APPENDIX A

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT
No. 23-4467
UNITED STATES OF AMERICA,
Plaintiff – Appellee,
v.
ANITA LOUISE JACKSON,
Defendant – Appellant.

PHYSICIANS AGAINST ABUSE, INC.,
Amicus Supporting Appellant.
No. 23-4587
UNITED STATES OF AMERICA,
Plaintiff – Appellee,
v.
ANITA LOUISE JACKSON,
Defendant – Appellant.

PHYSICIANS AGAINST ABUSE, INC.,
Amicus Supporting Appellant.
Appeal from the United States District Court for the Eastern District of North Carolina, at
Raleigh. James C. Dever, III, District Judge. (5:21-cr-00259-D-1)
Argued: November 1, 2024 Decided: January 21, 2025

Before DIAZ, Chief Judge, AGEE, and BENJAMIN, Circuit Judges.
Affirmed by published opinion. Judge Agee wrote the opinion in which Chief Judge Diaz and Judge Benjamin joined.

ARGUED: Elliot Sol Abrams, CHESHIRE PARKER SCHNEIDER, PLLC, Raleigh,
North Carolina, for Appellant. Katherine Twomey Allen, UNITED STATES
DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. **ON BRIEF:** Ripley E.
Rand, WOMBLE BOND DICKINSON (US) LLP, Raleigh, North Carolina, for Appellant.
Nicole M. Argentieri, Principal Deputy Assistant Attorney General, Lisa H. Miller,
Criminal Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.;
Michael F. Easley, Jr., United States Attorney, David A. Bragdon, Assistant United States
Attorney, Appellate Chief, OFFICE OF THE UNITED STATES ATTORNEY, Raleigh,
North Carolina, for Appellee. Eric O. Husby, HUSBY LAW, Land O Lakes, Florida, for
Amicus Curiae

AGEE, Circuit Judge:

Dr. Anita Jackson appeals her convictions for various offenses arising from the operation of her private medical practice in North Carolina. She raises multiple arguments challenging her conviction for violating the Food, Drug, and Cosmetics Act ("FDCA") by holding for re-sale adulterated medical devices, in violation of 21 U.S.C. § 331(k). Flowing from her challenge to the FDCA conviction, she also asserts that the prejudicial spillover effect of evidence introduced to support that count requires vacatur of her other convictions. And, assuming her case is remanded for a new trial, she submits that

the Court should reassign the case to a different district judge. Separately, Jackson challenges her convictions for two counts of aggravated identity theft, in violation of 18 U.S.C. §§ 1028A(a)(1) and 2.

Finding no reversible error as to any of the challenged convictions, we affirm.

I.

Jackson is a board-certified otolaryngologist, commonly referred to as an ear, nose, and throat physician. During the relevant timeframe, she ran a multi-location private practice in Lumberton and Rockingham, North Carolina. At one time, Jackson was the leading Medicare biller in the nation for a procedure known as balloon sinuplasty surgery, which treats chronic sinusitis.2 The procedure consists of the doctor inserting a device through the patient's nose into one or more of the sinuses and inflating a small balloon to widen the cavity. The device Jackson used for this procedure during the relevant timeframe was an Entellus XprESS Multi-Sinus Dilation Tool ("Entellus" or "the device"). The insertable part of this device has a small tip, an inflatable balloon, and a thin hollow metal tube. The balloon slides up and down the tube and is inflated after it is placed in the patient's sinus cavity. The rest of the Entellus remains outside the patient's body and consists of the slide mechanism for the balloon, a suction port, and a light fiber that runs through the hollow tube to allow the physician to see into the sinus during the procedure. The device also has small retractable parts that often come into contact with and trap bodily fluids and hair from the patient during the procedure. These parts are fragile and may break easily, particularly if the Entellus is reused. The device was, accordingly, designed for single use and is labeled by the

Food and Drug Administration as being approved only for single use. Physicians who perform sinuplasty surgeries can be reimbursed by Medicare. In fact, this particular procedure does not require preapproval to submit a claim. Medicare reimbursement levels for sinuplasty and other procedures factor in "three main parts: The amount of time and effort it takes to provide service, the costs associated with that service that the doctor will incur, and the costs that the[] doctor incurs for malpractice." J.A. 1402.

This formula, which takes into account the cost of the equipment needed to perform the procedure, was used to calculate Medicare's reimbursement amounts for a sinuplasty using the Entellus. Becoming the nation's leading Medicare biller for sinuplasty surgery was far from happenstance, as Jackson's employees recounted how she incentivized recruiting Medicare patients to agree to the procedure. For her employees, Jackson tied work hours to surgery marketing efforts, set surgery quotas for her offices, and paid bonuses related to how many sinuplasty procedures were performed. She encouraged employees to recruit patients throughout the community, targeting rural localities and seeking out individuals likely to have Medicare because it did not require preapproval for the procedure. Employees testified, for example, that they were told to pitch balloon sinuplasty to potential patients at locations like Wal-Mart parking lots, churches, barbershops, and doctor's offices. In addition, Jackson offered some potential patients financial enticements such as not requiring any front payment or limiting fees to a $50 copayment rather than the higher Medicare-directed copayment amounts. By

agreeing to have the sinuplasty procedure, patients could also receive free transportation to Jackson's office and gift cards to local stores. In conjunction with these efforts to drum up new sinuplasty patients, Jackson streamlined the process she followed before deeming a patient eligible for the procedure. Early on, Jackson ordered diagnostic scans and considered alternative treatments before performing the procedure. Later, Jackson would simply perform the procedure on a patient's first visit, implementing what Jackson's employees termed an "assembly line" to "get to 'yes'" for the sinuplasty to be performed, thereby skipping a *bona fide* assessment of the patients' medical condition, alternative treatments, or even determining whether the procedure was medically appropriate. J.A. 1766, 1953–55.

In many cases, Jackson's recruitment efforts left patients without understanding that the proposed procedure was actually a surgery. Instead, it was described to them as a "sinus spa" or "rinse." J.A. 1749–50, 2045. Many patients were also unaware that the procedure worked by having the balloon micro-fracture bones. And they were similarly unaware that Jackson elected to perform the procedure using the same device on more than one patient. Instead, patients were informed that a "small sterile balloon" would be used during the procedure. S.J.A. 172. When investigators searched Jackson's offices, they discovered that aged, used devices were being stored loose in drawers. Those conditions were typical. Employees reported that many Entelluses used on patients were rusted and the retractable parts no longer operated smoothly. After use, Jackson's employees would wash the device using a variety of cleaning methods because they were not given clear instructions for how to do so. They lacked appropriate tools to assist in cleaning

the devices' hollow and delicate parts, and they could not see many areas of an Entellus to ensure that it was clean, much less sterile. Usually, employees would wash the device with tap water and soap while gently scrubbing it so as not to break any of its parts. They would then place it in two chemical solutions for around thirty minutes (well below the solutions' recommended cleaning times), rinse with tap water, and then leave the device to dry on top of a pad on the counters of exam rooms. Once dry, the Entelluses were put in drawers where they were interspersed with other supplies. This process created a significant likelihood that some reused devices still contained prior patients' bodily fluids.

Jackson's billing practices related to sinuplasty surgeries drew the attention of federal investigators, and she was audited four times between 2016 and 2018. After a 2016 audit, Jackson was forced to repay over $30,000 in Medicare reimbursements because of noncompliant (incomplete) recordkeeping. The 2016 audit did not cause Jackson to implement better recordkeeping measures; instead, she and her employees began falsifying documents to support her billing practices. The record shows that each time Jackson was informed of an audit and asked to produce complete copies of her medical records supporting various claims, she submitted altered records.3 Specifically, Jackson created entirely new records, omitted incomplete records, and changed other records. In response to one of the 2018 audits (the "2018 Palmetto audit"), Jackson submitted declarations purporting to be from sinuplasty patients. The declarations represented that the patients had chronic sinusitis and had been unsuccessfully treated with antibiotics before Jackson performed the sinuplasty

surgery. The declarations contained a statement representing the truth and correctness of the contents, under penalty of perjury. Some of the declarations, including those belonging to patients with the initials of L.J. and W.F., contained false notarizations and forged signatures.3 As a result of the audits and related investigations into Jackson's practice, a grand jury returned an indictment charging Jackson with an array of federal crimes. The twenty count superseding indictment alleged the following offenses:

- Count 1: violating 21 U.S.C. § 331(k) by holding for resale adulterated medical devices, namely, the Entellus with which Jackson performed the sinuplasty surgeries;
- Counts 2–11: violating the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, by billing Medicare for procedures without advising patients of their copayment responsibilities and without collecting copayments from patients, as required by federal law;
- Counts 12–14: making materially false statements, in violation of 18 U.S.C. §§ 1035(a)(2) and 2, during the course of the three 2017 to 2018 Medicare audits;
- Counts 15–16: committing aggravated identity theft, in violation of 18 U.S.C. §§ 1028A(a)(1) and 2, by submitting forged and fabricated documents purportedly from patients L.J. and W.F. as part of Jackson's response to the 2018 Palmetto audit described in Count 14;
- Counts 17–19: committing mail fraud, in violation of 18 U.S.C. §§ 1341, 1349, and 2, relating to mailing falsified documents responding to the audits described in Counts 12 to 14; and
- Count 20: conspiring to commit the federal offenses described in the prior counts, in violation of 18 U.S.C. § 371.

During the multi-week trial that ensued, the jury heard evidence from multiple witnesses, including Jackson's employees and patients, as well as the designer of the Entellus. In addition, Jackson testified in her defense. After the presentation of evidence, the jury convicted Jackson on all charges, specifically finding that she acted with the intent to defraud or mislead as to the FDCA violation (Count 1) and that she had obtained $4,794,039.31 as "gross proceeds traceable to the commission of the federal health care offenses." J.A. 3657.4 Jackson moved for a judgment of acquittal as to Counts 2 through 19 (but, notably, not Count 1) and included a blanket cross-reference to "the entirety of her preserved objections, submissions, legal arguments, motions, denials of said motions, requests, and rights preserved in the trial record . . . as grounds for [a] motion for new trial." J.A. 3674. The district court denied these motions. Jackson was sentenced to a below-Guidelines sentence of twenty-five years' imprisonment and ordered to pay $5,726,218.26 in restitution. Jackson noted a timely appeal, and the Court has jurisdiction under 28 U.S.C. § 1291.

II.

In this appeal, Jackson does not directly challenge seventeen of her convictions.5 As to the FDCA conviction (Count 1) and aggravated identity theft convictions (Counts 15 and 16), she raises multiple arguments. Although Jackson also broadly contends that she is entitled to vacatur and remand for a new trial as to all of her convictions, those arguments all flow solely from errors that she claims occurred as to Count 1, which she contends prejudicially infected the rest of the trial.

We begin by considering Jackson's challenge to Count 1,

in which she was charged with violating the FDCA. Two elements of the offense are undisputed—that the conduct at issue involves a "device" as that term is defined in the FDCA, and that the devices had been shipped in interstate commerce. The remaining elements are, in relevant part, that the defendant (1) engaged in prohibited conduct with respect to the device, (2) while the device was "held for sale (whether or not the first sale)," and (3) the prohibited conduct resulted in the device "being adulterated." § 331(k).6 The prohibited conduct set out above encompasses "two distinct offenses," the first relating to the label itself and potential misbranding and the second—the conduct at issue here—relating to adulteration, which "is concerned solely with deterioration or contamination of the commodity itself." *United States v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 89–90 (1964). The FDCA states that a "device shall be deemed to be adulterated" "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).6 Jackson raises several arguments aimed at undermining her conviction on Count 1, asserting alternatively that problems with the indictment require dismissal of the charge outright or that trial errors require vacatur of the conviction and remand for a new trial. As reflected in the analysis that follows, most of Jackson's arguments are raised here for the first time on appeal. The fact that she failed to preserve those issues affects our standard of review, as outlined below.

In broad terms, Jackson presses the following arguments: (1) the Entellus devices were not "held for sale," as required to violate § 331(k); (2) her actions were protected under 21 U.S.C. § 396, which she claims

insulates certain physician conduct that would otherwise violate § 331(k) so long as it occurs within a legitimate doctor-patient relationship; (3) the Government relied on a defective theory of *per se* adulteration arising from re-use of a device labeled for single use; (4) she should have been permitted to demonstrate her cleaning and sanitation process as part of her defense; (5) she should have been permitted to introduce documentary evidence about the prevalence of re-using single use devices and proper sanitization as part of her defense; (6) the jury should not have been instructed that it was "irrelevant" that none of her patients were harmed or that she believed the device was clean; and (7) the Government made an improper "Golden Rule" argument during closing argument. We address each of these contentions in turn.7 Jackson posits that the indictment was deficient, the jury instructions erroneous, and the evidence insufficient to support the verdict. She argues that each of these alleged errors permitted the element of § 331(k) requiring that the device be "held for sale" to be satisfied by conduct falling outside the scope of that statutory language. In sum, Jackson asserts that, at most, she held the Entelluses *for use* during sinuplasty surgeries and that they were not "held for sale" to her patients. Her rationale is that she did not hold the devices for sale because ownership of or title to an Entellus never transferred to the patient as a part of the procedure. In her view, because "re-use" falls outside the scope of holding the device "for sale," the indictment should have been dismissed because it did not charge her with conduct that the statute prohibits. She further asserts that this mismatch between the statutory language and her conduct carried forward to the jury instructions, which stated that "[t]he phrase 'held for sale' includes a single-

use device that a doctor used in the course of treating a Medicare patient. A device is 'held for sale' at the time the holder of the device, including a doctor, intends it to be sold or used in the course of treating a Medicare patient." J.A. 3515. For the same reasons, she asserts the trial record is insufficient to support her conviction.

Because Jackson makes each of these arguments centered on the Entellus being "held for sale" for the first time on appeal, we apply plain-error review. *See Puckett v. United States*, 556 U.S. 129, 134–35 (2009) (stating that appellate courts review "unpreserved claim[s] of trial error" for plain error). Before proceeding with that review, however, we briefly discuss our basis for concluding that she failed to preserve any argument with respect to whether the Entellus was "held for sale." Jackson first maintains that she preserved her argument related to the indictment by moving to dismiss Count 1 for failure to state an offense. Reviewing Jackson's arguments in support of that motion reveals that she asserted three reasons why Count 1 should be dismissed. First, she claimed that § 331(k) was "[u]nconstitutionally [v]oid for [v]agueness," J.A. 138, because it failed to adequately notify individuals when a device is left in sufficiently unsanitary conditions so as to be deemed "adulterated." Second, she argued the indictment did not sufficiently allege her intent to defraud or mislead her patients. Third, she claimed that the indictment did not allege that she failed to engage in a permitted off-label use of the Entellus. None of these arguments challenges any aspect of the "held for sale" element of § 331(k), let alone reflects

some variant of the specific grounds she raises on appeal about this element. We therefore reject her contention that her motion to dismiss the indictment was sufficient to preserve the issue she now brings before the Court.8 As for the jury instructions on this matter, Jackson did not object to them and instead expressed that she was "satisfied with" the instructions to which she did not object. J.A. 3401. So that part of her argument likewise was never brought before the district court. Lastly, Jackson did not move for judgment of acquittal on a basis remotely related to whether the Entellus was "held for sale," so she also failed to preserve that component of her argument.

The Supreme Court set out the standard for plain-error review in *United States v. Olano*, 507 U.S. 725 (1993). First, there must be an error. *Id.* at 732–33. Second, the error "must be clear or obvious, rather than subject to reasonable dispute." *Puckett*, 556 U.S. at 135 (citing *Olano*, 507 U.S. at 734). "Third, the error must have affected the appellant's substantial rights, which in the ordinary case means he must demonstrate that it 'affected the outcome of the district court proceedings.'" *Id.* (quoting *Olano*, 507 U.S. at 734). Fourth, even when "the above three prongs are satisfied, the court of appeals has the *discretion* to remedy the error—discretion which ought to be exercised only if the error seriously affect[s] the fairness, integrity or public reputation of the judicial proceedings." *Id.* (cleaned up) (emphasis in original).

Notably, only one circuit court has confronted the merits of this particular "held for sale" issue in a directly analogous context, and it has rejected Jackson's argument. In *United States v. Kaplan*, 836 F.3d 1199 (9th

Cir. 2016), the Ninth Circuit rejected the argument that a physician merely held for "use" (and not for "sale") single-use devices used during biopsy exams. *Id.* at 1208. The Ninth Circuit held that § 331(k)'s requirement that the allegedly adulterated device be "'held for sale' included a physician's use of a device in treating patients." *Id.* In doing so, it relied on the statutory text and the purpose of the FDCA, noting that the statute "is to be interpreted broadly in order to protect public health." *Id.* It also recounted the reasoning of other courts that had interpreted this phrase, recognizing that it "extends to physicians using both drugs and devices in the treatment of patients" given the commercial nature of a physician's treatment of patients. *Id.* at 1209. Agreeing with this reasoning, the Ninth Circuit described the doctor–patient relationship as setting up a "sale" of services, with the device being part and parcel of those services. *Id.* at 1210 (a "physician [is] engaged in the business of providing medical services in exchange for payment: a commercial actor in a commercial setting, using a commercial product"). The Ninth Circuit also placed particular significance on the "single-use nature" of the device at issue in that case, observing that such devices are "meant to be 'consumed' in the course of treating a patient—just like a drug." *Id.* It then elaborated:

> Once the single-use device is used or consumed there is nothing left to be done with the device. It no longer possesses a functional purpose in the medical practice and, rather than giving the used device to the patient, the doctor disposes of it. Therefore, when a physician uses a disposable device on a patient, the device is "held for sale"

> within the meaning of the FDCA provided that there is a commercial relationship between the doctor and the patient and that the device is one that is meant to be 'consumed' in the process.

Id.

While acknowledging the common-sense persuasiveness of the Ninth Circuit's reasoning and the body of caselaw from other courts on which it rests, we do not ultimately need to determine whether we would hold the same. Even were we to assume that *Kaplan* was wrongly decided and that Jackson can demonstrate error, her argument fails at the second prong of plain-error review—she cannot show a clear or obvious, *i.e.*, a "plain," error. *See Olano*, 507 U.S. at 734 ("'Plain' is synonymous with 'clear' or, equivalently, 'obvious.'"). In discussing this prong, the Supreme Court has recognized that, "[a]t a minimum, court[s] of appeals cannot correct [unpreserved] error pursuant to Rule 52(b) unless the error is clear under current law." *Id.* Thus, we have previously recognized that "[a]n error is plain 'if the settled law of the Supreme Court or this circuit establishes that an error has occurred.'" *United States v. Carthorne*, 726 F.3d 503, 516 (4th Cir. 2013) (quoting *United States v. Maxwell*, 285 F.3d 336, 342 (4th Cir. 2002) (citation omitted)).

Applying this understanding of what constitutes "plain" error to this case, we observe that it's not "obvious" that Jackson's conduct falls outside the meaning of "held for sale" as it is used in § 331(k). Neither the Supreme Court nor we have taken a position

on this issue, placing it outside the ordinary circumstances in which we would conclude error is "plain." And we have previously recognized that a "district court does not commit plain error by following the reasoning of another circuit" "where we have yet to speak directly on a legal issue and other circuits are split." *United States v. Strieper*, 666 F.3d 288, 295 (4th Cir. 2012) (citing *United States v. Rouse*, 362 F.3d 256, 263–64 (4th Cir. 2004)); *cf. United States v. Alli-Balogun*, 72 F.3d 9, 12 (2d Cir. 1995) (per curiam) (stating, "we do not see how an error can be plain error when the Supreme Court and this court have not spoken on the subject, and the authority in other circuit courts is split"). If a position in line with one side of an existing sister-circuit split cannot cause error to be plain, *a fortiori*, a position in line with the sole circuit court to address an issue cannot be obviously wrong. In short, where the only circuit court to address the issue goes against the defendant, as does a substantial body of case law across courts addressing underlying points that the circuit court relied on, any error by the district court in this case was not "plain." *Accord United States v. Green*, 996 F.3d 176, 185 (4th Cir. 2021) (recognizing that an error is "clear" or "obvious" when, even though there is no binding precedent from the Supreme Court or the Fourth Circuit, circuit courts of appeals "have uniformly taken a position" *contrary* to the district court's).

We therefore reject Jackson's assertion that the conduct relied on to support the indictment and her conviction falls outside the scope of § 331(k) because it does not involve the device being "held for sale."

B.

Jackson next argues that the district court erred by failing to recognize that 21 U.S.C. § 396 protects

physicians from being prosecuted under § 331(k) for off-label use of medical devices that occur within a doctor–patient relationship. That central premise forms the basis of another multi-faceted assertion of error: (1) that the district court should have dismissed the indictment for failure to allege that the relied-on conduct occurred outside a doctor–patient relationship, (2) that the court abused its discretion by rejecting her proposed jury instruction that "[i]n order to find [her] guilty of the [FDCA] offense . . . [it] must find that the defendant was not acting within the scope of . . . a legitimate doctor patient relationship when she re-used the medical device at issue in this case," J.A. 238; and (3) that the court should have entered a judgment of acquittal because insufficient evidence existed to prove that Jackson acted outside of a legitimate doctor–patient relationship.9

All three facets of this argument rest on a fundamental misunderstanding of the relationship between §§ 396 and 331(k). Moreover, adopting Jackson's position would thwart congressional intent and create a huge loophole in the FDCA. *See United States v. Regenerative Sciences, LLC*, 741 F.3d 1314, 1320 (D.C. Cir. 2014) (observing that "classifying [acts prohibited by other provisions of the FDCA] as the practice of medicine" for purposes of § 396 would "create an enormous gap in the FDCA's coverage"). The mere fact that the individual charged is a physician cannot be sufficient to prohibit prosecution under § 331(k). On its face, § 331(k) prohibits certain conduct, regardless of the individual who engages in that conduct. So, nothing in § 331(k) itself suggests that it would not apply to a physician who engaged in the proscribed conduct.

Although § 396 protects a doctor's ability to practice medicine by limiting how the FDCA is to be applied to them, the statute does not apply to the circumstances presented here. In that regard, the statute provides:

> Nothing in [the FDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

§ 396. In discussing this provision, the Supreme Court has recognized that it protects "offlabel" usage of medical devices, which it understood to mean "use of a device for some purpose other than that for which it has been approved by the FDA." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

The principal problem with Jackson's argument is that she equates the sort of off label usage that § 396 is designed to protect with the holding for sale of an adulterated device, an action *not* protected by the statute. Section 396 protects only physicians who

"prescribe or administer any *legally marketed* device" (emphasis added). The FDCA bars adulterated devices from the stream of commerce entirely, so they cannot be lawfully sold. 21 U.S.C. § 331(a), (c). They therefore are not legally marketed devices within the meaning of § 396. *Judge Rotenberg Educ. Ctr., Inc. v. U.S. FDA*, 3 F.4th 390, 397 (D.C. Cir. 2021). And while off-label use is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine," *Buckman Co.*, 531 U.S. at 350, holding adulterated devices for sale is not.

Once again, the Ninth Circuit's decision in *Kaplan* addressed and rejected the view Jackson espouses of how §§ 331(k) and 396 operate. And on this point, we expressly agree with its conclusion that "[w]hile a physician may exercise professional judgment in the off label use of unadulterated products, nothing in the FDCA or caselaw suggests that the use of adulterated products is ever permissible." 836 F.3d at 1211; *accord United States v. Cal. Stem Cell Treatment Ctr., Inc., 117 F.4th 1213, 1220 (9th Cir. 2024).*10 Section 396 simply does not cover the type of conduct at issue in the charged violation of § 331(k) proven at trial here. We therefore reject Jackson's argument to the contrary.

C.

Allied with her defective § 396 theory, Jackson also argues that her § 331(k) conviction cannot stand because it is grounded in a faulty theory that re-use of a device labeled for single use constitutes per se adulteration. In her view, "FDA-mandated labels do not have the force of law as to doctors' use of devices" and "it cannot be a per se violation of the FDCA for a

doctor to use a device in a manner different from the way its manufacturer intended as provided on the label—including reusing a device labeled as a 'single use' device." Opening Br. 45, 47. She contends that because the indictment, jury instructions, and evidence were directed to show that she was liable based on this flawed theory, the Court should vacate her conviction and dismiss the charges.11

We reject Jackson's argument because it misunderstands the basis for her conviction. In short, her conviction followed statutory requirements and is not based on the theory she claims as the Government's basis for her prosecution. To the contrary, the theory for holding Jackson liable was that she "held for sale" an adulterated device—exactly as § 331(k) envisions. That fact is borne out in both the superseding indictment and the jury instructions, as well as how the Government prosecuted the case.

For example, the superseding indictment repeatedly cited and quoted § 331(k) and § 351(a)(2)(A)'s statutory language about when a violation occurs and when a medical device is adulterated. In connecting that statutory language to Jackson's alleged violation, the indictment described why the Entellus could not be cleaned effectively or sterilized. It also described the conditions in Jackson's practice that caused the device to be adulterated. This language does not suggest that mere off-label use such as re-use of a device labeled for single use was a *per se* basis for charging Jackson with violating § 331(k).

The jury instructions similarly tracked the statutory language for what constitutes a § 331(k) violation and adulteration. At no time was the jury instructed that it could convict Jackson solely based on her re-use of a device labeled for single use. Indeed, the only time the instructions mentioned that the device was labeled for "single-use" is in the context of finding Jackson's intent to defraud—an add-on finding to the threshold determination that Jackson had violated § 331(k). That instruction provided the example that "if [the jury] f[ou]nd beyond a reasonable doubt that [Jackson] did not disclose to a patient that she was reusing a single-use . . . device that she had used on a different patient and that one of her reasons for doing so was to enrich herself, then the Government has proven an intent to defraud and mislead." J.A. 3516. This finding about Jackson's *intent* became relevant only *after* the jury's initial determination that the device was adulterated and that Jackson had violated § 331(k).12

To be sure, that the Entellus was labeled for single use came up at trial. And rightly so, as it was relevant background information. But the testimony at trial centered on *why* the device had been labeled for single use, not on the fact *that* it was labeled so. Parallel with evidence about the Entelluses' labeling, the Government developed a thorough case about what happened to the device after its first use and the risks associated with attempting to clean a used device and then reusing it. And the totality of *that* evidence was directly relevant to the issue before the jury—whether Jackson had "do[ne] any other act with respect to" the device while it was being "held for sale" that "result[ed] in such [device] being adulterated." § 331(k). In addition, evidence about

the Entellus's single-use label was relevant to establishing how Medicare reimbursed doctors for performing a sinuplasty procedure on patients, and it supported the Government's theory about Jackson's profit motive for engaging in the prohibited conduct. But again, it was not the single-use labeling that formed the basis for finding that the Entelluses were adulterated.

In sum, Jackson's argument ignores large swaths of the Government's case and myopically focuses on and takes out of context one component of admitted evidence to argue that a theory of *per se* adulteration from re-use led to her conviction. Based on the totality of the record, including the language of the superseding indictment and the jury instructions, we reject this argument.

D.

Jackson also argues that the district court improperly curtailed her ability to present her defense when it prohibited her from introducing a video she recorded in which she demonstrated how she cleaned the Entellus. She maintains that the district court mistakenly believed that she wanted to testify as an expert witness when her purpose was to offer lay testimony about "how she cleaned and sanitized the device[]," so that the jury would hear her side of the story. Opening Br. 54.

The record presents a different picture of why the district court disallowed this evidence. The night after Jackson began to testify at trial, her attorneys disclosed for the first time their intent to introduce a video recording the following day when Jackson resumed her testimony. The video would depict Jackson demonstrating her cleaning methods, taking culture samples from the

device, and then handing over the samples for testing. Initially, Jackson explained to the court that she wanted to introduce the video as background evidence for introducing her testimony both about her cleaning methods and about the results of the culture tests. with the Government, observing that this request was a "blatant violation of Rule 16 and [the court's] scheduling order," J.A. 3078, and was "an effort to have [Jackson] testify as an expert" without following the pre-trial process, J.A. 3079. Jackson then shifted gears, asking the court if it would permit a silent version of the video recording to play while Jackson testified about it as "an example of how she washes [the device]." J.A. 3080. The district court denied that request too, observing "there's a process of reviewing information or videos like this in a timely fashion. And to produce it the night before—in the middle of testimony . . . . No lawyer has tried to do this, and it's because it's patently improper." J.A. 3080.

Jackson's arguments on appeal fail to grapple with the fundamental ground of untimeliness that the district court relied on when denying admission of the video, regardless of whether it was classified as expert testimony or not. Because Jackson requested discovery from the Government, Federal Rule of Criminal Procedure 16(b)(1)(A)(ii) required Jackson to allow inspection of any evidence she wished to use in her "case-in-chief at trial." The district court's scheduling order required Jackson to make her Rule 16(b) disclosures by July 2022—*six months* before Jackson did so. S.A. 2.

District courts have broad discretion "in all rulings related to the admission and exclusion of evidence, and this Court will not reverse the decision to exclude such

evidence absent abuse of that discretion." *United States v. Holmes*, 670 F.3d 586, 598 (4th Cir. 2012). We see no abuse of discretion in the district court's refusal to reward Jackson for her disregard of the court's scheduling order. We reject Jackson's evidentiary challenge to the exclusion of her video evidence.13

E.

Jackson's second evidentiary argument relates to the district court's exclusion of certain documents about disinfection and sterilization from the Centers for Disease Control and Prevention ("CDC"). Though their specifics vary, the documents generally discuss sterilization techniques for medical equipment. One such document, titled "Reuse of Single-Use Medical Devices," recounts that "[a]pproximately 20 to 30% of U.S. hospitals reported that they reuse at least one type of single-use device." J.A. 3638. When ruling on their admissibility, the district court excluded them as hearsay and rejected Jackson's argument that they were nonetheless admissible to show their effect on her and thereby had the potential to negate a finding that she intended to defraud her patients.

On appeal, Jackson again asserts that these documents were admissible for a purpose other than for their truth, *i.e.*, for their effect on her. She contends that had this evidence been admitted, the jury "may well have had a reasonable doubt as to whether [she] had a reason to cover up her re-use of devices, and thus may have acquitted her of the adulteration offense[.]" Opening Br. 55.

Assuming, without deciding, that the evidence was admissible, we conclude that any purported error was

harmless. To prove nonconstitutional error harmless, "the Government must demonstrate that the error did not have a 'substantial and injurious effect or influence in determining the jury's verdict.'" *United States v. Curbelo*, 343 F.3d 273, 278 (4th Cir. 2003) (quoting *Kotteakos v. United States*, 328 U.S. 750, 776 (1946)). "An appellate court does not inquire into whether absent the error sufficient evidence existed to convict, but rather whether we believe it highly probable that the error did not affect the judgment." *United States v. Ibisevic*, 675 F.3d 342, 350 (4th Cir. 2012) (internal quotation marks and citation omitted). So, to affirm, we "must be able to '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.'" *Id.* (citation omitted). We have the requisite "fair assurance" here. The CDC documents provide scant support for the propositions Jackson uses them to advance. None of them address the disinfection or sterilization of the Entellus or a similar device. And the document about re-use of single use devices likewise does not mention this device as one that is reused by other medical providers. At bottom, the documents do not show that this device could be sterilized effectively or that Jackson was justified in believing that they could be. For this reason, we conclude it is "highly probable that [their exclusion] did not affect the judgment." *Ibisevic*, 675 F.3d at 350 (quotation marks and citation omitted).

F.

Next, Jackson asserts the district court prejudiced her case by instructing the jury that it was "irrelevant" that no patient was harmed.14 The instructions she challenges were given in response to objected-to questioning during her testimony (i.e., not immediately before deliberations). Though the specific instructions

vary, in each instance, the district court returned the jury's attention to the Government's burden with respect to the § 331(k) violation, cautioning them, for example, that evidence that no patients were harmed as a result of Jackson's methods "is irrelevant. . . . The United States does not have to prove in Count 1 that a single patient got sick because of the defendant's process." J.A. 3167.
Jackson contends these instructions erroneously prohibited her "from showing that the devices were not adulterated," "that she had no motive to—and thus did not—adulterate the devices . . . or otherwise scheme to cover up the fact that she was using dirty devices,"
and that they "misinformed the jury about how they should consider evidence related to adulteration." Opening Br. 60.

Jackson's argument misapprehends what § 331(k) required of the Government. As the statutory definition makes clear, the district court was correct when it instructed that § 331(k) did not require proof of actual harm to patients for a jury to find that the Entellus had been adulterated. Section 351(a)(2)(A) states that a device "shall be deemed to be adulterated" if it is "held under insanitary conditions whereby it *may have been* contaminated by filth, or whereby it *may have been* rendered injurious to health." (Emphases added). A device can satisfy this definition without causing someone actual harm; it is sufficient that the potential for contamination or injury exist. Thus, the district
court was well within its discretion to instruct the jury to that effect.

G.

Jackson's final challenge to this count contends

that reversible error occurred during the Government's closing argument as a result of an impermissible "Golden Rule" argument. An invitation "urg[ing] jurors to identify individually with the victim" is an improper "Golden Rule" closing argument. *United States v. Huskey*, 90 F.4th 651, 671 (4th Cir. 2024) (quoting *United States v. Al-Maliki*, 787 F.3d 784, 795 (6th Cir. 2015)); *accord* *United States v. Moreno*, 947 F.2d 7, 8 (1st Cir. 1991) (observing that improper "golden rule" arguments "encourage[] the jury to depart from neutrality and to decide the case on the basis of personal interest and bias rather than on the evidence"). "A golden-rule objection typically arises when a lawyer asks jurors to place themselves in the plaintiff's position with respect to the calculation of *damages*," with "[t]he rationale for prohibiting such an argument [being] that the jury's sympathy will be unfairly aroused, resulting in a disproportionate award of damages." *Ermini v. Scott*, 937 F.3d 1329, 1340 (11th Cir. 2019) (quoting *Burrage v. Harrell*, 537 F.2d 837, 839 (5th Cir. 1976)).

Jackson asserts that two portions of the Government's closing argument violated this precept. In suggesting that every patient would prefer a sterile device to an adulterated one, the Government asked, "Which one would you want? . . . . If you could have a device that had been here fully coated and contaminated with another person's blood and mucous, or you could have that perfectly pristine device, which one would you want? Which one would you choose?" J.A. 3418. The Government then "add[ed] another factor to [the juror's] choice," observing that the unused device was "completely sterile" and posed "zero risk that another human's bodily fluids would get inside your body . . . . Would that impact your decision?" J.A. 3418.

Assuming, without deciding, that these statements constitute an impermissible "Golden Rule" argument, we conclude that they were not prejudicial in context and therefore do not require reversal. We will reverse a conviction based on an improper closing argument only when the impropriety "so prejudicially impacted the defendant's substantial rights as to deprive him of a fair trial." *United States v. Webb*, 965 F.3d 262, 267 (4th Cir. 2020) (quotations and citation omitted). And here our review is further constrained by the plain-error standard because Jackson neither lodged a contemporaneous objection nor moved for judgment of acquittal on this ground in the district court.15 *See id.*

Jackson has not met her burden. The allegedly improper argument consists of three lines in a closing argument that spans some thirteen pages devoted just to Count 1. Quite apart from these brief references, the jury had overwhelming evidence supporting Jackson's culpability. Indeed, Jackson admitted to reusing Entelluses, and it's undisputed that she did not inform her patients that she did so. Other evidence supported the jury's conclusion that Jackson's re-use and cleaning methods nonetheless "adulterated" the device. And still more evidence supported the jury's finding that by reusing the devices, Jackson profited by billing Medicare in full for the sinuplasty procedure that factored in the full price of a new device. Jackson profited handsomely from her approach. On this record, we cannot discern that Jackson's substantial rights were impacted and, absent that showing of prejudice, reversal is not warranted. See Huskey, 90 F.4th at 671.

* * * *

Having rejected each of Jackson's arguments as to Count I, we affirm her conviction for violating 21 U.S.C. § 331(k).16

III.

Jackson next challenges her convictions for aggravated identity theft, in violation of 18 U.S.C. §§ 1028A(a)(1) and 2, which formed Counts 15 and 16 of the superseding indictment. This offense imposes a mandatory consecutive two-year term of imprisonment if an individual has been convicted of other qualifying offenses and, during or in relation to those offenses, the defendant "knowingly transfers, possesses, or uses, without lawful authority, a means of identification of another person." § 1028A(a)(1), (b)(2); see United States v. Abdelshafi, 592 F.3d 602, 607 (4th Cir. 2010) (recounting the four elements of this offense).

The superseding indictment charged that Jackson aided and abetted in aggravated identity theft by manufacturing backdated declarations purporting to be from two patients, using their names and, most importantly, their forged signatures. Jackson then submitted those declarations as part of her responses to the 2018 Palmetto audit.

After the jury convicted Jackson, the Supreme Court decided Dubin v. United States, 599 U.S. 110 (2023), which clarified what it meant to "use" an individual's identity "in relation to" another qualifying

offense. Arguing that Dubin invalidated her convictions, Jackson moved for a judgment of acquittal or a new trial as to Counts 15 and 16. The district court denied her motion. It concluded that the concerns present in Dubin about when a defendant's "use" of another's identifying information is sufficiently close to the qualifying offense to be deemed "in relation to" to it were not at issue in this case. In the court's view, the requisite hook between the identity theft and qualifying other offense existed here because Jackson had forged the patients' signatures on declarations purporting to be from those patients and then submitted them as part of the false statements that constituted the qualifying other offense (making false statements relating to health care matters).

On appeal, Jackson does not challenge the denial of her motion for judgment of acquittal. Instead, she relies on Dubin to make two different arguments: that Dubin rendered the superseding indictment and the jury instructions deficient because it requires a specific finding—by the grand jury and the petit jury, respectively—that the alleged misuse of the victim's identity was what made the qualifying offense criminal. Because the grand jury did not so find as part of Counts 15 or 16, she contends the Court should vacate those convictions and remand for the district court to dismiss those charges. Alternatively, because the jury instructions did not require the jury to make this finding before convicting her, she asserts the Court should vacate those convictions and remand to permit a new trial.

Because Jackson did not raise either of these challenges in the district court, we review for plain error.

See Greer v. United States, 593 U.S. 503, 507–08 (2021).17 Jackson has not met her burden of showing any error, let alone an obvious one.

In *Dubin*, the Supreme Court "clarified the scope of the statute prohibiting aggravated identity theft" by resolving a circuit split (which we were not part of) about when a defendant "uses" another's identifying information "in relation to" another qualifying offense. *United States v. O'Lear*, 90 F.4th 519, 532–33 (6th Cir. 2024). The defendant in *Dubin* conducted certain psychological tests on a patient and then submitted claims to Medicaid for reimbursement. *Dubin*, 599 U.S. at 114. That paperwork referred to the patient by name and described the procedures performed, but fraudulently inflated the amount to be reimbursed by misrepresenting the qualifications of the person performing the procedures. *Id.* Unlike this case, the patient's signature did not appear on the paperwork. And while the patient's name appeared on the provider-submitted paperwork, services had been performed on that named patient. *Id.* The provider's "fraud" thus related to identifying the type and dates of services identified for reimbursement, not the identity or existence of any particular patient.

The Government charged the *Dubin* defendant with aggravated identity theft based on the submitted paperwork bearing the name of the patient. *Id.* at 114–15. But the Supreme Court held that § 1028A(a)(1) does not cover such conduct, observing identity theft offenses occur "when the defendant's misuse of another person's means of identification is at the crux of what makes the conduct criminal," *i.e.*, when the means of identification

Nor do we discern any reason to believe that *Dubin* undercuts the factual basis on which Jackson was charged or convicted. The "crux" of Jackson's fraud was in submitting falsified paperwork as part of a Medicaid audit. But crucially, for § 1028A purposes, that falsified paperwork contained the two declarations that then formed the basis of the aggravated identity theft counts. And "who" created and signed those declarations was essential to the qualifying offense's fraud—Jackson submitted them claiming that they were declarations signed by her patients supporting what they represented and thus supporting her responses to the audit. Instead, the declarations were not the patients' representations at all, nor did they bear the patients' real signatures. Rather, it was Jackson (or those under her direction) who both crafted the declarations purporting to be from her patients *and* attested to those representations by forging the patients' signatures.

Thus, unlike the circumstances in *Dubin*, the circumstances here present a classic case of identity theft, falling cleanly within the aggravated identity theft statute's scope. At bottom, the facts in *Dubin* differ significantly from this case, and the concerns the Supreme Court targeted there are not implicated here. *See, e.g.*, *United States v. Gladden*, 78 F.4th 1232, 1245 (11th Cir. 2023) (concluding that no *Dubin*-like mismatch existed where the defendant used others' identities "to continue refilling prescriptions in their names," making that forgery "the heart of" the fraudulent practice of billing for medically unnecessary prescriptions). We reject Jackson's contention that the indictment or instructions were deficient in view of *Dubin*'s clarifying language about the scope of the
offense. Discerning no error—plain or otherwise—with Jackson's convictions for aggravated identity theft (Counts 15 and 16), we affirm them.

IV.

For the reasons set forth above, we affirm all of Jackson's convictions.

AFFIRMED

APPENDIX B

FILED: March 4, 2025

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 23-4467 (L) (5:21-cr-00259-D-1)
UNITED STATES OF AMERICA Plaintiff – Appellee
v.
ANITA LOUISE JACKSON Defendant – Appellant

PHYSICIANS AGAINST ABUSE, INC. Amicus Supporting Appellant

No. 23-4587 (5:21-cr-00259-D-1)

UNITED STATES OF AMERICA Plaintiff - Appellee v.
ANITA LOUISE JACKSON
Defendant - Appellant

PHYSICIANS AGAINST ABUSE, INC. Amicus Supporting Appellant

O R D E R

The court denies the petition for rehearing and rehearing en banc. No judge requested a poll under Fed. R. App. P. 40 on the petition for rehearing en banc.
Entered at the direction of the panel: Chief Judge Diaz, Judge Agee, and Judge Benjamin.
For the Court

/s/ Nwamaka Anowi, Clerk

APPENDIX C

Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff Document issued on July 6, 2001

This document supersedes Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff, May 27, 2001.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs
Div. of Device User Programs and Systems Analysis

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at

(http://www.fda.gov/cdrh/ohip/guidance/1333.pdf) .
You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1333) to identify the guidance you are requesting.

Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff
This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

Background

On August 14, 2000, the Food and Drug Administration released a document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" to provide guidance to third-party and hospitals reprocessors about their responsibilities as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third-party and hospital reprocessors of single-use devices (SUDs) are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission

requirements (Section 513 and 515 of the Act; 21 *Code of Federal Regulations* Parts 807 and 814).

Since its release on August 14, 2000, the agency has received numerous questions about the enforcement priorities guidance. The following questions and answers are meant as clarification of the original document. This guidance will be updated as the need arises. The Least Burdensome Approach We believe FDA should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

Question related to SELECTION OF A THIRD-PARTY REPROCESSOR

Question. *How can I obtain information about third-party reprocessors of single-use devices (SUDs)?*

Answer. At this time, FDA cannot provide a list of reprocessors because our registration and listing database was not designed to identify third-party reprocessors. We plan to create a specific code that will identify reprocessors.

To help you select a third-party reprocessor, we suggest you talk with other hospitals to determine their experiences with third-party reprocessors and arrange to visit the reprocessors' facilities. In addition, you may consider asking a potential reprocessor the following questions:

- When did FDA last inspect your facility? What were the results of that inspection?
- Do you have documentation that demonstrates that your company has been cleared/approved by FDA to reprocess SUDs?
- How do you monitor the manufacturing processes and what records do you maintain in order to comply with FDA's Quality System regulation?
- What aspects of your overall process have been validated, for example, cleaning, packaging, sterilization?
- Has your company set limits on the number of times a SUD can be reprocessed? If yes, how did you determine the number of times a SUD can be reprocessed? What procedures do you have in place to ensure that a SUD is not reprocessed beyond the set number of times?

To obtain the 483 inspection report from a reprocessor's most recent FDA inspection, contact FDA's Freedom of Information Staff by fax at 301-443-1719 or 301-443-1726. You also can obtain information about a reprocessor's inspection history at http://www.fda.gov/cdrh/foicdrh.html.

Question related to
MEDICAL DEVICE REPORTING

Question. *What are FDA's requirements for reporting an adverse event with a SUD reprocessed by the hospital?*

Answer. If a hospital reprocesses a device that was previously marketed as a single-use device, FDA considers the hospital to be the manufacturer of that device and subject to the same adverse event reporting requirements (Medical Device Reporting or "MDR") as original equipment manufacturers or commercial reprocessors. A manufacturer is defined in Title 21 of the *Code of Federal Regulations* (CFR) at 803.3(o) as "any person who manufactures, prepares, propa-gates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure." The manufacturer MDR requirements are in addition to the hospital's current user facility adverse event reporting requirements. Information on MDR requirements is available on the Internet at http://www.fda.gov/cdrh/mdr.html and http://www.fda.gov/cdrh/osb/guidance/1334.pdf.

Questions related to QUALITY SYSTEM
GENERAL

Question. *Should my hospital comply with the Quality System regulation even if the SUDs that we are reprocessing do not require premarket submissions to the FDA?*

Answer. Yes. Regardless of whether or not the SUDs that your hospital is reprocessing require premarket submissions, your hospital should comply with the requirements of the Quality System regulation [which also is referred to as the current Good Manufacturing Practice (cGMP)] as described in 21 CFR Part 820 (see Appendix question #7 below). The following Internet web sites provide information about the requirements of the regulation:
http://www.FDA.gov/CDRH/dsma/gmpman.html –

Medical Device Quality Systems Manual:

A Small Entity Compliance Guide
http://www.FDA.gov/CDRH/comp/designgd.html - Design Control Guidance for Medical Device Manufacturers
http://www.FDA.gov/ora/inspect_ref/igs/qsit/qsitguide.pdf - Quality System Inspection Technique (QSIT) Handbook
http://www.FDA.gov/CDRH/ode/425.pdf - Guideline on General Principles of Process Validation

Question. *Is the CEO of a hospital responsible for quality policy and implementation under the Quality System (QS) regulation?*

Answer. Under 21 CFR 820.20 (Management responsibility) management with executive responsibility is the level of management that has the authority to establish and make changes to the facility's quality policy. The implementation of the quality system may be delegated; however, it is up to the highest level of management to establish quality policy and ensure implementation. Management reinforces understanding of policies and objectives by demonstrating a commitment to the quality system visibly and actively on a continuous basis. This can be demonstrated by providing adequate training and resources to support quality system development and implementation.

STERILIZATION

Question. *What sterilization activities does FDA expect in a hospital reprocessor that is reprocessing single-use devices (SUDs)?*

Answer. A hospital reprocessor that reprocesses SUDs is considered a device manufacturer as defined under 21 CFR 820.3(o). As such, FDA expects that its sterilization reprocessing of SUDs will meet the requirements of the Quality System (QS) regulation (21 CFR Part 820). This regulation is applicable to the sterilization activities in many ways. Several key elements affect whether a device is sterile or nonsterile and whether it will function as intended at the conclusion of the process. The success of a sterilization process is dependent to a large degree on how well the hospital reprocessor:

- has validated the sterilizing equipment and process;
- controls the routine processing; and
- reaches decisions to assure that only a sterile product is released for use.

A hospital SUD reprocessor should prove during validation studies that each sterilization process is capable of achieving sterility for each run (21 CFR 820.75). The sterilization process should achieve a sterility assurance level (SAL) of 10 -6 for devices used in normally sterile areas of the body. A hospital reprocessor cannot just assume that standard sterilizer cycles will effectively and safely reprocess devices; it should demonstrate with microbiological lethality study data that the SAL is achieved by the process utilized. Also, a hospital reprocessor should develop evidence that the sterilization process does not have an adverse impact on the materials or functioning of the SUDs being reprocessed.

Process controls used for routine sterilization should be adequate to assure that the specifications for process

parameters established during validation are always met [21 CFR 820.70(2)]. By doing validation studies, a hospital reprocessor can prove that when certain parameters (for example, temperature or humidity) are used, sterility will be achieved. A hospital reprocessor should establish controls over the routine processing to assure that the specifications for these parameters are met during each run.

Finally, a hospital reprocessor should have procedures for releasing the SUDs for use, so that any possibly non-sterile reprocesssed SUD is detectable [21 CFR 820.80(d)]. It should review documentation from each run to be sure that the parameter specifications have been met. Many hospital reprocessors also include biological confirmation of sterility by using biological indicators (BIs) with each run. While FDA strongly encourages the use of biological indicators, there may be circumstances when the validation studies and the process controls are so rigorous that BIs might not be needed. In these cases, the process should meet the parametric releases that are defined in recognized consensus standards.

Question. What kinds of documentation should a hospital reprocessor maintain for sterilization reprocessing of SUDs? **Answer.** A hospital that reprocesses SUDs should maintain written procedures and data to show that it is meeting requirements of relevant portions of the Quality System (QS) regulation (21 CFR Part 820).

In the area of sterilization, a hospital reprocessor should maintain documentation to show that equipment

has been installed correctly and operates as intended. Likewise, it should have documentation that shows the sterilization process has been validated as being effective in achieving sterility without adversely affecting the devices [21 CFR 820.75(a)]. Also, a hospital reprocessor should maintain documentation for process control procedures and data to prove that for each run the specifications for sterilization parameters have been met [21CFR 820.70(a) and 820.184]. FDA may also ask to see any test results relating to the validation or routine sterilization of SUDs.

Question. What guidance is applicable to hospital reprocessors that are sterilizing SUDs?

Answer. FDA has guidance documents that apply generally to all types of manufacturing processes including sterilization. For example, the "Guideline on General Principles of Process Validation" applies to sterilization activities as well as to other manufacturing processes. This document is located on the Internet at www.fda.gov/cdrh/ode/425.pdf. FDA documents relating to the Quality System (QS) regulation also are applicable for sterilization processes. These documents are located on the Internet at www.fda.gov/cdrh/dsma/cgmphome.html. General guidance is available from other sources such as the Global Harmonization Task Force document entitled "Process Validation Guidance for Medical Device Manufacturers." Many national and international consensus standards provide specific sterilization processes. We encourage you to become familiar with these standards. FDA has worked closely with other experts from industry, healthcare facilities, and academia in developing these standards for the various

types of sterilization processes commonly used for medical devices. FDA recognizes many of these standards as providing acceptable guidance for good sterilization practices. Although acceptable to FDA, these standards are voluntary, and there is no regulatory requirement that they be followed. If these standards are not followed, FDA expects that processing will meet the same levels of scientific soundness as the standards. The FDA consensus standards program is described on the Internet at www.fda.gov/cdrh/stdsprog.html. A list of standards useful in the reprocessing sterilization of SUDs is located at www.fda.gov/cdrh/reuse/reuse-standards.shtml. Although consensus standards for the sterilization of medical devices have been directed either to healthcare facilities or to industrial users, many are being rewritten to include both types of facilities. For example, in the area of sterilization methods commonly used in hospitals (moist heat or ethylene oxide), there are standards for both industrial users and for healthcare facilities, as follows:

STERILIZATION METHOD	INDUSTRIAL FACILITY USE	HEALTHCARE FACILITY USE
ETHYLENE OXIDE	ISO 11135	ANSI/AAMI ST 41
MOIST HEAT	ISO 11134	ANSI/AAMI ST 46

Note that ANSI/AAMI ST 41 states that it does not cover the reprocessing of items labeled for single-use only. Revisions of ANSI/AAMI ST 46 have been written and indicate a similar exclusion for reprocessing of SUDs.

When deciding which standards to use for sterilization of SUDs, remember that FDA considers hospitals to be

be reprocessed safely. In fact, such a list would be impossible to develop. Whether or not a device can be reprocessed safely depends not only on the device but on the reprocessor and the methods used for cleaning and sterilizing. Because of materials used or design of the device, some models within a particular type of device may be able to be reprocessed safely while others may not.

Question. *If a device is identified as "Exempt" on the List of SUDs (Appendix A), is it exempt from both premarket and non-premarket requirements?*

Answer. No. A "Y" (yes) in the column identified as "Exempt (Y/N)?" means that the device is exempt from the premarket requirements only. It does not provide any information on whether or not the device is exempt from any of the non- premarket regulatory requirements. A revised list that includes a column titled "Premarket Exempt" and another column titled "GMP Exempt" has been provided to clarify the types of exemptions that apply to a particular type of device. That list can be found on the Internet at www.fda.gov/cdrh/reuse/1168a.html.

Questions related to SPECIFIC DEVICES

Question. *Where can I obtain specific guidance for the SUD that I am interested in reprocessing?*

Answer. You can search for guidance on a specific device on our Internet web site at

http://www.fda.gov/cdrh/guidance.html and http://www.fda.gov/cdrh/devadvice/11.html.

Question. *How can I obtain information on the status of a premarket notification [510(k)] submission or a premarket approval (PMA) application for a reprocessed SUD?*

Answer. The status of an application under FDA review is confidential. Once an application has been cleared or approved, it is included in FDA's releasable database on the Internet at http://www.fda.gov/cdrh/databases.html. Click on the Premarket Notifications Database [510(k)s] or the Premarket Approvals Database (PMA).

Question related to
REGISTRATION AND DEVICE LISTING

Question. *How do we register our facility and list the SUDs that we are reprocessing?*

Answer. A medical device establishment that is registering for the first time should complete form FDA 2891 (Initial Registration of Device Establishment). Enter the establishment type code "MB" for a reprocessor if the form you receive does not have the code preprinted on it. You should list all SUDs that your facility reprocesses. Submit a form FDA 2892 (Device Listing) for each type of device being reprocessed. Information on how to obtain blank registration and listing forms and how to complete them is located on the Internet at http://www.fda.gov/cdrh/reglistpage.html.
Note: Additional Questions are available at:
http://www.fda.gov/cdrh/ohip/guidance/1408.html