No. 2025- 387

In The
Supreme Court of the United States

ANITA LOUISE JACKSON, M.D.

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

ORIGINAL

FILED
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SUPREME COURT, U.S.

On Petition for Writ of Certiorari to the Fourth Circuit Court of Appeals

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

In what world do physicians have to disclose to patients that their surgical procedure will be performed with previously used surgical instruments in order to avoid criminal liability of fraud pursuant to 21 U.S.C. § 331(k) and Section 301(k) of the Food, Drug and Cosmetic Act?

And in what world does adulteration of a surgical device occur when that device is used for its intended purpose?

PARTIES TO THE PROCEEDING

Petitioner is Anita Jackson, M.D.

Respondent is United States of America

PRELIMINARY STATEMENT

Dr. Jackson is currently held in custody in FPC Alderson located at Glen Ray Road Box A, Alderson West Virginia. Dr. Jackson has directed the filing of this petition on her behalf by staff at Physicians Against Abuse which is an advocacy group whose sole mission is to bring an end to the criminalization of the practice of medicine. All writing, opinions and references made herein belong to Dr. Jackson which were transmitted to staff at Physicians Against Abuse for transcription and submission to the United States Supreme Court.

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OPINIONS AND RULINGS BELOW

The opinion of the Fourth Circuit Court of Appeals appears at Appendix, ("App") A designated as United States v. Jackson, 126 F.4th 847 (C.A.4 (N.C.), 2025). Order Denying Motion for Rehearing is at App B.

JURISDICTION

The Fourth Circuit Court of Appeals denied Petitioner's direct appeal on January 21, 2025. Motion for rehearing was denied on March 4, 2025. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Two statutory provisions are at issue.

21 U.S.C. § 331(k) states in pertinent part:

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

This corresponds to Section 301(k) of the Food Drug, and Cosmetic Act, ("FDCA").

21 U.S.C. §396 states in pertinent part:

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

STATEMENT OF THE CASE

Dr. Anita Jackson is a board-certified ear nose and throat surgeon who had her private practice in North Carolina devoting her practice in large part to the treatment of chronic sinusitis. Most of her patients had Medicare insurance.

Chronic sinusitis is infection of the hollow spaces surrounded by facial bones in the upper facial zone. When bacteria infects these hollow spaces, the condition of chronic sinusitis ensues. An accepted form of treatment for this condition is balloon sinuplasty. This procedure is not classified as a sterile procedure because the area that is operated on is already infected with bacteria.

Dr. Jackson was performing the accepted form of treatment on her patients suffering from chronic sinusitis when the government decided to charge her criminally pursuant to 21 U.S.C. § 331(k) for performing these procedures with surgical instruments, to wit, sinus scopes, which were previously used on prior patients.

A. Statutory and Regulatory Framework

There is nothing in the two statutory provisions or in the regulatory framework of the FDCA which criminalizes the non-disclosure by a physician that previously used surgical instruments will be used in the course of a surgical procedure.

Similarly, there is no regulatory or statutory language which defines adulteration of a surgical device when that device is used for its intended purpose.

B. Factual Background

1. Petitioner is Dr. Anita Jackson. Dr. Jackson owned two clinics in North Carolina which was in large part dedicated to the treatment of chronic sinusitis in patients who had Medicare as their insurance for the most part.

2. The government's entire case was based on the fact that Dr. Jackson's repeated use of a single-use FDA labeled sinus scopes was fraudulent because she did not inform her patients that previously used surgical instruments were going to be used to perform their sinuplasties.
3. The government also made the wild assertion that the sinus scopes were adulterated after their use for their intended purpose.
4. Incredulously, the district court judge and then the Fourth Circuit bought this nonsensical and entirely out-of-touch with reality argument about re-use of surgical instruments which had been labeled as single-use by the FDA.
5. Dr. Jackson was convicted on all counts on January 27, 2023 pursuant to the superseding indictment that was filed on January 4, 2022.

This Petition for Writ of Certiorari now follows.

REASONS FOR GRANTING THE PETITION

This is a case of first impression. Dr. Jackson is the only physician who has been charged and convicted under this statute on the premise that her nondisclosure to patients about using previously used surgical instruments constitute fraud so as to criminalize the billing to Medicare for the surgical procedure.

Dr. Jackson's conviction is in contravention of the intent expressed by Congress.

I. FOURTH CIRCUIT PANEL CANNOT JUST MAKE UP THINGS AS THEY GO ALONG REGARDING DISCLOSURES THAT DOCTORS MUST MAKE TO PATIENTS AND THEN USE THIS AS BASIS FOR FRAUD TO UPHOLD DR. JACKSON'S SECTION 301 (K) CONVICTION

The Opinion of the Fourth Circuit knocks down Dr. Jackson's argument on appeal, asserting that Dr. Jackson was not convicted for using the sinus scope off label, but rather she was convicted because she did not inform her patients that she was going to be using previously used sinus scopes in performing balloon sinuplasty on her patients. The Fourth Circuit categorizes this non-disclosure as fraud in justifying Dr. Jackson's conviction.

But in what world has any surgeon notified his or her patient that he or she would be using previously used surgical equipment? That is the real question. The answer is in no world does any surgeon ever tell a patient that there will be previously used instruments utilized in performing a patient's surgical procedure. This is largely because thousands of surgical instruments are re-used and re-circulated all day every day in this country across operating rooms and office surgery centers. That is why the most critical components of surgical instruments are made up of stainless steel because bacteria cannot adhere to the surface of stainless steel making it impossible for bacterial to be transmitted from one use to another use.

This is why Dr. Jackson's patients did not have a single infection for the four years that she was purportedly carrying on a scheme of using single-use labeled sinus scopes for multiple use. If there was anything wrong with what Dr. Jackson was doing in re-circulating these single-use labeled scopes, for the amount of patients that the government claims Dr. Jackson saw and treated, common sense dictates that at least one patient would have suffered from some horrific infection. The government did not have a single patient to present who suffered any infection. This is because the sanitization process that Dr. Jackson was employing was working. Contrary to Fourth Circuit's uninformed assessment, the gauge of whether the sanitization process is effective is not determined by low level employees who all align with the government when crap hits the ceiling and their testimony is shaped by the ten-second fame they seek, but rather by expert witnesses in the field.

Whether or not the sanitization process was working is evident in the fact that the government could not present a single patient who suffered an infection related to the re-use of the single-use scopes that Dr. Jackson was charged with and convicted for.

Other common sense evidence that establishes that the Fourth Circuit, the district court and the government were making up things as they were going along is what is contained in Informed Consents that patients sign prior to undergoing surgical procedures. No INFORMED CONSENT in this country contains any language where disclosure is made to patients that they will be operated on with previously used surgical instruments. In fact, this

is nothing short of an oxymoron assertion because ultimately all surgical instruments that have any stainless steel as their main composition are circulated and re-used without disclosing this information to patients.

Let's take the example of colonoscopies. The scopes used in colonoscopies are re-used and re-circulated in countless ambulatory surgery centers and hospitals in this country every day. And in re-using these surgical devices, there is not a single informed consent that any patient signs in which disclosure is made to the patient that the scope to be used for their colonoscopies was previously used on other patients. This is and would be oxymoronic if informed consents made such a disclosure.

This Court needs to step in to stop this insanity of judges making up things in a field they know nothing about.

The Fourth Circuit's reasoning and making up of things that are this out-of-touch with reality is no different than what happened to hundreds of doctors before this Court decided *Ruan v. US*.[1] Pre-*Ruan*, there was the insanity of equating doctors writing prescriptions for controlled substances to drug lords dealing and trafficking drugs on street corners. Only in America!

Undersigned need not remind this Court how nonsensical it was for prosecutors not to come to the realization that the "except as otherwise authorized" language in Section 841 brings into operation the *mens rea* requirement when it comes to criminalizing the behavior of doctors authorized to write prescriptions for controlled substances. It took decades and hundreds of

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[1] *Ruan v. United States* 597 U.S. 450 (2022)

physicians being wrongfully prosecuted and convicted based on this one out-of-touch with reality stance that prosecutors and judges took in their interpretation of 21 U.S.C §841.

Undersigned begs this Court's attention so that this vicious cycle is, not now, repeated with this new obsession by prosecutors in distorting 21 U.S.C. § 331(k) by making the claim that it was fraud because patients were not told that previously used surgical instruments were going to be used on them during their surgical procedure.

II. IN THE REAL WORLD OF MEDICINE, ADULTERATION DOES NOT OCCUR BECAUSE A SURGICAL INSTRUMENT PICKS UP MUCUS AND TISSUE IN THE COURSE OF ITS INTENDED USE

According to the district court, the Fourth Circuit panel, and the government, a surgical instrument is adulterated when it is used in one patient and in the course of its use, picks up mucus, hair, and tissue. Nothing more nonsense can even be articulated.

It was not the intent of Congress to define adulteration of a surgical instrument when it picks up tissue, mucus and hair in the course of being used to perform a surgical procedure- an intended purpose. The statutory text does not even remotely suggest that intended use of a scope would adulterate the scope. Only Fourth Circuit Panel and others along the way in the lower court proceedings who are so out-of-touch with reality of the practice of medicine, could come up with such a twisted justification of the unjustifiable.

In no common sense world could any surgical device can be said to be adulterated because it was utilized for its intended use. The Opinion by the Fourth Circuit is however riddled with this assertion that Dr. Jackson adulterated the scopes because she was using them to perform the surgical procedures the scopes were intended for.

III. FDA ITSELF AUTHORIZED THE RE-USE OF SINGLE-USE DEVICES IN ITS JULY 2001 PUBLICATION

It is a sad day in America when the Department of Health and Human Services collaborating with the FDA puts out a document outlining procedures to be employed in sanitization of devices labeled as single-use when they are purposed for re-use and yet the government prosecutes a physician who was doing just what this publication by FDA establishes. App C.

The title of this document is "reprocessing and reuse of single use devices". All of the ruckus created by the DOJ prosecutors, and then condoned by the district court judge and the Fourth Circuit flies in the face of this document that FDA in collaboration Department of Health and Human Services put into circulation for guidance on July 6, 2001. It is clear as per FDA that re-use of single use devices was a recognized occurrence and guidance was provided by the FDA regarding such re-use of single use devices. Dr. Jackson was neither the first nor the last to engage in such a "monstrous" practice as the Fourth Circuit Opinion appeared to treat her practices.

This publication demonstrates that at best what Dr. Jackson could be accused of is malpractice. But there was not even a single patient whom the government presented was infected or suffered some ailment as a result of re-use of single device scopes by Dr. Jackson. So even a malpractice action could not hold up in court but criminal conviction on accepted practice and re-use of single use devices was held up putting a pillar of society, like Dr. Jackson, behind bars for 25 years.

The shows that are put on in the courtrooms in America have to have some connection to reality in order to stop the rapid deterioration of our criminal court system and the public's confidence in the judiciary.

IV. QUESTION PRESENTED IS IMPORTANT BECAUSE DOJ WILL BE EMBOLDENED WITH THIS OUT- OF- TOUCH WITH REALITY RULING BY THE FOURTH CIRCUIT

The Opinion sets a clear precedence and more so than the Ninth Circuit case referenced in the Opinion. The Opinion boldly and inaccurately assumes that disclosure about the age and usage frequency of surgical instruments must be made to patients *or otherwise* it is fraud. This is not only oxymoronic but it has no connection to the reality of the practice of medicine.

If this Court does not intervene now and set this record straight, hundreds if not thousands of medical professionals will suffer the same fate that the medical professionalS suffered pre-Ruan before this Court finally put an end to the insanity that is no different than the insanity present in this case of criminalizing the practice of medicine by manipulating statutory text.

In order to sustain respect for rule of law, those who are deciding the rule of law must at least have the appearance that they are in touch with reality. The Fourth Circuit panel has demonstrated that it is out of touch with this reality because it is undisputable that when any of the panel judges went for their routine colonoscopies, there was no disclosure made to the judges that their colonoscopies would be performed with previously used colonoscopes on other patients. Judges who underwent their routine screening colonoscopies were not defrauded or duped by their gastroenterologists in the same way that Dr. Jackson's patients were not defrauded or duped by her.

CONCLUSION

For all the foregoing reasons, Petitioner respectfully moves this Honorable Court to grant this Petition for Writ of Certiorari, directing the Fourth Circuit Court of Appeals to vacate its opinion of January 21, 2025, and directing this matter for a new trial to the district court.

Dated: August 1, 2025.

Respectfully submitted,

/s/ Anita Jackson, MD
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APPENDIX