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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-cr-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

Emergency Motion for Relief, Motion to strike Jury's Verdict per the 8th Amendment, Common Law Right to set aside verdict, 5th Amendment Due Process Violation, Ultra Vires Agency Action, Rule 33 Motion for a New Trial and Impossibility, Miscarriage of Justice, Motion to Strike Verdict due to Lack of Jurisdiction, Motion to Reconsider, and Motion to remain on bond pending Appeal and Habeas Corpus[1]

Defendant Dr. Sanjeev Kumar respectfully asks the Court to set aside the jury's verdict, or, in the alternative, allow Dr. Kumar to remain on bond pending resolution of an appeal and/or habeas corpus claim. Dr. Kumar supports the above as follows:

This case presents an unusual question concerning the relationship between the Department of Justice's criminal theory and the FDA's own regulatory framework governing medical devices. And this motion concerns a single question: whether the Department of Justice may obtain a criminal conviction under the Federal Food, Drug, and Cosmetic Act using a theory that conflicts with the FDA's own published regulatory framework governing single-use medical devices. It can't.

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[1] Dr. Kumar requests that this Motion be heard prior to the sentencing enhancements on July 7 because addressing this motion will save judicial resources. The undersigned apologizes to this Honorable Court, as will be explained further *infra*., but counsel failed to find this law timely.

As such, Dr. Kumar would humbly request that this Honorable Court strike the jury's verdict from the record and remit this matter to the FDA; or, in the alternative, grant bond pending appeal and/or a 2255 motion.

Brief Background & Legal Framework

Dr. Kumar was convicted of adulteration and misbranding under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*.

Congress passed the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq*. (the "Act"), and granted the FDA authority to promulgate rules to interpret and enforce the Act. *See* 21 U.S.C. § 371 (the FDA, by and through the direction of Secretary Kennedy at HHS, has the "authority to promulgate regulations for the efficient enforcement of this chapter"). The FDA has continually released guidance, rules and regulations on the Act for decades. And the FDA interprets and promulgates rules for the Act. *Id*.; *see also id*. at (h) (referencing guidance documents interpreting statutory schemes under the Act); *Apotex, Inc. v. Food & Drug Admin*, 226 Fed.App'x. 4 (Fed.Cir. 2007)(per curiam)(stating that the FDA's interpretation of the Act is deferred to unless its interpretation is arbitrary or capricious).

Law & Argument

A. Single Use Devices.

The FDA candidly states that it does not regulate reprocessed single use devices ("SUDs") in the outpatient physician context. *See* FDA Compliance Policy Guides Manual, Mar. 20, 2015, 2004 WL 3363378 at *3(Sec. 300.500) ("the following policy does not apply to: (1) health care facilities other than hospitals"); Guideline for Disinfection and Sterilization in Healthcare Facilities, Reuse of Single-Use Medical Devices (2008, updated Jun. 2024), Pg. 81 (these requirements do not apply to "healthcare settings other than acute-care hospitals");

Guidance for Industry and for FDA Staff Enforcement of Single-use reprocessed devices, 2000 WL 34503051, at * 5 (Aug. 14, 2000)(stating that regulations don't apply to "health care facilities that are not hospitals); Guidance for Industry and FDA Reprocessing and reused of single use devices, 2000 WL 34503060, at *2-3(Feb. 8, 2000)(stating that the regulations don't apply to health care facilities that aren't hospitals)[2]; *see also* Sworn Declaration (hereinafter, "Dec") of Stephen Terman (former FDA counsel); Dec. of Ed Teitel, Dec. of Daniel Vukelich and Association of Medical Device Reprocessors. Again, the FDA explicitly states that these regulations apply only to acute hospital healthcare and third-party processors.[3]

Dr. Kumar contends that counts and verdicts 1-32 must be tossed out because the FDA created a safe harbor for outpatient physicians. Again, the FDA was bestowed by congress to enforce and regulate the Act and its own guidance and requirements specifically carve out outpatient physicians.

a. Misbranding.

The government believed that if a "single-use device is reprocessed but not labeled as being reprocessed, it's misbranded". ECF 290, PID#7358-59. That's wrong. First, marketing, labeling and 21 U.S.C. 301, *et seq*, are not applicable to outpatient physician offices. *See* 21 C.F.R. § 807.65(d); *see* attached Decs; *see also* ECF 349; 21 U.S.C. 360(g); FDA Compliance Policy Guides Manual, Sec. 300.500 Reprocessing of SUDs, 2004 WL 3363378 at *3 (discussing that these regulations do not apply to "(1) health care facilities other than hospitals, (2) permanently implantable pacemakers, (3) hemodialyzers, and (4) "opened-but-unused" SUDs.

[2] Additionally, these sources are available on the Fed. Regs., and the FDA's and CDC's webpage.
[3] In case there's any doubt, the FDA explicitly states what a third party processor is: a third party reprocessor is a "[p]arty who reprocesses used SUD's for another party." *See* FDA's guidance, Labeling for Single-Use Devices Reprocessed (Jul. 30, 2001)(attached as Exhibit A).

"Opened-but-unused" devices are defined as single use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but have not been used on a patient and they have not been in contact with blood or bodily fluids."), and at *4 (discussing the amendments to the Act that require labeling "reprocessed device for single use. Reprocessed by []); Dec. of Professor Grisoni at para. 12-14; Dec. of Terman; Dec. of Teitel, Dec. of Daniel Vukelich and Association of Medical Device Reprocessors. And, 21 U.S.C. 360(o), as amended, which discusses misbranding and labeling requirements per the Act, explicitly carves out a safe harbor for "practitioners licensed by law to…administer…devices….solely for use in the course of their professional practice". 21 U.S.C. 360(g). But, even if the FDA hadn't created a safe harbor for outpatient doctors it further made a carveout for branding requirements for certain SUDs too. *See* 21 CFR § 884.1690 Hysteroscope and accessories; *see also* 66 Fed. Reg. 38808 (Jul. 25, 2001). Some of these exempted items are cannulas, graspers, and forceps.[4] The FDA has exempted multiple items in the indictment from the marketing, labeling and branding requirements. These include the CooperSurgical Disposable Alligator Grasper Forceps, CooperSurgical Endosee PX Cannula, and LiNA OperaScope Biopsy Forceps. *See id*.; *see also* Dec. of Grisoni; Dec. of Garcia. So, because the FDA not only doesn't apply SUDs labeling to outpatient physicians, but also doesn't apply labeling for the devices themselves that Dr. Kumar had, counts 17-32 must be dismissed.

[4] Please note also, that graspers, forceps and cannulas are device-accessories according to the FDA. *See* 21 CFR § 884.1690; *see also* section 513(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the FDA Reauthorization Act of 2017 (FDARA; Pub. L. 115-52); and the Act (21 U.S.C. § 360c); FDA Medical Device Accessories – Describing Accessories and Classification Pathways, Dec. 20, 2017) (2016 WL 7972531).

b. Open but Unused.

Finally, the FDA does another carveout – open but unused devices. "opened-but-unused" devices; "open-but-unused devices are defined as single use, disposable devices who sterility has been breached or compromised or whose sterile package was opened but have not been used on a patient and they have not been in contact with blood or bodily fluids") 2004 WL 3363378 at *3; *see also* Guideline for Disinfection and Sterilization in Healthcare Facilities, Reuse of Single-Use Medical Devices (2008, updated Jun. 2024), Pg. 81 (these requirements do not apply to "opened but unused single-use devices or healthcare settings other than acute-care hospitals"); Guidance for Industry and for FDA Staff Enforcement of Single-use reprocessed devices, 2000 WL 34503051, at * 5 (Aug. 14, 2000)(stating that regulations don't apply to "health care facilities that are not hospitals… or opened but unused SUDs"); Guidance for Industry and FDA Reprocessing and reused of single use devices, 2000 WL 34503060, at *2-3(Feb. 8, 2000)(stating that the regulations don't apply to health care facilities that aren't hospitals and don't apply to open but unused devices); *see* Dec. of Terman; Dec. of Teitel, Dec. of Vukelich and Association of Medical Device Reprocessors. While the government argued the items needed to be held in insanitary conditions to be adulterated – which, would almost always be the case – that isn't true for SUDs, which the FDA doesn't regulate if they are opened but unused. *See supra*. So here, in this particular, specific case, the government would actually need to prove use because of the FDA's regulations. The only argument that the government might make is that the devices did

have some debris on them[5] – however, the government stressed[6], both in filings and to the jury, that Dr. Kumar's guilt was predicated on insanitary conditions of the devices – but again, that does not apply here because the FDA explicitly chose not to regulate open-but-unused devices. So, first, the government mentioning this allows for the jury to pick a verdict on two different grounds, but second, and paramount to this matter, the FDA demands that there be blood or bodily fluid on the device in order for it to be considered open but unused. FDA Compliance Policy Guides Manual, Sec. 300.500 Reprocessing of SUDs, 2004 WL 3363378 at *3. Not for foreign materials, not for dirt, but for bodily fluids. And here, there was no blood or bodily fluids on the devices. *See* ECF 244 ("And each place was negative for blood, correct? That is correct"). But under the FDA's own policies, the government would have needed the jury to convict Dr. Kumar on actually used and reused SUDs.

To dove-tail section A: 1) Reprocessed SUDs for outpatient physician's offices are not regulated by the FDA[7]; 2) open but unused devices also are not regulated[8]; and 3) all of Dr.

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[5] As a brief note, properly cleaned devices, including new unused devices, may have foreign materials on debris on them. Residual organic debris on processed surgical instruments - PubMed That's why the FDA states blood or bodily fluids must be present. *See also supra*.

[6] "In attempting to follow the defendant's argument, it appears that the defendant is asking this Court to find that there is no violation of the FDCA until an adulterated (or misbranded) device is actually used on a patient. This constrained reading of 21 U.S.C. § 331(k)—requiring patients to be victimized in order to have a violation of the FDCA—frustrates the purpose of the FDCA and goes against the courts that have addressed this issue." ECF 174, PID#1606; *see also* ECF 171; *see also* ECF 290, PID#7393 ("adulterated means it's held under insanitary conditions…we do not have to prove that it has become contaminated, although we have… the statute requires is that we show you that the device is held under conditions that are insanitary".

[7] FDA Compliance Policy Guides Manual, Mar. 20, 2015, 2004 WL 3363378 at *3(Sec. 300.500); *see also* Dec. of Terman; Dec. of Teitel.

[8] *Id.*

Kumar's SUDs in the indictment are exempt from labeling and branding requirements per FDA policy[9].

B. Criminal Proceedings under the Act.[10]

Congress figured that there would be times for criminal proceedings and violations under the Act.

"To enforce the various substantive prohibitions contained in the FDCA, the Act provides for injunctions, 21 U.S.C. § 332, criminal sanctions, §§ 333 and 335, and seizure of any offending food, drug, or cosmetic article, § 334. The Act's general provision for enforcement, § 372, provides only that "[t]he Secretary is authorized to conduct examinations and investigations ..." (emphasis added). Unlike the statute at issue in Dunlop, § 332 gives no indication of when an injunction should be sought, and § 334, providing for seizures, is framed in the permissive—the offending food, drug, or cosmetic "shall be liable to be proceeded against." The section on criminal sanctions states baldly that any person who violates the Act's substantive prohibitions "shall be imprisoned ... or fined." Respondents argue that this statement mandates criminal prosecution of every violator of the Act but they adduce no indication in case law or legislative history that such was Congress' intention in using this language, which is commonly found in the criminal provisions of Title 18 of the United States Code. See, e.g., 18 U.S.C. § 471 (counterfeiting); 18 U.S.C. § 1001 (false statements to Government officials); 18 U.S.C. § 1341 (mail fraud). We are unwilling to attribute such a sweeping meaning to this language, particularly since the Act charges the Secretary only with recommending prosecution; any criminal prosecutions must be instituted by the Attorney General. The Act's *enforcement provisions* thus commit complete discretion to the Secretary to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985).

Prior to criminal prosecution, "the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing". 21 U.S. Code § 335. And, while the FDA does not always issue a warning letter, for criminal prosecutions it must. *Id*.; *see* Advisory Actions of the FDA, 2004 WL 3363386 at *2-3.

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[9] *See* 21 CFR § 884.1690 Hysteroscope and accessories; *see also* 66 Fed. Reg. 38808 (Jul. 25, 2001); 21 U.S.C. § 360(g)(this would also include multi-use devices, too).

[10] For additional information throughout this section, please see Dec. of Terman.

And indeed, in *United States v. Kaplan*, the FDA agent met with Dr. Kaplan to discuss the matter. *See United States v. Kaplan*, 836 F.3d 1199, 1206 (9th Cir. 2016). According to the FDA, however, there are times these protocols potentially can be skipped, for example if the FDA believes that evidence will be destroyed. *See* 21 CFR § 7.84. And that's what happened in *United States v. Jackson*, 126 F.4th 847 (4th Cir. 2025). In *Jackson*, the defendant had been mandated by federal investigators to repay Medicare reimbursements previously for fraudulent billing, had submitted false, perjured and faked affidavits, aggravated identity theft, and variety of other dishonest maldeeds. *Id*. at 854. In *Jackson*, the defendant had already proved herself a bad actor. Even if we contend that what Dr. Kumar did was a crime, the testimony, according to the government, seems to purport that things changed at PAC.[11] Again, the FDA assumes that "the majority of persons will voluntarily comply with the law when given information as to what is required, what violations appear to exist, and, in the case of violations of regulatory significance, that failure to comply may result… in enforcement". 10-2 Prior Notice, 10-2-3-Policy, FDA, Office of Regulatory Affairs, 2013 WL 10904643, at *5 (Apr. 1, 2013); *see also* FDA Regulatory Procedures Manual, 2004 WL 3363386, at *2 (Mar. 1, 2020).

Here, the FDA had the ability to seek injunctive relief if it thought that Dr. Kumar's practice was a health concern. *See* Chaney, 470 U.S. at 835. In fact, even permanently. *United States v. Universal Management Services*, 191 F.3d 750, 753 (6th Cir. 1999); *see also United States v. American Mercantile Corp*., 889 F.Supp.2d 1058 (W.D. Tenn. 2012). The FDA also could have warned Dr. Kumar and requested he cease all activities. 21 U.S. Code § 335. In *Jackson*, the defendant had submitted falsified records including forged affidavits and committed aggravated identity theft and in *Kaplan*, the FDA and the medical board of the State had already

[11] "things dramatically changed after the search warrant". ECF 290, PID#7361.

sat down with the defendant to inquire as to why he was doing what he was doing – giving him a chance to cease any malfeasant. But here, Dr. Kumar wasn't afforded that opportunity. Dr. Kumar was investigated by the State medical board and cleared. But he wasn't afforded that chance by the government.

Normally, an agency's violation of the law, or failing to adhere to congressional limitations, is ultra vires. *See NRC v. Texas*, 605 U.S. 665 (2025). And the agency failed to adhere to 21 USC 335. An agency's failure to act is an action in and of itself. *See Barrios Garcia v. U.S. Dep't of Homeland Security*, 25 F.4th 430, 441-42 (6th Cir. 2022). "The Act's enforcement provisions thus commit complete discretion to the [FDA] Secretary to decide how and when they should be exercised." *Id*. Here, the FDA's failure to adhere to congressional mandates violated Dr. Kumar's rights, but also overstepped its congressional authority. And the Act's enforcement, according to the Supreme Court and the Sixth Circuit, is within the sound discretion of the FDA, with limitations. Those limitations were violated. As such, Dr. Kumar's verdict must be struck because the FDA's actions were ultra vires.

C. Kaplan, Jackson, Devices and Dr. Kumar.

Although the government relied heavily upon *Kaplan* and *Jackson*, neither case resolves the issues presented here.

First, both cases arose under materially different factual circumstances. In *United States v. Kaplan*, the FDA investigated the defendant, met with him, provided notice of its concerns, prior to instituting criminal prosecution. *United States v. Kaplan*, 836 F.3d 1199, 1206, 1214 (9th Cir. 2016). Dr. Kaplan nevertheless continued reusing single-use devices after receiving those warnings, and he admitted that he had done so. *Id*. Likewise, in *United States v. Jackson*, the defendant admitted reusing single-use devices. *United States v. Jackson*, 126 F.4th 847, 866 (4th

Cir. 2025). *Jackson* also involved extensive fraudulent conduct, including fictitious affidavits and aggravated identity theft. *Id*. at 854, 868. According to the FDA's policies, those circumstances justified immediate enforcement because the FDA concluded that evidence might be destroyed. *See* 21 C.F.R. § 7.84.

Nothing comparable occurred here. Dr. Kumar never admitted reusing any single-use device,[12] the jury was never asked to determine whether any single-use device had actually been used and reused, the Tennessee Medical Board cleared him, and the government itself acknowledged that practices at PAC changed following execution of the search warrant. Unlike *Kaplan* and *Jackson*, this case therefore presents neither admitted reuse, nor proven initial use or reuse, nor the aggravating circumstances that prompted the FDA's enforcement decisions in those cases. Nor did either defendant argue that the FDA's outpatient physician carve-out; and paramount here, the device-specific exemptions precluded prosecution. Consequently, neither appellate court addressed those issues.

Second, the devices and medical procedures involved here differ substantially from those at issue in *Kaplan* and *Jackson*. The devices identified in Counts 17 through 32 are expressly exempt from the FDA's labeling and marketing requirements because they are Class I. *See* 21 C.F.R. § 884.1690; *see also* 66 Fed. Reg. 38808 (Jul. 25, 2001); Dec. of Grisoni; See Dec. Terman; Dec. Teitel. Those exempted devices include the CooperSurgical Disposable Alligator Grasper Forceps, the CooperSurgical Endosee PX Cannula, and the LiNA OperaScope Biopsy Forceps. *Id.* Neither *Kaplan* nor *Jackson* involved devices that the FDA itself exempted from the regulatory requirements underlying the charged offenses.

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[12] Indeed, Dr. Kumar instructed staff just the opposite. *See* Dec. of Garcia.

The procedures likewise are materially different. *Jackson* involved instruments used within the sinus cavity, with tools and procedures that are more likely to cause issues compared to hysterscopies,[13] and involved critical and semi-critical devices. Dr. Kumar's practice involved hysteroscopies utilizing semi-critical and non-critical devices within the uterine cavity. *See* 21 C.F.R. § 884.1690; see also Dec. of Grisoni; Dec of Garcia; Dec. of Caruthers. The government repeatedly argued that hysteroscopes and their accessories must always be treated as sterile, critical devices. *See* ECF 244, PID#3796, 3810; ECF 290, PID#7380.[14] The FDA's own regulations, however, classify hysteroscopes and their accessories differently. *See* 21 C.F.R. § 884.1690 (describing them as semi-critical and non-critical); *see also* 21 C.F.R. § 880.6885. Likewise, the FDA's Spaulding Classification guidance recognizes that semi-critical devices

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[13] https://pubmed.ncbi.nlm.nih.gov/31638866/ (discussing the procedure and devices in Jackson – Ballon Sinuplasty - which has a high chance of resulting in issues. Compare with the Hysteroscopy procedures and devices which do not. *See* Teitel, pg.3; *see also* Garcia Dec.; moreover, the uterus is not sterile, *see* Garcia, and that's why the FDA has labeled these devices as semi-critical and non-critical devices. *Id*.;; Declaration of Roberto Levi- D'Ancona; Thomas Caruthers; Teitel; *see also* 21 C.F.R. § 884.1690.

[14] "they can be reprocessed, re-sterilized…it has to be sterile. Sterile means sterile." PID# 8013. "we hold them to the same level of reprocessing as for a critical device…they were not cleared for high level disinfection. They were only cleared for sterilization." Dr. Nandy, PID#3796; "the FDA has not cleared any hysterscopes with high level disinfection. All hysterscopes, including this… Olympus, was cleared with sterilization." Dr. Nandy, PID#3810. Government in closing ECF 290, 7380 "the FDA has never cleared a reprocessable or any hyserscope as anything other than as a sterile device, as a critical device that must be sterile". First, very briefly, as can be seen by the FDA's own regulations, hysteroscopies are semi-critical devices (again, not all of the items in the indictment are: many are non-critical), but the womb also isn't a sterile environment – as shown by the FDA's classification and the experts' affidavits.
And, just for a brief discussion, In malpractice cases and medical device cases, the IFU is the standard set for malpractice and considered for standard of care, not 510ks. *See Thacker v. Ethicon, Inc.*, 47 F.4th 451, 460 (6tth Cir. 2022)("did the treating physician rely on relevant warning (i.e. the IFUs)" and discussing how doctors are the "learned intermediary"); *See generally Heath v. C.R. Bard*, 2021 WL 3172315, at 15 (M.D. Tenn. Jul. 27, 2021); *Sexton v. Ethicon*, 2021 WL 4138399, at *3 (E.D. Ky. Sept. 10, 2021)- even for device product liability claims, the IFU is controlling. See Huskey v. Ethicon, 29 F.Supp.3d 691, 718 (S.D. Wv. 2014). Not only is the Olympus a semi-critical device which is okayed for disinfectant by the FDA, its IFU says its fine too. (Which is also a binding FDA document).

require sterilization or high-level disinfectant. FDA Guidance, *Reprocessing Medical Devices in Health Care Settings*, 2015 WL 1735397, at *11 (Mar. 17, 2015); Dec. of Garcia; Teital; Caruthers; D'Ancona. That includes multiuse devices and reprocessed SUDs.[15]

Finally, the government's theory of prosecution differs fundamentally from the FDA's regulatory framework. Throughout trial, the government repeatedly argued that it was unnecessary to prove that any single-use device had actually been used and reused, asserting instead that adulteration could be established merely by showing that the devices were held under insanitary conditions. That theory may be sufficient in an ordinary adulteration case. It is not sufficient under the FDA's own regulatory scheme governing single-use devices. The FDA expressly distinguishes between reprocessed single-use devices and opened-but-unused devices, and, perhaps most consequential too, Congress likewise defines a "reprocessed" single-use

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[15] "B. Semi-Critical Devices
Semi-critical devices are devices that contact intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body. Intact mucosal surfaces are relatively resistant to small numbers of spores. However, these devices should be reprocessed to be free from all microorganisms. Users should be instructed to thoroughly clean these devices and then reprocess them by sterilization. If the device design does not permit sterilization (e.g., device materials cannot withstand sterilization), then high level disinfection should be used.
Examples of semi-critical devices include duodenoscopes, endotracheal tubes, bronchoscopes, laryngoscope blades and other respiratory equipment, esophageal manometry probes, diaphragm fitting rings, and gastrointestinal endoscopes.
Heat-stable devices (e.g., rigid endoscopes) should be processed by steam sterilization. For heat-labile devices, available "low temperature" reprocessing technologies include hydrogen peroxide (H2O2) sterilization, ozone (O3) sterilization, ethylene oxide (EO) sterilization3 (including device aeration) and liquid chemical sterilant/high level disinfectant chemical systems used to provide either liquid chemical sterilization or high level disinfection. High-level disinfection methods used in health care settings include liquid chemical sterilants used at high level disinfection conditions and hot water pasteurization (often used for respiratory and anesthesia equipment reprocessing)."

device as one that "has previously been used on a patient." *See* 21 U.S.C. § 321[16]. So, the government would need to prove initial use of the device, even if it didn't have to prove reuse, because otherwise it's not a reprocessed SUD.[17] And again, under the FDA's published policies, opened-but-unused devices fall outside the enforcement policy discussed throughout this motion. Thus, unlike *Kaplan* and *Jackson*, where the defendants admitted reuse, the government's theory here deliberately avoided proving the very factual predicate upon which the FDA's regulatory framework depends (initial use and reuse).

Accordingly, *Kaplan* and *Jackson* do not control this case. They involved admitted reuse, materially different enforcement histories, materially different devices, and materially different factual records. Most importantly, neither decision considered whether the FDA's own regulations, exemptions (including Dr. Kumar's specifically exempted devices), and enforcement policies foreclosed the theory of prosecution advanced here.

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[16] *See also* 21 USC 321(mm) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

[17] That's why the FDA doesn't regulate open but unused devices and the government would need to prove The way to prove that for medical devices would be blood or bodily floods. And, foreign debris and materials are found on all kinds of equipment. https://pubmed.ncbi.nlm.nih.gov/7574561/

D. Case law for the Court to consider the Motion.[18][19]

Here's where perhaps the rubber meets the road for Dr. Kumar. He essentially asserts this in a multitude of fashions – including lack of jurisdiction (because what he did was not a crime given the carve-outs), estoppel, the common law right to overturn a verdict, a Rule 33 Motion, and a bond pending appeal and an Habeas/2255 proceeding. Dr. Kumar recognizes that the Court may conclude one or more procedural mechanisms are unavailable. Accordingly, because the issues presented involve substantial questions regarding the scope of the FDA's statutory authority and the legality of the prosecution itself, Dr. Kumar raises these arguments under every procedural mechanism that could potentially permit review. In full candor, this motion's contents should have been brought prior to trial. Dr. Kumar lodges this as a likely 2255 issue and therefore humbly asks this Honorable Court to consider allowing him to remain on bond pending resolution of an appeal and an IAC should this Honorable Court not overturn the judgment of the jury.

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[18] Dr. Kumar briefly reasserts previous arguments about medical care and practice being exempted by 21 U.S.C. 396, *see* OLC Opinion, 2019 WL 2235666 at *3 (May 3, 2019) ("As a general matter, FDA does not regulate the practice of medicine, which includes "off-label" prescribing—that is, when physicians prescribe FDA-approved drugs or devices for non-FDA-approved uses. As the Supreme Court has explained in the context of medical devices, "'offlabel' usage ... (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." B*uckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 350 (2001); *see also Caronia*, 703 F.3d at 153. Thus, while the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses.) It would be wild indeed if Dr. Kumar could use a dental hygienist brush instead of grasper (because one may use a device for unapproved uses) but couldn't re-use a SUD that is safe for reprocessing. Policy-wise, that doesn't make sense and it seems the Courts are at odds with Congress and the FDA on that – nonetheless, Dr. Kumar does not bring forth that argument as the Court has already addressed it here previously.

[19] There has been conflict between the DOJ and FDA before, while not on point, the Court may find some of the case helpful for discussing the issues herein: *United States v. Caronia*, 703 F.3d 149, 160 (2d. Cir. 2012).

To briefly address some of these issues, Dr. Kumar states there is also a common law rule of consistency, tracing to *Marsh v. Vaughan*, 78 Eng. Rep. 937 (Q.B. 1599), which prohibited logically impossible verdicts - for example, convicting one defendant of conspiracy while acquitting the only alleged co-conspirator. This rule was applied by the Supreme Court in *Morrison v. California*, 291 U.S. 82 (1934), and *Hartzel v. United States*, 322 U.S. 680 (1944), to set aside irreconcilable jury verdicts[20]. And as the 6th Circuit recognized in *Felton v. Spiro*, 78 F. 576 (6th Cir. 1897), a federal court has the power to set aside a verdict when, in its opinion, it is contrary to the decided or overwhelming weight of the evidence or law, and may properly do so in the exercise of legal discretion even where it would not have been proper to direct a verdict. Again, when a jury's verdict is impossible to reach a Court may vacate its determination. *Felton*, 78 F.576, 580, 583 (6th Cir. 1897)(Taft, J., former Solicitor General of the United States, future President and Chief Justice of the United States Supreme Court). Here, the jury was permitted to reach a legally impossible verdict; one that criminalizes conduct explicitly carved out of the federal regulatory state.

Where a federal regulatory scheme is so dense, shifting, or contradictory that a trained professional cannot reasonably ascertain the boundary between lawful practice and criminal exposure, the Rule of Lenity bars conviction. *Liparota v. United States*, 471 U.S. 419, 427 (1985). The necessity of lenity is vividly illustrated by the government's theories in this very trial.

[20] And, just as way of example of further inconsistencies – the jury exonerated Dr. Kumar on some of the Olympus counts but not others – even though they were cleaned in the exact same way and held in the exact same fashion.

The Court previously excluded the CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities*.[21] Yet, this document is an official component of the federal guidance matrix that cross-references and interprets the FDA's own boundaries. Indeed, the FDA's own webpage takes a viewer to this guidance.[22] Crucially, the CDC guidelines explicitly state that these stringent reprocessing requirements do not apply to "healthcare settings other than acute-care hospitals"; and so do the FDA's. *See supra*.

If a licensed physician reviews the FDA's public webpage, tracks its official definitions, and reads the cross-referenced CDC guidance, they are repeatedly told the same thing: *this framework does not govern an outpatient clinic*. Given that, Dr. Kumar would ask that this Court invoke the Rule of Lenity. *Liparota*, 471 U.S. at 427.

Closely tied to lenity is the principle of administrative reliance: the Executive Branch cannot publish formal, binding regulatory safe harbors upon which an entire class of professionals rely, and then allow the Department of Justice to criminalize that exact reliance. Individuals and industries must be permitted to build a "serious reliance upon [an agency's] interpretation of regulations." *FDA v. Wages and White Lion Investments, LLC*, 604 U.S. 542, 544 (2025).

A long line of appellate precedent confirms that agencies cannot punish citizens for relying on their public, legal regulations. *See Retail Wholesale and Dep't Store Union v. NLRB*, 466 F.2d 380 (D.C. Cir. 1972); *McDonald v. Watt*, 653 F.2d 1035 (5th Cir. 1981); *NLRB v.*

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[21] CDC guidelines ECF 260, PID#6801-02.

[22] https://www.fda.gov/medical-devices/products-and-medical-procedures/reprocessing-single-use-medical-devices-information-health-care-facilities#additional Third link from the bottom – and the CDC gives the same exceptions.

Majestic Weaving Co., 355 F.2d 854 (2d Cir. 1966). Dr. Kumar relied on the formal, published, and legal guidance of the FDA itself.

The FDA's own guidance documents and Compliance Policy Guides Manual state that its reprocessing enforcement policies do "not apply to... health care facilities other than hospitals". When the state medical board investigated Dr. Kumar's clinic under standard medical practice guidelines, he was cleared. To allow the DOJ to override the FDA's published safe harbors upends the reliance interests protected by *Wages and White Lion,* and cases and law like it. The government cannot build a regulatory harbor, invite citizens to anchor there, and then prosecute them for failing to outrun a storm in open water.

Respectfully submitted,

/s/ Brian Daniel Mounce
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the forgoing was forward by electronic means via the Court's electronic filing system to all parties to this matter this 30th day of June, 2026.

s/ Brian Daniel Mounce

CERTIFICATE OF CONSULTATION

Counsel shared this motion with the government the previous evening. The government is considering its stance on this matter, and has been in correspondence with the government, because counsel requested three things: 1) whether the government opposed the motion in full; 2) if the government, while still opposed to the motion, agreed that substantial questions of law were raised and thus Dr. Kumar should be allowed to remain on bond pending appeal and an ineffective assistance of counsel claim; or 3) whether the government joins the motion in full. We will file an update to the Court accordingly.

s/ Brian Daniel Mounce

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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-cr-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

DECLARATION OF STEPHEN TERMAN

I have been practicing FDA law for 50 years. I am currently a senior counsel at OFW Law and concentrate my legal practice in the areas of medical device law and FDA regulatory issues. From 1990 through 2023, I was a partner in the firm.

Since joining OFW Law in 1990, I have represented hundreds of corporations, individuals and associations in civil, criminal, and regulatory matters. Beginning in 1999/2000, I was the primary outside FDA counsel to the Association of Medical Device Reprocessors for over 10 years and continue to represent third party reporcessors. My expertise covers all areas of medical device law including: development of strategies to bring medical devices to market, pre-submission advocacy with key FDA officials, and preparation of necessary regulatory filings; compliance with Medical Device Reporting (MDR) requirements, including employee education and system audits; classification and reclassification of medical devices; compliance with Quality System Regulation (QSR) requirements, including employee education and system audits; pre- and post-distribution issues regarding the labeling, advertising, and promotion of medical devices; highly specialized medical device regulatory matters, such as medical software, combination products and custom devices; managing risks associated with and responding to FDA enforcement actions; preparing for and managing FDA inspections; conducting product recalls and other field actions; medical device listing and establishment registration requirements; medical device import and export issues and matters concerning clinical trials.

In addition to writing and editing book chapters and articles, I have given over a hundred speeches and was a frequent lecturer before trade and professional groups including AAMI, AdvaMed, AFDO, ACI, FDLI, HMS, IBC, MedTech, and RAPS.

For eight years I taught Food and Drug Law to FDA's Center for Device and Radiological Health personnel.

Prior to joining OFW Law, I worked in the Office of Chief Counsel, U.S. Food and Drug Administration from 1976-1987 where I served as Associate Chief Counsel for Enforcement. While at FDA, I received the prestigious Award of Merit for outstanding consumer protection efforts, and the Commendable Service Award "in recognition of superior performance in litigating complex enforcement cases raising significant questions concerning the agency's jurisdiction and the scope of its authority".

I left the FDA in 1987and joined the Health Industry Manufacturer's Association (HIMA) now AdvaMed, a national trade association representing over 300 medical device, diagnostic product and healthcare information systems manufacturers. While at HIMA, I served as Associate General Counsel where I was responsible for handling the Association's FDA-related legal, regulatory, and Congressional issues. I also represented the medical device industry in negotiations on the Safe Medical Device Act of 1990 ("SMDA").

I received a B.S. in economics in 1973 from the University of Maryland where I was Phi Kappa Phi, and a J.D. in 1976, also from the University of Maryland. I was admitted to the Maryland Bar in 1976 and the District of Columbia Bar in 1979. I am currently a member of the District of Columbia Bar. I have also been admitted to following Bars:

- Court of Appeals of Maryland, 1976;
- United States Fourth Circuit Court of Appeals, 1977;
- United States District Court for the District of Maryland, 1977;
- United States Eighth Circuit Court of Appeals, 1978;
- United States Ninth Circuit Court of Appeals, 1978;
- United States Court of Appeals for the District of Columbia, 1979;
- United States District Court for the District of Columbia, 1979;
- District of Columbia Court of Appeals, 1979;
- Supreme Court of the United States, 1980;
- United States Seventh Circuit Court of Appeals, 1981.

BRIEF HISTORY OF FDA LAW

Summary

Pursuant to The Federal Food Drug & Cosmetic Act and implementing regulations, FDA has the authority to:

- Enforce & regulate the FDCA (21 U.S.C. §§ 301 et seq., 21 U.S.C. §§331-332, 21 U.S.C., 21 U.S.C. §393)
- Create rules (21 U.S.C. §371(a)) and
- Interpret the FDCA and implementing regulations (21U.S.C. §371, 21 CFR Parts 1 et seq.)

(A History of Medical Device Regulation & Oversight in the United States (https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states)

1906: Pure Food and Drugs Act (sometimes also called the Federal Food and Drugs Act)

Established the precursor to today's FDA.

Prohibited interstate commerce of misbranded and adulterated food, and drugs.

1938: Federal Food, Drug, and Cosmetic Act (FD&C Act)

- Primary statute that authorizes the FDA's regulation and oversight of medical products
- Extended prohibition of interstate commerce to misbranded and adulterated cosmetics and therapeutic medical devices
- Authority for factory inspections

1976: Medical Device Amendments to the FD&C Act

- Intended to provide reasonable assurance of the safety and effectiveness of medical devices
- Created a three-class, risk-based classification system for all medical devices
- Established the regulatory pathways for new medical devices (devices that were not on the market prior to May 28, 1976, or had been significantly modified) to get to market: Premarket Approval (PMA) and premarket notification (510(k))
- Created the regulatory pathway for new investigational medical devices to be studied in patients (Investigational Device Exemption (IDE))
- Established several key postmarket requirements: registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices
- Authorized the FDA to ban devices

1990: Safe Medical Devices Act (SMDA)

- Improved postmarket surveillance of devices by:

o Requiring user facilities such as hospitals and nursing homes to report adverse events involving medical devices

o Authorizing the FDA to require manufacturers to perform postmarket surveillance on permanently implanted devices if permanent harm or death could result from device failure

• Authorized the FDA to order device recalls and to impose civil penalties for violations of the FD&C Act

• Defined substantial equivalence (the standard for marketing a device through the 510(k) program)

• Modified procedures for the establishment, amendment, or revocation of performance standards

• Created the Humanitarian Use Device (HUD)/Humanitarian Device Exemption (HDE) programs to encourage development of devices targeting rare diseases

2002: Medical Device User Fee and Modernization Act (MDUFMA)

• Granted the FDA the authority to collect user fees for select medical device premarket submissions to help the FDA improve efficiency, quality, and predictability of medical device submission reviews

• Enacted the Small Business Determination (SBD) program to permit reduced premarket approval fees for qualifying small businesses

• Created FDA performance goals for decisions on certain premarket submissions

• Established new regulatory requirements for 'reprocessed' devices

• Authorized electronic registration of medical device firms

• Established the Office of Combination Products

EXEMPTIONS AND DISCUSSION

Single Use Device Regulation Exempt From FDA Regulation

In August 2000. "FDA intended to make clear its plans to subject hospitals and other third-party establishments that reprocess SUDs to FDA inspection for compliance with applicable regulatory requirements." To accomplish this the FDA published its final guidance: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, issued on August 14, 2000 ("2000 Enforcement Guidance"). The document states "[t]his guidance document is applicable to third party and hospital reprocessors. The enforcement priorities set forth in this guidance do not apply to: (emphasis added)

1. Permanently implantable pacemakers. The reuse of permanent pacemakers

is addressed in Compliance Policy Guide 7124.12 (issued on October 1, 1980 and revised in March 1995);

2. "Opened-but-unused" SUDs (see Definitions in Appendix B);

3. Health care facilities that are not hospitals; or

4. Hemodialyzers. The reuse of hemodialyzers is addressed in "Guidance for

Hemodialyzer Reuse Labeling (final draft issued on Oct. 6, 1995). A copy

of this guidance is available on FDA's web site at www.fda.gov/cdrh/ode/dilreuse.pdf

The 2000 Enforcement Guidance goes on to acknowledge that "FDA is aware that hospitals are not the only health care facilities that reprocess devices labeled for single use. "[However,] at this time, the agency is limiting its focus to SUDs reprocessed by third party and hospital reprocessors." Hence, the FDA carefully carved out multiple types of SUD users who would not be subject to enforcement of the requirements for SUD reprocessors, i.e., users of SUDs. Physician's offices and clinics, such as Dr. Kumar's facility, are exactly the type of facilities that are "Health care facilities that are not hospitals" and fit squarely within the safe harbor carved out by the FDA in their guidance. This safe harbor extends beyond just using the SUDs in the clinic to include the other requirements of hospitals and third party reprocessors that include such things as labeling them as reprocessed to inform users that the devices used in their procedures are reprocessed.

FDA's guidance adds that the 2000 Enforcement Guidance "does not preclude FDA from taking immediate action against any particular product that is causing significant harm. There are two salient points in this statement: 1) FDA retains the right to take action against "any particular product," not against any person or entity (emphasis added); and 2) it clearly infers that FDA did not believe the safe harbor it created for health care facilities that are not hospitals would result in causing significant harm because it states it reserved the right to act if such harm occurs in the future.

Hysteroscope Accessories Are Class I and Not Subject to FDA Regulation

The indictment further alleges that Dr. Kumar reused hysteroscope accessories, rendering them adulterated on the basis that their reuse was illegal because they were labeled for single use, and did not have a pre-market notification (known as a 510(k)) to provide for reuse. However, not only was his office, as a health care facility other than a hospital or third-party reprocessor, exempt from the reprocessing of SUD enforcement, but these accessories were Class I devices based on FDA's risk prioritization and, hence, exempt from such regulations. The product code for hysteroscopes and their accessories fall under the FDA's product code HIH. HIH is controlled by the regulation, 21 C.F.R. § 884.1690, which designates hysteroscopes as Class II devices subject to FDA's regulatory paradigm, and the accessories e.g., cannulas, graspers, scissors, and instrument guides as Class I devices that are exempt for the premarket -

notification procedures, i.e., 510(k) submissions. Hysteroscopes and their accessories each fall under totally different regulatory paradigms, with the accessories that are Class I devices falling well outside the regulatory purview of the FDA. By conflating the hysteroscopes which are Class II with the hysteroscope accessories, which are Class I and not subject to significant FDA regulation, it could markedly amplify the perception of counts related to hysteroscopes by lumping these low risk, Class I devices together with the Class II-level semi-critical risk devices.

Misbranding Based on Labeling

The indictment charges that reused SUDs must be labeled and consented to when reprocessed devices are used. However, this requirement does not apply to Dr. Kumar. He is not a reprocessor subject to the labeling requirement because that requirement is for hospitals and third-party reprocessors, not for healthcare facilities that are not hospitals. The FDA's safe harbor for physicians' practices exempts them from all the requirements imposed on hospitals and third-party reprocessors. This is because the FDA does not view facilities that are not hospitals or third party reprocessors as a manufacturer. Because FDA does not view physicians' offices and clinics as manufacturers, none of the requirements of manufacturers, e.g., registering and listing, labeling, or packaging are required of outpatient physicians. This serves as the rationale for the safe harbor and, inter alia, for physicians being exempt from most, if not all, the requirements of manufacturers. Again, these carve outs exempt Dr. Kumar from the manufacturers' requirements for labeling and, hence, from being violative of misbranding within his own medical practice.

21 USC §335 mandates that Dr. Kumar should have been provided an opportunity to respond to the Government's decision to bring criminal charges against him.

As far back as 1906, The Pure Food & Drug Act (June 30, 1906, Public Law 59-384, 34 STAT 768) stated that "if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid".

In 1938, The Federal Food, Drug & Cosmetic Act ((June 25, 1938, ch. 675, §1, 52 Stat. 1040.) ("FDCA"), 21 USC §335 , required that the U.S. Food & Drug Administration ("FDA") "Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding". This provision is titled "Hearing before report of criminal violation". (June 25, 1938, ch. 675, §305, 52 Stat. 1045 .)

FDA has promulgated regulations that provide additional specificity regarding an individual's rights to a hearing pursuant to 21 USC §335, which include an opportunity for presentation of views before report of criminal violation (21 CFR 7.84), the conduct of a

presentation of views before report of criminal violation (21 CFR 7.85) and the rules related to the records related to the opportunity to present views (21 CFR 7.87).

In addition, FDA has published a Compliance Policy Guide (CPG Sec 160.400), the purpose of which is to explain the agency's compliance policy on various substantive matters, including the exercise of enforcement discretion as to whether to bring enforcement actions against certain products, individuals or companies.

As an indication of the importance of §305 hearings, the CPG adopts the statutory concept regarding §305 hearings by stating that they should be used only when initiation of prosecution is actually being considered by the agency.

Furthermore, FDA's Regulatory Procedures Manual (Regulatory Procedures Manual- June 2021- Chapter 5 Administrative Actions) describes the FDAs procedures for issuing §305 Notices (21 USC §335). The Regulatory Procedures Manual ("RPM") is a reference manual for FDA personnel. It provides FDA personnel with information on internal procedures to be used in processing regulatory and enforcement matters. While not specifically drafted for use by the regulated industry, it provides regulated individuals and companies with insights as to FDA's view of certain regulatory issues.

Again, as with the FDCA, promulgated regulations, and the Compliance Policy Guide, the RPM references a §305 Citation is to be used only when a prosecution recommendation is contemplated.

While neither the CPG nor the RPM have the force and effect of law, since both of these are publicly available, as a practical matter, individuals and the regulated industry know of their existence and likely rely on them to assure that FDA will comply with the statutory dictate that "Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding" which does have the force and effect of law. 21 U.S.C. §335.

Beyond the FDCA, promulgated regulations, FDA's Regulatory Procedures Manual and FDA's Compliance Policy Guide, FDA issues "Warning Letters" and "Untitled Letters" which also provide the regulated industry with notice prior to the agency taking regulatory or civil actions.

A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. Warning Letters are issued to achieve voluntary compliance and to establish Prior Notice. The agency's position is that Warning Letters are issued only for violations of regulatory significance.

"When it is consistent with the public protection responsibilities of the agency and depending on the nature of the violation, it is the Food and Drug Administration's (FDA's) practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action…. The use of Warning Letters and prior notice are based on the expectation that most individuals and firms will voluntarily comply with the law. The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected". RPM Chapter 4 (Advisory Actions).

An Untitled Letter "cites violations that do not meet the threshold of regulatory significance for a Warning Letter". However, it still provides prior notice by advising the firm about these violations. Section 4-2 of RPM Chapter 4 (Advisory Actions).

It has been an accepted fact in the FDA regulated industry, as well as the FDA bar, that pursuant to §305, FDA "SHALL" provide individuals and companies it regulates with notice when the agency decides to recommend a criminal prosecution. And again, 21 USC §335 carries the force and effect of law.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of June, 2026.



Stephen D. Terman

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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-cr-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

DECLARATION OF EDWARD R. TEITEL, MD., ESQ.

I graduated from Sul Ross State University and earned my M.D. degree at the University of Texas Health Science Center in San Antonio, Texas in 1974. I completed a surgical internship at The Henry Ford Hospital in Detroit, Michigan and my surgical residency, including a year as chief resident, at St. Joseph Mercy Hospital in Pontiac, Michigan before entering private practice, primarily in Ozark, Alabama. I practiced general and vascular surgery for nearly 15 years. A significant part of my practice also involved endoscopy. Beginning in 1997, I took five years off to earn a master's in business administration from the Bauer School of Business at Auburn University and a juris doctor from the University of Houston, being admitted to the bar in Texas in 2003. I spent about 15 years in the medical device industry beginning as the Chief Medical Officer for Micromed Technology, which was a NASA spinoff developing and commercializing the DeBakey Left Ventricular Assist Device, working with Drs. Michael DeBakey and George Noon before founding my own venture backed medical device company based on a platelet monitoring technology spun out from Brigham Young University and the University of Utah. In my device industry roles I was heavily involved with the regulatory aspects of intensely regulated Class III and Class II devices. Following my time in the device industry, I joined OFW Law, a boutique Food and Drug Law firm in Washington, D.C., as a regulatory attorney. My law practice focuses on medical devices and, serendipitously, has evolved a significant concentration in the areas of endoscopy, reprocessing, and single use device regulation. I am uniquely situated at the intersection of medicine, business, and regulatory law.

Introduction

Dr. Kumar was indicted, tried and convicted by the United States on multiple counts, most of which were predicated on violations of the Food, Drug and Cosmetic Act. ("FDCA") relating to the repeated use of devices, including single use hysteroscopes, reusable hysteroscopes and accessories of hysteroscopes and billing for procedures in which these devices were used. The indictment alleges that Dr. Kumar began using and billing for using adulterated and mislabeled products in his gynecologic oncology practice beginning at least by 2019. Since the use of these devices served as the predicate for claiming fraud, I will, as both a regulatory lawyer with extensive

experience dealing with endoscope reprocessing and single use products ("SUD") and as a physician who practiced general and vascular surgery, including endoscopy, explore these issues in this declaration.

Single Use Device Regulation Exempt From FDA Regulation

In August, 2000. "FDA intended to make clear its plans to subject hospitals and other third-party establishments that reprocess SUDs to FDA inspection for compliance with applicable regulatory requirements."[1] To accomplish this the FDA published its final guidance: *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,* issued on August 14, 2000 ("2000 Enforcement Guidance"). The document states "[t]his guidance document is applicable to third party and hospital reprocessors. The enforcement priorities set forth in this guidance do not apply to: (emphasis added)

> 1. Permanently implantable pacemakers. The reuse of permanent pacemakers is addressed in Compliance Policy Guide 7124.12 (issued on October 1, 1980 and revised in March 1995);
>
> 2. "Opened-but-unused" SUDs (see Definitions in Appendix B);
>
> 3. *Health care facilities that are not hospitals*; or
>
> 4. Hemodialyzers. The reuse of hemodialyzers is addressed in "Guidance for Hemodialyzer Reuse Labeling (final draft issued on Oct. 6, 1995). A copy of this guidance is available on FDA's web site at www.fda.gov/cdrh/ode/dilreuse.pdf[2]

The 2000 Enforcement Guidance goes on to acknowledge that "FDA is aware that hospitals are not the only health care facilities that reprocess devices labeled for single use. "[However,] at this time, the agency is limiting its focus to SUDs reprocessed by third party and hospital reprocessors."[3] Hence, the FDA carefully carved out multiple types of SUD users who would not be subject to enforcement of the requirements for SUD reprocessors, i.e., users of SUDs. Physician's offices and clinics, such as Dr. Kumar's facility, are exactly the type facilities that are "Health care facilities that are not hospitals" and fit squarely within the safe harbor carved out by the FDA in their guidance. This safe harbor extends beyond just using the SUDs in the clinic to include the other requirements of hospitals and third party reprocessors that include such things as labeling them as reprocessed and to inform users that the devices used in their procedures are reprocessed.

FDA's guidance adds that the 2000 Enforcement Guidance "does not preclude FDA from taking immediate action against any particular product that is causing significant harm.[4] There are two salient points in this statement: 1) FDA retains the right to take action against "any particular

[1] GAO-08-147, *Single Use Medical Devices, A report to the Committee on Oversight and Government Reform, House of Representatives*, p. 5.
[2] *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,* issued on August 14, 2000, p. 11.
[3] *Id*.
[4] *Id,* p.15.

product," not against any person or entity (emphasis added); and 2) it clearly infers that FDA did not believe the safe harbor it created for health care facilities that are not hospitals would result in causing significant harm because it states it reserved the right to act if such harm occurs in the future. This assumption is born out by actual experience with hysteroscopes. Hysteroscopes, including both single use and those that are reusable and their accessories e.g., sheaths fall under FDA's product code HIH. A search by this author of the Manufacturer and User Facility Device Experience ("MAUDE") database using the search terms "HIH" and "Product Problem: Microbial Contamination of Device" from 5/1/2000 through 5/31/2026, a span of more than 25 years, revealed zero patient infections or harm. Hence, there is no evidence that hysteroscopes are susceptible to high risks of significant infectious contamination, and, hence, adulteration that would require urgent FDA action beyond its standard operating requirements outlined in Part 305 under the Food Drug & Cosmetic Act. Part 305 requires notice and a meaningful opportunity for interaction with FDA before it takes punitive actions regarding adulteration or misbranding.[5]

Discussion

Safe Harbor for Health Care Facilities That Are Not Hospitals

Physicians rely on numerous sources of information to inform their use of medical procedures, drugs, devices, and diagnostics in their practices. When I was a practicing surgeon, before attending law school, I had no idea how to look up case law or use Westlaw. I would look for authoritative government sources to guide my actions related to government rules and regulations. When dealing with medical devices, a primary resource is FDA's library of published Guidance documents. These Guidance documents, while not law, provide authoritative guidance to industry and users of FDA's policies based on FDA management's thinking, including issues raised during comment periods dealing with such issues as enforcement practices, regulations, and practical effects on safety and effectiveness of devices.

The Kumar indictment alleges that Dr. Kumar began using single use hysteroscopes around or before September 2019. Even assuming for argument's sake, that Dr. Kumar started reusing single use hysteroscopes at that time or before (which he denies), he would be on firm ground to assume such reuse in his own office/clinic was allowed. As noted above, the FDA carved out a safe harbor that applies to "health care facilities that are not hospitals," to wit, physicians' offices and clinics. This was the most authoritative and accessible information available from the FDA until at least 2020, well before and continuing beyond the beginning of Dr. Kumar's alleged reuse of SUDs. While there have been a number of clarifications of the 2000 Enforcement Guidance over the years, there has never been a change or retraction of the safe harbor carved out in the Guidance. The FDA continues to use the same language, i.e., that "[t]he FDA ensures the safety and effectiveness of reprocessed SUDs by regulating device manufacturers, third party reprocessors, and hospitals" without mentioning health care facilities that are not hospital.[6] On the same, current FDA webpage, it lists, under "Additional Resources," the FDA's Compliance Policy Guide relating to enforcement guidelines for SUDs. This current Compliance Policy Guide states, "the following policy does not apply to "health care facilities other than hospitals."[7] American Medical

[5] 21 U.S.C. § 335. See also Terman's Declaration.

[6] https://fda.gov/medical-devices/products-and-medical-procedures/reprocessing-single-use-medical-devices-information-health-care-facilities, downloaded on June 6, 2028.

[7] Sec. 300.500, Reprocessing of Single Use Devices (CPG 7124.16). While originally released 3/18, 2005, it remains the reference for FDA enforcement cited to on the FDA's website as of today, 6/28/2026.

Device Reprocessors ("AMDR") is the trade association the represents the reprocessing industry and is in frequent dialogue with the FDA. AMDR is unaware of any FDA enforcement actions "against any facilities that are not hospitals or commercial reprocessors," and AMDR is unaware of any indication that their enforcement priorities have changed since the 2000 Enforcement Guidance.[8] Therefore, this safe harbor for physicians was the FDA's policy when the government alleges Dr. Kumar's "scheme" began in 2019 and remains the agency's policy today.

Finally, the mere fact that a device is labeled SUD by the manufacturer is not dispositive that the device is inherently unsafe or adulterated if it is reused. The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function.[9] Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chose not to conduct the studies needed to demonstrate that the device can be labeled as reusable. Their decision can be made based on economics because it was not economically feasible or that reuse was not part of its marketing plan because making them SUD created an additional revenue source. Therefore, the government's conclusion that SUDs are inherently unsafe to reuse, without more, is in conflict with the government's own position outlined in the 2008 GAO report.

Because Dr. Kumar acted within the bounds of the safe harbor created by the FDA and made public in multiple, authoritative ways, Dr. Kumar could not have acted knowingly or with intent to adulterate FDA regulated products while operating within the FDA-created safe harbor. Therefore, even if he had reused SUDs, it would have been done from within the safe harbor and could not support the notion that he illegally reused SUDs and, hence, he could not be guilty of adulteration and the alleged fraud that would flow from that adulteration.

Reusable Hysteroscopes

The governments indictment alleges that Dr. Kumar also adulterated reusable hysteroscopes by not properly reprocessing them. The government admits that Dr. Kumar's clinic possessed and used HYF-XP Hysterofiberscopes in his practice. They vaguely allege the clinic did not properly reprocess them, although they admit they are not SUDs and are reprocessable. The conclusory statement in this count that the reusable Olympus hysteroscope was also adulterated by inadequate reprocessing belies the government's nefarious intention to just throw the kitchen sink at Dr. Kumar and undermines their allegation that Dr. Kumar reused SUDs, which he has repeatedly denied. Dr. Kumars clinic had over 30 of these reuseable hysteroscopes and a Medivator automatic endoscope reprocessor ("AER"), an expensive machine manufactured and sold by Steris Corporation specifically to reprocess flexible fiberoptic endoscopes such as the Olympus HYF-XP Hysterofibersope. He also had a drying and storage cabinet specifically designed to safely dry and store these type endoscopes by subjecting them to dry, medical grade airflow. Furthermore, Dr. Kumar's facility had a contract with Steris for maintenance and preventive maintenance for his Medivator AER that included staff training. Reusable flexible fiberoptic endoscopes e.g., the Olympus HYF-XP cannot be "held for sale" because they are not consumed at their use. Instead, the reuseable endoscopes, the light source, video screens, AER, drying and storage cabinets and

[8] See personal communication from Daniel J. Vukelich, Esq., President of AMDR, Jun 28, 2026.
[9] GAO-08-147 report, p. 1.

other equipment needed to use the reusable endoscopes are expensive capital investments, not consumables held for sale. Indeed, they are used repeatedly for years and not consumed. Hence, the allegation that these reusable Hysterofiberscopes were "held for sale after shipment in interstate commerce that resulted in the medical devices being adulterated" is patently false and should be thrown out.

The presence of the capital equipment in Dr. Kumar's clinic also undermines the notion that he reused SUD (even though such reuse would have been legal under the safe harbor discussed above). Having made the large capital investment for reusable equipment and the AER, he would, logically, use SUDs only when the reusables were unavailable, e.g., on weekends, during hours when the trained reprocessors were unavailable, when the AER was down for service, etc. On these occasions it would make sense to use single-use hysteroscopes even though they are relatively expensive. Of note, normal infection control measures require used SUDs, such as consumable hysteroscopes to be rendered safe for disposal. Therefore, even though one does not intend to reuse them, frequently they are stored in disinfectant until being disposed of in red bio-hazard trash bags/bins.

Hysteroscope Accessories Are Class I and Not Subject to FDA Regulation

The indictment further alleges that Dr. Kumar reused hysteroscope accessories, rendering them adulterated on the basis that their reuse was illegal because they were labeled for single use, and did not have a pre-market notification, known as a 510(k) to provide for reuse. However, not only was his office, as a health care facility other than a hospital or third-party reprocessor, exempt from the reprocessing of SUD enforcement, but these accessories were Class I devices based on FDA's risk prioritization and, hence, exempt from such regulations. The product code for hysteroscopes and their accessories fall under the FDA's product code HIH. HIH is controlled by the regulation, 21 C.F.R. § 884.1690, which designates hysteroscopes as Class II devices subject to FDA's regulatory paradigm, and the accessories e.g., cannulas, graspers, scissors, and instrument guides as Class I devices that are exempt from the premarket notification procedures, i.e., 510(k) submissions. Hysteroscopes and their accessories each fall under totally different regulatory paradigms, with the accessories that are Class I devices falling well outside the regulatory purview of the FDA. By conflating the hysteroscopes, which are Class II with the hysteroscope accessories, which are Class I and not subject to significant FDA regulation, the government, not only created additional inappropriate counts based on the reuse of the accessories, but markedly amplified the perception of counts related to hysteroscopes by lumping these low risk, Class I devices together with the Class II-level risk devices. Not only did this conflation create out of thin air the indictment counts related to the Class I accessories, but this also likely biased the triers of fact relating to the other device reuse allegations by leading them to falsely consider the cumulative effect of the devices that were not subject to FDA regulation with those that are. Since they were Class I devices not subject to FDA regulation, it follows that they could not be adulterated and serve as the predicate for fraud.

Billing for Single Use Devices

The Indictment alleges on page 2 that doctor Kumar billed Health insurers, including Medicare, the value of single use hysteroscopes even when he was in fact reusing them. This cannot be true because, as indicated in the indictment in ¶ 16, physicians are reimbursed based on the American Medical Association's CPT codes. There are several CPT codes for hysteroscopy depending on

what concurrent procedures accompany the hysteroscopy, e.g., biopsy, removal of fibroids, removal of impacted foreign bodies, or endometrial ablation. What all the associated hysteroscopy CPT codes have in common is that they all provide for the same reimbursement regardless of the type of hysteroscope used. There is no difference in reimbursement for single use verses reusable hysteroscopes. Therefore, distinguishing between them in this case is a red herring since there is no difference in the reimbursement rate for any of the hysteroscopy codes within the 5855 code family and he could not have billed a different amount for single use versus reusable instruments during hysteroscopic procedures.

Misbranding Based on Labeling

The indictment charges that reused SUDs must be labeled and consented to when reprocessed devices are used. However, this requirement does not apply to Dr. Kumar. He is not a reprocessor subject to the labeling requirement because that requirement is limited to hospitals and third-party reprocessors, not for healthcare facilities that are not hospitals. The FDA's safe harbor for physicians' practices exempts them from all the requirements imposed on hospitals and third-party reprocessors. This is because the FDA does not view facilities that are not hospitals or third party reprocessors as manufacturers. Because FDA does not view physicians' offices and clinics as manufacturers, none of the requirements of manufacturers, e.g., registering and listing, labeling, or packaging are required of physicians. This serves as the rationale for the safe harbor and, *inter alia*, for physicians being exempt from most, if not all, the requirements of manufacturers.[10] Again, these carve outs exempt Dr. Kumar from the manufacturers' requirements for labeling and, hence, from being violative of misbranding within his own medical practice.

Held for Sale

The government's indictment states that the "adulterated" medical devices were held for sale. There are two cases that address the issue of SUD reuse serving as a basis for Medicare Fraud: U.S. v. Kaplan[11] and U.S. v. Jackson.[12] Kaplan held that "a physician's use of a consumable single-use device on a paying patient satisfies the 'held for sale' element under § 331(k) under the FDCA. Section 331(k) prohibits "the doing of any. . . act with respect to . . . [a] drug [or] device . . . if such act is done while such article is held for sale . . . after shipment in interstate commerce and results in such article being adulterated." A device is adulterated if it is "held under insanitary conditions whereby it may have been contaminated with filth, or . . . rendered injurious to health."[13]

The Kaplan Court held that the case "turn[ed] on the interpretation of 'held for sale.'"[14] The Kumar case is distinguishable in several respects. Kaplan admitted to reusing SUDs. In the instant case Dr. Kumar denied reusing SUD hysteroscopes and had over 30 reusable hysteroscopes available, including the capability and equipment to properly reprocess them. Because their reuse is pivotal to a finding that the hysteroscopes were adulterated, the mere assumption that they were reused by virtue of their presence is insufficient to prove adulteration. More importantly, the FDA-created safe harbor for SUDs used in facilities that are not hospitals or third party reprocessors was not

[10] 21 C.F.R. § 807.65(d).
[11] *United States v. Kaplan*, No. 15-10241, Jul 19, 2016.
[12] *United States v. Jackson,* 126 F. 4th 847, (4th Cir. 2025).
[13] Kaplan, at p. 12.
[14] *Id.*

raised by Kaplan or addressed by the Court. That Dr. Kumar, at all times he is alleged to have held adulterated devices for sale, was operating within a safe harbor indicates that he was not holding adulterated devices for sale in interstate commerce.

The Kaplan Court specifically noted it did not decide whether capital equipment or reusable equipment or the guides, which would be akin to the Class I accessories in the instant case, could be considered "held for sale."[15] Therefore, there is no case law to support the conviction in the Kumar case regarding the reusable Olympus HYF-XP hysteroscopes or the Class I accessories and any counts related to those should be thrown out. Not only are they unsupportable, but their inclusion unfairly contributes to bias against the defendant.

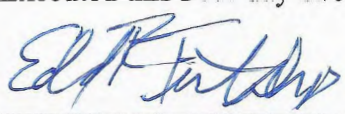
Because the Jackson case mirrored the Kaplan case so closely and the Jackson Court acknowledged it relied on Kaplan, I will not separately explore Jackson, except to note that in Kaplan, the defendant was given an opportunity to be heard by the FDA prior to being indicted. This is consistent with the FDA's long-standing statutory requirement for an opportunity to meet with the FDA prior to a referral or indictment, a requirement not afforded to Dr. Kumar.[16]

No Knowing and Willful Violation of the FDCA

Because Dr. Kumar's practice fell squarely within the FDA's safe harbor for facilities that are not hospitals or third-party reprocessors, he was not in violation of the FDCA. But even if he were, the authoritative and public guidance relating to the safe harbor clearly precludes a finding that he intentionally or knowingly was in violation of the FDCA. Indeed, it would be a very rare practicing physician who would know that following formal FDA Guidance and publications subject to formal public comment periods and publication in the Federal Register could leave him exposed to criminal liability.

The safe harbor is significant because due to the public and ongoing existence of the safe harbor, Dr. Kumar was subject to having a well-founded good faith belief that his activities even regarding SUDs were legal. Therefore, he could not knowingly or willfully be in violation of the FDCA, a prerequisite for the FDCA violations to be valid, and hence, the Medicare fraud and abuse claims flowing from them to be valid. The very close parsing of terms such as "held for sale" in a complex case like Kaplan, in a circuit remote from the doctor and where there are multiple distinguishing elements in the instant case can't possibly serve as a source of knowledge to attach criminal culpability.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.
Executed this 30th day of June, 2026.



Edward R. Teitel, MD., Esq.

[15] *Id*, FN 7.
[16] 21 U.S.C. § 335.

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30 June 2026

Stephen Terman, Esq.
Edward Teitel, Esq.
Olsson Frank Weeeda Terman Matz PC
2000 Pennsylvania Ave., NW Suite 4003
Washington, DC 20006

Dear Steve and Ed:

Nice catching up with you Saturday Steve. To memorialize AMDR's history and understanding, see below the following which may be helpful.

First, see FDA's original "enforcement priorities" document which put in place FDA manufacturer requirements for SUD reprocessors. Note, on page 16 in the scope, FDA specifically omits from its enforcement priorities "opened but unused" devices and reprocessing of SUDs in facilities that are not hospitals. Note also the link to this document points to an AMDR web link, as Ed found, this document, probably being so old, is no longer accessible on FDA's site. To AMDR's knowledge, however, FDA's enforcement priorities have not changes. AMDR is not aware of enforcement action against by FDA against any facilities that are not hospitals or commercial reprocessors.

Second, if helpful, AMDR Best Clinical Practice document at link. The bottom of page 1 to 5 may prove helpful in describing FDA's regulation of SUD reprocessing. It is fully cited to FDA requirements.

Third, more recently, AMDR worked recently with FDA to create some clarifying language on the FDA's website about SUD reprocessing. That information may be helpful and is found here. While a summary and not legally binding, FDA, in short, says that it "ensures the safety and effectiveness of reprocessed SUDs by regulating device manufacturers, third party reprocessors, and hospitals that reprocess SUDs in the same manner as the original equipment manufacturer (OEM)." No mention of clinical facilities that are not hospitals, further signaling FDA's enforcement priorities have not changes since 2000.

AMDR is the global trade association representing regulated, commercial SUD reprocessors and remanufacturers. Our members fully comply with FDA (and analogous global competent authority) medical device manufacturer requirements including premarket review.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of June 2026."



Daniel J. Vukelich, Esq., President

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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-cr-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

DECLARATION OF AMY GARCIA

Summary

1. The FDA 510(k) document, along with all guidance, classifies hysteroscopes as semicritical instruments that, under the Spaulding Criteria, can be reprocessed with high-level disinfection.
2. This same document is intended for manufacturers of 510 (k) devices and was never intended for use by practicing gynecologists.
3. The IFU is approved and issued by the FDA. The FDA directs physicians to follow the IFU guidelines for hysteroscope reprocessing.
4. The FDA has cleared the Olympus HYF-P and HYF-XP flexible hysteroscopes for reprocessing by high-level disinfection, per their IFUs.
5. Leak testing of single-channel flexible hysteroscopes is unnecessary because the hysteroscope's mechanics provide an automatic self-leak test with each use.
6. Small cleaning brushes used in tiny inflow ports may pose a risk of patient harm, and the CDC recommends flushing ports with fluid when brushes are not feasible or appropriate.
7. The uterine cavity is not a sterile organ.
8. In their IFUs, the FDA recommends that physicians exercise their clinical judgment when selecting the reprocessing method for the HYF-P and HYF-XP flexible hysteroscopes, based on the specific needs of the clinic or institution. The physician/endoscopist is given discretion per the IFU to use the exact protocol that works best for their setting.
9. In the gynecological medical literature, channel brushing or leak testing has not been reported to affect infection rates during hysteroscopy, and no infections have been reported with HYF flexible hysteroscopes after high-level disinfection.
10. The standard of care centers on reasonable competence and accepted medical practices.
11. I reviewed numerous trial documents and clinic videos demonstrating that Dr. Kumar gave the staff written, appropriate, and consistent instructions to use, clean, disinfect, and sterilize multi-use hysteroscopes from 2019 to 2024. No instruction suggested reusing any specific single-use device. Staff responded with emails confirming compliance.

12. A medical device cannot be deemed adulterated while it's stored in a physician's office. Reasons for storing a device include educational, research, repair, student training, awaiting reprocessing, demonstrative use, and decontamination before disposal.
13. The FDA classifies hysteroscope accessories, including graspers, scissors, cannulas, forceps, and brushes, as Class I devices, thereby exempting them from the 510(k) regulatory process.
14. The FDA regulations governing the reuse of single-use instruments apply only to hospital systems, leaving physician offices exempt from the requirement to register as either a reprocessing facility or a manufacturer.
15. As a board-certified OB-GYN, I completed a fellowship in minimally invasive gynecologic surgery (MIGS) and have spent over two decades in private practice, focusing exclusively on operative hysteroscopy and in-office hysteroscopic procedures for the past 10 years. My 30-year career is defined by expertise in hysteroscopy: I teach operative and office hysteroscopy nationally and internationally for the American College of Obstetricians and Gynecologists (ACOG) and the American Association of Gynecologic Laparoscopists (AAGL). I've served as a leader on the AAGL Board of Directors and currently serve as President of the AAGL Foundation. For more than 25 years, I've also collaborated with the medical device industry to design innovative gynecologic surgical tools—including hysteroscopes.

Report and Analysis

1. Hysteroscopes are Semi-Critical Devices

I want to make it clear that the FDA classifies hysteroscopes, which are endoscopes, as **semicritical.** The document provided by the FDA expert, Dr. Nandy, which forms the basis for her erroneous conclusion that the FDA considers hysteroscopes critical instruments, states on page 5, section B, verbatim, "Hysteroscopes are considered limited duration surface devices *contacting a mucosal membrane or compromised surface*." (1) This is nearly identical to the FDA and CDC's use of the Spaulding Classification definition, "Semicritical items *contact mucous membranes or nonintact skin*." (2, 11) These two definitions are nearly identical in wording and, more importantly, identical in meaning and content. The FDA plainly states that it considers the hysteroscope a semicritical device. Still, this FDA 510 (k) document is intended for instrument manufacturers and was never intended for use by practicing gynecologists.

When considering clinician guidance, the FDA has required each manufacturer to provide an FDA-approved Instruction for Use (IFU) manual detailing the appropriate hysteroscope reprocessing procedures, validated by the manufacturer using "worst-case" scenarios. (3) Instruments must be validated as properly disinfected under worst-case conditions, including

intentional soiling, allowing debris to dry onto and in the instruments, minimal washing, shortened chemical exposure times, and decreased concentrations of chemical disinfectants. This worst-case FDA requirement for manufacturers ensures that following the IFU results in appropriate disinfection. Practicing gynecologists rely on the IFU to follow FDA guidance because any information in the IFU has already been approved and recommended by the FDA.

The CDC's primary aim is to guide clinical practice in accordance with scientific research and FDA recommendations. The CDC states, "Semicritical items minimally require high-level disinfection using chemical disinfectants." In addition, the CDC states, "All heat-sensitive endoscopes must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use" (2). According to both the FDA and the CDC, Cidex OPA is a sporicidal chemical sterilant. When used for the recommended 12 minutes at 68°F, it functions as a high-level disinfectant: "That should eliminate enough pathogens to prevent transmission of infection." Therefore, when high-level disinfecting with OPA, "There is no indication for sterilization" (2, 3). Flexible hysteroscopes are heat-sensitive, semicritical instruments that are appropriately disinfected at a high level with OPA.

The CDC states, "Provided that high-level disinfection is achieved, and all microorganisms except bacterial spores have been removed from the endoscope, the device should not represent an infection risk and should remain in the semicritical category. In the uterus, infection with spore-forming bacteria has not been reported from appropriately high-level disinfected endoscopes." (2) According to the FDA, when high-level disinfection is used, sterilization of semicritical instruments is unnecessary. At the FDA's direction, the IFU for the Olympus HYF-P and HYF-XP flexible hysteroscope provides guidance to the gynecologist on reprocessing the instrument with high-level disinfection. (4, 5)

2. Flexible Hysteroscope Leak Testing

The primary function of the endoscope leak test is to detect internal channel and external sheath damage before submerging the endoscope in liquid for cleaning, thereby preventing damage to its electronic components and costly repairs or replacements. This can be done with dry testing by pressurizing the hysteroscope and using a pressure gauge, or with wet testing by pressurizing

the endoscope and submerging it in water to detect bubbles. The flexible hysteroscope, unlike other complex endoscopes, has only a single channel, used exclusively for saline inflow, and no instrument enters it, making internal channel damage extremely improbable. A leak in the internal channel or the external sheath of the HYF-XP (the device in question here) will allow saline to enter and damage sensitive electronics, rendering the hysteroscope inoperable and preventing its use on the next patient. Because of the flexible hysteroscope's design, leak testing need not be performed after every use, as the camera itself serves as a clinical leak tester.

3. Channel Brushing

The flexible Olympus HYF-XP hysteroscope's inflow port has an inner diameter of only 1.2 mm. The tiny brushes recommended for use with the port risk damaging the channel and leaving bristles behind during processing. This risk has been reported to the FDA and could harm the patient. (6) Since no operative instruments are used in the channel, no tissue is ever removed through it. Therefore, the channel will not contain debris that would require brush removal, as the port serves only as the inflow for saline or air.

The CDC states, “Fluidics (i.e., fluids under pressure) is used to remove soil and debris from internal channels after brushing and when the design does not allow passage of a brush through a channel.” (2) This means that during reprocessing of the hysteroscope, pushing a syringe of fluid through the small channel results in very high pressure (Bernoulli's equation in physics states that the smaller the channel, the higher the fluid's velocity and pressure), capable of removing any debris. During usual reprocessing, this is done multiple times: first with water or saline, then with an enzymatic detergent, then with a high-level disinfectant, followed by water, and finally with alcohol, resulting in the appropriate removal of debris and ensuring full contact of the inner channel with the cleaner and disinfectant, as a reasonable alternative to brushing in this circumstance.

No adverse events have been reported to the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database involving the Olympus HYF-XP flexible hysteroscope related to the foregoing inflow channel brushing and/or leak testing.

4. The Uterine Cavity Is Not Sterile

The female genital tract, consisting of the vagina, uterus (with cervix and endometrium), uterine tubes, and ovaries, harbors a characteristic microbiota (7). In short, the uterus is not a sterile organ. Bacteria in the genital tract maintain a symbiotic relationship with the host. Similar bacteria are found in the vagina, cervix, and uterine cavity, whereas unique bacteria are found in the ovaries. Hysteroscopy, therefore, typically does not alter the genital tract flora and is unlikely to introduce new bacteria into the uterine cavity. This, along with the washing and flushing that occur when saline is used as a uterine distention medium, makes post-hysteroscopy endometritis uncommon. It also means that a hysteroscope should not be considered a critical instrument and is appropriately deemed semicritical by the FDA.

5. Scientific Data Regarding Infection after Hysteroscopy

In the gynecological medical literature, channel brushing or leak testing has not been shown to affect infection rates during hysteroscopy, and no infections have been reported with HYF flexible hysteroscopes after high-level disinfection. The standard of care is the level of attention, caution, and treatment that a reasonably prudent, similarly trained healthcare professional would provide under similar circumstances. It focuses on reasonable competence and accepted medical practice. The recommendations of the CDC and the FDA, as reflected in the IFU provided by the hysteroscope manufacturer, are the primary tools available to the gynecologist for clinical decision-making to meet the standard of care. Indeed, the IFU for the Olympus HYF-P and HYF-XP hysteroscopes also states that the gynecologist may make reasonable decisions regarding hysteroscope reprocessing that are best suited to their clinical practice, based on FDA and CDC guidelines and local medical or hospital guidelines. (4, 5)

6. Summary of Training and Information Documents from Dr. Kumar and Poplar Avenue Clinic

A number of documents from 2019 to 2024 were reviewed, including protocols, emails, photos, and videos from the clinic. (8) These documents show that Dr. Kumar, through direct communication or protocol, provided the staff with instructions for reprocessing reusable

hysteroscopes. The instructions covered the use, cleaning, disinfection, and sterilization of the instruments. Email responses from staff indicated compliance with these instructions. I found no instructions suggesting the reuse of any specific single-use device.

7. Code of Federal Regulations (21 CFR § 884.1690(b))

Under FDA regulations, simple manual hysteroscope accessories, such as graspers, scissors, cannulas, forceps, and brushes, are classified as Class I devices because they are non-powered, non-inflatable mechanical instruments that pose the lowest risk to patients. These instruments are specifically exempt from the 510(k) premarket submission requirement under 21 CFR § 884.1690(b). This exemption reflects a regulatory presumption of mechanical safety based on their simple, well-characterized design. (9) Therefore, the gynecologist applies this understanding when using these hysteroscopic accessories in the office and is more likely to consult the MAUDE Database for adverse event reports involving such instruments to inform clinical decision-making, given their 510(k) exemption. (6)

8. FDA Regulations on Reprocessing of Single-Use Devices (CPG Sec. 300.500)

The FDA published the Compliance Policy Guide (CPG) Sec. 300.500, a federal policy on the reprocessing of devices labeled or intended for single use, available online. (10) The document makes clear that the regulations in the policy guide do not apply to healthcare facilities other than hospitals, which are required to use a third-party reprocessor or to register as manufacturers and adhere to stringent manufacturer guidelines when reprocessing single-use devices. These same requirements do not apply to the gynecologist's office, which is explicitly exempt from this policy. As with all published guidance from the FDA, the practicing clinician can apply this information to reasonable clinical decisions.

References

1. FDA Hysteroscopes and Gynecologic Laparoscopes. Submission Guidance for a 510(k). Final March 7, 1996.

2. William A. Rutala, P.D., M.P.H.1,2, David J. Weber, M.D., M.P.H.1,2, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)3, *Guideline for Disinfection and*

Sterilization in Healthcare Facilities, 2008 Update: June 2024, in *Centers for Disease Control*. 2024.

3. Administration, U.F.a.D., *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. 2017.* https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and

4. Olympus, *Instructions For Use. Visera Hysterovideoscope OLYMPUS HYF TYPE XP.*

5. Olympus*, Instructions For Use. Hysterofiberscope OLYMPUS HYF TYPE P.*

6. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=7591744&pc=MNL

7. Liptáková A, et. al. Microbiota of female genital tract - functional overview of microbial flora from vagina to uterine tubes and placenta. Physiol Res. 2022 Dec 27;71(Suppl 1):S21-S33

8. Documents reviewed: binder rigid endoscope sterlization USA-0003680, maual disinfection flexible scopes _cidex opa USA-0003689P, rigid endoscope autoclave USA-0003681P, room 11 USA-0003755, sarah office scopes and checking copay and deductables_standing instruction USA-0003991, scope sterlization protocol page 1 found in washer room room, scope sterlization protocol page 2 found in washer room room, standing staff instruction_wash scopes USA-0003772, sterlize scopes_lab card on wall USA-0003666P, TAG but no picture, Gmail - Clinic housekeeping, K1 - Abdu Email Cystoscope Sterilization, K2 - Abdu Updated Scope Protocol, K3 - Alaeddin Email re office procedure course, K4 - Alaeddin Email re tasks_washer active logs protocol complete, K12 - Ibrahim Email re Autoclave repair need attach, K13 - Ibrahim Email to UroViu with issues, K19 - Ibrahim Email re AER training videos Gmail - Fwd_ Links for Videos DSD-201 and Scope Buddy, K20 - gyn-md.com Mail - Fwd_ SCOPE INDICATIONS DOCUMENT-----sent to all to edit, doesnt say all pts need hysteroscopy, K21 - Ibrahim scope training and staff Gmail – Tasks, K23 - Email from Gayla Cheatham re Raise, no tower room_2.9mm flexible scopes_staff instruction, scope washer CER Washer email to staff, USA-0003689_lab staff instruction chart for Manual HLD of scopes, USA-0003957 cidex HLD bin on 4.16.2024, USA-0089693 kumar training staff multiuse scopes 3.12.2020, USA-0089694 kumar training staff multiuse scope use 3.12.2020, USA-0089695 huda scope washing video june 2021, wash scopes after each use_never leave unwashed overnight

9. U.S. Food and Drug Administration. 21 C.F.R. § 884.1690

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-884/subpart-B/section-884.1690

10. FDA Compliance Policy Guide for Reprocessing Single-Use Devices. (CPG Sec. 300.500).

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-300500-reprocessing-single-use-devices

11. FDA Guidance on Reprocessing Medical Devices in Health Care Settings, March 17, 2015. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of June 2026.



Amy Garcia, MD

Thomas J. Caruthers, Jr., MD, FACOG

Curriculum Vitae

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EDUCATION

Wayne State University / Hutzel Hospital, Detroit, Michigan, Obstetrics and Gynecology Residency Training Program, 7/1993-6/1997

University of Tennessee, Knoxville, Tennessee, 12 hours and Pre-Med Enrichment Program, 5/1995-8/1995

Meharry Medical College, Nashville, Tennessee, 8/1987-12/1992

Tennessee State University, Nashville, Tennessee, Bachelor's of Science, Biology (Cum Laude) with Honors, 8/1982-5/1987

Meharry Medical College, Biomedical Science Program, 6/1984-8/1984

LICENSURE

Tennessee State License NO. 0000029623 valid thru 11/2027

Diplomat, National Board of Medical Examiners, 1994

American Board of Obstetrics and Gynecology, Board Certified as of December 2004 and have maintained my certification though the end of 2026.

RESEARCH / PUBLICATIONS

Caruthers, T.J., Tomlinson, M., Whitty, Gonic, B. "Does Delivery Improve Maternal Condition in the Respiratory-Compromised Gravida?" Published in January 1998 issue of Obstetrics and Gynecology.

HONORS AND AWARDS

1997 Chairman's Award, Hutzel Hospital, Wayne State University

1992 Omega Psi Phi Scholar of the Year

1989 Outstanding Young Men of America

1987 Graduated with Honors, Tennessee State University

1986 Who's Who Among American Students at Colleges and Universities

1985 Beta Kappa Chi (Science Honor Society)

WORK EXPERIENCE

01/2021 -6/2024 Chief Medical Officer of HCCHC-Present

03/2018- Present Hardeman County Community Health Center

7/1999-6/2017 Premier Women's Care (solo practice)

8/1998-12/1998 Caring Choice Women's Care

8/1997-6/1998 Chattanooga OB/GYN

7/1995-6/1997 OB Affiliate, Bon Secours Hospital - Grosse Pointe, Michigan

7/1995-6/1997 OB Affiliate, Crittenton Hospital - Rochester Hills, Michigan

8/1993-6/1997 Wayne State University Hospital and Grace Hospital OB/GYN Training Program

MEMBERSHIPS

1987-Life Member Omega Psi Phi Fraternity, Inc.

1993-Present Junior Fellow, American College of Obstetrics and Gynecology

1993-Present American Medical Association

1993-Present National Medical Association

1997-1999 Mountain City Association

2004-present American Board of Obstetrics & Gynecology

EXTRACURRICULAR ACTIVITIES

1999-Present Mentor with Crestview Middle School

1993-1997 Hutzel Hospital Intramural Basketball League

1987-1993 Work with the Nashville Rescue Mission in Ministry

1984-1993 Associate Minister of Mt. Hopewell Baptist Church

1982-1993 Big Buddies Program

HOBBIES

Traveling, Golf, Racquetball, Exercising, and all ways of reducing the stress of medicine.

REFERENCES

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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-cr-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

DECLARATION ON RISK OF INFECTION WITH HYSTEROSCOPY

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1. I am a physician, trained in OBGYN to take care of patients. I have extensive experience in clinical OBGYN field and completed residency training in OBGYN including hysteroscopy.

2. I am familiar with the devices used in hysteroscopy.

3. Spaulding classification is used by both, CDC and FDA to classify devices for cleaning. According to the principles outlined in the Spaulding classification, hysteroscopes are semi-critical devices because they come in contact with intact mucus membranes.

https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html

https://www.fda.gov/media/80265/download

https://disinfectionandsterilization.org/wp-content/uploads/2022/06/SemicriticalAPICJune2022-1.pdf

4. Hysteroscope devices may be cleaned with high level disinfectant and then re-used safely. For hysteroscopic devices, high level disinfection vs sterlization has no difference in infection rates according to published literature; because no infection outbreaks after hysteroscopy have been reported in literature. https://disinfectionandsterilization.org/wp-content/uploads/2022/06/SemicriticalAPICJune2022-1.pdf

https://newsscope.aagl.org/hysteroscopy/office-hysteroscopy-simple-set-up-is-the-best-approach/

5. Additionally, the uterine cavity is not a sterile cavity. Uterine microbiome studies provide scientific evidence. https://pmc.ncbi.nlm.nih.gov/articles/PMC8745284/

6. Baseline risk of infection after hysteroscopy is low. According to pubmed search, the most reliable source of peer reviewed literature, no cluster infection outbreaks have ever been reported after hysteroscopy with use of high level disinfection. https://disinfectionandsterilization.org/wp-content/uploads/2022/06/SemicriticalAPICJune2022-1.pdf

7. Finally, the patient population in Memphis that Dr. Sanjeev Kumar serves contain more African American patients. According to the National Cancer Institute, African American Women experience higher uterine cancer rates and higher death rates due to this cancer than Caucasian Women. Hence the clinical need for hysteroscopy is much higher in this population than in Caucasian or Asian counterparts. https://www.cancer.gov/news-events/press-releases/2022/uterine-cancer-deaths-black-women

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct with the referenced material.

Executed this 26th day of June, 2026.

THOMAS J. CARUTHERS JR. MD

MD 6/29/26

Name-

Roberto Levi-D'Ancona
9 Bridge Terrace
Springfield, IL 62704
Cel. (708) 203-2536
E-mail: robertolevidancona@yahoo.com

Place of Birth: Trieste, Italy

Citizenship: U.S.

Languages: Italian, English, Spanish, French

Undergraduate:

1996	Medical License - USA
1984	Medical License – Italy
1977– 1984	Medical Diploma University of Florence School of Medicine, Florence, Italy

Residency:

1997 – 2001	Residency in Obstetrics and Gynecology University of Illinois at Chicago, Chicago, IL
1984– 1988	Residency in Obstetrics and Gynecology Department of Obstetrics and Gynecology University of Florence School of Medicine, Florence, Italy

Postgraduate Training:

07/2001 – 11/2002	Fellow in Advanced Gynecology and Critical Care Department of Obstetrics and Gynecology University of Illinois at Chicago, Chicago, IL
09/1994– 05/1997	Research Fellow Department of Obstetrics and Gynecology Section of Maternal Fetal Medicine Yale University School of Medicine, New Haven, CT Working with Ray Bahado Singh, MD and Giancarlo Mari, MD
12/1992	Visitor Maternal Fetal Medicine Unit University of Colorado Health Sciences Center, Denver, CO Director - John Hobbins, MD
12/1991	Visitor Maternal Fetal Medicine Unit University of Colorado Health Sciences Center, Denver, CO Director – John Hobbins, MD

Medical License:	Tennessee Medical License # 52426 Illinois Medical License # 36108168 Connecticut Medical License #040803
Board Certification:	Board Certified in Obstetrics and Gynecology – 2009 Recertification – April 2015 and 2021

University Appointments:

7/01/20 to present	Associate Professor Southern Illinois University, Springfield, IL Department of Correctional Medicine Department of Obstetrics and Gynecology Department of Family Medicine

08/01/19 – 6/30/20	Assistant Clerkship Director University of Tennessee Health Science Center, Memphis, TN Department of Obstetrics and Gynecology
2017 – 6/30/20	Specialty Advisor University of Tennessee Health Science Center, Memphis, TN College of Medicine
07/01/17 – 6/30/20	Associate Professor University of Tennessee Health Science Center, Memphis, TN Department of Obstetrics and Gynecology

University Appointments:

7/01/20 to present	Division Director of Woman Health Services Office of Correctional Medicine Southern Illinois University, Springfield, IL Department of Obstetrics and Gynecology
07/01/17 –6/30/20	Division Director of Gynecology University of Tennessee Health Science Center, Memphis, TN Department of Obstetrics and Gynecology
05/01/15 – 07/31/19	Clerkship Director University of Tennessee Health Science Center, Memphis, TN Department of Obstetrics and Gynecology
05/01/15 – 06/30/17	Assistant Professor University of Tennessee Health Science Center, Memphis, TN Department of Obstetrics and Gynecology
02/2012– 04/2015	Assistant Professor Loyola University Medical Center, Maywood, IL Department of Obstetrics and Gynecology
2009 – 02/2012	Instructor Loyola University Medical Center, Maywood, IL Department of Obstetrics and Gynecology
11/1992 –08/1994	Instructor University of Florence, Florence, Italy

	Department of Obstetrics and Gynecology
1991– 1992	Attending Physician University of Trieste, Trieste, Italy Department of Obstetrics and Gynecology

Hospital Appointments:

7/01/20 to present	St. John's Hospital Springfield, IL Department of Obstetrics and Gynecology
7/01/21 to present	Springfield Memorial Hospital Springfield, IL Department of Obstetrics and Gynecology
05/2015 –6/30/20	Attending Physician University of Tennessee Regional One Physicians, Memphis, TN Department of Obstetrics and Gynecology
01/2009-04/2015	Attending Physician Loyola University Medical Center, Maywood, IL Department of Obstetrics and Gynecology
10/2003 – 04/2015	Attending Physician Gottlieb Hospital, Melrose Park, IL Department of Obstetrics and Gynecology
12/2002 – 10/2003	Ob/Gyn Attending Physician Hospitalist Michael Reese Hospital, Chicago, IL Lincoln Park Hospital, Chicago, IL St. Alexius Hospital, Hoffman Estates, IL
11/1992 –08/1994	Instructor Careggi Hospital, University of Florence, Florence, Italy Department of Obstetrics and Gynecology

1991– 1992	Attending Physician Hospital Burlo Garofolo, University of Trieste, Trieste, Italy Department of Obstetrics and Gynecology
1990– 1991	Attending Physician Hospitals of San Dona' di Piave and Jesolo, Italy Department of Obstetrics and Gynecology
1989 – 1990	Instructor Hospital Burlo Garofolo, University of Trieste, Italy Department of Obstetrics and Gynecology
1989	Obstetric Gynecology Practitioner Unita' Sanitaria Locale 10/A, 10/B, 10/E, 10/F Florence, Italy

Awards:

2018	Excellence in Student Education University of Tennessee Health Science Center Department of Obstetrics and Gynecology
2016	APGO Excellence in Teaching Award University of Tennessee Health Science Center Department of Obstetrics and Gynecology
2015	Best Medical Students' Attending of the Year Teaching Award Loyola University Medical School, Maywood, IL
2000 – 2001	Best Resident Teaching Award University of Illinois at Chicago, Chicago, IL Excellence in Research Award – 3rd Place Senior Research Project

Society Memberships:

NCCHC - since 2021
AAGL – since 2016
APGO – since 2015
SLS – since 2015

AIUM – since 2000
ACOG – since 1997
SIGO (Italian Society of Gynecology and Obstetrics) – since 1985

Areas of Interest: Perinatology, Ultrasound in Obstetrics and Gynecology, Color Doppler flow measurement, ovarian cancer, monoclonal antibodies, Reproductive Endocrinology, Endoscopy, in particular, laparoscopic and vaginal hysterectomy

Teaching Experience:

October 2022 to present
Teaching Medical Students and Residents
Department of Family Medicine
Southern Illinois University
Springfield and Decatur, IL

October 2020 to present
Teaching Medical Students
Department of Correctional Medicine
Southern Illinois University
Springfield, IL

October 2020 to present
Participant of the Quality Improvement Committee
Department of Correctional Medicine
Southern Illinois University
Springfield, IL

July 2020 to present
Creating a portfolio and curriculum for Women Health Service
Office of Correctional Medicine
Southern Illinois University
Springfield, IL

May 2015 – July 2019
Clerkship Director
University of Tennessee Health Science Center
Department of Obstetrics and Gynecology
Memphis, TN

May 2015 – June 2020

Teaching Medical Students and Residents
Interacting at all levels, both clinical and educational
University of Tennessee Health Science Center
Department of Obstetrics and Gynecology
Memphis, TN

2009 – April 2015

Teaching Medical Students and Residents
Interacting at all levels, both clinical and educational
Loyola University Medical School
Department of Obstetrics and Gynecology
Maywood, IL

Created a teaching portfolio and curriculum for Medical Students
Loyola University Medical School at Gottlieb Hospital
Department of Obstetrics and Gynecology
Melrose Park, IL

Started and developed a clinical session for Residents to learn and improve technical skills in Ultrasound in Obstetrics and Gynecology, with more focus on the transvaginal approach
Loyola University - Department of Obstetrics and Gynecology
Maywood, IL

Invited Lectures - Oral Presentations:

Moderator
33rd Annual Contemporary Issues in Obstetrics and Gynecology
Sandestin, FL, July 23, 2019

Osteoporosis - Screening, Diagnosis and Management
33rd Annual Contemporary Issues in Obstetrics and Gynecology
Sandestin, FL, July 23-27, 2019

A practical approach to management of menopause
31st Annual Contemporary Issues in Obstetrics and Gynecology
Sandestin, FL, Aug 1-5, 2017

Ultrasound features of benign adnexal pathology
XX National Congress SIEGO (Congresso Nazionale SIEGO Ostetricia e Ginecologia)

Florence, Italy, May 14-17, 2017

Menopause
29th Annual Contemporary Issues in Obstetrics and Gynecology,
Sandestin, FL, July 28-Aug 1, 2015

Influences of embryonic surface/heart rate on amniotic fluid accumulation before the 11th week of gestation
AIUM Annual Conference
Orlando, FL, March 11-14, 2001

The effect of intravascular blood transfusion on the flow velocity waveform of the portal venous system of the anemic fetus
AIUM Annual Conference, 1997

GnRH analogues in gynecologic surgery
Bologna, Italy, 1991

Use of GnRH depot analogue in the treatment of uterine fibroids
Villach, Austria, 1990

Committees:

October 2020 to present	Participant of the Quality Improvement Committee Department of Correctional Medicine Southern Illinois University Springfield, IL
4/2016 – 6/30/20	Graduation Awards Committee University of Tennessee Health Science Center Memphis, TN
11/2015 – 6/30/20	Chair of the Progress and Promotion Committee University of Tennessee Health Science Center College of Medicine Memphis, TN
10/2015 – 6/30/20	Surgery Committee University of Tennessee Regional One Physicians Memphis, TN
10/2015 – 6/30/20	Labor and Delivery Committee

	University of Tennessee Regional One Physicians Memphis, TN
07/2015 – 6/30/20	Mentoring Committee University of Tennessee Health Science Center Department of Preventive Medicine Memphis, TN
07/2015 – 6/30/20	A Step Ahead Foundation Memphis, TN
05/2015 – 6/30/20	Clinical Science Subcommittee University of Tennessee Health Science Center College of Medicine Memphis, TN
07/4-6/1991	Italian National Conference of the Italian Society of Endoscopy and Laser-therapy in Gynecology Organizer Committee – Department of Obstetrics and Gynecology University of Trieste - ITALY
05/25/1991	Conference on Contraception Organizer Committee – Department of Obstetrics and Gynecology University of Trieste – ITALY
11/10/1990	Veneto Society of Obstetrics and Gynecology. Conference on Endometrial hyperplasia and endometrial cancer in the young patient Organizer Committee – Department of Obstetrics and Gynecology University of Trieste - ITALY

Residents Mentored:

University of Tennessee Health Science Center, Memphis, TN

Dr. Ulm: Gynecology-Oncology, Memphis, TN, mentored for 6 months

Dr. Andrade: MFM fellowship, Wake Forest University Medical Center, Winston-Salem, NC, mentored for 6 months.

Dr. Pedro Argoti: MFM Fellowship, Memphis, TN

Dr. Watson: Gynecology-Oncology, Duke University, NC, mentored for 3 years

Dr. Ziebarth: Generalist, Memphis, TN, mentored for 3 years

Dr. Burana: Generalist, Memphis TN, mentored for 3 years

Dr. Santa Cruz: Generalist, Memphis TN, mentored for 3 years

Dr. Phinehas: Generalist, Memphis TN, mentored for 3 years

Dr. Mallorie Hoover: Urogynecology Fellowship, Cincinnati, OH mentored for 4 years

Dr. Robert Roman: REI Fellowship, Augusta, Georgia, mentored for 4 years

Dr. Patrick Blackburn, Gynecology Oncology, Memphis, TN mentored for 4 years

Dr. Naiha Mussarat, MFM fellowship in New Orleans, LA mentored for 4 years

Dr. Eric Rios, Gyne Onc research fellowship at Sloan Kettering, NY mentored for 4 years

Dr. Jennifer Gordon, Gyne Onc at Cleveland Clinic, OH mentored for 4 years

Dr. Liao Cajun, REI Fellowhip -Yale New Haven University, New Haven, CT mentored for 4 years

Dr. Claudio Schenone, MFM Fellowship – Tampa, FL mentored for 4 years

Loyola University Medical Center, Maywood, IL

Dr. Anderson: Oncology Fellowship, University of Colorado Health Science, Aurora, CO, mentored for 1 year

Dr. Kennedy: Oncology Fellowship, UCLA, Sacramento, CA, mentored for 2 years

Dr. Rivard: Oncology Fellowship, University of Michigan, Ann Arbor, MI, mentored for 2 years

Dr. Broach: Oncology Fellowship, Sloan Kettering, New York, NY, mentored for 3 years

Dr. Barenberg: Urogynecology Fellowship, University of Oklahoma, Oklahoma City, OK, mentored for 3 years

Dr. Garbe: REI fellowship, Case Western University, Cleveland, OH, mentored for 4 years

Dr. Gadzinsky: Oncology Fellowship: Magee Women's Hospital, Pittsburg, PA, mentored for 4 years

Dr. Fitzgerald: MFM fellowship, John Hopkins, Baltimore, MD, mentored for 4 years

Grant Support:

1990-1991	Grant recipient – Ultrasound as an indicator of first trimester miscarriages– Department of Obstetrics and Gynecology, University of Trieste, Italy

Abstracts:

1. Siani E, **Levi-D'Ancona R**, Nelson-Rigg R, Khanna P.
   Developing a Hospital Specific and Evidence based Management Protocol for Pregnancies of Unknown Location and Ectopic Pregnancies: A retrospective Chart Review and Quality Improvement Project
   Presented at the TIPQ (Tennessee Improvement Project Quality) 2021

2. Christiansen ME, Peregrin-Alvarez I, Roman R, **Levi-D'Ancona R**, Gordon J, Detti L.
   Uterine Subseptations An Indication for Surgical Correction: A Comparison of Four Systems.
   Submitted to the ASRM 75th Scientific Congress & Expo 2019

3. Van De Velde N, Gordon JC, Black P, Brackman S, Phillips O**, Levi-D'Ancona R**.
   The Impact of Adverse Childhood Experience on Maternal Depression.
   Submitted to the 2019 SMFM Conference

4. Detti, L. Harper AK, Fan R, Peregrin-Alavarez I, Roman AR, **Levi D'Ancona R**, et al.
   The loss of response to the Inhibitory Action of Anti-Mulleran Hormone (AMH) through downregulation of its receptor is a potential mechanism of Chemoresistance in Ovarian Cancer Cells.
   Society of Reproductive Investigation Annual Meeting, March 12-19, 2019, Paris, France

5. Detti L, Uhlmann RA, **Levi D'Ancona R**, Norwick H, Christiansen ME.
   Surgical correction of uterine subseptations re-establishes standard uterine cavity measurements.
   American Institute of Ultrasound in Medicine Annual Meeting, March 17-21, 2016, New York, NY

6. Appelbaum AH, Zuber JK, **Levi-D'Ancona R**, Cohen RH.
   Vaginal Anatomy on MRI - New Information Obtained Using Distention.
   Oral Presentation, Southern Medical Association Annual Scientific Assembly, November 3-5, 2016, Chattanooga, TN

7. Influences of Embryonic surface/heart rate on amniotic fluid accumulation before the 11th week of gestation**.**
   ***(**March 2001**)** Proceedings, American Institute of Ultrasound in Medicine, Orlando, FL*

8. Mari G, Abuhamad AZ, Detti L, **Levi-D'Ancona R**, Ozcan T, Sbracia M., Copel J. (February 1998).
   Outcome in Twin-twin transfusion syndrome treated with therapeutic amniocentesis.
   Proceedings, Society for Perinatal Obstetricians, Miami Beach, FL. Am J Obstet Gynecol, 178:S150

9. Detti L, **D'Ancona RL**, Ozcan T, Copel JA, Sbracia M, Mari G. (February 1998).
   Perinatal outcome of the co-twin after the demise of the first twin in pregnancies complicated by twin-twin transfusion syndrome.
   Proceedings, Society for Perinatal Obstetricians, Miami Beach, FL. Am J Obstet Gynecol, 178:S151

10. **D'Ancona RL**, Rahman F, J Copel, Mari G. (March 1997).
    The effect of intravascular blood transfusion on the flow velocity waveform of the hepatic venous system on the anemic fetus.
    Proceedings, American Institute of Ultrasound in Medicine, San Diego, CA. (Abstract 2988)

11. Mari G, Penso C, Sbracia M, **R Levi D'Ancona**, J Copel. (March 1997).
    Delta OD 450 and Doppler velocimetry of the middle cerebral artery peak velocity in the evaluation for fetal alloimmune hemolytic disease. Which is the best?
    Proceedings, American Institute of Ultrasound in Medicine, San Diego, CA. (Abstract 2985)

12. **D'Ancona RL**, Rahman F, Bahado-Singh R, Copel J, Mari G. (January 1997).
    Doppler assessment of the splenic artery blood flow velocity waveforms in the anemic fetus before and after intravascular transfusion.
    Proceedings, Society for Perinatal Obstetricians, Anaheim, CA. Am J Obstet Gynecol, 176:S152

13. **D'Ancona RL**, Rahman F, Copel J, Mari G. (January 1997).
    The effect of intravascular blood transfusion on the flow velocity waveform of the hepatic venous system on the anemic fetus.
    Proceedings, Society for Perinatal Obstetricians, Anaheim, CA. Am J Obstet Gynecol, 176:S152

14. Mari G, Penso C, Sbracia M, **D'Ancona RL**, Copel J. (January 1997).
    Delta OD 450 and Doppler velocimetry of the middle cerebral artery peak velocity in the evaluation for fetal alloimmune hemolytic disease. Which is the best?
    Proceedings, Society for Perinatal Obstetricians, Anaheim, CA. Am J Obstet Gynecol, 176:S18

Poster:

Pseudo Twin-twin transfusion syndrome and fetal outcome.
Mari G, Detti L, **Levi D'Ancona R**, Kern L.
SPO 1998

The Impact of Adverse Childhood Experience on Maternal Depression.
Van De Velde N, Gordon, JC, Black P, Brackman S, Phillips O, **Levi D'Ancona R**.

Presented to the 2019 SFMF Conference

Book Chapter:

The Garden of the Renaissance: Botanical symbolism in Italian painting
Author: Mirella Levi D'Ancona
Roberto Levi-D'Ancona role: Collaborator
Olschki Editor, 1977

Schenone M, Duncan J, **Levi D'Ancona R**, Mari G.
Doppler ultrasonography for the diagnosis and management of fetal anemia, hydrops, and fetal lung maturity.
Sonography in Obstetrics and Gynecology, Fleischer AC., 8th Edition, Chapter 13, p. 303-319

Contribution:

Curator of the "News Bulletin" section of the Journal "LASER"

Author of more than 60 publications in Italian, European and American Journals

Peer Review Publications:

1. Immunodetection of ovarian cancer and its recurrences.
   Masi R, Pieroni C, Ferri P, Salvischiani E, Cappelli G, Massi GB, **Levi D'Ancona R**, et al.
   The Journal of Nuclear Medicine and Allied Sciences, Minerva Medica Ed., 1987, vol.31, N.1, p. 105

2. CA 125 and CA 15-3 in monitoring ovarian carcinoma.
   Bartolozzi D, Cefaratti C, D'Agata A, Cappelli G, Amunni G, **Levi D'Ancona R,** Massi GB.
   The Journal of Nuclear Medicine and Allied Sciences, Minerva Medica Ed., 1989, vol. 33, N.2, p. 67

3. I-B72.3: immunoscintigraphic study for diagnosis of ovarian cancer.
   De Cicco C, Pieroni C, **Levi D'Ancona R**.
   The Journal of Nuclear Medicine and Allied Sciences, Minerva Medica Ed., 1989, vol.33, N.2, p. 102

4. "Le anomalie della statica pelvica conseguenti al parto"(anomalies of the pelvic floor after delivery)
   Pregazzi R, Bouchè C, Cossutta L, Ricci G, Toffoletti FG, **Levi D'Ancona R**.
   Minerva Ginecologica, 1990, vol.42, p.n1

5. "Baby bust a Trieste: testimoni e protagonisti" (baby bust in Trieste: witnesses and protagonists)
   Candussi G, Lui A, Carlomagno G, Barciulli F, **Levi D'Ancona R**, Toffoletti FG, Ricci G, Noci, I.
   Acta Europea Fertilitatis, vol 21, n.5, 1990, p. 251-256

6. Our experience with direct intraperitoneal insemination (DIPI) as a treatment for infertile couples.
   Barciulli F, Ricci G, **Levi D'Ancona R**, Noci, I, et al.
   Acta Europea Fertilitatis, 21,5:1990, p. 251-256

7. Use of GnRH depot analogue in the treatment of uterine fibroids.
   Auber G, Ricci G, Barciulli F, Pregazzi R, **Levi D'Ancona R**, Toffoletti FG.
   Acta Europea Fertilitatis, vol. 21, n.4, 1990, p. 185-189

8. “Proposte terapeutiche nella distrofia vulvare e nella “burning vulva” (therapeutic proposals in vulvar dystrophy and burning vulva).
   Scrimin F, Baraggino E, Paladini V, Antonaglia V, Toffoletti FG, **Levi D'Ancona R,** Tracanzan G.
   Minerva Ginecologica, 1990, vol. 42, n.12, p. 495-498

9. “Valutazione funzionale del perineo in gravidanza: l’inversione del comando” (functional evaluation of the perineum in pregnancy: the inversion of the command).
   Pregazzi R, Bouchè C, Ricci G, Toffoletti FG, **Levi D'Ancona R,** Barciulli F.
   Minerva Ginecologica, Torino, 1991, vol.3

10. “Valutazione funzionale del perineo in gravidanza: l’ipertonia dei muscoli elevatori dell’ano” (functional evaluation of the perineum in pregnancy: the hypertony of the levator ani muscles).
    Pregazzi R, Bouchè C, Ricci G, Toffoletti FG, **Levi D'Ancona R**, Barciulli F.
    Minerva Ginecologica, Torino, 1991, vol. 43

11. “Monitoraggio della gravidanza protratta: due metodiche a confronto”(monitoring the post-date pregnancy: comparison of two methods).
    Pregazzi R, Bouchè C, Ricci G, Toffoletti FG, **Levi D'Ancona, R.**
    Minerva Ginecologica, 1991, vol. 43:p.1-4

12. “Predizione della gestosi EPH mediante roll-over test” (Prediction of EPH by mean of the roll-over test).
    Pregazzi R, **Levi D'Ancona R**. Venuleo V, Scrimin F, Ricci G, Toffoletti FG, Barciulli F.
    Minerva Ginecologica,1991, vol 43:p.545-548

13. “L’oligoamnios nella gravidanza oltre il termine”(oligoamnios in the post-term pregnancy).
    Pregazzi R, Bouchè C, Ricci G, **Levi D'Ancona R**, Toffoletti FG, Barciulli F.
    Minerva Ginecologica Ed., Marzo 1991, Torino, vol.43, n.3; p.105-107

14. Endometrial cytology (endocyte) and vabra in abnormal uterine bleeding: analysis of 1596 cases.
    Baraggino E, Wiesenfeld U, **Levi D'Ancona R**.
    European Journal of Gynaecological Oncology, vol.XII, Supplement 1991

15. “L’ematocrito e l’emoglobina, parametri di viscosita’ ematica in corso di gravidanzaipertensione indotta”(The hematocrit and hemoglobin, parameters of hematic viscosity in P.I.H.).

Di Tommaso MR, Ferretti C, Conforti D, **Levi D'Ancona R**, Baronci D, Cianciulli D., Branconi F.
Minerva Ginecologica, 1991, vol43, n.5, p.237-240

16. "Importanza e limiti dei tests di laboratorio per valutare il passaggio transplacentare di emazie fetali nel circolo materno" (Usefulness and limits of the laboratory tests in the evaluation of the transplacental passage of fetal red blood cells in the maternal circulation.
Molaro GL, Ricci G, Alberico S, Pregazzi R, Maso GP, **Levi D'Ancona R**.
Minerva Ginecologica, 1993, vol 45 n.9 p.391-394

17. "Riserva di sangue autologo in gravidanza" (Autologous blood storage in pregnancy; The donation of autologous blood in pregnancy. Observations on its safety and the cost-benefit relationship) Pregazzi R, Levi **D'Ancona R**, Ricci G, Lui A, Maso GP, Parco S, Piunti R.
Minerva Ginecologica, 1994, vol.46 n.3, p.95-98

18. "Utilizzo dell'ultrasonografia nella predittivita' abortiva del primo trimestre" (Ultrasonography in the prediction of miscarriage in the first trimester of pregnancy).
Levi D'Ancona R, Pinzano R, Maso GP, Ricci G, Bogatti P, Alberico S.
Minerva Ginecologica, 1994, vol.46 n.3, p.63-67

19. Ultrasound adjusted mid-trimester risk of trisomy 21 and significant chromosomal defects in advanced maternal age.
Bahado Singh R, Deren O, Tan A, **Levi D'Ancona R**, Hunter D, Copel JA, Mahoney J.
American Journal Of Obstetrics and Gynecology, 1996;175(6):p.1563-1568

20. The effect of intravascular blood transfusion on the flow velocity waveform of the portal venous system of the anemic fetus.
Levi D'Ancona R, Rahman F, Ozcan T, Copel JA, Mari G.
Ultrasound Obstet Gynecol 1997;10(5):p.333-337

21. Arterial and venous Doppler velocimetry in the severely growth restricted fetus as predictors of perinatal death.
Ozcan T, Sbracia M, **Levi D'Ancona R**, Copel JA, Mari G.
Ultrasound Obstet Gynecol 1998 Jul;12(1):p.39-44

22. Pseudo Twin-twin transfusion syndrome and fetal outcome.
Mari G, Detti L, **Levi D'Ancona R**, Kern L.
Journal of Perinatology 1998 Sep-Oct;18(5):p.399-403

23. Evolution of the Amniotic Sac and Extracelomic Space as Seen by Early Ultrasound Examination.

Santolaya-Forgas J, De Leon-Luis J, **D'Ancona RL**, Morgan J, Kauffman RP.
Fetal Diagn Ther 2003;18:p.262-269

24. Relevance of uterine subseptations: What length should warrant hysteroscopic resection.
Detti L, Hickman H, **Levi D'Ancona R**, Wright AW, Christiansen ME.
J Ultrasound in Medicine, Apr 2017:36:757-765.

25. Vaginal Anatomy on MRI – New Information Obtained Using Distention.
Appelbaum A, Zuber J, **Levi D'Ancona R**, Cohen H.
Southern Medical Journal, 2019; 691-97.

26. Detti L, Christiansen ME, **Levi-D'Ancona R**, Gordon JC, Van De Velde N, Peregrin-Alvarez I.
Surgical correction of uterine subseptations re-establishes standard uterine cavity measurements.
Journal of Obstetrics and Gynecology Research (JOGR-2019-0223),

27. Detti L, Christiansen ME, **Levi-D'Ancona R**, Gordon JC, et al
Restoration of Uterine Cavity Measurements after Surgical Correction.
Journal of Imaging 2020, *6*(7), 58

28. Developing a Hospital Specific and Evidence based Management Protocol for Pregnancies of Unknown Location and Ectopic Pregnancies: A retrospective Chart Review and Quality Improvement Project
Siani E, **Levi-D'Ancona R**, Nelson-Rigg R, Khanna P.
Gynecology and Reproductive Health, 2020; 4 (4):1-7.

29. Impact of Covid-19 on maternal and neonatal outcomes: a systematic review and meta-analysis.
Di Toro F, Gjoka M, Di Lorenzo G, De Seta F, Maso G, Risso FM, Romano F, Wiesenfeld U, **Levi-D'Ancona R**, Ronfani L, Ricci G.
Clinical Microbiology and Infection, Volume 27, Issue 1, January 2021, Pages 36-46

30. A comparison of four systems for uterine septum diagnosis and indication for surgical correction
Detti L, Peregrin-Alvarez, I, Roman, R., **Levi-D'Ancona R**, Gordon JC, et al
Minerva Obstet Gynecol. 2021;73(3):376-383

31. Van De Velde N, McClure L., Gordon JC, Phillips O, Khanna, P., Bursac, Z., **Levi-D'Ancona R.**
Identifying Maternal Depression in the Perinatal period in low socioeconomic patients.

Int. J.Obst & Gync. 2021;1(1):09–13. DOI: 10.51626/ijog.2021.01.00002.

32. Alignment of the Cervix with the Vagina in Uterine Retroversion. A Possible Risk Factor for Uterine Prolapse.
ALAN APPELBAUM, Tirandaz, Mehran, Ricci Giuseppe, **Roberto Levi-D'Ancona**
Diagnostics 2022,12, 1428 doi.org/10.3390/diagnostics12061428

33. Telehealth Utilization in High-Risk Pregnancies During COVID-19
Margie A. Rayford, Joshua M. Morris, Ramona Phinehas, Elizabeth Schneider, Amanda Lund, Sarah Baxley, Jim Y. Wan, Patricia J. Goedecke, **Roberto Levi-D'Ancona**
Submitted for publication on Telemedicine Reports on January 2023

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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-cr-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

DECLARATION ON RISK OF INFECTION WITH HYSTEROSCOPY

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1. I am a physician, trained in OBGYN to take care of patients. I have extensive experience in clinical OBGYN field and completed residency training in OBGYN including hysteroscopy.

2. I am familiar with the devices used in hysteroscopy.

3. Spaulding classification is used by both, CDC and FDA to classify devices for cleaning. According to the principles outlined in the Spaulding classification, hysteroscopes are semi-critical devices because they come in contact with intact mucus membranes.

https://www.cdc.gov/infection-control/hcp/disinfection-sterilization/rational-approach.html

https://www.fda.gov/media/80265/download

https://disinfectionandsterilization.org/wp-content/uploads/2022/06/SemicriticalAPICJune2022-1.pdf

4. Hysteroscope devices may be cleaned with high level disinfectant and then re-used safely. For hysteroscopic devices, high level disinfection vs sterlization has no difference in infection rates according to published literature; because no infection outbreaks after hysteroscopy have been reported in literature. https://disinfectionandsterilization.org/wp-content/uploads/2022/06/SemicriticalAPICJune2022-1.pdf

https://newsscope.aagl.org/hysteroscopy/office-hysteroscopy-simple-set-up-is-the-best-approach/

5. Additionally, the uterine cavity is not a sterile cavity. Uterine microbiome studies provide scientific evidence. https://pmc.ncbi.nlm.nih.gov/articles/PMC8745284/

6. Baseline risk of infection after hysteroscopy is low. According to pubmed search, the most reliable source of peer reviewed literature, no cluster infection outbreaks have ever been reported after hysteroscopy with use of high level disinfection. https://disinfectionandsterilization.org/wp-content/uploads/2022/06/SemicriticalAPICJune2022-1.pdf

7. Finally, the patient population in Memphis that Dr. Sanjeev Kumar serves contain more African American patients. According to the National Cancer Institute, African American Women experience higher uterine cancer rates and higher death rates due to this cancer than Caucasian Women. Hence the clinical need for hysteroscopy is much higher in this population than in Caucasian or Asian counterparts. https://www.cancer.gov/news-events/press-releases/2022/uterine-cancer-deaths-black-women

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct with the referenced material.

Executed this 26th day of June, 2026.

___Dr. Roberto Levi-D'Ancona_____

Name-

On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA

Document issued on: July 30, 2001

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Enforcement III
Office of Compliance

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.

For questions regarding the use or interpretation of this guidance contact Larry D. Spears at 301-594-4646 or by electronic mail at lxs@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/comp/guidance/1392.pdf or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1392 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA

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.

I. Introduction

The "Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals: Final Guidance for Industry and FDA" document provides guidance to third party and hospital reprocessors about their responsibility 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 are subject to all the regulatory requirements currently applicable to original device manufacturers. Further information can be found in Labeling-Regulatory Requirements for Medical Devices (FDA 89-4203) http://www.fda.gov/cdrh/dsma/470.pdf.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be approved/cleared for marketing. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that information is being requested that is not relevant to the regulatory decision for your pending application or that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

II. Definitions

For purposes of this guidance, FDA has defined the following terms:

Hospital: A hospital is an acute care facility

Labels and labeling: Sections 201(k) and (m) of the Act define the terms "label" and "labeling."

A "label" is a "display of written, printed, or graphic matter upon the immediate container of any device." Any information required on the immediate container of a device must also appear on the outside container or wrapper, if any, of the retail package for the device, or be easily legible through the outside container or wrapper. Section 201(k) of the Act; 21 CFR 1.3(b).

"Labeling" is defined as: "all labels and other written, printed, or graphic matter"

(1) Upon any device or any of its containers or wrappers, or

(2) Accompanying such device.

Section 201(m) of the Act; 21CFR 1.3(a).

Labeling is a broad term that includes the label and other written, printed, or graphic matter accompanying a device. For example, labeling would include device inserts, leaflets used to promote the device, text written on the box, and the immediate container for the device. Certain provisions of the Act apply only to the "label" of the device, (e.g. 21 CFR 801.1) and other provisions related to the device's "labeling."

Single-use device: A single-use device, also referred to as a disposable device, intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. The labeling may or may not identify the device as single use or disposable and does not include instructions for reprocessing.

Third party reprocessor: Party who reprocesses used SUD's for another party.

Premarket Requirements: These requirements relate to submissions that contain safety and effectiveness information that FDA reviews prior to marketing a device. The two types of premarket submissions that may be required before you reprocess a SUD are: (1) an application for premarket approval (PMA); see section 515(a) of the Act, and (2) a premarket notification submission (510(k). See section 510(k) of the Act.

Reuse: The repeated use or multiple use of any medical device including devices intended for reuse or single-use, with reprocessing (cleaning, disinfection or sterilization) between uses.

Reprocessing: Reprocessing includes all the steps performed to make a contaminated reusable or single-use device ready for patient use. The steps may include cleaning, functional testing, repackaging, relabeling, disinfection or sterilization.

III. WHO DOES THIS GUIDANCE COVER?

This guidance applies to hospitals and third parties that reprocess single-use devices (SUD's).

IV. WHAT ARE THE LABELING REQUIREMENTS?

There are several labeling requirements that apply to reprocessed SUD's. The questions and answers below help to explain labeling requirements that apply to single use devices that are reprocessed for reuse in humans.

1. Do SUDs reprocessed by hospitals and third parties have to meet FDA labeling requirements?

Yes. All devices, including reprocessed SUDs, need to meet the labeling requirements of the Federal Food, Drug, and Cosmetic Act (the Act). A failure to meet FDA's statutory and regulatory labeling requirements will result in a device being misbranded under the Act. See section 502 of the Act.

2. What are your labeling responsibilities if you reprocess, or use, or ship, or sell SUD's?

Certain labeling responsibilities apply to persons who reprocess, use, ship, or sell reprocessed SUD's, regardless of whether the person is the one who is required to submit a premarket submission (510(k)) or premarket approval application (PMA), and regardless of whether the device is exempt from premarket requirements.

The following scenarios will help describe the labeling responsibilities that are independent of premarket requirements:

(1) If a hospital reprocesses a SUD, the hospital is responsible for ensuring that the device complies with all applicable FDA labeling requirements, even if the device is exempt from the premarket requirements. If the hospital does not ensure the device complies with FDA labeling requirements, the device is misbranded, and the hospital may be considered responsible for causing the misbranding of the device in violation of section 301(k) of the Act.

(2) If a hospital ships a SUD to a third party for reprocessing, the hospital needs to ensure that the device is in compliance with labeling requirements before the device is sent to the third party, so that the device is not considered misbranded. See section 301(a) of the Act. A

hospital, however, may label devices that are shipped for further processing in a manner that exempts the devices from labeling requirements. (See Response to question 12 for possible exemption from certain labeling requirements).

(3) If a hospital receives reprocessed SUD devices from a third party that are misbranded, the hospital may be considered responsible for receiving misbranded devices. See section 301(c) of the Act.

(4) If a third party reprocessor receives reprocessed SUD devices from a hospital that are misbranded, the third party reprocessor may be considered responsible for receiving misbranded devices. See section 301(c) of the Act.

(5) If a third party reprocessor ships devices to a hospital that do not comply with labeling requirements, the third party reprocessor may be considered responsible for shipping misbranded devices. See section 301(a) of the Act.

In summary, you should ensure that all reprocessed SUD's that you receive, use, ship, or sell are properly labeled in accordance with FDA regulations. Failure to comply with FDA labeling requirements will cause a device to be "misbranded" and, therefore, in violation of FDA law. Section 502 of the Act.

3. If I submit a premarket submission or application for a reprocessed SUD, what labeling do I have to submit to FDA for review?

For devices that require premarket clearance or approval, FDA reviews the proposed label for the device before FDA makes the decision of whether the device can be commercially distributed. The persons required to submit the marketing submissions are responsible for the label.

4. What are the general labeling requirements that apply to reprocessed SUD devices?

To satisfy FDA's general device labeling requirements, the labeling of a reprocessed SUD must:

a. include the name and place of business of the manufacturer, packer, or distributor (section 502(b) of the Act; 21 CFR 801.1).

b. bear the common or usual name of the device (Section 502(e)(2) of the Act).

c. state the quantity of contents (Section 502(b)(2)).

d. include adequate directions for use (section 502(f)(1) of the Act; 21 CFR 801.5) or qualify for an exemption from adequate directions for use (the prescription device exemption, 21 CFR 801.109).

e. include adequate warnings (section 502(f)(2) of the Act).

f. not be false or misleading (section 502(a) of the Act).

g. give adequate prominence to information required to appear on the label (section 502(c) of the Act; 21 CFR 801.15).

   Required labeling information needs to be displayed in a manner that is obvious to the reader. Section 801.15 describes specific requirements that relate to how the labeling information must be displayed.

h. appear in English with the exception of devices distributed solely within Puerto Rico or a US territory where the predominant language is not English, or devices solely distributed outside the United States that comply with FDA's export requirements (21 CFR 801.15(c)).

5. What information has to appear on the device's label?

FDA regulations require that certain information be on a device's label if the device is in a package. Specifically, section 801.1 of FDA's regulations, and Section 201(k) of the Act require that the label on the immediate container of the device, and any outside container or wrapper of a retail package include in a conspicuous manner, the name and place of business of the manufacturer, packer, or distributor. These label requirements apply to Third Party and hospital reprocessors of single-use devices.

The requirement in section 801.1 to include the name of the manufacturer, packer, distributor, or reprocessor will be met, such as in the case of a corporation, if the label includes the actual corporate name together with the name of the particular division of the corporation. Abbreviations for "Company" and "Incorporated", etc. may be used. "The " may be omitted. In the case of an individual, partnership, or association, the name under which the business operates must be used.

The statement of the place of business must include the street address, city, state, and zip code. However, FDA regulations do permit exceptions to the requirement to include the street address and zip code on the label in certain limited circumstances. (21 CFR 801.1(d) and (e)).

If a person manufactures, packs, distributes or reprocesses a device at a place other than his principal place of business, the label may state the principal place of business instead of the actual place the device was manufactured, packed, or distributed, unless doing so would be misleading.

6. What name should be designated on the SUD's label as the manufacturer?

Persons who reprocess single use devices are engaged in manufacturing activities. See e.g. 21 CFR 803.3(o); 806.2(g); 807.3(d); 820.3(o); 821.3(c). Accordingly, the name of the reprocessor should

appear on the label as the manufacturer of any SUD device that it reprocesses. This information helps to identify the firm or business that is responsible for introducing the SUD into commerce.

The following examples describe who should be listed as the manufacturer in two common situations:

a. If a SUD is reprocessed by the hospital, the hospital is engaged in manufacturing activities, therefore the hospital should state its name, and place of business on the device's label.

b. If a SUD is reprocessed by a third party, the third party reprocessor is engaged in manufacturing activities, therefore the third party reprocessor should state its name, and place of business on the device's label.

7. What does it mean for labeling to bear adequate directions for use?

Adequate directions for use means directions that would allow a layperson (i.e., a person who is not a health professional) to use a device safely and for the purposes for which it is intended to be used. FDA regulations at 21 CFR 801.5 set out some factors that are relevant to meeting this requirement.

Some devices are exempt from the requirement that their labeling include adequate directions for use by a layperson. One such exemption applies to prescription devices provided they meet the prescription device labeling requirements and certain other requirements outlined in FDA's regulations. (21 CFR 801.109).

Almost all reprocessed SUD devices are prescription devices and therefore will need to comply with the prescription device requirements in order to be exempt from the requirements for adequate directions for use by a layperson. The prescription device exemption and other exemptions from the adequate directions for use requirement are explained below (see question 8, 12, and 13 for exemptions to adequate directions for use), and in FDA regulations, 21 CFR 801.109.

8. What are the labeling requirements for prescription devices?

As stated above, the term "adequate directions for use" is defined as directions that would allow a layperson to safely use the device (21 CFR 801.5). Because it is not possible to write adequate directions for the safe use of a prescription device by a layperson, prescription devices are exempt from this requirement if certain conditions are met.

One of those conditions is that the labeling must meet the prescription device labeling requirements. These requirements are designed to ensure that a practitioner licensed by law to administer the devices can use them safely and for their intended purpose.

FDA regulations at section 21 CFR 801.109(b) require that the label of prescription device (other than a surgical instrument) include:

- The statement “Caution: Federal law restricts this device to sale by or on the order of….(e.g., a physician),"; and[1]

- the method of its application or use.

Section 801.109 further requires that the labeling on or within the package from which the prescription device is dispensed include, among other things, the following information:

- indications

- contraindications

- directions for use

- any relevant precautions, hazards, warnings, and other information---unless providing this information is unnecessary because it is already commonly known to practitioners who are licensed to use the device

Other conditions that must be met in order for a prescription device to be exempt from the "adequate directions for use" requirement relate to possession and sale of the device rather than to the device's labeling. These other requirements, however, are beyond the scope of this document. (See 21 CFR 801.109(a)).

In addition to the labeling requirements of 801.109, prescription devices must meet other labeling requirements described in this guidance and in FDA's labeling regulations.

9. Do over-the-counter (OTC) devices have to meet any specific labeling requirements, in addition to the general labeling requirements?

Yes, over-the-counter devices must meet certain specific OTC labeling requirements relating to the principal display panel, the statement of identity, and the declaration of net quantity of contents. These requirements are described in detail in 21 CFR 801.60, 801.61, and 801.62.

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1 FDA does not intend to enforce the requirement for the full textual prescription statement under 21 CFR 801.109(a) if the product labeling states, "Rx Only" instead of quoting the text required by the regulation. See FDA's prescription labeling guidance, which is available on the Internet at http:/www.fda.gov/cdrh/comp/rxlabeling.pdf, or request a fax copy by telephone at 1-800-899-0381 and specify number 1150 when prompted for a shelf number.

10. If I reprocess another manufacturer's device that was intended for single use, can I use the previous manufacturer's labeling?

FDA regulations would require that some parts of the previous manufacturer's labeling be modified. For example, under section 801.1, the device needs to be have a label with the name and address of the reprocessor of the SUD. See question 6 above.

Each over the counter device must have labeling that carries adequate directions for use, as described in 21 CFR 801.5, or if it is a prescription device, other information about how to use the product, as described in 21 CFR 801.109 and in response to question 8.

If your device is the same in all respects to the device as manufactured by the previous manufacturer, the way in which you describe the directions for use for the device in your labeling may be similar to the previous manufacturer's labeling. If you have changed the operation, design, intended use, or any other aspect of the device, the directions for use may have to be different from that of the previous manufacturer's labeling. The changes in the directions for use may be required in order for FDA to determine that the labeling contains adequate directions for use (21 CFR 801.5), or sufficient information to satisfy applicable prescription device requirements, as described in 21 CFR 801.109.

In addition, you must ensure that your labeling is not false and misleading. This would include making sure that any statements that you make in the labeling that are similar to the previous manufacturer's, are still truthful and not misleading with respect to the reprocessed SUD. For example, if you have made changes to the previous manufacturer's device specifications, a labeling statement that represents the out-dated specifications of the device's previous manufacturer would be false.

11. If I copy some of the previous manufacturer's labeling, is it a copyright or trademark violation?

FDA does not have authority or the expertise to provide advice on what constitutes copyright or trademark violations. You should consult with your own legal counsel with expertise on these types of matters.

12. If a hospital ships a device to a third party for reprocessing, does the device need to be labeled with adequate directions for use or have prescription labeling?

Devices need to comply with these requirements, unless there is an applicable exception. Shipments of devices that are intended to be reprocessed by another entity are exempted from adequate directions for use requirements if their label bears the statement "Caution: For manufacturing, processing, or repacking." 21 CFR 801.122. This exemption would also apply to prescription devices that are labeled in this manner. Accordingly, a hospital that ships devices to a third party reprocessor could be exempt from adequate directions for use and prescription labeling requirements by labeling the device as

described above.

13. If a third party reprocessor ships a device back to a hospital, does it need to be labeled?

Yes, unless the shipment falls within one of the exemptions specified in the regulations, a third party reprocessor shipping devices to a hospital needs to comply with all the labeling requirements. Otherwise the devices would be misbranded.

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

UNITED STATES OF AMERICA,	*	
Plaintiff,	*	
v.	*	**Case No. 25-CR-20032**
SANJEEV KUMAR,	*	
Defendant.	*	

DECLARATION OF BERNARD GRISONI
EXPERT IN REGULATORY AFFAIRS FOR MEDICAL DEVICES

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1. I am Bernard Grisoni, Ph.D., and I have more than 30 years of experience in the medical device industry. Throughout my career, I have developed numerous medical products and technologies that have generated multimillion-dollar sales within the healthcare sector. I have held leadership positions at several medical device and healthcare companies, including Allergan, Wright Medical Technology (now part of Stryker), Schering-Plough, and Merck. My curriculum vitae is attached as Attachment 1.

During my career, I have been awarded more than 50 U.S. and international patents and have published articles in peer-reviewed scientific journals. In 1997, I founded BioGeneration, Inc., a medical device company focused on the development of bone graft substitute technologies.

I personally prepared and obtained FDA 510(k) clearances for two implantable and injectable calcium sulfate bone graft substitute medical devices (K031838 and K973704), and I established the company's manufacturing operations, including implementation of a comprehensive Quality Management System. As a consultant, I also prepared and obtained FDA 510(k) clearance for the Single Size Tendon Spacer device (K000019).

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Over the past five years, I have been affiliated with the Department of Biomedical Engineering at the University of Memphis, where I have taught courses in Medical Device Design Principles, Biomaterials Science, and Regulatory Affairs for Medical Devices. The latter course serves as a core requirement for the University's Certificate in Regulatory Affairs for Medical Devices.

3. A 510(k) is a premarket submission made to the U.S. Food and Drug Administration (FDA) pursuant to 21 CFR Part 807, which governs Premarket Notification procedures. Its purpose is to demonstrate that a medical device is substantially equivalent to a legally marketed predicate device. A 510(k) submission contains detailed technical and proprietary information, including testing data, engineering drawings, manufacturing information, and risk analyses. This information constitutes confidential commercial information and is not provided to physicians or other end users. Only limited information, such as the 510(k) Summary described in 21 CFR § 807.92, is publicly available.

7. The Olympus HYF TYPE XP obtained FDA clearance through the 510(k) process (K891451) before being marketed. Physicians using the device are expected to follow its FDA-cleared labeling, including the Instructions for Use (**IFU**), consistent with 21 CFR Part 801, including 21 CFR §§ 801.5 and 801.109(c).

8. Under 21 CFR Part 801, medical device labeling must provide adequate Instructions for Use (**IFU**). For prescription devices, 21 CFR § 801.109(c) requires labeling to provide licensed practitioners with the information necessary for the safe and effective use of the device, including methods of preparation, handling, operation, and, where applicable, reprocessing of reusable devices.

9. Accordingly, the reprocessing requirements applicable to a physician's use of the Olympus HYF TYPE XP are those set forth in the FDA-cleared **IFU**, which is reviewed by the FDA as part of the 510(k) clearance process, and not in the confidential 510(k) submission governed by 21 CFR Part 807

10. The Olympus HYF TYPE XP was cleared under 510(k) K891451. I searched the FDA's publicly available records for this submission but was unable to locate a publicly

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available 510(k) Summary or other documentation describing the device, its indications for use, predicate device comparison, testing, safety and effectiveness rationale, or FDA clearance letter (see attachment below). I also reviewed the device's FDA-cleared Instructions for Use (IFU), which provide physicians with discretion regarding the cleaning and sanitization of the device.

New Search | Back To Search Results

Device Classification Name	Hysteroscope (And Accessories)
510(k) Number	K891451
Device Name	OLYMPUS HYF-P FLEXIBLE HYSTEROFIBERSCOPE
Applicant	Olympus Corp. 4 Nevada Dr. Lake Success, NY 11042
Applicant Contact	JOSEPH R WILLIAMS
Correspondent	Olympus Corp. 4 Nevada Dr. Lake Success, NY 11042
Correspondent Contact	JOSEPH R WILLIAMS
Regulation Number	884.1690
Classification Product Code	HIH
Date Received	03/15/1989
Decision Date	10/02/1989
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Obstetrics/Gynecology
510k Review Panel	Obstetrics/Gynecology
Type	Traditional
Reviewed by Third Party	No
Combination Product	No
Predetermined Change Control Plan Authorized	No

11. Indictment CR. No. 25-CR-20032-SHL make reference to multiple hysteroscope accessories such as the CooperSurgical Disposable Alligator Grasper Forceps, the CooperSurgical Endosee PX Cannula, and the LiNA OperaScope Biospsy Forceps. Per 21 CFR Part 884.1690 (Obstetrical and Gynecological Devices) cannulas, graspers, and forceps as hysteroscope accessories that are exempt from the FDA's 510(k) premarket notification requirements.

12. Poplar Avenue Clinic (PAC) is an outpatient clinic and is not subject to the FDA's hospital-specific requirements governing the reprocessing of single-use devices (SUDs). Compliance Policy Guide (CPG) "Sec. 300.500 Reuse of Medical Disposable Devices

(CPG 7124.16) does not classify physician offices or outpatient clinics as manufacturers when they do so. Rather, the guidance expressly excludes health care facilities other than hospitals from the FDA policy imposing manufacturer requirements on SUD reprocessors. While FDA expects any reused device to be adequately cleaned or sterilized and to maintain its safety and effectiveness, the guidance distinguishes outpatient physician practices from hospitals and commercial reprocessors for purposes of these regulatory requirements.

13. Compliance Policy Guide (CPG) "Sec. 300.500 Reuse of Medical Disposable Devices (CPG 7124.16) also exempt "opened-but-unused" surgical devices from the reprocessing requirements applicable to single-use devices.The FDA defines an "opened-but-unused" device as a single-use disposable device whose sterile package has been opened or whose sterility has otherwise been compromised, but that has not been used on a patient and has not come into contact with blood or bodily fluids.

14. The Medical Device User Fee and Modernization Act (MDUFMA), Section 302, "2(A), defines a "reprocessed" single-use device as "an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient." (page 116 Stat. 1620).

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29th day of June, 2025.

BGrisoni

Bernard Grisoni, PhD