No. _____

In the
Supreme Court of the United States

MARGARET TEMPONERAS,
Petitioner,
v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

PETITION FOR WRIT OF CERTIORARI

ALEXANDRA C. SISKOPOULOS
Counsel of Record
SISKOPOULOS LAW FIRM, LLP
33 West 19th Street, 4th Floor
New York, New York 10011
(646) 942-1798
acs@siskolegal.com

Counsel for Petitioner

March 12, 2021

Becker Gallagher · Cincinnati, OH · Washington, D.C. · 800.890.5001

QUESTION PRESENTED

The Controlled Substances Act, 21 U.S.C. § 841, and its corresponding regulation at 21 C.F.R. § 1306.04 are hopelessly vague laws that criminalize perfectly reasonable behavior by medical doctors. The federal circuits have wild, differing interpretations of how to apply these vague laws and a circuit split is painfully obvious here. Unlike a standard medical practice, prescribing pain medication is an integral part of a pain management practice making the term "legitimate medical purpose" inherently vague. Prosecutors have arbitrarily applied these laws to secure criminal convictions even though doctors were prescribing lawful medications pursuant to the standards set forth by medical boards and pharmaceutical companies. This Court's intervention is desperately needed here.

The question presented is:

1. Whether 21 U.S.C. § 841 and 21 C.F.R. § 1306.04 are unconstitutionally vague whereas the term "legitimate medical purpose" does not provide fair notice of a standard upon which pain management medical practices can be held criminally liable.

LIST OF DIRECTLY RELATED PROCEEDINGS

1. *United States of America v. Margaret Temponeras*, District Court Case No. 1:15-cr-00065- TSB-1, United States District Court for the Southern District of Ohio (Cincinnati) (final judgment of conviction entered on February 3, 2020).

2. *United States of America v. Margaret Temponeras*, Sixth Circuit Case No. 20-3192, United States Court of Appeals for the Sixth Circuit (unpublished decision affirming judgment of conviction entered on October 16, 2020).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

CONSTITUTION AND STATUTES

REGULATIONS

RULES

OTHER AUTHORITIES

PETITION FOR WRIT OF CERTIORARI

Petitioner Margaret Temponeras respectfully petitions for a writ of certiorari to review the decision and judgment of the United States Court of Appeals for the Sixth Circuit in this case, or in the alternative, Petitioner respectfully requests that this Honorable Court summarily reverse the decision and judgment of the United States Court of Appeals for the Sixth Circuit pursuant to Supreme Court Rule 16.

OPINIONS BELOW

The United States Court of Appeals for the Sixth Circuit issued its unpublished opinion on October 16, 2020 and is reproduced at App.1-4. The opinion of the United States Court of Appeals for the Sixth Circuit is available at *United States v. Temponeras*, 828 F. App'x 320 (6th Cir. 2020). On February 3, 2020, the District Court entered a criminal judgment of conviction. App.5-14.

JURISDICTION

The Sixth Circuit issued its opinion on October 16, 2020. On March 19, 2020, this Court extended the deadline to file any petition for a writ of certiorari due on or after that date to 150 days. This Court has jurisdiction under 28 U.S.C. §1254(1).

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

The Fifth Amendment of the United States Constitution provides in relevant part:

"No person shall…be deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

21 U.S.C. § 841 provides in relevant part:

"Except as authorized by this title, it shall be unlawful for any person knowingly or intentionally - (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance." 21 U.S.C. § 841. The full text of 21 U.S.C. § 841 is reproduced at App.15-33.

21 C.F.R. § 1306.04 provides in relevant part:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the

> person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04. The full text of 21 C.F.R. § 1306.04 is reproduced at App.34-35.

STATEMENT OF THE CASE

1. Factual and Procedural History

Margaret Temponeras was a medical doctor who was indicted by the federal government (hereinafter "government") in June 2015. Indictment, RE 1, Page ID # 1. Ms. Temponeras was charged with the following criminal counts: Count 1 charged a conspiracy between defendants to distribute and dispense "diazepam, carisoprodal, hydrocodone, oxycodone, and alprazolam, not for a legitimate medical purpose and outside the scope of medical practice, in violation of 21 U.S.C. §§ 846, 841(a)(1), (b)(1)(C), (b)(1)(E), and (b)(2)"; Count 2 alleged a death resulted from the distribution of Oxycodone and other controlled substances not for a "legitimate medical purpose and outside the scope of medical practice…in violation of 21 U.S.C. §§ 841(a), (b)(1)(C), and 18 U.S.C. § 2"; Count 3 and Count 4 alleged defendant maintained a premises for the purposes of distributing controlled substances "in violation of 21 U.S.C. § 856(a)(1) and 18 U.S.C. § 2." Presentence Report ("PSR"), p. 4, ¶¶ 2-5.

Additionally, Ms. Temponeras' eighty plus year old father who was also a doctor, John Temponeras, and pharmacist, Raymond Fankell, were also charged in this alleged criminal conspiracy. Indictment, RE 1,

Page ID # 1-2. John Temponeras and the government entered into a plea agreement on or about March 15, 2017. PSR, p. 5, ¶ 11. Thereafter, Raymond Fankell and the government entered into a plea agreement on or about March 28, 2017. PSR, p. 5, ¶ 12. Margaret Temponeras forcefully defended herself against these criminal charges, but ultimately decided to resolve this criminal matter via a plea agreement filed on April 3, 2017. Plea Agreement, RE 89, Page ID # 658-665.

The plea agreement states that the "Defendant agrees to plead guilty to Count 1 of the Indictment in this case, which charges her with Conspiracy to Distribute a Controlled Substance, in violation of 21 U.S.C. § 841 and 846." Plea Agreement, RE 89, Page ID # 658. The plea agreement statement of facts sets forth that Dr. Temponeras owned and was the physician at a chronic pain management clinic and that many patients received similar combinations of medications. Plea Agreement, RE 89, Page ID # 663. The plea agreement further states that "Dr. MARGARET TEMPONERAS increased a prescription of 2mg Xanax to four pills per day…These controlled substances, to-wit: the 2mg Xanax pills. Dr. MARGARET TEMPONERAS never tapered them down from November 9, 2009 through May 9, 2011…Patient C.L. states that he believes that the number of oxycontin and oxycodone were decreased after he complained." Plea Agreement, RE 89, Page ID # 663-64. The plea agreement further sets forth that Dr. Temponeras "was aware of a high probability that such distributions were occurring…under her directions and deliberately closed her eyes to what was obvious, over prescription of the Xanax medicine, in violation of 21

U.S.C. § 846 and 841(a)(1)." Plea Agreement, RE 89, Page ID # 664.

After the plea agreement was entered into, a Presentence Report ("PSR") was prepared. The PSR reflects that Ms. Temponeras has always maintained that she was following what she believed to be appropriate medical guidelines. Ms. Temponeras maintained that "she spent sufficient time with her patients" and disputed allegations that she did not discuss alternative treatments with her patients and ignored the results of urine tests administered to her patients. PSR, p. 7, ¶ 22; p. 8, ¶ 24. The PSR also notes that Ms. Temponeras "participated in certain courses and obtained certifications in pain management." PSR, p. 5, ¶ 14. The Report notes "[l]ike many other doctors, she was being told by pharmaceutical companies that Oxycontin and other similar medications were not addictive. She was encouraged by pharmaceutical representatives to prescribe as much medication as it took to address a patient's pain." PSR, pp. 5-6, ¶ 14. The PSR also makes mention of the medical term of "titration" commenting that "doctors are supposed to follow titration which means the patients have optimal pain relief with minimal side effects." PSR, p. 7, ¶ 21.

The PSR also notes Ms. Temponeras had established safeguards to ensure that medications were not misused by patients and "had policies such as running a patient's name in OARRS and KASPER which are systems in Ohio and Kentucky that tracked controlled substance prescriptions to see if they had been flagged as abusing controlled substances, and

doing random pill counts at the clinic." PSR, p. 9, ¶ 27. Ms. Temponeras also "employed security staff … who would run record checks on patients to determine if they had been arrested or convicted for drug offenses." PSR, p. 9, ¶ 29. Ms. Temponeras' pain management clinic "was treating some of the sickest patients in the area. Those patients were typically referred to her by other physicians or they were her former patients." Sentencing Hearing Transcript, RE 107, Page ID #798.

The Sentencing Guidelines required the PSR to determine what number of pills fell outside the acceptable range. The PSR contains *an assumption* as to what prescriptions fell outside of a legitimate medical purpose. PSR, p. 11, ¶ 40. The PSR notes that only "6-8%" of prescriptions were for non-controlled substances. PSR, p. 10, ¶ 37. The PSR *contains no information as to whether this was atypical* for a pain management medical practice. The PSR then utilized the records of 26 patients to make assumptions at to what prescriptions were deemed inappropriate and came to a total by explicitly stating that "[i]f it is assumed that the amount of Oxycodone and Oxycontin prescriptions given to these patients … were improper and outside appropriate medical practice, the total would be …." PSR, p. 11, ¶ 40. This assumption never considered that "doctors are supposed to follow titration which means the patients have optimal pain relief with minimal side effects." PSR, p. 7, ¶ 21. Despite acknowledging that the dosage of the medication must provide optimal pain relief with minimal side effects, the PSR did not determine which amounts were in excess, but *rather assumed* every pill dispensed was inappropriate.

Thereafter, a sentencing hearing was held to determine Ms. Temponeras' sentence. The plea agreement had established an agreed upon sentencing range of thirty-six months to eight-four months. Plea Agreement, RE 89, Page ID # 659. At the Sentencing Hearing, the government acknowledged the Ohio Medical Board had failed Ms. Temponeras. Sentencing Hearing Transcript, RE 107, Page ID # 780-781. Despite this acknowledgement, the government argued that Ms. Temponeras was essentially running a pill mill with no legitimate medical purpose. The government argued that red flags made her aware that her prescription practices were excessive and brought in last-minute exhibits at the sentencing hearing to establish this argument. The government argued these exhibits clearly showed that Ms. Temponeras was warned and on notice. The exhibits provided by the government, however, clearly note that even though a letter from a pharmacy may alert a doctor to an issue with a prescription, the letter does not usurp the doctor's professional medical judgment explicitly stating "[w]hile this information is not intended to replace your clinical judgment, we hope you find it helpful in planning the best course of therapy for your patients." Sixth Cir. Apx 24. The government argued that OARRS reports indicated that Ms. Temponeras' prescriptions were excessive. Again, these reports are considered an aid to doctors to ensure that patients are not obtaining prescriptions from multiple sources. These OARRS reports found in Exhibit 4 clearly forewarn that this may not be accurate information. Sixth Cir. Apx 36-37. Indeed, public information reveals that OARRS reports have been plagued with

inaccuracies, inconsistencies and material falsehoods.[1, 2] These OARRS reports are not intended to usurp a doctor's medical opinion.

At the conclusion of the sentencing hearing, Margaret Temponeras was sentenced to 84 months in a federal prison – the maximum sentence under the terms of the plea agreement. Dkt 11/12/2019 Minute Entry, Sixth Cir. Apx 15-16; Plea Agreement, RE 89, Page ID # 659. The criminal judgment was entered on February 3, 2020. App.5-14. A timely appeal was filed

---

[1] In November 2017, the State Medical Board of Ohio issued the following release:

> Please be advised that the State of Ohio Board of Pharmacy sent out emails this morning to approximately 7,000 prescribers indicating failure to comply with laws requiring the use of the Ohio Automated Rx Reporting System (OARRS). The emails were erroneously distributed without the knowledge of the State Medical Board of Ohio, Ohio Board of Nursing or the Ohio State Dental Board and may contain inaccurate information. If you received this morning's email, please disregard it. You do not need to take any further action at this time. The Pharmacy Board apologizes for this mistake and any concerns it may have caused.

See, https://med.ohio.gov/Publications/Recent-News/state-of-ohio-board-of-pharmacy-mistakenly-sends-oarrs-email

[2] In October 2018, the Ohio Academy of Family Physicians wrote a letter to the Medical and Pharmacy Boards regarding the inaccuracies in the OARRS Reports such as "missing codes," "tying a physician to the wrong medical license number," and even an instance of "a physician received a non-compliance report for August when the physician was not even practicing medicine." *See*, https://www.ohioafp.org/wfmu-article/oafp-addresses-problems-with-august-oarrs-compliance-reports/

on February 14, 2020. Notice of Appeal, RE 111, Page ID # 853-854.

Thereafter, Petitioner pursued an appeal in the United States Court of Appeals for the Sixth Circuit. On appeal, Ms. Temponeras argued that the in the context of a pain management medical practice, 21 U.S.C. § 841 and 21 C.F.R. §1306.04 are unconstitutionally vague.

The Sixth Circuit affirmed the judgment of the District Court on October 16, 2020. App.1-4.

2. How the federal question sought to be reviewed was raised.

On direct appeal to the United States Court of Appeals for the Sixth Circuit, the Petitioner argued that in the context of a pain management medical practice, 21 U.S.C. § 841 and 21 C.F.R. § 1306.04 are unconstitutionally vague because 21 U.S.C. § 841 and 21 C.F.R. § 1306.04 do not provide fair notice of a standard upon which pain management medical practices can be held criminally liable. Unlike a standard medical practice, prescribing pain medication is an integral part of a pain management practice making the term "legitimate medical purpose" inherently vague.

REASONS FOR GRANTING THE WRIT

The Sixth Circuit's decision is the ideal vehicle to address whether the Controlled Substances Act, 21 U.S.C. § 841, and 21 C.F.R. § 1306.04 are unconstitutionally vague as applied to pain management medical practices. These laws do not provide fair notice of a standard upon which doctors who have pain management medical practices can be held criminally liable. The inherent nature of a pain management medical practice is to treat pain for which all other medical remedies have failed. As such, the long-term treatment of patients through controlled substances is an inherent part of the medical practice.

"Congress enacted the Comprehensive Drug Abuse Prevention and Control Act of 1970 ('the Act') in response to President Nixon's declared 'war on drugs.'" *United States v. Green*, 222 F. Supp. 3d 267, 271 (W.D.N.Y. 2016)(citation omitted). The problem with this statute which has been in effect for approximately fifty years is that it does not reflect the modern medical practice of pain management and it fails to take into account the ever-changing medical standards regarding prescribing practices. For instance, medical marijuana clinics have recently been established to treat those afflicted with chronic pain even though the federal government classifies marijuana as a drug with no legitimate medical purpose. This makes the term "legitimate medical purpose" inherently vague in the context of pain management.

Currently, medical doctors who have never had any criminal record are being swept up in a political push

to punish someone for the opioid epidemic that has plagued this country. These vague terms are being used by federal prosecutors to round up and prosecute doctors who were prescribing opioids at a time when the medical profession was advising doctors that their prescribing practices were appropriate, legitimate, and lifesaving. This national roundup is based upon the number of pills doctors prescribed to patients without regard to the medical standards at the time the pills were prescribed. These doctors have had their careers ruined and have been banished to long prison sentences based upon a prosecutor's interpretation of what a legitimate medical practice entails rather than what the medical profession believed at the time. Prosecutors have failed to remember that pharmaceutical companies touted these drugs as critical treatment to combat chronic pain, and medical boards throughout this country echoed this sentiment.

I. This Court has never provided clarity on the vague term "legitimate medical practice" encompassed in 21 U.S.C. § 841 and 21 C.F.R. § 1306.04 resulting in haphazard application of these laws and a circuit split. Ultimately, this vague term has allowed the government to criminalize a practice of medicine that was accepted and practiced by doctors in the medical community.

The Controlled Substances Act, 21 U.S.C. § 841, states "[e]xcept as authorized by this title, it shall be unlawful for any person knowingly or intentionally - (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a

controlled substance." 21 U.S.C. § 841. The statute provides an exception for medical professionals to dispense these controlled substances if they are registered. *United States v. Birbragher*, 603 F.3d 478 (11th Cir. 2010).

While medical professionals are permitted to dispense controlled substances, in 1975, this Court established that a medical professional can be prosecuted "under 21 U.S.C. § 841 when their activities fall outside the usual course of professional practice." *United States v. Moore*, 423 U.S. 122, 124 (1975). With regard to the prosecution of doctors, the statute is read in conjunction with 21 C.F.R. § 1306.04 which provides that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. In *United States v. Moore*, 423 U.S. 122 (1975), this Court never addressed what constituted a legitimate medical purpose because the Court noted "[i]n the case of methadone treatment the limits of approved practice are particularly clear," the defendant admitted he was not authorized to conduct a methadone maintenance clinic and had previously agreed to abide by "certain medical procedures in future methadone programs" which he admittedly failed to follow. *Id.* at 144-45. As such, what constituted a "legitimate medical purpose" and "outside the scope" were never put at issue and thus, never decided by this Court.

In the context of a pain management medical practice, 21 U.S.C. § 841 and 21 C.F.R. § 1306.04

simply do not clearly define its prohibitions and does not give "ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Johnson v. United States*, 576 U.S. 591, 595 (2015); *Grayned v. City of Rockford,* 408 U.S. 104, 108 (1972). Due process principles advise that a penal statute is void for vagueness if it does not clearly define its prohibitions. *Grayned v. City of Rockford,* 408 U.S. 104, 108 (1972). The Fifth Amendment provides that "[n]o person shall ... be deprived of life, liberty, or property, without due process of law." *Johnson v. United States*, 576 U.S. 591, 595 (2015). United States Supreme Court cases clearly "establish that the Government violates this guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Id.*; *Kolender v. Lawson,* 461 U.S. 352, 357 (1983).

The law provides that "a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process." *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926). As such, it is essential that a criminal statute make clear what conduct is prohibited so that an ordinary citizen can "conform his or her conduct to the law." *City of Chicago v. Morales*, 527 U.S. 41, 58 (1999). Criminal statutes must also "establish minimal guidelines to govern law enforcement." *Smith v. Goguen*, 415 U.S. 566, 574 (1974). This Court has held "[n]o one may be required at peril of life, liberty or property to speculate as to the

meaning of penal statutes." *Lanzetta v. New Jersey,* 306 U.S. 451, 453 (1939).

This Court has stated "it would certainly be dangerous if the legislature could set a net large enough to catch all possible offenders and leave it to the courts to step inside and say who could be rightfully detained, and who should be set at large." *United States v. Reese*, 92 U.S. 214, 221 (1875). Unfortunately, these laws as applied to pain management medical practices casts such a net. Moreover, the vagueness of these terms is only compounded by the Sixth Circuit precedent which provides that "[t]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice." *United States v. Volkman*, 797 F.3d 377, 388 (6th Cir. 2015). The Sixth Circuit has explicitly stated that "we have endorsed a broad approach to determining what conduct falls outside the accepted bounds of professional practice so as to constitute a CSA violation, eschewing a preestablished list of prohibited acts in favor of a case-by-case approach." *Id*. at 386. This acknowledgment by the Sixth Circuit is an admission that *this is a vague statute*. This Court has noted "[v]ague laws invite arbitrary power…they can invite the exercise of arbitrary power all the same – by leaving the people in the dark about what the law demands and allowing prosecutors and courts to make it up." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1223-24 (2018). It has been noted that "although *Moore* affirmed that practitioners can be prosecuted under Section 841…[the] startling facts and the limited questions presented to the Court

have left lower courts to interpret the appropriate boundaries for practitioner liability. Understandably, this has led to uncertainty and a circuit split." *United States v. Houdersheldt*, No. 3:19-00239, 2020 U.S. Dist. LEXIS 241736, at *17-18 (S.D. W. Va. Dec. 23, 2020). The First, Seventh and Ninth Circuits have held that criminal liability only attaches if a "defendant deliberately acted without a legitimate medical purpose or outside the bounds of medical practice." *Id*. The Tenth Circuit held that "nothing in the statutory language at 21 U.S.C. § 841(a)(1), the regulatory language at 21 C.F.R. § 1306.04, or any case law [] requires the physician to 'knowingly" act without a legitimate medical purpose or outside the usual course of professional practice." *Id*. at *19. Simply put, the application of these laws is a legal mess.

II. The inherent vagueness of the law is exacerbated by continuing changes in medical opinion and conflicting laws. What was deemed appropriate while Petitioner was practicing medicine, has now been castigated as illegitimate by the government by virtue of these inherently vague provisions.

Throughout her time practicing pain management, the Medical Board of Ohio saw *no issue* with Ms. Temponeras' prescription practices. Defendant's Sentencing Memorandum, RE 106, Page ID # 721. "The Medical Board is responsible for, among other tasks, conducting random patient and record reviews. From 2005 through 2011, Ms. Temponeras and *her clinic received positive feedback from the Medical Board*." *Id.* (emphasis added). "Not once did the

Medical Board indicate that she should lower the amount of controlled substances she prescribed or alter her treatment protocols." *Id.* "The Medical Board even cleared Ms. Temponeras after several complaints were made about her clinic, *telling her each time that she was operating it appropriately and in full compliance with the law*." *Id.* (emphasis added). In fact, "[o]ne year before her clinic was shut down, Ms. Temponeras also applied for a three-year DEA license. The DEA inspected her practice, indicated there were no problems, and granted her the license." *Id.*

At the sentencing hearing, the government took the positive feedback Ms. Temponeras received from the Medical Board and touted it as no excuse for Ms. Temponeras' prescription practices. Instead, the government stated that the Medical Board admitted under oath that they failed in their duties and used this to sidestep the fact that the Medical Board at the time she was practicing found Ms. Temponeras' prescribing practices legitimate and therefore lawful. Sentencing Hearing Transcript, RE 107, Page ID # 780-781.

The government's argument that the Ohio Medical Board failed Ms. Temponeras highlights the inherent vagueness of the laws at issue. These amorphous provisions are now being used to prosecute doctors for a change in medical and public opinion regarding the prescription of opioids. What the Medical Board deemed appropriate while Ms. Temponeras was practicing, has now been castigated as inappropriate. Ms. Temponeras could have no knowledge at the time she was practicing medicine that the legitimacy of her

practice *would be retroactively deemed illegitimate*. The danger of this amorphous statute is that "[a] vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1228 (2018)(citation omitted).

The ambiguity as to what falls outside the scope of a legitimate medical practice becomes evident in the PSR and the sentencing hearing. The PSR notes that Ms. Temponeras "participated in certain courses and obtained certifications in pain management." PSR, p. 5, ¶ 14. The PSR notes "[l]ike many other doctors, she was being told by pharmaceutical companies that Oxycontin and other similar medications were not addictive. She was encouraged by pharmaceutical representatives to prescribe as much medication as it took to address a patient's pain." PSR, pp. 5-6, ¶ 14. The PSR references the medical term "titration" commenting that "doctors are supposed to follow titration which means the patients have optimal pain relief with minimal side effects." PSR, p. 7, ¶ 21.

After recognizing that legitimate medical practice requires a doctor to prescribe dosages that give patients "optimum pain relief with minimum side effects," the PSR contains assumptions which completely ignore this medical standard. The PSR required the probation officer to determine what pills were prescribed outside of a legitimate medical practice. The inherent ambiguity in the statute resulted in an absurd calculation relied upon in Ms. Temponeras' sentencing. In the PSR, the probation officer notes that only "6 to 8%" of prescriptions were

for non-controlled substances but contains no information if this percentage is uncommon for a pain management medical practice. PSR, p. 10, ¶ 37. The PSR then utilized the records of 26 patients to make assumptions at to what prescriptions were deemed inappropriate. In calculating the drug totals, the PSR explicitly states "[i]f it is assumed that the amount of Oxycodone and Oxycontin prescriptions given to these patients … were improper and outside appropriate medical practice, the total would be …." PSR, p. 11, ¶ 40. Given the inherently vague provisions of the statutes, the PSR assumed every pill dispensed was illegitimate.

Ms. Temponeras' clinic was not a general doctor's office. It was solely for the treatment of people in chronic pain. Ms. Temponeras' pain management clinic "was treating some of the sickest patients in the area. Those patients were typically referred to her by other physicians or were her former patients." Sentencing Hearing Transcript, RE 107, Page ID #798.

Of course, Ms. Temponeras would distribute more pills than the average family practitioner. This is because pain management focuses on patients who suffer from debilitating, chronic pain. Unfortunately, there are people who suffer from unforeseen car accidents, sporting injuries, military combat injuries and freak occurrences that lead to chronic pain. Additionally, there are other people who develop chronic conditions simply because this is the cards that life has given them or perhaps, they practice an occupation that is particularly taxing on the body. For instance, it is not uncommon for a person to suffer from

a spinal injury in their early thirties. In another instance, a coal miner's body may be afflicted with more chronic pain ailments than the average person. Pain management practices were started to attend to the needs of these particular people. These laws, drafted so many decades ago, are simply void for vagueness in their application to a pain management practice – a medical practice which often requires the prescription of pain alleviating drugs.

At the time *Moore* was decided in 1975, the medical community and the public at large believed that opioids were inherently dangerous. This widely held belief took a drastic swing in the 1990s. During the 1990s, there was a tremendous change in public opinion as well as medical opinion regarding the efficacy and legitimacy of opioid prescriptions. Opinions began to shift from the belief that prescription of opioids caused addiction to the opinion that the underprescription of opioids was a contributing factor to the illicit drug epidemic.[3] The rationale became that people were seeking illicit narcotics because doctors were not adequately addressing patients' pain.[4] At the time, articles were published linking the inability to obtain prescriptions for intractable pain as a reason why

---

[3] *See*, Science Direct, *Clinical Solutions to Chronic Pain and the Opiate Epidemic*, https://www.sciencedirect.com/science/article/pii/S0091743518303098?via%3Dihub

[4] *Id.*

individuals were seeking illicit drugs.[5] A change in medical and public opinion took place.

The medical community was urged to treat pain as a "Fifth Vital Sign" and doctors were being admonished for not adequately treating patients' pain.[6] The concept of pseudoaddiction became accepted by the medical community and was advanced by independent medical societies.[7] Pseudoaddiction was the belief that patients with pain will exhibit drug seeking behaviors if their pain is not adequately treated by their doctor.[8] Doctors were advised that addiction was rare in patients under medical supervision and drug seeking behavior was simply a doctor failing to adequately prescribe pain medication.[9] Medical journals detailed that pain and anxiety were inextricably linked and doctors should treat both issues concurrently.[10] Doctors were advised that opioids, such as Oxycontin, and anxiety medication, such as Xanax, should be used together to effectively treat pain.

---

[5] *Id.*

[6] *Id.*

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] *See*, Practical Pain Management, *Benzodiazepines and Opioids: Only Trained Pain Practitioners Should Prescribe*, https://www.practicalpainmanagement.com/treatments/pharmacological/benzodiazepines-opioids-only-trained-pain-practitioners-should-prescribe

This change in medical consensus led to the passage of Intractable Pain Laws. California was the first state to pass intractable pain laws with the reasoning that doctors were not adequately treating patients' pain because doctors feared criminal prosecution if they prescribed opioids.[11] Other states began to follow California's lead and began passing their own intractable pain laws.[12] These laws were intended to allow doctors to prescribe opioids in amounts that were previously thought to be improper with the new medical guidance that underprescribing was the real issue and not overprescribing.[13] The State of Ohio's intractable pain law, pursuant to which Ms. Temponeras practiced, explicitly allowed for the use of prescription drugs "on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions." App.36; OAC Ann. 4731-21-02 (2005). Oxycontin was touted as a safe and effective opioid. At the time, it was believed that the slow-release nature of the medication made it

---

[11] *See*, Practical Pain Management, *State Pain Laws: A Case for Intractable Pain Centers Part III*, https://www.practicalpainmanagement.com/resources/ethics/state-pain-laws-case-intractable-pain-centers-part-iii

[12] *Id.*

[13] *Id.*

a safe medication for treating intractable pain.[14] The FDA approved dosing instructions on these opioids clearly set forth doctors should increase dosages as tolerance for a drug increases. Additionally, the American Pain Society and other industry leaders promoted the concepts of pain as the "5th Vital Sign" and pseudoaddiction. Medical journals propounded these concepts as well. Medical societies also hosted medical education seminars and issued treatment guidelines throughout the late 1990s until mid-2010s.

Unbeknownst to doctors at the time, was that the medical boards and the medical community at large were defrauded by the pharmaceutical companies. App.52-53, ¶ 88-89. Specifically, the Attorney General of Ohio set forth that pharmaceutical companies engaged in a "deceptive marketing campaign [which] deprived Ohio patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype." App.50, ¶14. The Attorney General of Ohio set forth that these pharmaceutical companies "controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars." App.51, ¶ 45. The Attorney General of Ohio also set forth that the American Academy of Pain Management and the American Pain Society issued guidelines that were a "particularly effective channel of

---

[14] *See*, Cato Institute, *Overdosing on Regulation - How the Government Caused the Opioid Epidemic*, https://www.cato.org/policy-analysis/overdosing-regulation-how-government-caused-opioid-epidemic

deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Ohio during the relevant time period, are still available online, and were reprinted in the Journal of Pain." App.51-52, ¶ 84. In the early 2010s, newspaper articles began to expose that pharmaceutical companies had engaged in a pervasive campaign to promote prescription of their opioid products. Doctors and patients relied on this information. In the mid-2010s, this new information caused the medical community's attitude to shift again.

This societal pivot away from prescription opioids was palpable. Ohio's intractable pain law which provided that Ms. Temponeras could prescribe opioids "on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions" was eventually repealed in 2018 – well *after* the indictment of Ms. Temponeras. App.36; OAC Ann. 4731-21-02 (2005). Before the statute's repeal, however, this provision of the intractable pain law remained in the statute until it was removed in 2017 – *long after* Ms. Temponeras ceased practicing medicine. App.42; OAC Ann. 4731-21-02 (2017). A National Law Review article noted that "[o]n December 23, 2018, new State Medical Board of Ohio regulations became effective which marked another change in the legal standards governing provider use of opiates for treatment of pain. Notably, these new regulations also serve to rescind and replace Ohio's previously long-standing 'Chronic Pain Rules,' also known as the 'Intractable Pain Rules,' which were

first adopted as a component of the earlier '5th Vital Sign' era which preceded the current opioid epidemic. In this respect, these new rules eliminate the last remaining regulatory vestige of that prior era."[15]

The climate at the time Ms. Temponeras opened her pain management medical practice is akin to the medical marijuana industry today. The current opinion about marijuana has changed significantly over time. The pendulum of opinion has swayed significantly from the 1980s classroom lectures that you should "just say no" because marijuana is a "gateway drug" with absolutely no legitimate medical purpose. Today, medical marijuana is considered a legitimate medical industry by most state governments and has been touted in the medical community as an effective remedy for almost every ailment including chronic pain, anxiety, autoimmune disorders and infectious diseases.[16]

Incredibly, despite state laws allowing for the distribution of medical marijuana, marijuana is still classified as a Schedule I drug defined as having "no legitimate medical purpose" under federal law. *United States v. Green*, 222 F. Supp. 3d 267, 271-72 (W.D.N.Y.

---

[15] *See*, National Law Review, *Standards for Use of Opiates in Treatment of Pain Changes in Ohio*, https://www.natlawreview.com/article/standards-use-opiates-treatment-pain-changes-ohio

[16] *See*, Ohio Marijuana Card, *Understanding Pain that is Chronic, Severe or Intractable*, https://www.ohiomarijuanacard.com/post/understanding-pain-that-is-chronic-severe-or-intractable

2016). Ten years from now, doctors and clinicians who are now relying on state's medical marijuana laws may likely be subjected to the same criminal prosecutions as pain management doctors now face. Indeed, the government can utilize even stronger arguments against the medical marijuana industry citing that the federal law does not recognize any legitimate medical purpose for the dispensation of marijuana. Unlike medical marijuana, opioids have always been classified as having a legitimate medical use as is noted by its classification as a Schedule II drug.

To avoid engaging in a criminal act, a person must be aware of the prohibited conduct as defined by the law. The Sixth Circuit readily acknowledges that its approach to these laws is not to define any proscribed conduct. As such, a medical practitioner does not have any notice of what conduct is considered outside the legitimate bounds of practice. This is not a standard, but rather a hit or miss proposition. Ultimately, a case is not prosecuted on whether a criminal law is violated, but rather if a doctor is within the crosshairs of a federal prosecutor. These are inherently vague laws which give prosecutors way too much power in determining whether a crime is committed. Without specific guidelines, a prosecutor determines whether a doctor has engaged in criminal conduct inviting the arbitrary exercise of power which is exactly what the law prohibits. These vague laws are inherently dangerous and again cede too much power to an unelected federal prosecutor. For instance, a patient may be borderline diabetic and seek the advice of several doctors to treat this ailment. Doctor A may immediately argue that aggressive medication is

needed, but in contrast Doctor B may advocate for a change in diet and a daily exercise routine. Do we now live in an environment where we criminalize an alternative form of treatment?

Chronic pain has been treated by doctors in accordance with the standards set forth by the medical community. Medical standards fluctuate throughout time based upon new studies and discoveries. Often, there arises a medical debate as to appropriate medical standards and practices.[17] Medical doctors practice in this atmosphere and must make professional judgments as to courses of treatment based upon the information available to them. Doctors should not be prosecuted under amorphous legal standards that are impossible to clearly define and ultimately impossible to defend against. The government knows the actual culprit here. Many pharmaceutical companies deceived the public and the medical community regarding their product. As such, these vague statutes are providing a platform to pursue and punish the wrong people. Doctors are placed in the unenviable position of facing decades in prison and/or a ten-week trial which is financially crippling. Let us be frank, this is why most doctors prosecuted under these statutes take a plea of guilty. Unless this Court intervenes, the government can arbitrarily prosecute doctors even though these medical professionals followed the standards set forth

---

[17] These medical differences of opinion can be readily seen in the open debates as to the use of hydroxychloroquine for the treatment of Covid-19 just this past year. Numerous doctors said the treatment could save lives. Others deemed the usage of the drug dangerous.

by the medical community and pursuant to the direction of pharmaceutical companies.

This Court's intervention is also needed whereby there is an existing circuit split as to how to apply these very vague, dangerous laws. Currently, this is not a legal standard but a non-legal crapshoot. These vague laws may soon ensnare the purveyors of medical marijuana dispensaries which may face federal criminal prosecution because the winds of public and/or medical opinion have changed regarding the use of medical marijuana. The passage of time has made the terms "legitimate medical practice" and "outside the scope" too amorphous and they are clearly vague. This Court's intervention here is desperately needed.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

Alexandra C. Siskopoulos
Counsel of Record
Siskopoulos Law Firm, LLP
33 West 19th Street, 4th Floor
New York, New York 10011
(646) 942-1798
acs@siskolegal.com

Counsel for Petitioner

March 12, 2021