

No. _____

In The
Supreme Court of the United States

GREGORY MOLDEN, M.D.,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

**On Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Fifth Circuit**

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Petitioner in district court appeared in a jury trial with multiple co-defendants three of which like Petitioner were licensed physicians. All of the physicians were charged under an indictment alleging multiple federal criminal violations to wit:

1. “Conspiracy to commit Health Care Fraud” under 18 U.S.C. § 1349.
2. “Conspiracy to Receive and Pay Illegal Health Care Kickbacks” under 18 U.S.C. § 371 and
3. “Health Care Fraud” under 18 U.S.C. § 1347 and 2

All of the alleged criminal violations are also linked to parallel federal statutory provisions such as the False Claim Act at 31 U.S.C. §§ 3729-3733,[with its sub component Civil Health Care *Qui Tam Action*], Civil Monetary Penalties pursuant to 42 U.S.C. § 1320a-7a which may subject Health Care providers such as Petitioner to fines or civil penalty under applicable Administrative/Judicial Reviews regulations under the Federal Title XVIII Medicare Program. The option of pursuing a “Criminal Prosecution Path” verus a “Civil Disposition Path” associated with Health Care providers such as Petitioner alleged violations of Medicare Regulations pursuant to 42 U.S.C. § 1395 et seq. and 42 C.F.R. § 400 et seq. forms the basis for the Question Presented below:

QUESTION:

Is it a constitutional Fifth Amendment Due Process violation when a Health Care provider under the Federal

QUESTIONS PRESENTED – Continued

Title XVIII Medicare Program is pursued by way of a “Civil Disposition Path” as to alleged regulatory violations and is afforded a more “Expansive Application of Constitutional Due Process Rights” totally based on compliance and or non-compliance with “Federal Title XVIII Medicare Program Regulation”; while a similarly saturated health care provider being “Criminally Prosecuted” for parallel alleged criminal violations to wit: “Health Care Fraud” under 18 U.S.C. § 1349; “Receive and Pay Illegal Health Care Kickbacks” under 18 U.S.C. § 371 and “Health Care Fraud” under 18 U.S.C. § 1347 and 2, in a “Criminal Prosecution Path” is not afforded in a jury trial the ability to apply Federal Title XVIII Medicare Program Regulations in assessing a Government Testifying Medical Experts under Federal Rules of Evidence Rule 702, nor incorporate Federal Title XVIII Medicare Program Regulations into a jury charge nor apply recognized defenses (Safe Harbor) as dictated by the Regulations under the Federal Title XVIII Medicare Program.

QUESTION RESTATED

Can you divorce Medicare Federal Regulations from a Criminal Trial predicated on the alleged Health Care Criminal Violation under the Federal Title XVIII Medicare Program.

PARTIES TO THE PROCEEDING

Petitioner Gregory Molden, M.D., was the defendant in the district court criminal proceedings and appellant in the court of appeals proceedings. Respondents the United States of America prosecutor in the district court proceedings and appellees in the court of appeals proceedings.

CORPORATE DISCLOSURE STATEMENT

None of the parties are Corporate entities.

RELATED CASES

United States v. Jonathon Nora, No. 18-3178, Court of Appeals for the Fifth Circuit, Judgment entered February 21, 2021.

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The Fifth Circuit's opinion is reported at 979 F.3d (Fifth Circuit 2020) and reproduced at App. 1-63. The Fifth Circuit denial of petitioner's motion for reconsideration and rehearing en banc is reproduced at App. 66. The *Nora* opinions of the Fifth Circuit is reproduced at App. 70-94.

JURISDICTION

The Court of Appeals entered judgment on October 20, 2020 App. 64-65. The court granted an extension for filing petition for rehearing en banc; and denied a timely petition for rehearing en banc on January 4, 2021. App. 66.

On March 19, 2020, the United States Supreme Court extended the time for filing this petition 150 days to June 3, 2021. This Court has jurisdiction under 28 U.S.C. § 1254(1).

UNITED STATES CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Constitutional Provision:

The Fifth Amendment of the United States Constitution

(Due Process prong of the Fifth Amendment in criminal trials as to the "Burden of Proof")

Statutory Provisions:

Medicare Statutes and Regulations: 42 U.S.C. § 1395kk-1; 42 C.F.R. §§ 405.904(a)(2), 405.920-405.928

(Various provision under the Federal Title XVIII Medicare Program which allows private government contractors, to process claims and pay Medicare Health Care Providers in addition to permitting reimbursement payments made to Medicare Health Care Providers to be audited by Zone Program Integrity Contractors (“ZPICs”))

Medicare Statutes and Regulations: 42 U.S.C. § 1395ff(a)(3)(A); 42 C.F.R. § 405.904(a)(2); 42 U.S.C. § 1395ddd(f)(2); 42 C.F.R. § 405.371(a)(3); 42 U.S.C. § 1395ff(d); 42 C.F.R. § 405.1000(d); 42 C.F.R. § 405.1036(c)-(d); 42 U.S.C. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1100.

(Various provision under the Federal Title XVIII Medicare Program which allows a Medicare Program Health Care Provider a four-level appeal process if an over payment to the Medicare Program Health Care Provider is detected by Federal Title XVIII Medicare Program private contractors for claims processing, reimbursement and audits by Zone Program Integrity Contractors (“ZPICs”))

The False Claim Act: 31 U.S.C. §§ 3722(a)(1)(G)



STATEMENT OF THE CASE

Petitioner Molden a physician with other co-defendants three of which also are physicians on September 8, 2016 in a Second Superceding were Indicted for alleged multiple federal criminal Health Care offenses under the Federal Title XVIII Medicare Program. The criminal violations presented in the jury trial directly related to the provision of Medicare Home Health services; Medicare Regulatory definition of “Home Bound”, Fed. R. Evd. 702 testifying expert witness knowledge/adherence to Medicare Regulations and the extent that the jury charge incorporated Medicare Regulation for jury deliberation. In keeping with the stated issues Petitioner’s alleged criminal violation by Count were:

Count 1: alleged conspiracy to commit Health Care fraud, in violation of 18 U.S.C. §§ 1347 and 1349.

Count 2: alleged conspiracy with others to “knowingly and willfully solicit and receive . . . kickbacks and bribes . . . in return for referring individuals for” Medicare services in violation of 42 U.S.C. §§ 1320a-7b(b)(1), (b)(2), and 18 U.S.C. § 371. The Kickback allegation was tendered to the jury without incorporating a “Safe Harbor Jury Charge” an affirmative defense as to the contractual relationship that forms the basis of the Kickback Conspiracy allegation under Count 2.

Counts 32 through 42: each alleged a separate Health Care fraud violation of 18 U.S.C. § 1347; involving two patients Petitioner certified for entitlement to Home Health Service pursuant to the definition of

Home Bound under the regulations/definition utilized by Federal Title XVIII Medicare Program. Testimony as to the alleged regulatory violation was rendered by the Government's Medical Expert Witness who the district court and Fifth Circuit panel concurred lacked the ability to testify as expert pursuant Fed. R. Edv. 702 on several issues under the Title XVIII Medicare Regulations critical in assessing if an individual is or is not Home Bound as that term is defined and addressed under the Title XVIII Medicare regulations.

In a jury trial with other named defendants a verdict was rendered by the jury finding Petitioner Guilty on all Counts previously referenced herein.

REASON FOR ALLOWANCE OF THE WRIT

The Fifth Circuit Court of Appeals has over an extended period of time engaged in a compromise of the Petitioner and other Federal Health Care Program Providers; Due Process Rights under the Fifth Amendment of the United States Constitution as it relates to the concept of "Proof Beyond a Reasonable Doubt" in criminal trial associated with alleged criminal violations of Federal Health Care Programs including the Federal Title XVIII Medicare Program.

The "Proof Beyond A Reasonable Doubt" compromise lowers the evidential burden of proof in alleged Federal Health Care Fraud violations criminal trials in areas relating to:

1. Federal Rules of Evidence 702 in the case at hand as it relates to the Government Expert Witness lack of knowledge to testify on the foundation basis for Medicare Home Health Care entitlement to wit what is the definition of “Homebound.”
2. The failure to incorporation of Title XVIII Regulations into a Jury Charge and
3. Failure to incorporate statutory defenses associated with a Federal Health Care violation such as Kickback allegations.

The compromise is completely revealed when view in the context of parallel civil Federal Health Care violations addressed and resolved either by Administrative and or Judicial means as addressed in the following section presented to buttress Petitioner’s “Reason for Allowance of this Writ.”

**A. “PROOF BEYOND A REASONABLE DOUBT”
A CONSTITUTIONAL “DUE PROCESS RIGHT”
UNDER THE FIFTH AMENDMENT**

The United States Supreme Court in *Davis v. United States*, 160 U.S. 469 (1895); held the burden of proof, as those words are understood in criminal law, is never upon the accused to establish his innocence or to disprove the facts necessary to establish the crime for which he is indicted. It is on the prosecution from the beginning to the end of the trial and applies to every element necessary to constitute the crime. (*Davis* at 488) The United States Supreme Court also held in *In re Winship* 397 U.S. 358 (1970) that the concept

“Proof Beyond a Reasonable Doubt” is a Due Process command that no man shall lose his liberty unless the Government has borne the burden of . . . convincing the fact finder of his guilt.” To this end, the reasonable-doubt standard is indispensable, for it “impresses on the trier of fact the necessity of reaching a subjective state of certitude of the facts in issue. (*Winship* at 3364) The *Winship*’s Court’s confirmation that the concept of “Proof Beyond a Reasonable Doubt” is a Due Process Right protected by Fifth Amendment was further enhanced in 1975 when the U.S. Supreme Court noted the balance and application of the concept of “Proof Beyond a Reasonable Doubt”; in *Mullaney v. Wilbur* 421 U.S. 684, Supreme Court 1975; where the Court at page 695 n. 20 noted: the notion of “burden of proof” can be divided into “burden of production” (providing probative evidence on a particular issue) and a “burden of persuasion”(persuading the fact finder with respect to and issue by a standard such as proof beyond a reasonable doubt) (*Mullaney* at 695). Petitioner tenders for consideration in the following section that the United States Department of Justice “Federal Health Care Fraud and Abuse Initiative” provides the measuring stick to assess the Federal District and Appellate Courts compromise of “Proof Beyond a Reasonable Doubt” in federal criminal health care trials.

1. CIVIL MODE VS. CRIMINAL MODE

The United States Department of Justice has been a vanguard in the battle against “Federal Health Care Fraud and Abuse.” In a review of the Department’s

policy Handbook addressing Criminal Federal Health Care Fraud the following directives are found under Chapter 9 of the United States Department of Justice Handbook-referenced as Criminal with designation 9-44.000 – Health Care Fraud | JM | Department of Justice notes the following concerning Health Care Fraud:¹

a). Section 9-44.100 – HEALTH CARE FRAUD-
GENERALLY:

Health care fraud is a growing problem across the United States. In response to this growing problem, in 1993, the Attorney General made health care fraud one of the Department's top priorities. Through increased resources, focused investigative strategies and better coordination among law enforcement, the Department continues to upgrade its efforts in combating the full array of fraud perpetrated by health care providers. ***Health care fraud can be prosecuted both civilly and criminally under a variety of statutes and regulations (emphasis added).*** . . .² [updated January 2020]

b). Section 9-44.150 – FRAUD AND ABUSE
CONTROL PROGRAM AND JOINT GUIDELINES
MANDATED BY THE HEALTH INSURANCE PORT-
ABILITY AND ACCOUNTABILITY ACT OF 1996:

¹ Available at <https://www.justice.gov/jm/jm-9-44000-health-care-fraud> (accessed on May 24, 2021).

² *Id.*

The Health Insurance Portability and Accountability Act, signed by the President on August 21, 1996, established and funds a Health Care Fraud and Abuse Program to combat fraud and abuse committed against all health plans, both public and private. In addition, joint Guidelines issued by the Attorney General and the Secretary of the Department of Health and Human Services to carry out the Fraud and Abuse Program stress the importance of communication and shared information between private and public plans and the federal, state and local governments. The Guidelines also ***note the importance of parallel or joint proceedings (Criminal and Civil) to help maximize the government's recovery while minimizing duplication of effort.***³ (***emphasis added***)

c). Section 9-44.202 – OVERVIEW OF AUTHORIZED INVESTIGATIVE DEMANDS AND LIMITATIONS:

Subject Matter Limitation: Pursuant to 18 U.S.C. § 3486, the use of authorized investigative demands is limited to investigations relating to “Federal health care offenses.” The term “Federal health care offense” is defined in 18 U.S.C. § 24(a) to mean a violation of, or a criminal conspiracy to violate, 18 U.S.C. §§ 669, 1035, 1347, or 1518; and 18 U.S.C. §§ 287, 371, 664, 666, 1001, 1027, 1341, 1343, or 1954 if the violation or conspiracy relates to a health care benefit program. The term “health care benefit program” is defined in 18 U.S.C. § 24(b) as any public or private plan or contract,

³ See *id.* at n. 2.

affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.⁴

d). In 2007 in the furtherance of the “Federal Health Care Fraud and Abuse Initiative” the United States Department of Justice and Federal Department of Health and Human Services established the Medicare Fraud Strike Force Teams⁵ to harness data analytics and the combined resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. First established in March 2007, Strike Force teams currently operate in the following areas: Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Tampa and Orlando, Florida; Chicago, Illinois; Dallas, Texas; Washington, D.C.; Newark, New Jersey/Philadelphia, Pennsylvania; and the Appalachian Region.

2. THE SHIFT “HIGH CIVIL BURDEN OF PROOF” VS. “LOW CRIMINAL BURDEN OF PROOF”

In keeping with the dual mode stated under Section 9-44.100 of the United States Justice Department

⁴ See *id.* at n. 2.

⁵ Available at <https://oig.hhs.gov/fraud/strike-force/> (accessed on May 24, 2021).

Handbook noted *the directive is to pursue both civilly and criminally claims under a variety of statutes and regulations* (*emphasis added*)⁶ is the operational path. Petitioner tenders for consideration the clearly different “Heightened Burden of Proof for the Government in a Civil Health Care Fraud Case vs. Questionable Burden of Proof for the Government in a Criminal Health Care Fraud Case. In *Sahara Health Care, Inc. v. Azar*, 975 F.3d 523 (Court of Appeals, 5th Circuit 2020) the Fifth heard an appeal associated with a process by the Federal Title XVIII Medicare Program to recoup an overpay from a medicare provider in the initial amount of \$3.6 million which was subsequently reduced to \$2.4 million as the result of a multi-level review process. (*Sahara* at 526) In the *Sahara* opinion the court detailed the multi-level appeal process under the Medicare Regulations to protect *Sahara* Due Process Rights; the court note that:

1. **The First Phase** of the administrative review is a “redetermination” from an HHS contractor. See 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.948.
2. **The Second Phase** allowed the health care provider to obtain “reconsideration” from a qualified independent contractor. See 42 U.S.C. § 1395ff(b)-(c), (g); 42 C.F.R. §§ 405.902, 405.904(a)(2).

Concerning the Second Phase the concept that provide for “reconsideration” from a **qualified independent contractor** (*emphasis added*) is a critical

⁶ See *id.* at n. 2.

aspect of Petitioner's argument as to "Reason for Allowing Petitioner's Writ" and it underscores the "Critical Defect" in the trial and appellate circuit court assessment of to the qualifications of the "Government Testifying Medical Expert" pursuant to Federal Rules of Evidence 702. Under 42 U.S.C. § 1395ff(b)-(c), (g); 42 C.F.R. §§ 405.902, 405.904(a)(2) Qualified Independent Contractor is defined as:

For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1) of this section, and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general the qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations: (I) The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect

to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information, including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

In the Fifth Circuit Published Opinion *United States v. Barnes*, 979 F.3d 283 (Court of Appeals, 5th Circuit 2020) it is crystal clear that the Government's Testifying Medical Expert did not possess the abilities required by the referenced Medicare Regulations as reflected by the appellate court's statement below from its published opinion in the case at hand to wit:

Whether Dr. Lutz was qualified to testify about the "medical necessity of home health services" is a more difficult question. Although the record is not entirely clear, the district court appears to have drawn a distinction between "the medical necessity of home health services" and whether the patient qualified for home health care under Medicare. For example, the district court noted the following during a bench conference:

So [Dr. Lutz] was qualified as an expert in internal medicine and the medical necessity of home health services, which I interpreted to mean this was for – and

his testimony was more about, would this – does this person need someone to come to their home?

Would it be good for them for someone to come to their home as opposed to them going to the doctor's office? But he was not, he was not qualified as an expert in Medicare regulations and he wasn't questioned about that.

The district court ruled that Dr. Lutz could offer his opinion as a practitioner as to whether a particular patient needed home health care. In contrast, Dr. Lutz could not testify about whether a particular patient qualified for home health care under Medicare. Allowing Dr. Lutz to testify about whether he believed a patient was homebound arguably may have injected confusion at trial. Evans correctly notes that "whether a patient is 'homebound[]' . . . is a medico-legal determination." To the extent that the Medicare regulations provide guidance as to which patients qualify as homebound, it is akin to a term of art. But the word also has meaning outside of these parameters. At numerous times throughout Dr. Lutz's testimony, Dr. Lutz noted that certain patients were not homebound. But, for many of these occasions, Dr. Lutz failed to clarify whether his determination was based on his own definition of homebound or on Medicare's. Dr. Lutz's testimony as to his comparatively conservative view of home health care's requirements only served to further complicate the matter. For borderline cases, there thus existed a very real possibility that a patient would have qualified for home health care under Medicare while also not being homebound under Dr. Lutz's

standard. In these instances, Dr. Lutz's determinations as to the homebound status of these patients could have, at a minimum, confused the jury. At worst, his determinations could have misled them. Nevertheless, the fact that Dr. Lutz's determinations could have confused or potentially misled the jury fails to amount to an abuse of discretion by the trial court. The fact that some of Dr. Lutz's testimony may have been potentially misleading or confusing comes close, but ultimately does not amount to a "plain and indisputable" error. Nor can we conclude it rises to the level of "a complete disregard of the controlling law." We are certainly troubled by some aspects of Dr. Lutz's testimony. Nevertheless, we cannot conclude these aspects of Dr. Lutz's testimony amounted to manifest error. (*Barnes* at 308-309) (App. 37-39)

In summary Dr. Lutz did not possess the skills to meet the Medicare "qualified independent contractor" definition but he was permitted to testify and confuse the jury on the most critical aspect for Medicare Home Health services to wit a patient being "Homebound." Now Associate United States Supreme Justice the Honorable Neil Gorsuch; in his former role as member of the Federal Tenth Circuit Court of Appeals addressed an issue dealing with Medicare Homebound Regulations in *Caring Hearts Personal Home Services v. Burwell*, 824 F.3d 968 (Court of Appeals, 10th Circuit) in the preface to the opinion he noted:

"That's the problem we confront in this case. And perhaps it comes as little surprise that it arises in the Medicare context. Medicare is, to say the least, a

complicated program. The Centers for Medicare & Medicaid Services (CMS) estimates that it issues literally thousands of new or revised guidance documents (not pages) every single year, guidance providers must follow exactly if they wish to provide health care services to the elderly and disabled under Medicare's umbrella. Currently, about 37,000 separate guidance documents can be found on CMS's website – and even that doesn't purport to be a complete inventory. See Jessica Mantel, *Procedural Safeguards for Agency Guidance: A Source of Legitimacy for the Administrative State*, 61 Admin. L. Rev. 343, 353 (2009).

But how did CMS wind up confused about its own law? It began this way. Caring Hearts provides physical therapy and skilled nursing services to “homebound” Medicare patients. 42 U.S.C. § 1395f(a). Of course, any Medicare provider may only charge the government for services that are “reasonable and necessary.” Id. § 1395y(a)(1)(A). But Congress hasn’t exactly been clear about who qualifies as homebound or what services qualify as reasonable and necessary. So CMS has developed its own rules on both subjects – rules the agency has (repeatedly) revised and expanded over time. In a recent audit, CMS purported to find that Caring Hearts provided services to at least a handful of patients who didn’t qualify as “homebound” or for whom the services rendered weren’t “reasonable and necessary.” As a result, CMS ordered Caring Hearts to repay the government over \$800,000.” (*Caring Heart* at 970)

Associate Supreme Court Justice Gorsuch comments underscores Petitioner concerning as to the Government Testifying Expert in the case at hand who was confusing based on the assessment of the Fifth Circuit Panel dealing with confusing Medicare Regulations based on the assessment of Associate Supreme Court Justice Gorsuch.

An additional point in connection with not following Federal Medicare Title XVII Regulation the district court and the appellate court both fail to address in the jury charge Petitioner's request for a "Safe Harbor Defense" which excludes his personal service contract from prosecution under 18 U.S.C. §371 Count 2 of the indictment. The "Safe Harbor Defense" is not a novelty in the Fifth Circuit and was an issue of contention in *U.S.A. v. Mansour*, 876 F.3d 7225 (U.S. 5th Cir. Nov. 30, 2017) a case that also involved various alleged violations of 18 U.S.C. § 371. (See *Mansour* at 735,744) The issue is not address at any point in the *United States v. Barnes*, 979 F.3d 283 (Court of Appeals, 5th Circuit 2020) opinion

In *Barnes* the issue of Federal Medicare Regulation was also raised in connection with efforts for various regulations being read to the jury as instructions. These regulations covered a variety of topics, including, *inter alia*, (1) a list of services available to patients eligible for home health care, (2) the certification requirements necessary for a patient to receive home health care, (3) permissible financial relationships between physicians and health care agencies, and (4) Medicare's guidance concerning the frequency of

face-to-face meetings between physicians and their home-health patients. The district court ultimately declined to read those instructions to the jury. It was “particularly concerned about committing error by instructing the jury on the meaning of the Medicare regulations in a criminal trial,” relying heavily on this court’s decision in *United States v. Christo*, 614 F.2d 486 (5th Cir. 1980) (*Barnes* at 302) The Fifth Circuit Panel held no error in the district court’s refusal to read the proffered instructions to the jury. (*Barnes* at 302)

In a closing point on “Reason for Allowance of Writ” in the appellate court one Appellant Jonathon Nora appeal of his conviction was severed from the appellants referenced in *Barnes*. Nora matter moved to different appellant panel who on February 21, 2021 entered a judgment Reversing his convictions and Vacating his sentence. In *Nora* when juxtaposed with *Barnes*, the *Nora* Panel in a 17 page opinion presented 5 critical reasons associated with Nora lack of Medicare Regulation knowledge as the basis for reversing and vacating Nora conviction. (App. 70-94) The reasoning reflects a complete 180 degree shift from the *Barnes* Panel which divorced Medicare Federal Regulations from Petitioner’s Criminal Trial predicated on the alleged Health Care Criminal Violation under the Federal Title XVIII Medicare Program.

CONCLUSION

For all the foregoing reasons to wit inability as to apply Federal Title XVIII Medicare Program Regulations in assessing a Government Testifying Medical Expert under Federal Rules of Evidence Rule 702, failing to incorporate Federal Title XVIII Medicare Program Regulations into a jury charge nor apply recognized defenses (Safe Harbor) as dictated by the Regulations under the Federal Title XVIII Medicare Program, petitioner respectfully requests that the Supreme Court grant review of this matter.

Respectfully submitted,

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