

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	No. 2:25-cr-20032-SHL-1
)	
SANJEEV KUMAR,)	
)	
Defendant.)	

**ORDER GRANTING DEFENDANT’S MOTIONS TO DISMISS COUNTS 1–9, 12–13,
16–18, 21–22, 25 AND DENYING MOTION TO DISMISS OR NARROW COUNTS
10–11, 14–15, 19–20, 23–24, 26–36 OR TO STRIKE FELONY ENHANCEMENT**

Before the Court are three motions filed by Defendant Sanjeev Kumar, seeking to dismiss or limit certain counts of the Superseding Indictment (“Indictment”) returned on June 26, 2025 (ECF No. 70), or, in the alternative, to strike a felony enhancement. Kumar first filed the Motion to Dismiss Counts 1–4 of the Indictment (“First Motion to Dismiss”) on June 27, 2025. (ECF No. 74.) The Government responded two weeks later. (ECF No. 79.) Kumar replied the following week.¹ (ECF No. 81.) The Government was granted leave to file a sur-reply, and did so. (ECF No. 90.)

Kumar next filed the Motion to Dismiss Counts 5–9, 12–13, 16–18, 21–22, and 25 as Duplicitous (“Second Motion to Dismiss”) on July 10. (ECF No. 77.) The Government responded (ECF No. 83), and Kumar replied (ECF No. 91).

Then, on September 5, he filed the Motion to Dismiss Counts 5–26 and to Limit Counts 27–36 for Constitutional Vagueness and Insufficiency, or, in the Alternative, to Strike the

¹ There is no rule in this District that allows for replies to responses to motions in criminal cases. While the Court will consider Kumar’s replies here, in the future he is cautioned to seek permission to file replies, if he wishes to do so.

§ 333(a)(2) Felony Enhancement (“Third Motion to Dismiss”). (ECF No. 103.) The Government responded (ECF No. 108), and Kumar replied (ECF No. 110).

For the reasons stated below, the First Motion to Dismiss is **GRANTED**, the Second Motion to Dismiss is **GRANTED**, and the Third Motion to Dismiss is **DENIED**. As a result, Counts 1–9, 12–13, 16–18, 21–22, and 25 of the Indictment are **DISMISSED**.

BACKGROUND

Kumar operated the Poplar Avenue Clinic (“PAC”), a women’s health practice in Memphis, Tennessee. (ECF No. 70 at PageID 556.) The Government asserts that, between September 2019 and April 2023, Kumar “adulterated” single-use hysteroscopes in his clinic, that is, he reused on multiple patients the same disposable devices, which are instruments inserted through the vagina to inspect the uterus. (ECF No. 83 at PageID 661.) The Government alleges that Kumar performed “over 13,000 hysteroscopies with approximately 121 single use devices.” (*Id.*) The single-use devices were reused, the Government contends, “after being partially dipped in a liquid chemical disinfectant and briefly rinsed on the outside with tap water between most uses. This attempted reprocessing neither disinfected nor sterilized the instruments.” (*Id.*) According to the Government, Kumar later performed an additional 3,000 hysteroscopies using “a mix of single-use devices and reusable” versions between May 2023 and April 15, 2024. (*Id.*) However, the Government asserts that even the reusable versions were only partially cleaned “in a manner that fell well short of the manufacturer’s cleared instructions for use.” (*Id.* at PageID 661–62.) The Government recovered the devices on April 16, 2024, during a search pursuant to a warrant. (*Id.* at PageID 662.)

In addition to adulterating the devices, Kumar is also charged with “misbranding” the devices, meaning that he failed to add conspicuous labeling to the devices to indicate that they

had been reprocessed, as required by statute. (Id.) As a result, patients “had no way of knowing that the defendant and other providers at PAC were exposing them to used instruments that had only been cleared by the FDA for single use.” (Id.)

A federal grand jury returned the Indictment against Kumar containing the following thirty-six counts:

Counts 1–4: enticement and inducement to travel to engage in illegal sex acts, in violation of 18 U.S.C. §§ 2422(a) and 2;

Counts 5–15: adulteration of single-use medical devices, in violation of 21 U.S.C. §§ 331(k), 333(a)(1), 333(a)(2), 351(a)(2)(A), and 18 U.S.C. § 2;

Counts 16–24: misbranding of reprocessed single-use devices, in violation of 21 U.S.C. §§ 331(k), 333(a)(1), 333(a)(2), 352(v), and 18 U.S.C. § 2;

Counts 25–26: adulteration of hysteroscopes cleared for reprocessing, in violation of 21 U.S.C. §§ 331(k), 333(a)(1), 333(a)(2), 351(a)(2)(A), and 18 U.S.C. § 2; and

Counts 27–36: health care fraud, in violation of 18 U.S.C. §§ 1347 and 2.

(ECF No. 70.) Kumar seeks to dismiss or narrow all of these counts.

ANALYSIS

A defendant may seek dismissal of an indictment if he believes it “fails to invoke the court’s jurisdiction or to state an offense.” Fed. R. Crim. P. 12(b)(3)(B); see also United States v. Hackworth, 483 F. App’x 972, 979 (6th Cir. 2012). However, a party may only raise those pretrial defenses which “the court can determine without a trial on the merits.” Fed. R. Crim. P. 12(b)(1). In other words, resolution of a pretrial challenge to the indictment is appropriate “if trial of the facts surrounding the commission of the alleged offense would be of no assistance in

determining the validity of the defense.” United States v. Jones, 542 F.2d 661, 664 (6th Cir. 1976) (quoting United States v. Covington, 395 U.S. 57, 60 (1969)); see also United States v. Landham, 251 F.3d 1072, 1080 (6th Cir. 2001) (“[C]ourts evaluating motions to dismiss do not evaluate the evidence upon which the indictment is based.”). In ruling on a motion to dismiss, a court views the indictment as a whole and accepts its factual allegations as true. United States v. Palma, 58 F.4th 246, 250 (6th Cir. 2023).

Each Kumar motion is separately addressed below.

I. First Motion to Dismiss (ECF No. 74)

Kumar seeks dismissal of Counts 1–4 of the Indictment, arguing that the medical procedures he performed were not “sexual activity” and did not amount to rape. (ECF No. 74.) Counts 1–4 charge Kumar with violating the Travel Act, 18 U.S.C. § 2422(a), by persuading four out-of-state victims to visit his clinic for “unnecessary hysteroscopies with adulterated devices.” (ECF No. 79 at PageID 627.) In the Government’s words, Kumar “sexually penetrated these women, raping them under Tennessee state law.” (Id.) Or, in the vocabulary of the Travel Act, Kumar is charged with “Enticement and Inducement to Travel to Engage in Illegal Sex Acts.” (ECF No. 70 at PageID 562.)

Kumar contends that these counts fail to state an offense. He first argues that the hysteroscopies are not “sexual activity,” but rather are medical procedures without any “libidinal gratification.” (ECF No. 74 at PageID 596.) Although he concedes that the Travel Act does not define “sexual activity,” he argues that the requirement of libidinal gratification should be read into the Travel Act, relying on the unpublished opinion in United States v. Nagarwala, No. 17-CR-20274, 2018 WL 405122 (E.D. Mich. Jan. 14, 2018).

In Nagarwala, the defendant was charged with committing female genital mutilation. (Id. at *2.) The government argued that the mutilation counted as “sexual activity” under the Travel Act because the defendant “sexually abused her seven-year-old victims by digitally manipulating and penetrating the genitals with her hands and a cutting instrument.” (Id. at *4, *6 (citation modified).) The defendant, however, like Kumar, argued that the act was not of a sexual nature because it did not involve libidinal, or sexual, gratification. The district court agreed, adopting the Fourth Circuit’s definition of “sexual activity,” which required libidinal gratification. (Id. at *5–6 (quoting United States v. Fugit, 703 F.3d 248, 254–55 (4th Cir. 2012)).) The court reasoned that this definition comported with the Sixth Circuit’s definition of “sexual abuse,” defined as harm “for the purpose of sexual or libidinal gratification.” (Id. at *6 (quoting United States v. Mateen, 806 F.3d 857, 861 (6th Cir. 2015)).) Thus, Kumar argues that the Government cannot charge him with any “sexual activity” under the Travel Act because it has not alleged that he pursued libidinal gratification in his medical procedures.

Kumar further argues that his hysteroscopies do not fall under Tennessee’s rape statute, for these procedures are also not the kind of “sexual activity” prohibited by the Travel Act. (ECF No. 74 at PageID 600–01.) Tennessee defines rape in terms of “sexual penetration,” Tenn. Code Ann. § 39-13-503(a), which Kumar argues is a different term than “sexual activity” as used in the federal statute. (ECF No. 74 at PageID 600–01.) Because “criminal statutes must be construed strictly,” Nagarwala, 2018 WL 405122, at *4, Kumar contends that the hysteroscopies were not “sexual penetration” under Tennessee law. (ECF No. 74 at PageID 600.) Kumar also argues that the legislative history of both the Travel Act and its progenitor, the Mann Act, shows Congress’ intent to curb “prostitution and sexual acts for gratification, not medical procedures.” (Id. at PageID 600–01.) And, to the extent that “sexual activity” in the Travel Act is ambiguous,

he contends that the rule of lenity supports a ruling in his favor. (Id. at PageID 601–02.) Finally, Kumar argues that, if the Government’s theory were correct, then “every physician performing a procedure on the genital areas . . . could be subject to federal criminal liability if that procedure was unnecessary.” (ECF No. 81 at PageID 640.)

In response, the Government asserts that libidinal gratification “is not an element” of the Travel Act, and that the unpublished Nagarwala case is not binding and was wrongly decided. (ECF No. 79 at PageID 631–33.) Nagarwala relied on Mateen, a Sixth Circuit case about “whether non-penetrative offenses that were not overtly sexual should be considered ‘sexual abuse.’” (Id. at 631.) But, according to the Government, the penetrative acts in this case render Mateen inapposite. (Id.) Further, Mateen did not define “sexual activity,” nor did it “hold that genital penetration required a libidinal motivation.” (Id. at PageID 631–32 (citing 806 F.3d at 863).) Thus, contends the Government, there is no authority that binds this Court to read an element of libidinal gratification into the Travel Act.

The Government also points out that, “[i]n general, sexual crimes involving the penetration of the genitals do not require” an allegation of libidinal gratification. (Id. at PageID 632 (collecting federal and state statutes).) According to the Government, this is “common sense” because evidence of gratification “will frequently be unavailable,” and because “the victim suffers harm regardless of whether the defendant derived sexual gratification.” (Id.) As a result, rape is defined in Tennessee as “unlawful sexual penetration,” which in turn is defined broadly as “sexual intercourse . . . or any other intrusion, however slight, . . . of any object into the genital or anal openings of the victim’s . . . body” (Id. at PageID 633–34 (quoting Tenn. Code Ann. § 39-13-503(7)).) Thus, the Government argues that both “sexual penetration” in

Tennessee law and “sexual activity” in the Travel Act are terms broad enough to encompass these charges against Kumar.

The reasoning of the district court in Nagarwala, though not binding on this Court, is persuasive. “When the text of a statute contains an undefined term, that term receives its ordinary and natural meaning.” Nagarwala, 2018 WL 405122, at *5 (quoting Limited, Inc. v. Comm’r, 286 F.3d 324, 332 (6th Cir. 2002)). The adjective “sexual” is commonly understood to involve libidinal gratification. Id. (collecting cases). The plain meaning of “sexual activity” is activity for the purpose of sexual gratification. But the Indictment never alleges that Kumar harbored the purpose of sexual gratification. Instead, it focuses on his purpose “to unlawfully enrich himself” by continually reusing single-use medical devices. (ECF No. 70 at PageID 576, 579.) That is not a purpose that supports a charge under the Travel Act. And, because criminal statutes “must be strictly construed, and any ambiguity must be resolved in favor of lenity,” some allegation of sexual gratification should be required. See United States v. Enmons, 410 U.S. 396, 411 (1973).

By giving the undefined term “sexual” its ordinary meaning, the Court finds as a matter of law that the alleged acts against these four victims—although reprehensible if proven—were not “sexual activities.” “The temptation to stretch the law to fit the evil is an ancient one, and it must be resisted.” Nagarwala, 2018 WL 405122, at *6 (quoting Moskal v. United States, 498 U.S. 103, 132 (1990) (Scalia, J., dissenting)).

Therefore, the First Motion is Dismiss is **GRANTED**. Counts 1–4 are **DISMISSED**.

II. Second Motion to Dismiss (ECF No. 77)

Kumar next moves to dismiss Counts 5–9, 12–13, 16–18, 21–22, and 25 as duplicitous. (ECF No. 77.)

Federal Rule of Criminal Procedure 7(c) permits a single count of an indictment to allege that an offense was committed by “one or more specified means.” However, an indictment may not join “two or more offenses in the same count (duplicitous).” Fed. R. Crim. P. 12(b)(3)(B)(i). “An indictment is duplicitous if it sets forth separate and distinct crimes in one count.” United States v. Davis, 306 F.3d 398, 415 (6th Cir. 2002). “[O]ffenses are separate if each requires proof of an additional fact that the other does not.” Id. at 416 (quoting 2 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 142, at 17 (3d ed. 1999)).

“Duplicitous can potentially prejudice the defendant in sentencing, obtaining appellate review, and protecting himself against double jeopardy.” United States v. Washington, 127 F.3d 510, 513 (6th Cir. 1997). “While a duplicative indictment can prejudice a defendant in a variety of ways, the primary concern is that a defendant may be deprived of his right to a unanimous jury verdict.” United States v. Kakos, 483 F.3d 441, 443 (6th Cir. 2007). “That is, a jury might return a guilty verdict on the single count submitted to them without all twelve jurors agreeing that the defendant committed either of the offenses charged within that count.” Id. at 443. Generally, “proper jury instructions can mitigate the risk of jury confusion and alleviate the doubt that would otherwise exist as to whether all members of the jury had found the defendant guilty of the same offense.” Id. at 444 (quoting United States v. Lloyd, 462 F.3d 510, 514 (6th Cir. 2006)).

Counts 5–9, 12–13, 16–18, 21–22, and 25 describe ongoing conduct by Kumar, instead of a single, discrete act.² (ECF No. 77 at PageID 606.) Kumar contends that each of these thirteen

² To illustrate the distinction at the heart of Kumar’s duplicity argument, compare Count 10—which Kumar does not seek to dismiss in this motion—with Count 6. Count 10 alleges the adulteration of the CooperSurgical Endosee PX Cannula on just the single date of April 16, 2024, the day on which PAC was searched. Count 6, on the other hand, alleges the adulteration of that model from September 2019 to April 2023. (ECF No. 70 at PageID 573.)

counts individually charges “multiple instances of conduct occurring over multiple months or years,” even though the statute under which he is charged, 21 U.S.C. § 331(k), prohibits only “single acts of conduct.” (*Id.*) According to Kumar, “Congress intentionally used singular terms versus plural terms” in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (“FDCA”), which prohibits the following:

The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(*Id.* at PageID 612–13 (emphasis in original) (quoting § 331(k)).) Although Kumar concedes that “the United States Code provides that a term phrased in the singular can include the plural,” he argues that courts should do so only on “rare occasions” when “necessary [to carry] out the evident intent of the statute.” (*Id.* at PageID 614 (quoting *United States v. Hayes*, 555 U.S. 415, 422 n.5 (2009)).)

In support of his argument, Kumar cites a Pennsylvania district court case in which a defendant pharmacist, accused of recycling pills over a five-year period, moved to dismiss the charge of misbranding drugs as duplicitous. (*Id.* (citing *United States v. Salerno*, Criminal No. 3:10–CR–301, 2011 WL 6141017, at *2–3 (M.D. Pa. Dec. 9, 2011)).) The court agreed that the charge was duplicitous but nevertheless denied the motion to dismiss because the duplicity concerns could “be cured by appropriate jury instructions and special interrogatories.” *Salerno*, 2011 WL 6141017, at *3. Despite the result, Kumar relies on *Salerno* to argue that under § 331(k) a “violation consists of individual acts . . . and not many acts together.” (ECF No. 77 at PageID 614 (quoting *Salerno*, 2011 WL 6141017, at *3).)

In response, the Government asserts that the “presentation of multiple factual scenarios to prove [an] offense does not render the count duplicitous.” (ECF No. 83 at PageID 664 (quoting Washington, 127 F.3d at 513 (6th Cir. 1997)).) It argues that, in Washington, a charge of possession with intent to distribute crack cocaine was not duplicitous, even though it charged a defendant with “two separate drug transactions involving two defendants and six theories of involvement[,] for a combined 72 different possible factual scenarios to prove the allegation.” (Id. (citing 127 F.3d at 513 n.3).) Here, likewise, the Government “has elected to charge the defendant with only one count per device type during two to three different time ranges,” even though Kumar “held multiple adulterated medical devices during the times charged.” (Id.)

The Government further contends that Kumar’s reliance on Salerno is misplaced, given that “the ultimate holding of Salerno was that the government’s single count charging approximately ‘250,952 claims involving allegedly misbranded pharmaceuticals . . . [was] not impermissibly duplicitous’” because the duplicity could be cured without prejudice to the defendant. (Id. at PageID 665 (quoting 2011 WL 6141017, at *3).) Indeed, argues the Government, even if the charges here are duplicitous, they could likewise “be cured by appropriate jury instructions and special interrogatories.” (Id. (quoting Salerno, 2011 WL 6141017, at *3).) After all, “duplicity is only reversible if it prejudices the defendant.” (Id. (quoting United States v. Singer, 782 F.3d 270, 276 (6th Cir. 2015), abrogated on other grounds by Musacchio v. United States, 577 U.S. 237 (2016)).)

The Government also rejects Kumar’s contention that he lacks notice of the charges against him, reasserting the Government’s contention that “nearly all of the over 16,000 hysteroscopies . . . were performed with adulterated devices,” with the exception of only 200

procedures which were “conducted with freshly opened, sterile devices.” (Id. at PageID 666 & n.3.)

Finally, the Government argues that, even if § 331(k) concerns single acts of adulterating and misbranding devices, the Government can still charge Kumar with a continuing course of conduct. (Id. at PageID 666–68.) After all, § 331(k) prohibits the adulterating and misbranding of devices “while such article is held for sale,” and in this case the devices were “held for sale” over months of reuse. (Id. at 667.)

The Court finds that the thirteen counts identified in Kumar’s motion are duplicitous, as they join “two or more offenses in the same count.” Fed. R. Crim. P. 12(b)(3)(B)(i). The question turns on whether the thousands of alleged violations were separate offenses, see Fed. R. Crim. P. 12(b)(3)(B)(i), or merely separate means to commit a single offense, see Fed. R. Crim. P. 7(c). The former renders these counts duplicitous; the latter renders them permissible. See Davis, 306 F.3d at 415. Here, the sheer volume of the violations in these counts belies the Government’s assertion that they simply offer multiple factual scenarios on which the jury may base its decision. Cf. United States v. Algee, 599 F.3d 506, 514 (6th Cir. 2010) (affirming conviction where indictment charged one count of making a false statement to multiple different people on the same day, which merely amounted to “more than one potential basis for conviction”). As Kumar noted, distinct, separate events charged in one count “are not mere ‘multiple factual predicates’ but rather are entirely separate offenses.” United States v. Dedman, 527 F.3d 577, 600 n.10 (6th Cir. 2008). Although this footnote in Dedman is only dictum, the reasoning is persuasive. The decisive factor here is that these thirteen counts stretch over months and years, sweeping up around 16,000 acts of adulteration and misbranding. These are myriad

separate offenses, involving conduct on different days, that, when charged in one count, are duplicitous.

A continuing course of conduct theory does not resolve the duplicity. The Government cites several cases finding otherwise duplicitous counts not to be prejudicial because they formed a continuing course of conduct. (ECF No. 83 at PageID 667–68.) However, the course of conduct in those cases appears tied to each case’s relatively narrow facts—in one case, a small number of violations, in another, a limited number of victims or a relatively brief time period. See United States v. Alsobrook, 620 F.2d 139 (6th Cir. 1980) (six dates over three months); United States v. Berardi, 675 F.2d 894 (7th Cir. 1982) (three acts over four months); United States v. Davis, 471 F.3d 783 (7th Cir. 2006) (many violations but against a single victim). Here, however, for thousands of violations against thousands of victims over the course of years, a continuing course of conduct theory cannot overcome the specter of duplicity.

The most apposite case indeed appears to be Salerno, in which a single count charging 250,952 drug misbranding violations was duplicitous, but curable. 2011 WL 6141017, at *3. It is instructive to note that Salerno was also charged with two other counts, one for healthcare false statements in violation of 18 U.S.C. § 1035, the other for healthcare fraud under § 1347. Id. at *2. The court found that those counts were not duplicitous because those particular statutes explicitly prohibit any “scheme” to conceal facts or to defraud. Id. But, turning to the drug misbranding count under § 331(k), the same statute under which the Government charges Kumar in these counts, the court drew a distinction. Id. at *3. “Unlike the health-care fraud or false statements related to health-care matters statutes, § 331(k) does not refer to a ‘scheme.’ Instead, its language suggests that the violation consists of individual acts (‘doing of any other act’; ‘if such act is done’) and not many acts together.” Id. Here, likewise, although the Government

does separately charge Kumar with conducting a “scheme to defraud” under 18 U.S.C. § 1347, in Counts 27–36, it does not charge Kumar with any scheme to adulterate and misbrand devices under § 331(k) in the counts at issue in the Second Motion to Dismiss. Indeed, the language of § 331(k) appears inimical to the Government’s theory that thousands of instances of adulterating and misbranding devices are only multiple “means” or multiple “factual scenarios” for committing a single crime. Instead, these counts allege multiple, discrete crimes.

But something further separates this case, making Kumar’s duplicitous charges prejudicial where Salerno’s single duplicitous charge was not. Because all of Salerno’s misbranding conduct was charged in one count, the court found that Salerno ultimately “benefit[ed] from facing a single charge that encompasses all” his conduct, “as opposed to facing hundreds of thousands of separate counts for each individual act of misbranding.” Id.; see also Alsobrook, 620 F.2d at 143 (affirming that a single count “was neither duplicitous nor otherwise prejudicial” and that “it redound[ed] to the benefit of the defendant”). The same cannot be said here, where Kumar is separately charged with nine counts of single acts of adulterating and misbranding that are clearly not duplicitous.³ Unlike in Salerno, permitting the duplicitous charges to go forward here cannot be said to benefit Kumar.

Although the Government argues that proper jury instructions can cure duplicitous counts, see Crump, 65 F.4th at 297 (explaining that “[u]nanimity instructions are a method of curing ‘duplicitous’ charges” (quoting Kakos, 483 F.3d at 443)), the Government is asking too much of the jury instructions. For the Court to instruct the jury to come to an agreement on which discrete factual event supports a decision for each count—from the potentially thousands of events available—would create a greater “tangible risk of jury confusion” than it purports to

³ Namely, Counts 10–11, 14–15, 19–20, 23–24, and 26.

solve. See Algee, 599 F.3d at 514 (listing the circumstances requiring a specific jury instruction on unanimity). Thus, the appropriate remedy here is not a jury instruction, but dismissal.

In this case, where 16,000 acts of adulterating and misbranding are alleged, the Government has the discretion to present to the jury any factual circumstance it chooses. But it must do through the properly charged counts, Counts 10–11, 14–15, 19–20, 23–24, and 26, which allege single instances of adulterating or misbranding single devices recovered during the April 16, 2024 search of Kumar’s clinic. (See ECF No. 91 at PageID 749.)

Therefore, the Second Motion to Dismiss is **GRANTED**. Counts 5–9, 12–13, 16–18, 21–22, and 25 are **DISMISSED**.

III. Third Motion to Dismiss (ECF No. 103)

Kumar’s third motion seeks to dismiss Counts 5–26,⁴ the counts involving adulteration and misbranding, as “constitutionally vague and insufficient under the Fifth and Sixth Amendments.”⁵ (ECF No. 103 at PageID 796.) Also, if the Court “dismisses or narrows” those earlier counts, then Kumar requests that the Court likewise “impose corresponding limits” on Counts 27–36. (Id. at PageID 807.) In the alternative, Kumar moves to strike the felony enhancement under 21 U.S.C. § 333(a)(2). (Id. at PageID 796.)

A. Dismissal of Counts 5–36 as Vague and Insufficient

An indictment must contain a plain, concise, and definite written statement of the essential facts constituting the offense charged. Fed. R. Crim. P. 7(c)(1). “An indictment is ‘sufficient if it (1) contains the elements of the charged offense, (2) gives the defendant adequate

⁴ Counts 5–9, 12–13, 16–18, 21–22, and 25 have previously been dismissed, see supra, but are still included here for consideration.

⁵ Kumar makes one additional, brief argument that these counts represent a federal intrusion “on state regulation of medical practice.” (ECF 103 at PageID 805–06.) This policy argument lacks merit under the Supremacy Clause. See U.S. Const. art. VI, cl. 2.

notice of the charges, and (3) protects the defendant against double jeopardy.” United States v. Welborn, No. 21-5425, 2022 WL 1276024, at *3 (6th Cir. Apr. 29, 2022) (quoting United States v. Rankin, 929 F.3d 399, 404–05 (6th Cir. 2019)). “It must also include ‘such a statement of the facts and circumstances as will inform the accused of the specific offen[s]e, coming under the general description, with which he is charged.’” Id. (quoting Hamling v. United States, 418 U.S. 87, 117–18 (1974)). A statute is unconstitutionally vague if it “fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute.” Bouie v. City of Columbia, 378 U.S. 347, 351 (1964) (quoting United States v. Harriss, 347 U.S. 612, 617 (1954)).

1. “Held for Sale”

First, Kumar argues that Counts 5–26 should be dismissed as vague. (Id. at PageID 801–03.) In Counts 5–26, Kumar is charged under the FDCA with the adulteration and misbranding of devices “held for sale.” (Id. at PageID 801 (quoting 21 U.S.C. § 331(k)).) But Kumar contends that, because the phrase “held for sale” is meant to have a “commercial component,” it does not apply to the medical devices used, but not sold, in Kumar’s clinic. (Id. at PageID 801.) Although he concedes that several circuit courts have applied the phrase “held for sale” to medical single-use contexts, he argues that none of them are binding on this Court because they are all the progeny of one civil case, United States v. 10 Cartons, Labeled in Part “Hoxsey”, 152 F. Supp. 360 (W.D. Pa. 1957). (ECF No. 103 at PageID 801–02.) These courts were mistaken when extending the civil holding to the criminal context, he asserts. (Id. at PageID 801.) Although civil cases may permit this sort of ambiguity, “in the criminal context, due process demands clarity.” (Id.)

Expounding on the “vagueness” of these counts, Kumar argues that by applying the phrase “held for sale” to “any in-office use for which a provider is reimbursed for services,” the Government creates “an open-ended license” for prosecuting doctors. (Id. at PageID 802–03.) And because the phrase is vague, its meaning “must be resolved in the defendant’s favor under the rule of lenity.” (Id. at PageID 803.)

The Government responds that the Indictment is not vague in its description of devices “held for sale,” because “a physician’s use of a consumable, single-use device on a paying patient satisfies the ‘held for sale’ element.” (ECF No. 108 at PageID 914 (quoting United States v. Kaplan, 836 F.3d 1199, 1211 (9th Cir. 2016)).) In support, it quotes the allegation in the Indictment that Kumar “billed health insurers including Medicare the value of the single use hysteroscope medical devices even when he was in fact reusing them.” (Id. at PageID 916.) Thus, the Government argues, the Indictment was not vague about the commercial nature of Kumar’s transactions.

The phrase “held for sale” in the context of a for-profit medical clinic is not vague. It is true that no Sixth Circuit opinion defines this phrase, but several sister circuits have found that “a physician’s use of a consumable, single-use device on a paying patient satisfies the ‘held for sale’ element.” Kaplan, 836 F.3d at 1211 (9th Cir. 2016); see also United States v. Jackson, 126 F.4th 847, 858–59 (4th Cir. 2025) (citing approvingly Kaplan’s reasoning that “held for sale” includes a physician’s use of a single-use device in treating patients). Despite Kumar’s reliance on Geborde, it is inapposite. (ECF No. 103 at PageID 801 (citing United States v. Geborde, 278 F.3d 926 (9th Cir. 2002)).) There, Geborde’s items were not “held for sale” because the defendant was handing out homemade drugs for free. 278 F.3d at 927. Kumar, on the other

hand, was well paid for these devices—and was allegedly paid multiple times for each. The single-use devices in his clinic were indeed “held for sale.”

2. **Vagueness**

Many of those same counts are also dismissible, according to Kumar, because he had no way of knowing that his use of these devices in the clinic would violate the FDCA labeling requirements. (*Id.* at PageID 803–04.) Counts 16–24 charge Kumar with misbranding “reprocessed device[s] for single use” by failing to attach a label featuring the phrase “Reprocessed device for single use” along with the name of the person who reprocessed them. (*Id.* at PageID 804 (citing 21 U.S.C. § 352(v)).) Kumar argues that, although the Indictment describes his in-office reuse of these instruments, it never alleges that he “introduced any reprocessed device into commerce as a labeled product.” (*Id.*) Also, practically speaking, he asserts, he had no “mechanism for affixing a federal warning label to a single cannula used during a hysteroscopic procedure.” (*Id.*) Thus, according to Kumar, the Government’s theory “stretches § 352(v) beyond recognition,” rendering these counts “both insufficiently pleaded and unconstitutionally vague as applied.” (*Id.*)

The Government contends that Counts 16–24, charging Kumar with misbranding devices, include adequate facts and that the labeling requirements of 21 U.S.C. § 352(v) are plain, leaving no room for Kumar to be as confused as he says he is. (ECF 108 at PageID 917.)

Kumar attempts to inject vagueness into counts and statutes that are sufficiently clear. For instance, Kumar protests that the Indictment does not plead sufficient facts to show that he misbranded any devices. But the Indictment alleges that Kumar “failed to label the reprocessed devices” as “required by law” (ECF No. 70 at PageID 557), with a list of the law’s requirements

two pages later (id. at PageID 559). These allegations are sufficient to put a person of ordinary intelligence on notice.⁶

3. Whether Counts 27–36 Should Be Narrowed or Dismissed

Kumar argues that, if the Court dismisses or narrows Counts 5–26, it should also dismiss or narrow Counts 27–36, which charge Kumar with health care fraud, because those counts “incorporate the same factual premise” as the previous counts. (Id. at PageID 807.) Although this Order dismisses certain of the counts in this range,⁷ it does so on grounds other than a flaw in those counts’ “factual premise.” Thus, the Court will not dismiss or limit Counts 27–36.

B. Striking the § 333(a)(2) Felony Enhancement

In the alternative to dismissal, Kumar seeks to strike the § 333(a)(2) felony enhancement. (Id.) This enhancement elevates Counts 5–26 from misdemeanor offenses to felonies if the proof shows that Kumar acted “with the intent to defraud or mislead.” (Id. (quoting 21 U.S.C. § 333(a)(2)).) Kumar contends that this enhancement cannot apply to him because the Indictment lacks the necessary facts about “who was allegedly defrauded or misled, how such intent [was] manifested, or how it related to any particular device, patient, or act of reuse or labeling.” (Id.) The Indictment pleads only “a generic allegation that Dr. Kumar ‘failed to inform’ patients and insurers about reuse,” according to Kumar, not an allegation of fraud. (Id. at PageID 804–05.)

⁶ To the extent Kumar argues in his third motion to dismiss that the counts for adulterating and misbranding “impermissibly aggregate months or years of conduct into omnibus charges” (ECF No. 103 at PageID 807), that argument is addressed above as to his Second Motion to Dismiss.

⁷ Specifically, Counts 5–9, 12–13, 16–18, 21–22, and 25 are dismissed. See supra.

According to the Government, the Indictment does plead that Kumar had “the intent to defraud or mislead,” and thus the three-year felony enhancement in § 333(a)(2) applies to him, because he “concealed and omitted [his reuse of the devices] from patients, insurers[,] including Medicare and TennCare, and others.” (ECF No. 108 at PageID 918.) Thus, “the Superseding Indictment provides a statement of the facts and circumstances that inform the accused of the government’s theory behind the defendant’s intent to defraud.” (Id.)

The § 333(a)(2) felony enhancement will not be struck. Contrary to Kumar’s argument that it does not apply in the absence of facts about whom Kumar misled, or how he misled them, the Indictment sufficiently alleges that Kumar “concealed and omitted from patients, insurers including Medicare and TennCare, and others,” his practice of “boost[ing] his profits by subjecting patients to the use of adulterated medical devices rather than using a new, sterile device for every procedure.” (ECF No. 70 at PageID 572–73.) This, too, is sufficiently pled in the Indictment.

Therefore, the Third Motion to Dismiss is **DENIED**.

CONCLUSION

For the reasons stated above, the Motion to Dismiss Counts 1–4 is **GRANTED**; the Motion to Dismiss Counts 5–9, 12–13, 16–18, 21–22, and 25 as Duplicitous is **GRANTED**; and the Motion to Dismiss Counts 5–26 and to Limit Counts 27–36 for Constitutional Vagueness and Insufficiency, or, in the Alternative, to Strike the § 333(a)(2) Felony Enhancement is **DENIED**.

IT IS SO ORDERED, this 17th day of October, 2025.

s/ Sheryl H. Lipman

SHERYL H. LIPMAN
CHIEF UNITED STATES DISTRICT JUDGE