**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.** | * | |

---

**CONSOLIDATED MOTION FOR JUDGMENT OF ACQUITTAL AND MOTION FOR NEW TRIAL WITH INCORPORATED MEMORANDUM OF LAW IN SUPPORT**

---

Dr. Sanjeev Kumar, by and through undersigned counsel, respectfully submits this Consolidated Motion for Judgment of Acquittal and Motion for New Trial with an Incorporated Memorandum of Law in Support:

## BACKGROUND

After seventeen days of testimony and the revelation of multiple discovery violations by the Government—including the lead agent for the United States Food and Drug Administration "resetting" his phone, which contained correspondence with witnesses who testified during trial, and thus deleting its contents—the Jury convicted Dr. Kumar of nearly all charges brought against him under the Food, Drug, and Cosmetics Act ("FDCA") for adulterating and misbranding hysteroscopes, though the Government presented no proof that Dr. Kumar adulterated or misbranded the charged devices on or about the charged date of April 16, 2024. The Jury was unable to come to a unanimous verdict on Counts 34 and 36, which charged Dr. Kumar with adulterating hysteroscopes cleared for reprocessing (referred to herein as "multi-use devices").

After the Court dismissed several charged executions of health care fraud during trial due

to the Government's expert changing his subjective opinion that certain hysteroscopies performed at Poplar Avenue Clinic were unnecessary, the jury also found Dr. Kumar guilty of Counts 40, 41, and 44 for committing health care fraud in violation of 18 U.S.C. § 1347. The Jury was unable to reach a verdict on Counts 37, 39, 42, and 43. The Jury found Dr. Kumar guilty of only certain executions of health care fraud for Count 38 (January 5, 2021, April 8, 2021, and October 26, 2021) and Count 45 (October 16, 2021). The Court entered a verdict of guilty on those charges over Dr. Kumar's argument for a mistrial.

The Jury also found Dr. Kumar guilty of Count 46, which alleged that he committed health care fraud by submitting false certifications to government health care programs that he would follow all applicable laws, rules, and regulations of the Medicare program, including that devices used in the specific claims were not adulterated or misbranded under the FDCA.

**STANDARD**

A judgment of acquittal under Federal Rule of Criminal Procedure 29 is warranted where the evidence is insufficient to sustain a conviction. Fed. R. Crim. P. 29(a). The Court must view the evidence in the light most favorable to the government, drawing all reasonable inferences in its favor, and may grant relief only if no rational trier of fact could have found the essential elements of the offense beyond a reasonable doubt. *United States v. Connery*, 867 F.2d 929, 930 (6th Cir. 1989). By contrast, Federal Rule of Criminal Procedure 33 permits the Court to vacate any judgment and grant a new trial "if the interest of justice so requires." Fed. R. Crim. P. 33(a). Unlike Rule 29, a motion brought pursuant to Rule 33 allows the Court to weigh the evidence and assess witness credibility, and to grant a new trial if the verdict is against the manifest weight of the evidence or if substantial trial error likely affected the verdict. *United States v. Munoz*, 605 F.3d 359, 373–74 (6th Cir. 2010). Although Rule 33 relief is to be used sparingly and granted

only in exceptional cases, the Court's broader discretion under Rule 33 serves as a safeguard against a miscarriage of justice. *United States v. Turner*, 490 F. Supp. 583, 593 (E.D. Mich. 1979), *aff'd*, 633 F.2d 219 (6th Cir. 1980).

## LAW AND ARGUMENT

### 1. Improper Influence on the Jury Requires a *Remmer* Hearing, and Government's Pretrial Statements About Dr. Kumar Requires New Trial.

Dr. Kumar is filing contemporaneously herewith a sealed filing addressing how the Government's sexual misconduct allegations influenced the Jury during its deliberations and another issue regarding jury deliberations, both of which were brought to defense counsel's attention after trial. Dr. Kumar continues to maintain that the pretrial statements made by the United States Attorney's Office for the Western District of Tennessee in a press release that Dr. Kumar was "a predator in a white coat" unfairly impacted the jury. Prior to trial, the Defense moved to transfer the venue, which was denied. During jury selection, nearly every member of the venire appeared aware of the press; several prospective jurors expressed distress—even in tears—about serving. The Defense sought to explore their feelings individually outside the panel but was prevented from doing so. This was in error. For these reasons and those stated in his sealed filing, Dr. Kumar submits that a *Remmer* hearing is required and that a new trial should be ordered for all convictions against him due to the Government's pretrial statements.

### 2. No Proof of Specific Acts of Conduct Charged in Counts 1 through 36 Undermines Those Convictions.

The Government failed to prove that the conduct charged in Counts 1 through 36 occurred "on or about" April 16, 2024. "When 'on or about' language is used in an indictment, proof of the exact date of an offense is not required as long as a date reasonably near that named in the indictment is established." *United States v. Ford*, 872 F.2d 1231, 1236 (6th Cir. 1989). But "a

court cannot permit a defendant to be tried on charges that are not made in the indictment against him." *Stirone v. United States*, 361 U.S. 212, 217 (1960). In *Ford*, the Sixth Circuit reversed defendant's firearm possession conviction because it was "possible that the jury convicted [the defendant] based on an incident of possession not intended by the grand jury to be part of the charge." *Ford*, 872 F.2d at 1236 (scrutinizing "on or about" instruction given by trial court); *see also United States v. Critchley*, 353 F.2d 358, 361–62 (3d Cir. 1965) (reversing Hobbs Act conviction because Government failed to prove defendant committed act on dates charged in indictment). That possibility also raised questions of whether the jury's verdict was unanimous as to specific conduct. *Ford*, 872 F.2d. at 1236.

In Dr. Kumar's trial, no witness testified that they used the specific devices charged in Counts 1 through 36 on April 16, 2024, let alone on a date "reasonably near" in time. Rather, there was testimony that Dr. Kumar was not present at Poplar Avenue Clinic on April 16, 2024. There was also generalized testimony that devices were reused while employees worked at Poplar Avenue Clinic, and that testimony generally changed as witnesses were testifying, such as with Paige Theur and Gayla Cheatham. After the Grand Jury returned the First Superseding Indictment, this Court held that adulteration and misbranding are single-act offenses and dismissed numerous charges encompassing potentially thousands of acts of adulteration and misbranding occurring over multiple months or years. (Order Granting Defendant's Motions to Dismiss Counts 1–9, 12–13, 16–18, 21–22, 25 and Denying Motion to Dismiss or Narrow Counts 10–11, 14–15, 19–20, 23–24, 26–36 or to Strike Felony Enhancement, ECF No. 124, at PageID 1046–47.) The Court distinguished those charges from the counts alleging that Dr. Kumar or Poplar Avenue Clinic adulterated or misbranded devices on or about April 16, 2024. (*Id.*) The Grand Jury subsequently returned a Second Superseding Indictment against Dr. Kumar, with the result being that all the

charges brought to trial alleged that Dr. Kumar or Poplar Avenue Clinic adulterated or misbranded devices on or about April 16, 2024.

The proof at trial is insufficient to support the Jury's guilty verdicts on Counts 1 through 36. At best, the generalized and shifting testimony about the adulteration and misbranding of devices supports what the Government charged in the First Superseding Indictment—multiple acts occurring over a period of months and years. Thus, like in *Ford*, it is far from certain that the Jury's verdict was unanimous as to a specific act of adulteration or misbranding occurring on or about April 16, 2024. *Ford*, 872 F.2d at 1236. Given the lack of testimony about specific acts occurring on or about that date, the Jury's verdict includes conduct that the Grand Jury did not intend to include in Counts 1 through 36: acts occurring during the periods charged in the First Superseding Indictment, the corresponding counts for which were dismissed by this Court.

Further, the proof at trial demonstrated that it would have been impossible to re-use the Endosee cannulas on or about April 16, 2024. Though the Government attempted to elicit proof that there was a bypass code to override the Endosee's kill switch function, the physical proof and witness testimony belied that argument. Rowena Schimmel, the sales manager for the manufacturer of the Endosee, testified that she never remembered giving Poplar Avenue Clinic the bypass code which would have allowed the Clinic to reuse the Endosee cannulas. The only person to testify about having the kill switch function was Mrs. Huda Alaeddin Hussein. Mrs. Hussein testified that there was a sticker on the back of the Endosee device with the code that would have allowed Poplar Avenue Clinic to bypass the kill switch function. But the photographs of the Endosee devices taken by special agents on the date of the search warrant did not have stickers with the bypass code. Mrs. Hussein stopped working for Poplar Avenue Clinic in late 2022, and no other witness testified that a bypass code was used. Thus, no rational juror could have

concluded that the Endosee cannulas could have been re-used on or about April 16, 2024. Moreover, the proof at trial also showed that the CooperSurgical Disposable Alligator Grasper Forceps were designed to work with the Endosee PX cannulas. There was no proof that they could have worked with other devices, and thus the proof at trial is also insufficient to support that the graspers could have been reused.

Similarly, the proof at trial squarely showed that the LiNA forceps had to have been used with a LiNA handheld device. The device representative for LiNA, Adam Remoll, testified that the LiNA forceps were designed to work with the LiNA handheld device only. There was no contrary proof at trial that the LiNA forceps could work without the LiNA handheld device, which was not charged in the Indictment and which the proof showed was not functioning on or about the day of the search warrant because it lacked a functioning battery pack. Thus, no rational juror could have concluded that the LiNA forceps could have been reused on or about April 26, 2024.

As for the charged UroViu devices, the proof at trial showed that Poplar Avenue Clinic ordered cannulas from UroViu that could be used for hysteroscopies (Hystero-V hysteroscope cannulas) as well as cystoscopies (Uro-V diagnostic cystoscope cannulas). Multiple witnesses, including Thomas Lawson, testified that both of these types of cannulas look exactly the same. Thus, the cannulas charged in the Indictment had a 50% chance of being either a hysteroscope or a cystoscope. Given the total lack of testimony from any witness whatsoever that they used the charged devices or on what procedure they were used, no rational juror could have concluded *beyond a reasonable doubt* that those devices were Hystero-V cannulas.

Consequently, this Court should set aside the verdicts for Counts 1 through 36.

**3. The Government's Discovery Violations Warrant a Mistrial.**

Dr. Kumar continues to maintain that he is entitled to a mistrial due to the Government's

misconduct, including Special Agent Kriplean resetting his phone and thus destroying evidence, the Government's failure to disclose its unrestricted access and possession of Mrs. Hussein's phone and to produce exculpatory and/or impeachment evidence from that phone, and the Government's discovery violations under *Brady v. Maryland*, 373 U.S. 83 (1963) (requiring prosecution to turn over material exculpatory evidence to defense), *Giglio v. United States*, 405 U.S. 150 (1972) (extending *Brady* to evidence that contains relevant impeachment evidence), the Jencks Act, 18 U.S.C. § 3500, Federal Rule of Criminal Procedure 26.2, and Federal Rule of Criminal Procedure 16. Dr. Kumar incorporates herein the arguments raised in his oral Motion for Mistrial made during trial on December 4, 2025, his Renewed Motion for Mistrial (ECF No. 224), and his Supplemental Memorandum in Support of Motion for Mistrial (ECF No. 262), which have not yet been ruled upon by the Court. Dr. Kumar continues to request an evidentiary hearing regarding Special Agent Kriplean's resetting his iPhone, whether he followed FDA policies in doing so, and the extent to which his phone was backed-up and, for example, stored in a cloud-based system by the FDA and/or Apple.

**4. The "Held for Sale" Instruction Violated Due Process by Creating an Intent-Only Crime.**

The jury instruction defining "held for sale" allowed a conviction with no proof of any act beyond Dr. Kumar's intent. This transformed the charge into a thought crime—punishing mere intent alone. Such an "intent-only" offense contravenes fundamental due process principles. The Constitution requires proof of an actus reus (guilty act) to accompany the mens rea (intent); a defendant cannot be convicted based solely on bad intent unconnected to any concrete action. As the Oklahoma Court of Criminal Appeals long ago observed, "An unexecuted intent to violate the law amounts to no more than a thought, and is not punishable as a crime." *Lambert v. State*, 374 P.2d 783, 785 (Okla. Crim. App. 1962). Likewise, the Illinois Supreme Court has explained that

"[w]ith mere guilty intention, divorced from an overt act or outward manifestation thereof, the law does not concern itself." *People v. Belcastro*, 190 N.E. 301, 303 (Ill. 1934). In short, "bad thoughts alone cannot constitute a crime; there must be an act."

This bedrock requirement of an act in addition to intent pervades American criminal jurisprudence. Even inchoate offenses like attempt demand some overt act beyond mere intent. "As was true at common law, the mere intent to violate a federal criminal statute is not punishable as an attempt unless it is also accompanied by significant conduct." *United States v. Resendiz-Ponce*, 549 U.S. 102, 106–07 (2007). It is therefore unsurprising that no crime in our legal system is defined by intent alone; every offense, from petty theft to capital murder, requires an unlawful act or omission coupled with the guilty mind. Punishing someone for thoughts or intent alone is anathema to due process. As one court put it: "Guilty intention, unconnected with an overt act or outward manifestation, cannot be made the subject of punishment under the law." *Proctor v. State*, 176 P. 771, 772 (Okla. Crim. App. 1918) (quotation omitted).

By instructing the jury that the single use device merely needed to be "held for sale", which the Government argued was a device's mere presence in the clinic, the Court effectively relieved the Government of its burden to prove any concrete act by Dr. Kumar—such as an actual sale/reuse on a patient—in connection with his intent. The Due Process Clause, however, "protects the accused against conviction except upon proof beyond a reasonable doubt of every fact necessary to constitute the crime with which he is charged." *In re Winship*, 397 U.S. 358, 364 (1970). This constitutional mandate extends to all elements of the offense, including the requirement of a criminal act. An instruction that allows conviction without proof of an element—here, permitting the jury to find guilt based solely on intent to sell—is equivalent to an impermissible directed presumption in favor of the prosecution. Just as a court may not direct a jury to presume an element

(like intent or causation) and thereby lighten the prosecution's load it may not redefine the crime so that an essential act is no longer required. In effect, the "held for sale" charge created a mandatory presumption that if Dr. Kumar intended to sell the product, then it was "held for sale" (and thus misbranded)—without any further action on his part. This violated due process by stripping away the actus reus element and allowing a conviction on intent alone.

Because the jury could have convicted based on this unconstitutional theory, the verdict cannot stand. Convicting a defendant of an "intent-only" offense is repugnant to our system of justice and cannot be squared with the Fifth Amendment's guarantee of due process. The error here is structural or, at a minimum, not harmless—it affected the framework of the trial by permitting the jury to return a guilty verdict without finding an actual criminal act. Accordingly, the convictions related to single use devices must be vacated or a new trial ordered. At the very least, the Court should grant a new trial under Rule 33, as the instructions allowed a verdict that offends deeply rooted principles of due process and fundamental fairness. In sum, the "held for sale" instruction lowered the prosecution's burden of proof to zero on the actus reus, effectively criminalizing mere intent; this Court should set aside the verdict and prevent such a manifest injustice.

**5. The Evidence Was Insufficient to Support Health Care Fraud Convictions.**

**A. Dr. McDonald's Subjective Opinion Was Insufficient to Support Medical Necessity.**

The evidence is insufficient to support a conviction on Counts 38, 40, 41, 44, and 45 because the Government presented no proof of an objective standard by which the jury could measure Dr. Kumar's actions. Criminal fraud requires a lie—a knowingly false representation of a material fact. Specifically, under 18 U.S.C. § 1347, the Government must prove that a defendant "knowingly and willfully" executed a scheme to defraud a health-care benefit program, which

necessarily presumes a false statement that is objectively wrong. Thus, the Government must present proof of an objective standard by which to measure the conduct of a physician in determining whether the physician committed health care fraud in the performance of unnecessary procedures. *United States v. McLean*, 715 F.3d 129, 141 (4th Cir. 2013) (discussing that experts testified there was an objective standard of stents being unnecessary unless there is 70% or more stenosis in an artery and the patient suffers from symptoms of blockage); *United States v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018) (noting "the false-statement and fraud statutes require proof, beyond a reasonable doubt, that the defendant made a statement "'capable of confirmation or contradiction'" (quoting *United States v. Kurlemann*, 736 F.3d 439, 445 (6th Cir. 2013)); *c.f. United States v. AseraCare, Inc.*, 938 F.3d 1278, 1296–97 (11th Cir. 2019) ("It follows that when a hospice provider submits a claim that certifies that a patient is terminally ill 'based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness,' 42 U.S.C. § 1395f(7), 42 C.F.R. § 418.22(b), the claim cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood.").

The Government charged Dr. Kumar *only* under a theory of medical necessity for Counts 40, 41, and 44. When the theory of prosecution is that medical procedures were unnecessary, the Government must present expert proof regarding medical necessity standards. *United States v. Singh*, 147 F.4th 652, 662–63 (6th Cir. 2025). Here, there was no proof of any objective standard related to the performance of in-office hysteroscopies. Rather, the only expert proof that the Government presented is that Dr. McDonald himself would not have performed some of the hysteroscopies about which he was questioned. Problematically, Dr. McDonald also testified that he does not actually perform any in-office hysteroscopies at his practice. The Government's and

Defense's proof aligned in that there are *no* standards articulated by Medicare, Medicaid, or TennCare for the performance of hysteroscopies. Further, the Government presented no proof that Dr. McDonald's preference about how, where, and when to perform hysteroscopies is supported by peer-reviewed science, medical literature, or any local practices of gynecologist-oncologists in the Memphis area. Moreover, Dr. McDonald repeatedly advocated "change of venue", opining that hysteroscopies should have been performed in a hospital, and not that it was unnecessary *per se*. The defense's medical expert, Dr. Tahir Frazan, testified that the procedures in question were indeed indicated and medically necessary.

The fact that Dr. McDonald was able to so easily change his testimony on the stand regarding certain procedures[1]—even if, in his own words, to give the benefit of the doubt to providers at Poplar Avenue Clinic—further demonstrates the flaw in the Government's case. If Dr. McDonald could so easily change his testimony at trial, he could easily change his opinion as to the remaining procedures next week, or the week after. It is hard to imagine a greater chill on medical innovation and professional autonomy than the threat of criminal charges, unless a physician follows the Government's preferred, but ever-changing, standards for performing a medical procedure which are unannounced until criminal charges are brought. Indeed, Dr. McDonald's testimony made perfectly clear that his subjective clinical judgment, and nothing more, was the basis for all of the health care fraud charges in the Indictment.

[1] The Court ordered that the following procedures be removed from the special verdict form due to Dr. McDonald changing his opinion and stating these procedures were medically necessary: Count 42 – July 28, 2022; Count 42 – September 7, 2022; Count 44 – June 9, 2020.

**B. The Proof Does Not Support a Conviction for Fraudulent Representation of Medical Symptoms.**

Further, there is insufficient proof to sustain a conviction for fraudulent representation of medical symptoms in Counts 38 and 45. For Count 38, the Government charged Dr. Kumar with fraudulent representation of patient complaints for Patient 2 on the basis that Patient 2 never had post-menopausal bleeding. The patient, however, had clear documentation of post-menopausal bleeding and a polyp being diagnosed in postmenopausal age group from the referring physician's note. (Ex. 107, USA-0019648, 19896, 19604, 19997, 19515, 19373.)

For Count 45, in addition to allegations of unnecessary procedures, the Government charged Dr. Kumar with fraudulent representation of patient complaints for Patient 9 on the basis that Patient 9 never reported abnormal bleeding despite it being documented in the medical chart. (Exhibit 113, USA-0016805, 16714, 16686, 16696, 16599, 16569, 16567.) Thus, the evidence was insufficient to support fraudulent representation of medical symptoms for these two patients.

**C. The Proof Failed to Show Dr. Kumar Acted with Intent to Defraud.**

There was little to no evidence showing that Dr. Kumar acted with the "intent to defraud" when he performed the alleged unnecessary procedures. While Dr. McDonald opined that he would not have performed the procedures, his testimony offered no proof that Dr. Kumar, who believed the procedures were appropriate, acted with an intent to defraud. The undisputed data showed that Dr. Kumar did not treat every new patient with a hysteroscopy. Approximately 43 percent of Medicaid patients never received hysteroscopy procedure and only 21 percent of the Medicaid patients received more than one hysteroscopy. (Exhibit 198.) And only 19 percent of the Medicare patients received a hysteroscopy examination. (*Id.*) This undisputed data undermines the Government's burden in showing that these nine patients charged were subject to an intended fraudulent scheme. Likewise numerous employees, some called by the Government, testified Dr.

Kumar never told them to perform an unnecessary hysteroscopy. And still others verified his practice of aggressively diagnostically testing his patients.

To support its allegations of intent to defraud, the Government relied on a 2019 communication with Mrs. Hussein on the reimbursement rates for hysteroscopies. The rate discussed in the communication was for Mississippi Medicaid, not at issue in this case. Likewise, Dr. Kumar's lone comment to Dr. Abdu of "suckers" falls far short of proof beyond a reasonable doubt even in the light most favorable to the Government. Dr. Abdu testified that Dr. Kumar never directed him or any other practitioner to perform hysteroscopies that were not medically necessary. He continued to practice more than two years without any controversy. With the lack of direct proof on intent to defraud, the Government offers only speculation of is intent to defraud based on the narrative that Dr. Kumar was a "bad" doctor. The Government's use of "bad" acts alone falls short of proof beyond a reasonable doubt even when considered in its most favorable light.

**D. The Evidence Was Insufficient to Support Conviction on Count 46.**

Count 46 charged Dr. Kumar with, from September of 2019 through April of 2024, committing health care fraud by submitting claims for reimbursement for hysteroscopies to government health care programs "in that he falsely attested that he followed all pertinent rules and regulations in providing these services, including that the devices used during the procedures comported with all applicable regulations and were approved for use in patient care." (Indictment, ECF No. 136, at PageID 1221–22.) There appears to be no other decision dealing with a charge like Count 46, which appears to be a novel charging theory bringing a claim under the False Claims Act as one for health care fraud under 18 U.S.C. § 1347. Nonetheless, the proof at trial is insufficient to support a conviction for Count 46 under precedent for either the False Claims Act or the health care fraud statute.

Under the False Claims Act, a certification to a government health program can be either express or implied in nature. As the Government presented proof of here, a certification in an enrollment application to abide by "all applicable laws and regulations" is insufficient to support an express certification claim. *U.S. ex rel. Hobbs v. MedQuest Associates, Inc.*, 711 F.3d 707, 714–15 (6th Cir. 2013). Such a theory is tenable as an implied certification claim only if the allegedly violated regulation is a condition of payment. *Id.* at 715. Notably, the Sixth Circuit has recognized that "weaving together" sections of the complex and large body of Medicare regulations is insufficient to show that compliance with a regulation is a condition of payment. *Id.* "[I]t is not reasonable to expect Medicare providers to attempt such an approach to statutory interpretation in their efforts to comply with the FCA." *Id.* "The False Claims Act is not a vehicle to police technical compliance with complex federal regulations." *Id.* The Government's only proof that the adulteration or misbranding of devices would result in a claim being denied was from Daniel Coney. His testimony, however, was an application of the "cut-and-paste approach" to interpreting the Medicare guidelines that the Sixth Circuit has expressly rejected.

Under the health care fraud statute, the Government must prove the defendant "(1) created 'a scheme or artifice to defraud' a health care program, (2) implemented the plan, and (3) acted with 'intent to defraud.'" *United States v. Bertram*, 900 F.3d 743, 748 (6th Cir. 2018) (quoting *United States v. Martinez*, 588 F.3d 301, 314 (6th Cir. 2009)); 18. U.S.C. § 1347. The Government failed to prove the second element: that Dr. Kumar implemented a plan to defraud government health programs. The Government provided zero evidence that an adulterated device was used on a Medicaid or Medicare patient, instead presenting generalized testimony about the use of adulterated devices not linked to a specific date or a specific patient. Additionally, the Government provided no evidence that a specific claim submitted to either Medicare or Medicaid was false

because of the use of an adulterated device. Regarding intent, the testimony at trial was consistent that Dr. Kumar preferred to use multi-use scopes and that he invested a significant amount of money in purchasing multi-use scopes and the appropriate reprocessing equipment. Given the significant emphasis on use of multi-use scopes at Poplar Avenue Clinic, the proof does not support that Dr. Kumar had a scheme to defraud government healthcare programs by submitting false certifications and then failing to properly clean a reuseable device.

Finally, Count 46 fails for sufficiency because the Government failed to offer proof that the alleged scheme—submitting claims using adulterated devices—was a condition material to payment. Much like the False Claims Act, the Health Care Fraud criminal statute "is not 'an all-purpose antifraud statute,' *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 128 S. Ct. 2123 (2008), or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016)).

> A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

*Id.* It does not matter how the Government labels a requirement. *Id.* at 181. "What matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* The Supreme Court rejected the Government's theory of materiality here—"that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation." *Id.* at 195.

> [I]f the Government pays a particular claim in full despite its actual

> knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

*Id.* The Government failed to meet its burden during trial by failing to offer any proof that the use of adulterated devices was material to payment.

**6. The Jury Should Have Been Given Entrapment by Estoppel Instruction.**

A new trial is further warranted on Dr. Kumar's convictions for violating the FDCA because the Court should have given an entrapment by estoppel instruction (also known as a "reliance on government authority" instruction) to the jury related to the Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, published by the CDC (hereinafter "Guidelines").[2] The Government fought exceptionally hard at trial to keep from the Jury that these Guidelines instruct that hysteroscopes can be reprocessed using high-level disinfectant, rather than ethylene oxide ("EtO") gas as the Government contended throughout trial was the necessary reprocessing agent. The Government objected to the admission of the Guidelines into evidence, which the Court sustained, and opposed the entrapment by estoppel offense being given to the Jury.

It is error to fail to instruct the jury when "(1) the proposed instruction is substantially correct; (2) the proposed instruction is not substantially covered by other delivered charges; and (3) the failure to give the instruction impaired the defendant's theory of the case." *United States v. Triana*, 468 F.3d 308, 315 (6th Cir. 2006). "Although a jury instruction should not be given if it lacks evidentiary support or is based upon mere suspicion or speculation, so long as there is even weak supporting evidence, a trial court commits reversible error in a criminal case when it fails to

[2] https://www.cdc.gov/infection-control/media/pdfs/guideline-disinfection-h.pdf

given an adequate presentation of a theory of defense." *Id.* (quotations omitted).

All elements of the entrapment by estoppel defense were adequately supported by the proof at trial. The Sixth Circuit Pattern Criminal Jury Instruction provides that the defendant must prove by a preponderance of the evidence the following elements:

> (A) First, that an agent of the United States government announced that the charged criminal act was legal.
>
> (B) Second, that the defendant relied on that announcement.
>
> (C) Third, that the defendant's reliance on the announcement was reasonable.
>
> (D) Fourth, that given the defendant's reliance, conviction would be unfair.

6th Cir. Pattern Crim. Jury Instr. 6.09. There was no dispute at trial that the CDC published the Guidelines, which amount to stating that the use of high-level disinfectant was legal. Dr. Kumar testified that he relied upon the Guidelines, and the Government presented no proof to the contrary that reliance on the Guidelines was unreasonable. There is no question that it would be exceptionally unfair to permit a physician to be criminally punished—in this case with convictions carrying a sentence of imprisonment of up to three years—for following Guidelines posted on the CDC's website. Further, Dr. Kumar was not the only physician at trial that testified that hysteroscopes could be reprocessed using high-level disinfectant. Dr. Amy Garcia and Dr. Ramzy Rimawi corroborated his testimony. Even the Instruction for Use manual for the Olympus HYF-XP specifically stated that high-level disinfectant was an appropriate reprocessing agent for that specific device. (*See* Ex. 57.) The Court's failure to give this instruction to the Jury necessitates a new trial on those counts.

**7. The Hysteroscopes Charged in the Indictment Were Not "Held for Sale".**

Neither single-use nor multi-use hysteroscopes were "held for sale" under the FDCA when

used in the course of treating patients at Poplar Avenue Clinic. In deciding an issue of first impression, this Court followed what was a case of first impression for the Ninth Circuit, which extended the scope of the "held for sale" language of 21 U.S.C. § 331(k) to encompass the re-use of single-use devices on patients. *United States v. Kaplan*, 836 F.3d 1199, 1211 (9th Cir. 2016). Section 331(k) criminalizes "the doing of any . . . act with respect to" a device "if such act is done while such article is *held for sale* . . . after shipment in interstate commerce" and results in the device being "adulterated or misbranded." 21 U.S.C. § 331(k) (emphasis added). The FDCA was never meant to sweep so far to include the use of devices on patients as those devices being "held for sale", or to regulate the practice of medicine. *See* 21 U.S.C. § 396.

The problematic scope of the FDCA applied in this case is particularly reflected in this Court's holding that the re-use of multi-use hysteroscopes on patients rendered those devices "held for sale." The *Kaplan* Court in applying the "held for sale" provision to single-use devices found that other decisions, including *United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir. 1975) (per curiam), which the Court relied upon here in holding that multi-use devices are "held for sale" in the course of treating patients, were "quite conclusory and offer[ed] little guidance." *Kaplan*, 836 F.3d at 1209. The Ninth Circuit thus explained that "[t]he single-use nature of the guides is particularly critical to our decision." *Id.* at 1210. Single-use devices could be "consumed" by patients such that a "sale" occurred. *Id.* *Kaplan*'s strained effort to fit the re-use of single-use devices on patients under the FDCA undermines that the re-use of multi-use devices falls under the statute's purview or that Congress intended for § 331(k) to criminalize the re-use of devices on patients at all. Although the Supreme Court in *United States v. Sullivan*, 332 U.S. 689, 696 (1948), held that the FDCA's reach extends "to the moment of delivery to the ultimate consumer," it does not eliminate the statutory text; the phrase "held for sale" remains, and

in the physician-practice context its application is at best ambiguous. That ambiguity should have been resolved in Dr. Kumar's favor under the rule of lenity. *United States v. Rhody Dairy, L.L.C.*, 812 F. Supp. 2d 1239, 1244 (W.D. Wash. 2011).

The proof at trial did not show that multi-use hysteroscopes were "consumed" in the course of treating a patient, such that a sale occurred. The mere fact that government health programs reimburse providers generally for the cost of hysteroscopes used during procedures, as Daniel Coney testified, does not mean that all devices at Poplar Avenue Clinic were "held for sale" in the course of treating a patient. That testimony fails to show a clear transactional link between the patient and the provider. Further, as outlined *supra*, not one witness testified that the devices charged in Counts 1 through 36 were reused on patients on or about April 16, 2024. *See id.* at 1211 (holding that "a physician's *use* of a consumable, single-use device on a paying patient satisfies the "held for sale" element under 21 U.S.C. § 331(k)" (emphasis added)). Rather, the Government's proof was that the devices were found in Cidex on the date of the search warrant, and that there were multiple devices in Cidex. The latter tends to prove the opposite of reuse, instead one could infer that multiple different scopes were used. The first use of a device alone is not punishable under the anti-adulteration provision. Thus, a judgment of acquittal or new trial should be granted to Dr. Kumar for Counts 1 through 36 on these grounds as well.

## CONCLUSION

For the foregoing reasons, Dr. Kumar respectfully requests that the Court grant him judgment of acquittal or a new trial on all charges against him.

Respectfully Submitted,

s/ Lawrence J. Laurenzi
Lawrence J. Laurenzi (TN BPR No. 9529)
Elena R. Mosby (TN BPR No. 40562)
BURCH, PORTER & JOHNSON, PLLC

130 North Court Avenue
Memphis, TN 38103
901-524-5000
llaurenzi@bpjlaw.com
emosby@bpjlaw.com

Ronald Chapman, II (*pro hac*) (Mich. Bar No. P73179)
THE CHAPMAN FIRM
456 E. Milwaukee
Detroit, MI 48202
Phone: (346) Chapman
Ron@chapmanandassociates.com

Maritsa A. Flaherty (*pro hac vice*) (Cal. Bar No. 327638)
CHAPMAN LAW GROUP
1441 W. Long Lake Rd., Suite 310
Troy, Michigan 48098
(248) 644-6323
mflaherty@chapmanlawgroup.com

**CERTIFICATE OF SERVICE**

I hereby certify that on January 28, 2026, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will operate to provide notice of this filing to all counsel of record in this case.

s/ Lawrence J. Laurenzi
Lawrence J. Laurenzi