purpose of the statute--to protect consumers from misbranded and adulterated drugs--regardless of whether criminal proceedings might also ensue. This fact, regardless of Cordy's subjective intent, is dispositive. City of Indianapolis v. Edmond, 531 U.S. 32, 45-46, 48 (2000).

We come next to Gonsalves' challenge to the jury instructions. Context will be of assistance. Vaccines are typically provided in powder form and intended to be diluted with a sterile solution immediately before being administered; once reconstituted as solutions, they must be used promptly or discarded. Evidence permitted the jury to find that, for his

immigrant patients, Gonsalves had directed his staff to draw vaccinations from poorly marked water bottles stored for long periods in a refrigerator, the vaccine material itself being greatly diluted as well as aged.

Office records bore out the story. For example, Gonsalves' records for the period in question showed that 673 patients received chickenpox vaccines where Gonsalves' actual recorded supply was only 70 doses, 591 patients received measles, mumps, and rubella vaccines out of a supply of only 100 doses, and 499 patients received tetanus vaccines where Gonsalves had an actual supply of 90 doses. In addition, Walsh testified that Gonsalves had told her to give half-doses of the already diluted vaccines, and Walsh and another employee linked Gonsalves himself to the deliberate dilution of the vaccines.

Gonsalves' first objection to the instructions is that it was improper for the judge to allow the jury to convict if it found --as the instruction permitted--that the adulteration had been carried out not by Gonsalves personally but by others "at his direction." Gonsalves assumes that this reflects an aiding-and-abetting theory, notes that aiding and abetting was not charged in the indictment, and concludes that this was an impermissible constructive amendment of the complaint.

The premise of the argument is mistaken. A defendant who directs wrongdoing is guilty as a principal without regard to

aiding and abetting liability. 18 U.S.C. § 2 (2000); United States v. Rivera-Figueroa, 149 F.3d 1, 4 (1st Cir.), cert. denied, 525 U.S. 910 (1998). It is therefore beside the point that the government did not argue that Gonsalves was an aider or abettor or that the court did not give a standard aiding and abetting instruction. As it happens, aiding and abetting need not be separately charged to support an instruction. United States v. Keene, 341 F.3d 78, 84 (1st Cir. 2003).

Gonsalves is also mistaken in saying that the "at his direction" instruction was unsupported by the evidence. The evidence did not show just how Gonsalves had accomplished the dilution of the vaccines in each instance; implausibly, he denied any involvement whatsoever. But the evidence permitted the jury to infer that in different respects the wrongdoing had been done by Gonsalves himself, at his direction, or by either one of the two means (i.e., directly by him or at his direction), even though it might be uncertain which.

Gonsalves' next attack relates to the requirement, contained in the tampering statute that was one of the charges against him, that the tampering be done "with reckless disregard for the risk" of danger of death or bodily injury to another and "under circumstances manifesting extreme indifference to such risk." 18 U.S.C. § 1365(a). Where the term "recklessness" is used, the recurring question is whether some kind of conscious

indifference is required or whether objectively reckless behavior is enough. 1 LaFave, Substantive Criminal Law § 5.4 (2d ed. 2003). See also Boston Mut. Ins. Co. v. N.Y. Islanders Hockey Club, L.P., 165 F.3d 93, 96-97 (1st Cir. 1999).

Objectively reckless behavior is often strong evidence of conscious indifference, which certainly does not require admissions as to the defendant's subjective state of mind or other "direct" proof. See LaFave, supra, § 5.4(d). But conceivably, in some situations, one could be grossly careless in an objective sense without having a subjective awareness of or indifference to the risk being created. Accidents with rotating high-speed table saws provide more than a few examples of this situation.

We think that the better reading of the statute is that conscious or deliberate indifference to risk is required for conviction. This reading is supported by the statute's related reference to a requirement of "circumstances manifesting extreme indifference to such risk," 18 U.S.C. § 1365(a), and by clear-cut language in the committee report: "Because the possible penalty is so severe, the Committee believes that liability should be limited to those circumstances where the defendant consciously disregards a grave risk of serious danger to other persons." H.R. Rep. No. 98-93, at 5, as reprinted in 1983 U.S.C.C.A.N. 1257, 1259.

However, Gonsalves got instructions that gave him the equivalent of what we think Congress had in mind, namely, that

indifference to risk (connoting a state of mind)--and not mere carelessness (objectively reckoned)--was the minimum mens rea required. In addition to quoting the statutory requirement of "indifference to such risk," the court defined "reckless disregard," which is the more ambiguous of the two key phrases, in language sufficient to convey the idea of conscious disregard:

The phrase "reckless disregard" as used in these instructions, means that the defendant deliberately closed his eyes to what would otherwise have been obvious to him. No one can avoid responsibility for a crime by deliberately ignoring what is obvious. A finding beyond a reasonable doubt of an intent of the defendant to avoid knowledge or enlightenment would permit the jury to infer knowledge.

For convenience, we have underscored the connoting language, evidently adapted from standard "willful blindness" instructions usually used for a different purpose (i.e., as a substitute for "knowledge"). 1 Sand, et al., Modern Federal Jury Instructions ¶ 3A.01 (instruction 3A-2) (2005). This instruction is not the only way to convey the thought--explaining subjective recklessness is not easy--but it was sufficient. The precise choice of phrasing in jury instructions is reviewed with some deference, United States v. Teemer, 394 F.3d 59, 63 n.2 (1st Cir.), cert. denied, 125 S. Ct. 1964 (2005), and Gonsalves was not entitled to his particular choice of language.

As it happens, fine gradations as to the role of subjective awareness in recklessness cannot have mattered much on

the present facts. The government's evidence, which the jury evidently accepted, implicated Gonsalves in the systematic dilution of vaccines and misreporting of information over a substantial period. The idea that Gonsalves' conduct or directions were mere objective carelessness, as might be true if a few doses were mishandled, is unrealistic.

Gonsalves' next major concern is with the instructions on the interstate commerce nexus required for conviction on the tampering count, namely, that the product be one "that affects interstate or foreign commerce." 18 U.S.C. § 1365(a). The court charged that this could be satisfied in any of three alternative ways; Gonsalves objects only to one making it sufficient if "the drugs had been shipped in interstate commerce and had not yet reached the end user at the time of tampering." Both sides assume that "end user" means the patient.

Gonsalves argues that tampering at this stage is too late because the vaccines were no longer "in" interstate commerce once they came to rest in the doctor's office and were thereafter diluted. The objection was preserved and, while the jury may have rested on one of the alternative nexuses, we will not assume this to be so. Gonsalves' position finds some support in a Tenth Circuit decision, United States v. Levine, 41 F.3d 607, 613 (10th Cir. 1994), which has in turn been rejected by the Seventh Circuit,

Hays v. United States, 397 F.3d 564, 567 (7th Cir.), cert. denied, 126 S. Ct. 422 (2005).

The statute uses the phrase of art "affects interstate commerce," not the narrower phrase, "in commerce." By settled construction, the former reflects an intent to exercise Congress' full constitutional power. Citizens Bank v. Alafabco, Inc., 539 U.S. 52, 56 (2003); Allied-Bruce Terminix Cos. v. Dobson, 513 U.S. 265, 273 (1995). In such a case, it is clearly enough if the vaccines imported from out of state had "not yet" reached the consumer. Cf. United States v. Mennuti, 639 F.2d 107, 110-13 (2d Cir. 1981) (Friendly, J.), reasoning adopted by Jones v. United States, 529 U.S. 848, 854 n.6 (2000). Arguably, this quoted limitation was itself over-generous to Gonsalves.²

The next challenge concerns the instruction for the false statement counts under 18 U.S.C. § 1001. The core of the district court's charge on scienter was that the government was required to show that the "defendant knowingly made a material false statement" to the INS and "that the defendant made the statement voluntarily and intentionally," that is, knowing "that it was false or

²The Seventh Circuit in Hays said that it was enough that the product had once moved in interstate commerce, regardless of whether the tampering occurred later. 397 F.3d at 567-68. In other contexts, the courts have been willing to treat prior travel as sufficient. Compare Scarborough v. United States, 431 U.S. 563, 571-78 (1977) (firearm previously in interstate commerce).

demonstrat[ing] reckless disregard for the truth with a conscious purpose to avoid learning the truth."

Gonsalves says that a good faith instruction (which he requested) should have been given--a position not seriously developed and already rejected by the case law. United States v. Dockray, 943 F.2d 152, 155 (1st Cir. 1991). Then, more to the point, he argues that the scienter requirement for the offense was not sufficiently explained and that an "intent to deceive" instruction should have been given. It is debatable how far the full objection was preserved, but it warrants comment because of some tension in our own case law.

Two of our older cases associate section 1001 with an "intent to deceive" requirement. United States v. Manning, 955 F.2d 770, 773 (1st Cir. 1992); United States v. Corsino, 812 F.2d 26, 29 (1st Cir. 1987). Our more recent decisions impose no such requirement but do say that the false statement must be made knowingly and willfully. United States v. McGauley, 279 F.3d 62, 69 (1st Cir. 2002); United States v. Duclos, 214 F.3d 27, 33 (1st Cir. 2000). Normally, the more recent cases would control, but in this instance they govern also because the Supreme Court has itself rejected the claim that an "intent to deceive" is required. See United States v. Yermian, 468 U.S. 63, 73 (1984).

Willfulness--a term our cases do endorse--means nothing more in this context than that the defendant knew that his

statement was false when he made it or--which amounts in law to the same thing--consciously disregarded or averted his eyes from its likely falsity. See id. at 69. This is just what the district judge told the jury in this case, i.e., that the defendant made the statement knowing that it was false or demonstrating "reckless disregard for the truth with a conscious purpose to avoid learning the truth."

Gonsalves' final challenge to the jury instructions concerns the following statement made by the district court in advising the jury on its role of evaluating witnesses: "In this case, the defendant decided to testify. You should examine and evaluate his testimony just as you would the testimony of any witness with an interest in the outcome of the case." This, claims Gonsalves, inappropriately highlighted the fact that, as defendant, he had an interest in the outcome of the case, and may have prejudiced the jury against him.

In the past this court has held that certain instructions in this vein--but more egregiously phrased--amounted to error. See United States v. Dwyer, 843 F.2d 60, 63 (1st Cir. 1988); United States v. Rollins, 784 F.2d 35, 36-38 (1st Cir. 1986). The caution is still good law in this circuit but cannot be pressed too far. Indeed, in Reagan v. United States, 157 U.S. 301, 305-06 (1895), cited with approval in Portuondo v. Agard, 529 U.S. 61, 71 (2000), the Supreme Court expressly approved an instruction calling

attention to the testifying defendant's interest in the outcome.

In the present case, the reference to the defendant's interest was no different than the instruction given in Reagan or standard instructions used elsewhere. Sand, supra, ¶ 7.01 (instruction 7-4). It was immediately followed by the warning that "[y]ou should not disregard or disbelieve [Gonsalves'] testimony simply because he is charged as a defendant in this case." We think the instruction was not error and decline to extend Dwyer beyond its present reach.

Finally, Gonsalves in his opening brief urges us to depart from our decisions interpreting United States v. Booker, 125 S. Ct. 738 (2005), in which we have held that because the guidelines are now advisory, judicial fact-finding alone does not violate a defendant's sixth amendment rights so long as the defendant is sentenced at or below the statutory maximum for the offense of conviction. United States v. Antonakopoulos, 399 F.3d 68 (1st Cir. 2005). The invitation to reconsider Antonakopoulos is beyond both the panel's power and inclination.

Gonsalves argues that the Supreme Court's recent decision in Shepard v. United States, 125 S. Ct. 1254 (2005), somehow supports his position that adjustments in guideline calculations must be based on jury findings. Shepard involved determinations under the Armed Career Criminal Act, 18 U.S.C. § 924(e) (2000), that increased the statutory sentencing range and not merely the

guideline calculations. Whatever the scope of Shepard, it does not overrule Booker.

Gonsalves' further sentencing arguments do not merit detailed discussion. The only arguable error was that the district court may have departed upward without prior notice in imposing a fine of \$465,000 (the guideline maximum was \$175,000) because of the "vast greed" and self-enrichment of the defendant. Wisely, we think, the defendant at oral argument waived any request for a remand for re-sentencing under the new advisory guideline regime.

Affirmed.