# JAILING HIPPOCRATES:

## CRIMINALIZING DEVIATIONS FROM THE OPIATE PRESCRIBING STANDARD OF CARE AND ITS CHILLING EFFECT ON HEALTH CARE


### Abstract

Since the United States Supreme Court's landmark decision in United States v. Moore, Federal Courts disagree with the appropriate standard used to convict a physician as a "drug trafficker" under 21 U.S.C. § 841(a)(1). Historical decisions have slowly deviated from the standard set in Moore such that physicians are now being convict for mere deviations from the ambiguous, and often shifting, standard of care.



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"And is it not true that historically most, if not all of the great breakthroughs and advances in medical science are made by people who did not follow the conventional way of doing things. They followed a new way, their way, and most of the conventional physicians of their day would have disagreed with them because this is not the way it has always been done . . . . It bothers me that this kind of evidence . . . is the basis for criminal liability. This man was a physician, he was not a fraud."

- Justice Potter Stewart[1]

[1] At oral argument in *United States v. Moore*, 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.

# I. INTRODUCTION

Despite nearly 100 years of controlled substance jurisprudence, courts are still split and often confused about the standard of evidence required to convict a practitioner[2] of prescribing controlled substances unlawfully. Since the United States Supreme Court's landmark decision in *United States v. Moore,* finding that a doctor can be convicted as a drug trafficker under 21 U.S.C. § 841(a)(1) for unlawfully prescribing controlled substances, federal circuits have shifted to interpret 21 U.S.C. § 841(a)(1) as not prohibiting the non-medical prescribing of drugs, but rather, a deviation from a medical standard.[3] Such a shift presents a danger to the medical community as predicted by Justice Potter Stewart during oral argument in *United States v. Moore.*[4] A practitioner must not be convicted for a violation of 21 U.S.C. § 841(a)(1) for a simple deviation from a medical standard; a practitioner can only be convicted for trafficking controlled substances when a prescription is issued for what the practitioner believes to be a non-medical purpose. Applying an objective "standard of care" to 21 U.S.C. §841(a)(1) would create a chilling effect on the practice of medicine and impact the delivery and quality of health care.

In order to fully appreciate the current shift towards the application of an objective standard of care when analyzing a physician's prescribing practices, it is important to review the formation of the *Controlled Substances Act*, ("CSA") prior legislation including the *Harrison Narcotics Act*, and previous controlled substance jurisprudence.[5] The *Harrison Narcotics Act* is the first instance in United States history in which a physician's actions could be criminalized if the physician failed to comply with the "physician's exemption" by prescribing outside the bounds of professional

[2] The term "practitioner" is used to describe any health professional with prescriptive authority as defined by 21 C.F.R. § 1301.01. This includes physicians, nurse practitioners, physician assistants, veterinarians, dentists, and any other health professional or entity granted the ability to issue a prescription for controlled substances.
[3] *United States v. Moore,* 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.
[4] *Id.*
[5] Ch. 1, 38 Stat. 785 (1914).

practice.[6] The *Controlled Substances Act*, the successor to the *Harrison Narcotics Act*, borrowed the language of the *Harrison Narcotics Act* and also applied anti-drug trafficking laws to physicians.[7] Under the *Controlled Substances Act* (CSA), it is unlawful to knowingly manufacture, distribute, or dispense a controlled substance.[8] However, a physician is exempt from this provision if he or she issues a prescription "for a legitimate medical purpose in the usual course of professional practice."[9]

The *Harrison Narcotics Act* and related jurisprudence were also driving factors behind the Supreme Court's landmark decision in *United States v. Moore,* which was the first substantive challenge by a physician to the CSA's application of drug trafficking laws to physicians.[10] The Supreme Court held that a physician could be prosecuted as a drug trafficker for prescribing for no legitimate medical purpose and outside the course of professional practice.[11] Unfortunately, since the Supreme Court's decision in *United States v. Moore*, the Supreme Court has been silent regarding the standard to be applied to physicians accused of violating 21 U.S.C. § 841(a)(1). The dividing line between legal and illegal conduct also remained hazy due to circuit splits and varying interpretations by the lower circuit courts of appeals.[12] However, the Supreme Court seemed to answer the call in 2005 in its decision in *Gonzales v. Oregon*, making clear that the regulation of medical practice is reserved for the states and that the CSA does not regulate the practice of

[6] *Compare* § 2(a), 38 Stat. at 786, *with* 21 U.S.C. §§ 801 (2012).
[7] *Compare* § 2(a), 38 Stat. at 786, *with* 21 U.S.C. §§ 841. *See also* C.E. Terry, *The Harrison Anti-Narcotic Act,* 5 AMER. J. PUB. HEALTH, 518, 518 (1915).
[8] 21 U.S.C. § 841(a)(1).
[9] 21 C.F.R. § 1306.04
[10] *Moore*, 423 U.S. at 131-33.
[11] *Id.*
[12] *Compare United States v. Boccone*, 556 Fed. App'x. 215, 229 (4th Cir. 2014) (holding that a case-by-case analysis is required to determine if a physician prescribed unlawfully and that the government must prove that the physician knowingly and intentionally prescribed not for other than a legitimate medical purpose in the usual course of professional practice), *and United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006) (applying an objective standard of care to evaluate whether a physician's conduct was unlawful).

medicine beyond prohibiting a doctor from acting as a "pusher" instead of a physician.[13] The Supreme Court determined that states' rights to regulate the practice of medicine were only preempted insofar as the CSA prevents doctors from using their prescription-writing powers *as a means to engage in illicit drug trafficking as conventionally understood.*[14] However, the *Gonzales* decision was pigeonholed by lower courts as merely a prohibition on the Attorney General's authority to define the bounds of legitimate medical practice and not a reminder by the Supreme Court that § 841 is only to be applied to doctors who abandon their medical role and become drug pushers.[15]

Since *Gonzales*, varying federal circuit interpretations of the statutory language of 21 U.S.C. § 841(a)(1) regarding "legitimate medical purpose" and "course of usual professional practice" have held doctors to heightened, and often shifting, standards used to criminalize conduct such as failure to recognize signs of drug diversion or failure to perform a physical exam.[16] DEA guidance suggests that the term "legitimate medical purpose" means "in accordance with a standard of medical practice generally recognized an accepted in the United States."[17] Other courts have disagreed with this approach, holding that mere violations of the standard of care do not equate to criminal conduct.[18] The problem with the application of an objective "standard of care" to physician prescribing is that there is no objective empirical evidence supporting a specific

[13] *Gonzales v. Oregon*, 546 U.S. 243, 269 (2005).
[14] *Id.*
[15] *Feingold*, 454 F.3d at 1011 n.2 (*Gonzales* held only that the Attorney General lacked power to define legitimate medical practices so as to directly oppose state law); *see also United States v. Ahuja*, 209 F.Supp. 3d 489, 495 (D. Conn. 2016).
[16] *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006); *United States v. Kaplan*, 895 F.2d 618, 620-21 (9th Cir. 1990) (issuing prescriptions absent a physical exam is evidence of conduct "outside the course of usual professional practice"); *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978) (failure to conduct a physical exam and failure to recognize signs of diversion was evidence of an unlawful purpose).
[17] 71 FR 52716. *See also United States v. Norris*, 780 F.2d 1207, 1209 n.2 (5th Cir. 1986).
[18] *Feingold*, 454 F.3d at 1007-08.

standard of care, and physicians widely disagree about the propriety of administering narcotics for short term pain or to addicts.[19] Even physicians in the pain management community struggle with the standard to be applied to prescribing practices.[20] As a result from the fundamental shift from the Supreme Court's decision in *United States v. Moore*, federal drug trafficking cases against physicians are the only realm in which juries are tasked with applying complicated medical concepts to vague and overbroad elements in order to determine if a physician should be convicted and sentenced to decades in prison due to a medical disagreement. Due process demands that we more strictly define the concepts of "legitimate medical purpose" and "course of professional practice." The federal shift towards the use of "standard of care" in the context of physician drug trafficking cases usurps the power of the states to regulate the practice of medicine by permitting federal regulators to determine the scope of the appropriate practice of medicine and has a detrimental effect on access to care. It is incumbent upon the Supreme Court to reaffirm its decision in *United States v. Moore* that a physician may only be convicted for a violation of 21 U.S.C. § 841(a)(1) for prescribing controlled substances for what the physician believes is a non-medical purpose.

## II. THE HISTORY OF CONTROLLED SUBSTANCES LAWS AND REGULATIONS

In the nineteenth and twentieth centuries, drug control policy was largely a revenue measure in order to capture revenue from the extensive Chinese opium trade.[21] Noticing the

[19] Michael Potter et al., *Opioids for Chronic Nonmalignant Pain: Attitudes and Practices of Primary Care Physicians in the UCSF/Stanford Collaborative Research Network,* 50 J. FAM. PRAC. 145, 148 (2001).
[20] Katherine Goodman, *Prosecution of Physicians as Drug Traffickers: The United States' Failed Protection of Legitimate Opioid Prescription Under the Controlled Substances Act and South Australia's Alternative Regulatory Approach,* 47 COLUM. J. TRANSNAT'L L. 210, 226-227 (or example, physicians widely disagree about the propriety of administering narcotics for short-term pain or to addicts, and there is little agreement about the addiction risks that narcotics present).
[21] T.M. Quinn & G.T. McLaughlin, *The Evolution of Federal Drug Control Legislation,* 22:3 CATHOLIC UNIVERSITY L. REV. (1973).

growing problem of addiction due to the high availability of opium products, the United States enacted the *Tariff Act of 1832* to curb addiction.[22] While opium was not initially taxed as part of the law, in 1842, opium was placed on the tariff lists and a tax of 75 cents per pound was levied on all opium.[23] As opium use became more popular, subsequent amendments to the *Tariff Act of 1832* increased the tax until opium was taxed at the astonishing rate of 80% in 1862.[24] During the late nineteenth century the national appetite for opium continued to grow, and chemists began making patent medicines heavily laced with opium, morphine, and cocaine.[25] The federal response to rampant opiate addiction in the early twentieth century was swift, but only focused on labeling restrictions in order to increase consumer information about the effects of opiates.[26] The *Pure Food and Drug Act of 1906* made it unlawful to sell a mixture containing opium, cocaine, and other listed substances if the label did not clearly indicate the presence of the listed substance.[27] Further controls during the early twentieth century came in the form of import and export controls in order to stem the flow of opium from China.[28]

The *Harrison Narcotic Tax Act of 1914* ("the Act") was the first substantial step towards the closed system of distribution of narcotics and the limitation of narcotics to prescriptions issued by physicians for "legitimate medical purposes."[29] Interestingly, like its predecessors, the Act was still a revenue measure essentially making it illegal to distribute narcotics without a tax stamp, which cost one dollar per year.[30] However, the Act went further and required that distributors

[22] *See* Tariff Act of 1832, Ch. 227, § 3, 4 Stat. 590 (1832).
[23] Ch. 270 § 8, 5 Stat. 548 at 558 (1842).
[24] Ch. 163, § 5, 12 Stat. 543 at 548 (1862).
[25] *See* source cited *supra* note 21, p. 591.
[26] *Id.*
[27] Ch. 3915, 34 Stat. 768 (1906).
[28] Ch. 100, 35 Stat. 614 (1909); International Opium Convention, The Hague (Jan. 23, 1912), 38 Stat. 1912 (1915).
[29] Ch. 1, 38 Stat. 785 (1914).
[30] Ch. 1, § 6, 38 Stat. 785 (1914).

register with the local Internal Revenue Collector and keep meticulous records of drug transfers.[31] In addition, the Act required a "written order" which must be kept by the distributor or prescriber for two years.[32] The Act also contained a specific exemption where an order for a drug was issued by a physician to a patient in the "course of his professional practice."[33]

*United States v. Jin Fuey Moy* was one of the first cases in which the Supreme Court was asked to determine the applicability of the *Harrison Tax Act* to a physician's practice.[34] Dr. Jin Fuey Moy was indicted for engaging in a conspiracy with Willie Martin to distribute morphine sulphate.[35] Mr. Martin was not registered with the local Internal Revenue Collector as required by the Act and, as such, could only receive the morphine sulfate pursuant to a written prescription.[36] Dr. Moy issued prescriptions to Mr. Martin and the indictment alleged that the prescriptions were not written "in good faith" and not for a "medical purpose" but rather simply for the purpose of supplying Mr. Martin drugs to feed his addiction.[37] Given that Mr. Martin was not registered under the Act and was not a patient receiving medication for a "medical purpose," the government indicted Dr. Jin Fuey Moy.[38] The court reasoned that the Act was created pursuant to a treaty and was enacted pursuant to the government's spending power and, therefore, did not apply generally to the public but rather only to those that the Act sought to regulate.[39] The court declined to give

[31] *Id.*
[32] Ch. 1, § 3, 38 Stat. 785 (1914).
[33] *Id.*
[34] *United States v. Jin Fuey Moy,* 241 U.S. 394, 399 (1916).
[35] The combination of substances found in Oxycontin. *Id.*
[36] *Id.*
[37] *Id.*
[38] Neither the government nor the court addressed the presumption that supplying medication to Mr. Martin for the purpose of satisfying his addiction was for a "non-medical" purpose. The court would not do so until *Linder v. United States* in 1925. *Linder v. United States*, 268 U.S. 5 (1925).
[39] *Id.* at 400.

the Act the power of a general police measure because it was enacted as a revenue act under Congress's spending power.[40]

The constitutionality of passing a revenue measure that had the purpose and effect of an encroachment on the states' police power to regulate the practice of medicine was revisited three years later in *United States v. Doremus*.[41] Dr. Doremus was indicted for providing heroin to an individual "not in the course of professional practice" but because the patient was a "dope fiend."[42] The district court, following *Jin Fuey Moy*, declared that the Act was not a proper revenue measure and was an invasion of the police power reserved to the states.[43] Declining to usurp Congress' constitutional shell game, the Supreme Court disagreed and held that the Act cannot be declared unconstitutional simply because it accomplishes another purpose other than raising revenue.[44] The effect of *Doremus* was sweeping; the Supreme Court gave Congress the authority to "supplant any contrary state law and impose a nationwide blanket prohibition on the sale of narcotics to be enforced with severe criminal penalties, excepting only distribution that the Treasury Department (and the Court) deemed to be in the regular course of the professional practice of medicine."[45]

The Supreme Court did not waste any time in weighing in on whether a physician's practice was appropriate. On the same day as its decision in *Doremus,* the Supreme Court issued its opinion in *Webb v. United States* which was the first time the Supreme Court delved into the murky waters of determining the legality of a physician's prescribing practices.[46] Dr. Webb was a properly registered practicing physician who worked in close proximity with Mr. Goldbaum, a retail

[40] *Id.*
[41] *United States v. Doremus,* 249 U.S. 86 (1919).
[42] *Id.* at 90.
[43] *Id.* at 94.
[44] *Id.*
[45] Christopher Bryant, *The Third Death of Federalism,* 17 CORNELL J. L. & PUB. POL'Y 101, 109.
[46] *Webb v. United States,* 249 U.S. 96 (1919).

pharmacist in Memphis.[47] Dr. Webb prescribed morphine for "addicts" without examination and solely for the purpose of treating addiction, provided they apply and pay the necessary office visit fee of 50 cents. Dr. Webb claimed that he would prescribe morphine in such a way that would tend to "cure" or "break the addiction."[48] Mr. Goldbaum regularly filled the prescriptions and ultimately filled "thirty times as much morphine" as was bought by the average pharmacy in Memphis.[49] With little fanfare, the Supreme Court declared that to consider such an order a "prescription would be so plain a perversion of meaning that no discussion of the subject is required."[50]

Six years later in *Linder v. United States*[51] the Supreme Court appeared to claw back some of the power provided to Congress in its previous *Harrison Act* decisions. Justice McReynolds, joined by eight colleagues, writes, "[o]bviously, direct control of medical practice in the States is beyond the power of the Federal Government. Incidental regulation of such practice by Congress through a taxing act cannot extend to matters plainly inappropriate and unnecessary to reasonable enforcement of a revenue measure."[52] The court noted that the Act says nothing of "addicts" and does not undertake to prescribe methods for medical treatment. Furthermore, the unanimous opinion stated that the court cannot conclude that a physician acted inappropriately simply for prescribing to an "addict."[53] Interpreting the Act to mean that a physician may "never give an addict moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction would certainly "encounter grave constitutional difficulties."[54] Leaving no question that

[47] *Id.* at 97.
[48] Likely a form of "weaning" as is commonly done with Suboxone and other opiate addiction treatment regimes.
[49] *Id.* at 99.
[50] *Id.*
[51] *Linder v. United States,* 268 U.S. 5 (1925)
[52] *Id.* at 18.
[53] *Id.*
[54] *Id.* at 22.

the Supreme Court does not want Congress meddling in the proper bounds of the practice of medicine, the court left us with the following:

> The unfortunate condition of the recipient certainly created no reasonable probability that she would sell or otherwise dispose of the few tablets entrusted to her; and we cannot say that by so dispensing them the doctor necessarily transcended the limits of that profession, conduct with which Congress never intended to interfere.[55]

As the Nixon administration was attempting to reign in the rampant drug use left over from the 1960's and the effects of the Vietnam war, the Nixon administration unveiled its "War on Drugs" initiative.[56] President Nixon's major platform initiative during the 1970's was to stem drug abuse and drug crime in the United States. The President's anti-drug rhetoric was effective; Richard Nixon and Congress received a powerful mandate from the electorate, as President Nixon won every state but Massachusetts in the 1972 election.[57] The *Controlled Substances Act* was passed in 1970 as the *Comprehensive Drug Abuse Prevention and Control Act of 1970* and received strong bi-partisan support with only six votes against passage.[58] It would not be long until the law's applicability was challenged in the Supreme Court.

## III. THE SUPREME COURT'S DECISION IN *UNITED STATES V. MOORE*

Dr. Moore was charged in a 639 count indictment alleging that he knowingly distributed methadone in violation of 21 U.S.C. § 841(a)(1).[59] Interestingly, Dr. Moore was originally charged under the *Harrison Narcotics Act* in 1969.[60] In exchange for dismissal of charges, he promised the

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[55] *Id.* at 22-23.
[56] Richard Nixon, *28 - Statement on Establishing the Office for Drug Abuse Law Enforcement*, THE AMERICAN PRESIDENCY PROJECT (Jan. 28, 1972), http://www.presidency.ucsb.edu/ws/?pid=3552.
[57] *Election of 1972,* THE AMERICAN PRESIDENCY PROJECT, http://www.presidency.ucsb.edu/showelection.php?year=1972 (last visited May 20, 2018).
[58] *House Vote #355 in 1970 (91st Congress),* GOVETRACKhttps://www.govtrack.us/congress/votes/91-1970/h355 (last visited Jun. 6, 2018).
[59] *United States v. Moore,* 423 U.S. 122, 124 (1975).
[60] *United States v. Moore,* 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.

Grand Jury that he would change his ways by conducting thorough physical examinations, recording dosages of methadone, and conducting urinalysis tests.[61] Dr. Moore did not change his ways, did not take urinalysis samples, did not record dosages, and violated his prior agreement to modify his practice.[62] Dr. Moore also charged for the amount of narcotics dispensed instead of charging for his medical services, *e.g.*, a patient would pay $100 for 50 tablets of methadone and $200 for 100 tablets of methadone.[63] According to the prosecution, Dr. Moore was by all means acting as a drug dealer and was not performing any legitimate medical services, and he was convicted after a jury trial.[64] The Court of Appeals for the District of Colombia Circuit reversed the conviction and determined that Dr. Moore could not be prosecuted under 21 U.S.C. § 841(a)(1), holding:

> Congress intended to deal with registrants primarily through a system of administrative controls, relying on modest penalty provisions to enforce those controls, and reserving the severe penalties in § 841 for those seeking to avoid regulating entirely by not registering.[65]

The Court of appeals relied on 21 U.S.C. § 822(b) which provides: "Persons registered . . . under this subchapter to distribute, or dispense controlled substances are authorized to possess, distribute, or dispense such substances . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter."[66]

The criminal provisions of the CSA impose sanctions for three types of illegal conduct: *(1)* § 841 imposes the most severe penalties for drug traffickers; *(2)* § 842 is primarily aimed at "technical violations" and accordingly contemplates a civil penalty but affords a criminal penalty

[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Moore,* 423 U.S. at 126.
[65] *United States v. Moore,* 164 U.S. App. D.C., 319, 323; 505 F.2d 426, 430 (1973).
[66] *Id.*

punishable for up to one year where the violations are committed "knowingly"; and, finally, *(3)* § 843 includes regulatory provisions, but provides more severe sanctions than § 842, and prohibits the use of communication facilities such as the telephone, internet, or television signal in the commission of any offense.[67] The Court of Appeals suggested that Dr. Moore could only be prosecuted under § 842 for having violated the provisions of § 829 related to the legitimacy of prescriptions.[68]

At oral argument before the Supreme Court, the government argued that Congress could not have intended to exempt physicians from prosecution under the conventional drug delivery prohibition of 21 U.S.C. § 841(a)(1).[69] Further, the government argued that if Dr. Moore prescribes improperly he may be prosecuted under § 842 (a lesser offense), but if he acts as a drug trafficker and prescribes "without any medical justification" he can be prosecuted under § 841.[70]

The government was asked during oral argument whether there are some violations of a registrant's registration that could not be prosecuted under § 841 and instead must only be prosecuted under § 842.[71] Justice Potter Stewart, offering a prophetic question during oral argument, correctly pointed out that prosecuting physicians based on "professional disagreements" rests on dubious grounds when the government bases the legitimacy of a prescription on whether or not the practice is generally accepted.[72] In response, the government did not offer that physicians should only be prosecuted if they intend to prescribe for other than a legitimate medical purpose, which would have resolved Justice Stewart's concern, but stated that the determination of the legitimacy of a prescription "cannot be left to the individual practitioner because the potential for

[67] *Id.* at 449.
[68] *Id.* at 138.
[69] *United States v. Moore,* 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.
[70] *Id.*
[71] *Id.*
[72] *Id.*

abuse is simply too great" and should be left to the government. [73] Justice Stewart responded that the world would still be considered flat if Galileo had to go to get permission from the government to declare the earth round.[74] Despite this, the government rested on the theory that the facts were so blatant that no one could honestly believe that Dr. Moore believed that he was prescribing for a legitimate medical purpose.[75] The focus of the prosecution in *United States v. Moore* was not that Dr. Moore violated the standard of care, but that he acted as a large scale drug pusher and, therefore, the regulation that punishes registrants for technically violating the CSA does not apply and, rather, he should be prosecuted as a plain and simple drug dealer.[76]

The Supreme Court found that Dr. Moore was a drug pusher, a trafficker in illegal narcotics, and, thus, could be prosecuted under § 841. However, the court's opinion, as indicated during oral argument, hinged on the fact that Dr. Moore clearly was not acting in any way as a physician.[77] The court did not go so far as to say that Dr. Moore could be prosecuted for departing from ordinary standards of medical practice.[78] In the wake of *United States v. Moore*, federal circuits have struggled with the phrases "legitimate medical purpose" and "usual course of professional practice." This misunderstanding has led to the judicial creation of a criminal "standard of care" for appropriate prescribing.

## IV. POST *MOORE* VAGUENESS CHALLENGES

Since *United States v. Moore*, many practitioners challenged § 841 as being vague; however, despite the lack of uniformity in the appropriate standard to apply in § 841 prosecutions,

[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *Id.* at 01:02;46.

courts have unanimously rejected vagueness challenges.[79] In order to avoid constitutional vagueness, a statute must define the criminal conduct with enough precision that it permits an ordinary person to understand what is prohibited and that it does not encourage arbitrary or discriminatory enforcement.[80] Further, the statute must provide "objective criteria" that will "minimize the possibility of arbitrary enforcement and assist in defining the sphere of prohibited conduct under the statute."[81]

In *United States v. Rosenberg*, a case pending certiorari before the Supreme Court at the time *United States v. Moore* was being argued and decided, Dr. Rosenberg raised a vagueness challenge to the phrase "legitimate medical purpose" and "course of professional practice."[82] Dr. Rosenberg was a 75 year old doctor who had been practicing in California for approximately 50 years.[83] He was visited by five separate undercover agents working for various law enforcement agencies.[84] He did not conduct physical examinations on the agents and the agents never indicated that they had any medical problems which required prescription medication.[85] Dr. Rosenberg challenged his conviction on the basis that the term "in the course of professional practice" is so vague that it violates the due process clause of the Fifth Amendment.[86] In response, the Ninth Circuit offered that the Supreme Court has had several occasions to interpret the phrase and has consistently stated that the purpose of the physician exception is to confine lawful

[79] *United States v. Birbragher,* 603 F. 3d 478, 488 (8th Cir. 2010) (noting the absence of any successful vagueness challenge to § 481).
[80] *Kolender v. Lawson,* 461 U.S. 352, 357 (1983).
[81] *Posters 'N' Things, Ltd v. U.S.,* 511 U.S. 513, 525-526 (1994).
[82] *United States v. Rosenberg,* 515 F.2d 190 (9th Cir. 1975).
[83] *Id.* at 191.
[84] *Id.*
[85] *Id.*
[86] *Id.* at 197.

distribution to the regular and lawful course of professional practice.[87] The Ninth Circuit effectively side-stepped Dr. Rosenberg's challenge by parroting back the statutory language he challenged as vague.[88] Notably, other circuits have rejected similar vagueness challenges, but offer little clarification of the statutory phrase.[89]

Some federal district court opinions have shed interesting light on the trial court interpretation of the phrases "legitimate medical purpose" and "usual course of professional practice."[90] In *United States v. Quinones*, the District Court for the Eastern District of New York determined that the phrase "legitimate medical purpose" has an objective meaning that prevents arbitrary prosecution and conviction.[91] In *United States v. Brickhouse*, the District Court for the Eastern District of Tennessee engaged in a lengthy review of a physician defendant's well-pleaded vagueness challenge. The district judge deferred to the Supreme Court's *United States v. Moore*

[87] *Id.* (citing *United States v. Behrman*, 258 U.S. 280 (1922) ("[t]he purpose of the exception is to confine the distribution of these drugs to the regular and lawful course of professional practice")); *see also Boyd v. United States,* 271 U.S. 104, 105 (1926) ("[t]he disputed question was whether the defendant issued the prescriptions in good faith in the course of professional practice").
[88] *Id.*
[89] *United States v. Collier*, 478 F.2d 268, 270 (5th Cir. 1973) (rejecting "contention . . . that § 841(a)(1), as applied to physicians, is unconstitutionally vague"); *United States v. Darji*, 609 F. App'x 320, 334 (6th Cir. 2015) ("this Court has rejected the claim that § 841 and § 1306.04(a) are void for vagueness"); *United States v. Orta-Rosario*, 469 F. App'x 140, 143 (4th Cir.), *cert. denied*, 568 U.S. 902; 133 S. Ct. 311; 184 L. Ed. 2d 185 (2012) (rejecting argument of medical doctor that the CSA is impermissibly vague as applied to him because "there is no statutory definition of 'legitimate medical purpose' or 'usual professional practice'"); *United States v. Brickhouse*, No. 3:14-CR-124, 2016 U.S. Dist. LEXIS 59821, 2016 WL 2654359, at *4 (E.D. Tenn. Mar. 30, 2016) ("[t]he Court disagrees that § 841(a)(1) and the regulation at § 1306.04 leave medical practitioners rudderless and adrift in the murky waters of criminal liability"); *United States v. Quinones*, 536 F. Supp. 2d 267, 274 (E.D.N.Y. 2008) (rejecting vagueness argument because the phrase "within the usual scope of professional practice" has an "objective meaning that prevents arbitrary prosecution and conviction: neither the government nor the jury is free to impose its own subjective views about what is and is not appropriate; rather, the government is obliged to prove, and the jury constrained to determine, what the medical profession would generally do in the circumstances"); *United States v. Birbragher*, 576 F. Supp. 2d 1000, 1013 (N.D. Iowa 2008), *aff'd*, 603 F.3d 478 (8th Cir. 2010) ("courts have held the language 'legitimate medical purpose' and 'usual course of his professional practice' is not unconstitutionally vague as applied to physicians"); *United States v. Prejean*, 429 F. Supp. 2d 782, 805 (E.D. La. 2006) (rejecting argument that this framework is vague because "the medical community [**6] has not established clear, nationwide standards for what is considered 'legitimate medical purpose' in the field of pain management"); *United States v. Robinson*, 253 F. Supp. 3d 1, 3, 2017 U.S. Dist. LEXIS 73180, *4-6.
[90] 21 C.F.R. § 1306.04
[91] *United States v. Quinones,* 536 F.Supp. 2d 267 (E.D.N.Y. 2008).

decision that physicians could be prosecuted when the acts as a "large scale pusher."[92] Moreover, the district court cited *United States v. August*, a case in which the Sixth Circuit declared that "there are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice."[93] Despite citing *August* for the proposition that § 841 requires review on a case-by-case basis, the district court in *Brickhouse* rejected the defendant's arbitrary enforcement argument by citing *Quinones* for the proposition that the phrase "legitimate medical purpose and outside the course of professional practice" "has an objective meaning that prevents arbitrary prosecution and conviction."[94] The *Brickhouse* court's inconsistent and illogical position embodies the strained legal positions taken in other districts and circuits to avoid a serious look at the standard in § 841 prosecutions. Strangely, embedded in the *Quinones* reasoning, which was relied upon by the *Brickhouse* court, is the notion that "neither the government nor the jury is free to impose its own subjective views about what is and is not appropriate; rather, the government is obliged to prove, and the jury constrained to determine, what the medical profession would generally do in the circumstances."[95] The *Quinones* court and, by implication, the *Brickhouse* court defer to the "standard of care" to find an objective standard to avoid a vagueness challenge.[96] This is exactly the sort of reasoning Justice Potter Stewart was afraid of in *United States v. Moore* when he cautioned that jailing physicians as a result of professional disagreements had a chilling effect on medical advancement.[97]

[92] *Id.* at *13.
[93] *Id.* at *15 (citing *United States v. August,* 984 F.2d 705, 713 (6th Cir. 1992)).
[94] *Id* at. *18.
[95] *United States v. Quinones,* 536 F. Supp. 2d 267, 274 (E.D.N.Y. 2008).
[96] *Id.*
[97] *United States v. Moore,* 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.

## V. GONZALES V. OREGON AND ITS IMPACT ON CRIMINAL CONTROLLED SUBSTANCE JURISPRUDENCE

The landmark decision in *Gonzales v. Oregon* is the first instance in which the Supreme Court clearly addressed the intersection of the CSA and the states' right to regulate the practice of medicine.[98] In *Gonzales*, the Supreme Court analyzed an interpretive rule issued by the United States Attorney General stating that doctors who assist terminally ill patients in committing suicide pursuant to an Oregon law do so in violation of the CSA.[99] The court determined that the CSA's prescription requirement did not authorize the Attorney General's interpretive rule, which intentionally countered Oregon's physician-assisted suicide regime by declaring that suicide is not a legitimate medical purpose.[100] The Supreme Court set the lateral limits of the CSA and declared that the CSA and case law "amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking, as conventionally understood."[101]

The Supreme Court was clear that the CSA was not designed to displace the states as the primary regulators of the medical profession, or to override a states' determination as to what constitutes legitimate medical practice.[102] There was only one area in which the Supreme Court determined that the CSA set a "national standard" of medical practice—in the treatment of narcotic addicts—with all other areas implicitly left up to the states to regulate.[103] There are no specific guidelines concerning what is required to support a conclusion that a physician acted outside the usual course of professional practice.[104] Since *Gonzales*, courts have struggled with the question

[98] *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).
[99] *Id.*
[100] *Id.* at 255-269.
[101] *Gonzales v. Oregon,* 546 U.S. 243, 270 (2006).
[102] *Id.* at 271.
[103] *Id.*
[104] *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995).

of how to assess whether a physician's conduct falls within the accepted bounds of professional practice; in the wake of *Gonzales*, courts have settled on a broad case-by-case approach.[105] This approach, however, has encroached on the states' role to define what is proper medical practice and, instead, has created a *quasi* national standard of care.

The structure and limitations of federalism allow states "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."[106] Absent a positive conflict, none of the CSA's provisions should be "construed as indicating an intent on the part of Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State."[107] Therefore, the CSA must be interpreted in a way that does not conflict with a state's lawful exercise of its power to regulate the practice of medicine.[108]

In order to determine whether the circuits have encroached upon the states' right to regulate the practice of medicine, it is important to analyze one state's interpretation of what constitutes the unlawful prescribing of narcotics. For instance, Michigan's state law regulating the prescription of controlled substances is found in M.C.L. § 333.7401. M.C.L. § 333.7401 provides that a practitioner shall not "prescribe a controlled substance for other than legitimate and professionally recognized therapeutic or scientific purposes or outside the scope of practice."[109] While 21 C.F.R.

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[105] *United States v. Volkman*, 797 F.3d 377 (2015).
[106] *Id.*
[107] 21 U.S.C. § 903.
[108] *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991). *See also Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action").
[109] M.C.L. § 333.7333 defines "good faith" as the prescribing or dispensing of a controlled substance by a practitioner licensed under Section 7303 in the regular course of professional treatment to or for an individual who is under treatment by the practitioner for a pathology or condition other than that individual's physical or psychological dependence. However, M.C.L. § 333.7401 does not use the term "good faith" and, therefore, M.C.L. § 333.7333 has no effect on its interpretation.

§ 1304.06 and M.C.L. § 333.7401 appear to be similar at first glance, they are not. M.C.L. § 333.7401 concerns two inquiries. The first is whether the prescription was issued for a legitimate or professionally recognized purpose.[110] The second is whether the prescription was written within the scope of practice.[111] "Scope of practice" is not synonymous with "course of professional practice"; instead, "scope of practice" concerns whether the practitioner has authority to prescribe by nature of education training or experience.[112]

To the extent that the government interprets "in the usual course of professional practice" as setting forth some form of minimal standard of care, it would render 21 C.F.R. § 1306.04 inconsistent with M.C.L. § 333.7401 and infringe on Michigan's police power to regulate the practice of medicine. Michigan law focuses on the medical purpose for the prescription and the subjective "good faith" of the provider.

In *People v. Orzame,*[113] the Michigan Court of Appeals found that, despite the fact that a physician's actions did not constitute "good medical practice," the prosecution did not establish that the defendant acted "in bad faith" or intended to prescribe for a nonmedical purpose[114,115]:

> [I]t does not follow that because a physician may not traffic in drugs he can be prosecuted for simple departures from generally accepted standards of professional practice and ethics. Doctors not infrequently prescribe for patients who are not in their office, whom they have not examined, and over the telephone. Carelessness, bad judgment or malpractice is one thing; intent to traffic in drugs and distributing in bad faith for a non-medical purpose is [sic] quite another.[116]

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[110] *Id.*
[111] *Id.*
[112] *See* M.C.L. § 333.16215; *see also People v. Ham-Ying,* 142 Mich. App. 831 (1985) (delegating prescribing to a suspended physician rendered prescriptions written "outside the scope of practice").
[113] *People v. Orzame,* 224 Mich. App. 551, 565 (1997).
[114] *See also People v. Sun*, 94 Mich. App. 740, 744 (1980).
[115] The court echoed Justice Levin's dissent in *People v. Alford,* 405 Mich. 570, 592-594 (1979).
[116] *Alford,* 405 Mich. at 593-594

Michigan law is clearly concerned with the subjective "good faith" of the physician and the medical purpose of the prescription.[117] An interpretation of 21 C.F.R. § 1306.04 in the disjunctive would permit physicians to be prosecuted for simple departures from the "usual course of professional practice," or, as Justice Levin of the Michigan Supreme Court put it, simple departures from generally accepted standards of professional practice, without regard to the "legitimate medical" purpose of the medications. Courts have already begun to cross that line when interpreting the phrase "usual course of professional practice" as endorsing a "general practice standard."

The Eleventh Circuit in *United States v. Merrill* determined that courts should apply a "general practice standard" when determining whether a practitioner acted in the "usual course of professional practice."[118] In *United States v. Feingold*, the Ninth Circuit Court of Appeals applied a national standard to interpret whether or not a physician's conduct violated the CSA.[119] In addition, the Ninth Circuit dismissed the subjective intent of the doctor in determining whether his prescribing was appropriate.[120] The Fourth Circuit also declared a physician's subjective intent irrelevant when determining whether prescribing was appropriate and in accordance with the CSA.[121] Likewise, the Second Circuit also dismisses the subjective intent of the physician regarding what is "appropriate medical practice" because to do so would "weaken the enforcement of [the United States] drug laws."[122] The Fifth Circuit requires a "reputable group of people in the

[117] *Id.*
[118] *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008) (emphasis added).
[119] *United States v. Feingold*, 454 F.3d 1001, 1011 n.3 (9th Cir. 2006) (quotation omitted) (emphasis added).
[120] *Id.*
[121] *United States v. Hurwitz*, 459 F.3d 463, 478, 480 (4th Cir. 2006) ("allowing criminal liability to turn on whether the defendant-doctor complied with his own idiosyncratic view of proper medical practices is inconsistent with the Supreme Court's decision in *Moore*. . . . Because the instruction proffered by *Hurwitz* set forth a subjective standard for measuring his good faith, the instruction was not a correct statement of the law.")
[122] *United States v. Vamos,* 797 F.2d 1146, 1153 (2d Cir. 1986).

medical profession who agree that a given approach to prescribing is consistent with legitimate medical treatment" in order to acquit a physician.[123]

This growing body of case law suggesting that 21 C.F.R. § 1306.04 should apply an objective medical standard to 21 U.S.C. § 846(a)(1) is disrupted by the Supreme Court in *United States v. Gonzales* when viewed through Michigan's statutes (M.C.L. § 333.7401) and other state statutes because many states require that we view a physician's intent through the subjective standard and the medical purpose as opposed to an objective standard.

A number of district courts and some circuits have heard challenges pursuant to *Gonzales* and have summarily rejected the notion that *Gonzales* has altered 21 U.S.C. § 841(a) jurisprudence.[124] However, in each of these cases, the moving party failed to show a conflict between state law regulating the practice of medicine and the interpretation of what constitutes the lawful practice of medicine in that particular circuit. Future challenges to the CSA on this basis must highlight where courts have deviated from state medical practice standards and created a national "standard of care".

## VI. A Split Amongst the Circuits on the Role of "Standard of Care" in § 841(a) Jurisprudence

### A. The Introduction of a "National Standard of Care"

While the Supreme Court in its sole case determining the standard for physician prosecutions under § 841 never explicitly stated that standard of care considerations are of little value in determining whether a physician acted as a "drug pusher," it is clear from the court's

[123] *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986) (emphasis added) (relying on *Moore*, 423 U.S. at 139, in dismissing the defendant's argument that "his" standard requires that the government prove that the doctor prescribed drugs for a purpose contrary to the doctor's own standards of medical practice because "[o]ne person's treatment methods do not alone constitute a medical practice").

[124] *See United States v. Rydze*, 2017 U.S. Dis. LEXIS 55655 (W.D. Penn 2017); *see also United States v. Ahuja*, 209 F. Supp. 3d 489, 485 (2016); *United States v. Orta-Rosario*, 469 Fed. Appx. 140 (2012).

opinion that only physicians that abandon medical practice and engage in drug trafficking should be prosecuted under § 841.[125] Despite the seemingly clear direction from the Supreme Court as to the limits of federal power when prosecuting physicians for prescribing decisions, many circuit courts began to apply national "standard of care" analysis to physician prescribing cases.

In *United States v. Armstrong*, the circuit court upheld a jury instruction that provided:

> A controlled substance is prescribed by a physician in the usual course of professional practice, and therefore, lawfully, if the substance is prescribed by him or her in good faith, medically treating a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.[126]

In essence, the court in *Armstrong* held that a provider who deviates from a national standard of care is in essence in violation of § 841.[127] The court took support from the jury instruction read in *United States v. Moore*; however, the court admits in its opinion that the jury instruction read in *United States v. Moore* was not challenged by the defendant and was not an issue properly before the Court.[128]

Similarly, the Eleventh Circuit upheld a jury instruction in *United States v. Enmon* that permitted the jury to find the defendant guilty of a violation of § 841 if his conduct did not comport with "generally recognized" standards of medical practice.[129] The instruction specifically stated, "[w]hether the Defendant acted outside the usual course of professional practice is to be judged objectively by reference to standards of medical practice generally recognized and accepted in the United States."[130] Therefore, "whether the Defendant had a good faith belief that he dispensed a

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[125] *United States v. Gonzalez,* 546 U.S. 243, 269 (2006) (it comes as little surprise, then that we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug pusher instead of a physician).
[126] *United States v. Armstrong,* 550 F.3d 382 (5th Cir. 2008).
[127] *Id.*
[128] *Id.* ("[n]otably, while the jury instructions were not the issue directly before the *Moore* court . . . .").
[129] *United States v. Enmon,* 686 Fed. Appx. 796, 773 (11th Cir. 2017), *cert. denied*, 2017 U.S. LEXIS 5460 (U.S., Oct. 2, 2017).
[130] *Id.*

controlled substance in the usual course of his professional practice is irrelevant."[131] In its opinion, the circuit court admitted that its precedent "has not always been clear in specifying the standpoint from which a jury is to determine whether a prescription was issued . . . by an individual practitioner acting in the usual course of professional practice."[132]

### B. Circuits Are Split as to Whether Standard of care Has Any Role in § 841(a) Prosecutions

#### *1. Decisions Rejecting the Applicability of a Standard of Care Analysis*

In the Sixth Circuit, Dr. Paul Volkman, a physician charged with drug trafficking under 21 U.S.C. § 841(a), challenged a requested jury instruction derived from *Gonzales v. Oregon* that would require the jury to find that Dr. Volkman used his prescription-writing power "as a means to engage in the illicit drug-dealing and trafficking as conventionally understood" in order to convict.[133] Despite the standard being specifically adopted from the Supreme Court's only § 841 decision in the last 30 years, the court rejected the language requested in *Volkman* and instead pivoted back to the vague standard that "knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict."[134] However, the Sixth Circuit did offer guidance that is in conflict with several other circuits in upholding the instruction ultimately given to the jury, which read, "carelessness or negligence or foolishness on [Dr. Volkman's] part are not the same as knowledge and are not enough to find him guilty on any of these counts."[135] The court went further to say as follows:

> You've heard the phrase "standard of care" used during the trial by several witnesses. When you go to see a doctor as a patient, the doctor must treat you in a manner that meats the applicable standard of care that physicians of similar training would have given to you under the same circumstances. If a doctor fails to provide

[131] *Id.* at 774.
[132] *Id.* (citing *United States v. Tobin,* 676 F.3d 1264, 1282 (11th Cir. 2012)).
[133] *United States v. Volkman,* 736 F.3d 1013, 1020 (6th Cir. 2013).
[134] *Id.* at 1021.
[135] *Id.* at 1022.

> you with that care, the doctor may be found negligent in a civil lawsuit. This case is not about whether the Defendant acted negligently or whether he committed malpractice. Rather, in order for you to find the defendant guilty, you must find that the government has provide to you beyond a reasonable doubt that the defendant's action was not for a legitimate medical purpose in the usual course of professional practice.[136]

The court stated, "we conclude that these instructions amply and accurately conveyed the meaning of legitimate medical purpose to the jury."[137] The Sixth Circuit, in upholding *Volkman*'s jury instruction, clearly believes that departure from a standard of care or the practice generally accepted in the community does not render a prescription without a "legitimate medical purpose" or outside "course of professional practice."[138]

The Seventh Circuit aligns with the Sixth Circuit in the sense that the government must prove "something more than conduct below the usual standard of care to show an absence of a valid medical purpose."[139] In *United States v. Chube* (Chube II), Dr. Chube sought to exclude all expert testimony that suggested a violation of the standard of care applicable to civil medical malpractice cases.[140] The doctor argued that such testimony admitted during trial confused the jury and reduced the government's burden from criminal intent to negligence.[141] While the trial court did not grant the motion, the judge repeatedly spelled out the difference between the civil standard and criminal standard to the jury, and defense counsel was permitted to discuss the different standards during opening, closing, and cross examination.[142]

The Fourth Circuit in *United States v. Alerre* upheld a jury instruction much more similar to the Supreme Court's dicta in *Moore* which stated that the jury could "not convict on the

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[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] *United States v. Chube,* 538 F.3d 693, 698 (7th Cir. 2008).
[140] *Id.* at 697.
[141] *Id.*
[142] *Id.* at 699.

distribution and drug conspiracy charges if it found only that defendants' practices fell below that line of what a reasonable physician would have done."[143] The court further stated, "in order to convict on the distribution and drug conspiracy charges, the jury was required to find beyond a reasonable doubt that the defendants were selling drugs, or conspiring to do so, and not practicing medicine."[144]

The Ninth Circuit took the standard of care issue head on in *United States v. Feingold.*[145] Dr. Feingold's counsel argued that a physician should not be subject to prosecution for mere deviations of the standard of care, even if done intentionally, because it would permit the Attorney General to prosecute any physician who steps outside the bounds of conventional medical protocols in order to provide some sort of special treatment for uniquely needy patients.[146] In reviewing a line of its prior CSA precedent, the Ninth Circuit unequivocally held:

> An instruction is improper if it allows a jury to convict a licensed practitioner under § 841(a) solely on a finding that he has committed malpractice, intentional or otherwise. Rather, the district court must ensure that the benchmark for criminal liability is the higher showing that the practitioner intentionally has distributed controlled substances for no legitimate medical purpose and outside the usual course of professional practice.[147]

The Ninth Circuit acknowledged that it previously refused to overturn practitioner convictions simply because jury instructions deferred to the national standard of care.[148] However, the court cautioned that by doing so, "a district court may impermissibly lower the standard for criminal liability by instructing the jury to determine whether a practitioner-defendant has

[143] *United States v. Alerre, 430* F.3d 681, 687 (4th Cir. 2005).
[144] *Id.*
[145] *United States v. Feingold,* 454 F.3d 1001, 1010 (2006).
[146] *Feingold,* 454 F.3d at 1010.
[147] *Id.*
[148] *See United States v. Hayes,* 794 F.2d 1348, 1351 (9th Cr. 1986) (the Ninth Circuit upheld a conviction in which good faith was defined as a practitioner making an honest effort to conform to the standard of medical practice generally recognized and accepted in the country).

complied or attempted to comply with the standard of care."[149] The Ninth Circuit ultimately held that an instruction is improper if it permits a jury to convict a practitioner solely on the finding that he has committed malpractice, intentional or otherwise.[150] The Ninth Circuit affirmatively stated that "a practitioner becomes a criminal not when he is a bad or negligent physician, but when he ceases to be a physician at all."[151]

The First Circuit Court of Appeals believes that the term "usual course of professional practice" references violations of the "standard of care," and the "good faith" instruction is the fundamental difference between malpractice and criminal liability.[152] While the Second Circuit agrees with *Feingold* that a physician is insulated from prosecution as a result of a mere departure from the standard of care, it held that evidence that a physician consistently failed to follow generally recognized procedures "tends to show that in prescribing drugs he was not acting as a healer but as a seller of wares."[153] The court found it important when assessing whether under the current standard a physician could be convicted for mere malpractice, that the "good faith" instruction inoculates a defendant from being found guilty where he or she prescribes in "good faith" because the "good faith" defense is not an available defense in malpractice cases.[154]

The Eighth Circuit takes a refreshing approach to both the applicability of the "standard of care" and the debate over the disjunctive or conjunctive interpretation of 21 U.S.C. § 841(a). In *United States v. Smith*, the defendant challenged the use of the malpractice standard in the trial court, but was ultimately convicted.[155] In answering the defendant's concerns pertaining to the

[149] *Feingold,* 454 F.3d at 1011.
[150] *Id.*
[151] *Id.*
[152] *United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018).
[153] *Id.* (quoting *United States v. Alerre*, 430 681, 691 (4th Cir. 2005)); *see also United States v. Wexler*, 522 F.3d 194, 204 (2d Cir. 2008); *United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006).
[154] *Id.* at 45.
[155] *United States v. Smith*, 573 F.3d 639, 649 (8th Cir. 2009).

introduction of evidence related to the standard of care, the court emphasized that the jury instructions required the jury to find that Dr. Smith failed to adhere to prevailing medical standards and a lack of legitimate medical purpose(s) for the medication before it could convict.[156] In other words, a finding of malpractice alone is not sufficient; the jury must also determine that Dr. Smith knowingly prescribed for what he knew to be a non-medical purpose before a conviction is proper.[157]

### *2. Decisions Adhering to the Applicability of a "Standard of Care Analysis"*

Where a court views the "good faith" requirement as an objective one rather than a subjective one, the "good faith" exception is nothing more than a second inquiry into whether the physician adhered to the standard of care. For example, in *United States v. Boccone*, the Fourth Circuit held that "good faith" is generally relevant to determine whether a defendant acted outside the bounds of accepted medical practice, but also held that good faith is an "objective rather than a subjective standard."[158] The Fourth Circuit stated, "good faith is not merely a doctor's sincere intention towards the people who come to see him, but, rather, it involves his sincerity in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country."[159]

The genesis for this reasoning appears in the case of *United States v. Hurwitz*.[160] In reversing Dr. Hurwitz's conviction due to the trial court's failure to permit a "good faith" instruction, the Fourth Circuit was clear that "good faith" must be viewed in light of objective medical standards and a physician cannot seek refuge from criminal prosecution based on his or

[156] *Id.*
[157] *Id.*
[158] *United States v. Boccone,* 556 Fed. Appx. 215, 228 (2014).
[159] *Id.* (quoting *United States v. Hayes,* 794 F.3d 1348, 1351 (9th Cir. 1986)).
[160] *United States v. Hurwitz,* 459 F.3d 463, 480 (4th Cir. 2006).

her own idiosyncratic view of appropriate medical practice.[161] The Second Circuit is in agreement with the Fourth Circuit in application of an objective standard, to permit a physician "to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area."[162] Both the Eleventh Circuit and the D.C. Circuit agree with this approach and have clearly held that the standard for determining whether a prescription is used within the usual course of professional practice is an objective one.[163]

The problem with this view is twofold: *(1)* it was derived from a Ninth Circuit case decided decades prior to the Ninth Circuit's holding in *Feingold,* which clearly held that the "good faith inquiry" is subjective; and *(2)* permitting the "good faith" defense only when a physician sincerely attempts to practice within the standard of care continues to hold providers criminally responsible for deviations from the standard of care where they were unaware of such a standard.

For instance, let us assume that it is the "standard of care" to check a prescription monitoring report prior to issuing a prescription for a controlled substance.[164] Dr. Hippocrates is an older physician in his eighties gripping to his final few years of practice as a physician and is unaware of the changing trend in the "standard of care" that requires such a practice, but is otherwise good intentioned. If Dr. Hippocrates prescribes a controlled substance to a patient truly in pain without checking the database – according to the Fourth Circuit – he has committed a

[161] *Id.*
[162] *Id.*
[163] *United States v. Tobin,* 676 F.3d 1264, 1283 (11th Cir. 2012); see also *United States v. Robinson,* 255 F. Supp. 3d 199, 203 (D.C. Dist. 2017).
[164] A prescription monitoring report is a report that lists a patient's prescriptions for controlled substances, the provider that issued the prescription, and the pharmacy that filled the prescription. All states have some sort of prescription drug monitoring system with Missouri being the last. As of 2017, eight states require accessing a prescription database prior to each prescription of a controlled substance. Lisa Robin, *State CME and PDMP Overview*, FEDERATION OF STATE MEDICAL BOARDS (May 9, 2017), https://www.fda.gov/downloads/Drugs/NewsEvents/UCM558395.pdf.

crime. Surely, a prosecutor would argue that Dr. Hippocrates should have educated himself about the standard and his deliberate ignorance therefore lacked "good faith." In fact, information about physician overprescribing suggests that providers sanctioned by their state boards for overprescribing are older, male, lack board certification, and work in general practice family practice.[165] This is just the sort of population that may misunderstand the standard of care for prescribing due to age, lack of education, and lower reimbursement rates which may cause a more hurried practice.[166]

In the Second Circuit, the mistaken but well-intentioned physician can be convicted for a simple departure from the standard of care.[167] The Second Circuit in *United States v. Vamos* reasoned that medical practitioners have limited authority to engage in the distribution of controlled substances.[168] According to the Second Circuit, a practitioner is stripped of that authority when he or she acts in a manner that is not generally accepted in the medical community.[169] The Second Circuit acknowledged the argument that "subjecting physicians to an objective reasonableness standard exposes a physician to criminal responsibility for nothing more than malpractice," but dismissed the argument on the basis that a jury must still find proof beyond a reasonable doubt that the physician acted outside the scope of medical practice.[170] Troublingly, in the Second Circuit, the only difference between malpractice and criminal liability is proof beyond a reasonable doubt – Dr. Hippocrates would likely face conviction.

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[165] K.K. Dineen & J.M. DuBios, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42(1) AM. J. LAW MED. 7-52 (2016).
[166] J.M. DuBois et al., *A Mixed-Method Analysis of Reports on 100 Cases of Improper Prescribing of Controlled Substances,* 46(4) J. DRUG ISSUES 457-472 (2016).
[167] *United States v. Vamos,* 797 F.2d 1146 (2nd Cir. 1986).
[168] *Id.* at 1153.
[169] *Id.*
[170] *Id.*

### C. Exploring the Meanings of "Legitimate Medical Purpose" and "Usual Course of Professional Practice"

21 C.F.R. § 1306.04(a) (2017) 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."[171] One recent trend in federal physician prosecutions is the Department of Justice's attempts to charge practitioners for violating only one prong of the regulation – "outside the course of professional practice."[172] The theory is that if 21 C.F.R. § 1306.04 requires that a physician prescribe both "for a legitimate medical purpose" and within the "usual course of professional practice," charging physicians with violating only one of the prongs present in the regulation should be sufficient.[173] By ignoring the "medical purpose" of the prescription, prosecutors could simply convict based on the physician's compliance with the "usual course of professional practice."

The Tenth Circuit addressed such a case in *United States v. Nelson.*[174] In *Nelson*, the court permitted instructing the jury that it could convict the operator of a mail order pharmacy for distributing controlled substances "outside the usual course of medical practice *or* without a legitimate medical purpose."[175] The Tenth Circuit initially stated that there is considerable room to doubt whether the dispute of whether the use of "*or"* as opposed to "*and"* in the jury instruction is of any importance, citing *United States v. Kirk,* and then proceeded to consider the appellant's argument that the phrases should not be pleaded in the disjunctive but, rather, the conjunctive (*i.e.*, the prosecution must prove that the physician prescribed without a legitimate medical purpose and

[171] 21 C.F.R. § 1306.04(a) (2017).
[172] *United States v. Butt,* 2:17-CR-20155 (E.D. Mich. 2017).
[173] *Id.* (the indictment read only that the physician prescribed outside the course of professional practice and was silent as to the medical purpose of the prescription).
[174] *United States v. Nelson,* 383 F.3d 1227, 1233 (10th Cir. 2004).
[175] *Id.*

not in the usual course of professional practice.)[176] The court in *Nelson* ultimately held that pleading the elements in the disjunctive was appropriate, but it did not go so far as to say that the meaning of the two elements is the same.[177] To make matters more confusing, the Tenth Circuit in *Nelson* criticized the trial judge for issuing the jury instruction in the disjunctive and not in the conjunctive in accordance with the prior precedent in *United States v. Varma.*[178]

In *United States v. Kirk*, the case relied upon by the Tenth Circuit in *Nelson* to uphold the disjunctive pleading standard, the Sixth Circuit relied on *United States v. Rosenberg* and *United States v. Pleasons* for the proposition that "there is no difference in the meanings of the statutory phrase, in the usual course of professional practice and . . . legitimate medical purpose."[179] However, the Sixth Circuit erred in determining that there is no difference between these crucial phrases. In *United States v. Rosenberg,* the trial judge explicitly instructed the jury that they must explore Dr. Rosenberg's subjective state of mind when determining if he prescribed unlawfully, and the Ninth Circuit stated "he in no way indicated that the jury could find Dr. Rosenberg guilty if it found that he either acted not in the usual course of his professional practice or not for legitimate medical reasons."[180] In its dicta, the court stated "we find it difficult to understand how Dr. Rosenberg can argue that he was not acting for legitimate medical reasons yet was acting in the course of his professional practice."[181] The Ninth Circuit in *Rosenberg* did not hold that the phrases were the same, it determined that the court did not instruct the jury in such a manner and left open the possibility that the phrases are so similar that it would be impossible to prescribe for

[176] *United States v. Kirk,* 584, F.2d 773, 784 (6th Cir. 1978).
[177] *Id.*
[178] *Id. See also United States v. Varma,* 691 F.2d 460, 462 (10th Cir. 1982).
[179] *United States v. Kirk,* 584 F.2d 773, 784 (6th Cir. 1978) (citing *United States v. Rosenberg,* 515 F.2d 190 (9th Cir. 1975) *and United States v. Pleasons,* 560 F.2d 890, 897 (8th Cir. 1977)).
[180] *Rosenberg,* 515 F.2d, *supra* note 82, at 197.
[181] *Id.*

other than a legitimate medical purpose but still prescribe in the course of professional practice.[182] The holding in *United States v. Kirk* takes the *Rosenberg* decision out of context, an error that has rippled through 21 U.S.C. § 841 jurisprudence for decades. Similarly, the Eight Circuit in *United States v. Pleasons* did not discuss the similarity of the meanings of the phrases or suggest that they are interchangeable.[183] Rather, the court upheld a conviction where a portion of the indictment read as if it permitted the jury to find the defendant guilty if he prescribed "outside the course of professional practice."[184] However, the court did read the entire indictment to the jury as part of the instructions, and portions of the indictment stated that the jury must find that the defendant knew the drugs were not prescribed for a legitimate medical purpose; the phrase "legitimate medical purpose" was also repeated several times throughout the jury instructions.[185]

Despite the isolated holdings in the cases cited above, federal courts across the country have provided jury instructions in the conjunctive, requiring that the government prove that the defendant issued a prescription outside the course of professional practice *and* for a non-legitimate medical purpose. In *United States v. Kohli*, the Seventh Circuit upheld a district court's instruction that required the government to prove the controlled substance was prescribed "outside the usual course of professional medical practice, and not for legitimate medical purpose."[186] In *United States v. Feingold*, the Ninth Circuit clearly stated that to convict a practitioner under § 841, the government must prove the prescription was issued both outside the usual course of professional practice and lacked a legitimate medical purpose; in addition, the government must prove the defendant's intent to act as a pusher rather than a medical professional.[187] Similarly, in *United*

[182] *Id.*
[183] *United States v. Pleasons,* 560 F.2d 890, 896 (8th Cir. 1977).
[184] *Id.*
[185] *Id.*
[186] *United States v. Kholi*, 847 F.3d 483, 491 (7th Cir. Feb. 1, 2017).
[187] *Feingold*, 454 F.3d 1001, 1008 (2006).

*States v. Bartee*, the Tenth Circuit held ". . . and the converse of that proposition is equally clear and inescapable, namely, that when a medical practitioner issues a prescription which is not for a legitimate medical purpose and is not in the usual course of his professional practice, then he does violate the statute."[188] Moreover, the Seventh Circuit in *United States v. Chube* determined that 21 U.S.C. § 841(a) requires proof of both lack of a legitimate medical purpose and conduct outside the course of professional practice.[189]

Supporters of the theory that the phrases "legitimate medical purpose" and "usual course of professional practice" are the same may find the DEA administrative law decision in *In Re Wesley Pope* helpful to their cause.[190] In *Pope*, the DEA determined that both phrases have the same meaning and are thus interchangeable and indistinct. In *Pope*, just as in recent federal indictments, the government issued notice to Dr. Pope that his DEA registration should be revoked exclusively on the theory that he issued prescriptions "outside the usual course of professional practice."[191] Chief DEA Administrative Law Judge John J. Mulroney, in his most recent law review article, expressed disagreement with such an approach, pointing to the following language in *United States v. Nelson*, the DEA's supporting case:

> Similarly, it is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances with a legitimate medical purpose and yet be outside the usual course of medical practice. When asked at oral argument if the two phrases were not merely two ways of saying the same thing, appellant's counsel was unable to explain satisfactorily how or whether it might make a difference if the jury had been instructed in the conjunctive as he had requested**. Nevertheless, recognizing the limits of our imagination, we are hesitant to say that it never could make a difference, and we proceed to consider Nelson's argument**.[192]

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[188] *United States v. Bartee*, 479 F.2d 484, 488 (10th Cir. 1973).
[189] *United States v. Chube*, 538 F.3d 693, 698 (7th Cir. 2008).
[190] *Wesley Pope, M.D.*, 82 Fed. Reg. 14944, 14967 n.38. 14976 (Drug Enf't Admin. Mar. 23, 2017).
[191] John J. Mulrooney II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 MARQ. L. REV. 333, 425-426 (2017).
[192] *Nelson,* 383 F.3d, *supra* note 174, at 1231.

(Emphasis added.)

While Judge Mulrooney believes that a violation under 21 C.F.R. § 1306.04(a) may be proven by evidence of either lack of a legitimate medical purpose or lack of conduct that renders the prescription rendered in the "usual course of professional practice," he does not go so far as to suggest that the phrases carry the same meaning.[193]

The Supreme Court also appeared to struggle with the plain meaning of the phrase "legitimate medical purpose" and "usual course of professional practice" in *Gonzales v. Oregon*. In wrestling with the phrases, the court noted:

> The CSA allows prescription of drugs only if they have a "currently accepted medical use," 21 U.S.C. § 812(b); requires a "medical purpose" for dispensing the least controlled substances of those on the schedules, § 829(c); and, in its reporting provision, defines a "valid prescription" as one "issued for a legitimate medical purpose," § 830(b)(3)(A)(ii). Similarly, physicians are considered to be acting as practitioners under the statute if they dispense controlled substances "in the course of professional practice." § 802(21).[194]

The Court adheres to the concept that the term "medical purpose" relates to the purpose of the prescription while the term "course of professional practice" refers to the status of the person issuing the prescription.[195] Thus, a prescription could be unlawful if the practitioner is issuing the prescription to a patient with the knowledge that it would be diverted even if the physician first established a physician-patient relationship, kept a medical record on the patient, and saw the patient in a medical practice.

Despite a significant amount of jurisprudence, the Supreme Court, the DEA and its chief administrative law judge, and federal circuit courts widely disagree on the meaning and application

[193] *Id*. (it is true that the government only needs to prove that one of the elements was missing in order to support its prima facie case that the prescription was not "effective") (citing *Nelson,* 383 F.3d at 1233.)
[194] *Gonzales v. Oregon*, 546 U.S. 243, 257, (2006).
[195] *Id.*

of 21 C.F.R. § 1306.04 and whether it can be pleaded in the disjunctive. Unfortunately, this disagreement has led to widely differing opinions regarding the application of a "standard of care analysis" and the sufficiency of evidence necessary to convict a practitioner.

## VII. A DEA CREATED STANDARD OF CARE: "RED FLAGS" AND PROFILE EVIDENCE

Over the last decade, prosecutors have used another method to argue that a physician knew or should have known that a prescription lacked a legitimate medical purpose and was issued outside the usual course of professional practice – the use of "red flag" evidence. "Red flag" evidence has become a mainstay of physician prescribing prosecutions and has acted as a de-facto standard of care. The DEA began using "red flag" indicators to determine which doctors should be the subject of increased scrutiny by having undercover officers pose as patients who exhibit one or more "red flags."[196] However, "red flags" are not established using empirical data, but are rather an amalgamation of common "drug seeking" characteristics collected by DEA agents that are used as an investigative tactic to show knowledge on the part of the physician of the illegality of his or her practice.[197]

In 2007, the DEA investigated Dr. Johnston through the use of an officer posing as a patient.[198] The undercover officer presented to Dr. Johnston's practice and complained of pain radiating down his leg. Dr. Johnston commented on the long distance the patient traveled to see her and the undercover officer replied that he was living with his mother nearby. Dr. Johnston told the undercover that he had a herniated disc that was causing the pain and "sooner or later" he

[196] *See, e.g., United States v. Lovern*, 590 F.3d 1095, 1102 (10th Cir. 2009).
[197] *See United States v. Lovern,* 590 F.3d 1095, 1102 (10th Cir. 2009) ("red flag" testimony by a DEA diversion investigator with over 15 years of experience admitted because "courts have routinely upheld the admission of expert testimony from law enforcement officers seeking to identify for the jury typical indicia of drug trafficking activity").
[198] *United States v. Johnston,* 322 Fed. Appx. 660, 662 (11th Cir. 2009).

would need an MRI, which was not needed immediately. The undercover later testified at trial that he attempted to exhibit numerous "red flags" including: *(1)* he was the former patient of a doctor that was previously indicted; *(2)* he was using medication obtained from friends to self-treat his pain; *(3)* he traveled a long distance to Dr. Johnston's office for care; *(4)* he exhibited some drug seeking behavior including asking for the medication by name; and *(5)* he ran out of medication early.[199] The DEA also sent another undercover officer posing as a patient who mirrored the conduct of the prior undercover officer and presented with several "red flags." The government called a physician to testify as an expert, and the physician explained the concept of "red flags." Dr. Johnston was convicted and appealed the conviction, arguing that the admission of testimony about "red flags" permitted the government's expert to testify to legal conclusions and was contrary to the Supreme Court's decision in *Daubert* because the government failed to establish that such testimony was reliable or relevant.[200] The Eleventh Circuit Court of Appeals did not agree with Dr. Johnson's arguments, instead adopting the theory that the term "red flags" is synonymous with warning signs and was not used to create a medical standard.[201]

A federal judge in the Eastern District of Michigan raised some skepticism to the concept of "red flags" in the case of *United States v. Binder*. In *Binder,* the prosecution sought to present the evidence of a DEA agent who testified that a large number of Dr. Binder's files contained "red flags."[202] The government did not present an expert physician to testify that the actual treatment of the patients evidenced lack of a legitimate medical purpose and compliance with the usual course of professional practice.[203] Recognizing the lack of probative value of law enforcement

[199] *Id.*
[200] *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).
[201] *Johnston*, 322 Fed. Appx. at 662.
[202] *United States v. Binder,* 26 F. Supp. 3d 656 (2014).
[203] *Id.*

created "profile evidence," the trial judge dismissed the case stating, "where the government presents only 'pattern' or 'red flag' evidence sifted from a large number of patient files, particularly where no expert determination was made as to the suitability of the treatment in each case, the evidence is insufficient, without more, to demonstrate guilt beyond a reasonable doubt."[204]

In circular fashion, the DEA "red flags" are creeping into the common medical lexicon as the standard of care. In a 2017 article published in the *Permanente Journal*, Dr. Timothy Munzing sought to provide a definitive approach to the standard of care for prescribing opioids for noncancer pain.[205] In his article, Dr. Munzing presents a list of "red flags" developed from a document published by "stakeholders" in the opioid market, such as the major pharmacy chains, several large insurance companies, the Federation of State Medical Boards, various medical societies, and professional organizations.[206] Despite the warning on the document clearly stating that the document is not intended to inform or create a standard of care, it finds its way in Dr. Munzing's journal article that seeks, of all things, to establish a standard of care. Moreover, the "stakeholder" document does not provide any empirical data or support that the "red flags" are actual signs of apparent or drug seeking behavior. In fact, no empirical study exists that shows a causal link between "red flags" and drug abuse, addiction, or overdose. The list contains the following "red flags":

- Early refills/claims that the medications were lost or stolen—even with a police report
- Age 35 years or younger, especially combined with other red flags

[204] *Id.*
[205] Timothy Munzing, M.D., *Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain.* 21 PERM. J. 16-169 (2017).
[206] American Academy of Family Physicians et al., *Stakeholders' Challenges And Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances*, MOUNT PROSPECT, IL: NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (Mar. 2015 [cited Mar. 31, 2017]), https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf.

- Concurrent use of multiple pharmacies
- Obtaining controlled substances from multiple physicians or "doctor shopping"
- Excessive amounts or drug combinations
- Obtaining or buying controlled substances from family, friends, or others
- Giving or selling controlled substances to family, friends, or others
- Use/abuse of alcohol or drugs—current or past
- Use of tetrahydrocannabinol/marijuana, even with a medical marijuana card
- Use of drug culture street lingo for the names of the medications or other drugs
- Inconsistent results from urine drug screens or the prescription drug monitoring program report
- Patients driving long distances to see the physician for controlled substances
- Multiple family members or those residing in the same household receiving identical or similar controlled substances
- Similar or identical prescribing (*e.g.,* medication selection, strengths) regardless of specifics of symptoms such as pain severity, examination findings, diagnosis, etc. (lack of individual management plans)
- Failure to improve without adjustment of management plan
- Drug overdoses

Interestingly, the list of red flags developed in the "stakeholder challenges" document cite back to DEA decisions spanning from 2008 to 2012, DEA guidance letters issued by the DEA's Deputy Assistant Administrator of the Office of Diversion Control, and the DEA Practitioner's Manual wherein the DEA Administrator discusses "warning signs" that physicians and

pharmacists should recognize as possible evidence of diversion.[207] The DEA administrative cases that support the use of "red flags" as evidence against physicians all have two things in common: *(1)* they are DEA decisions wherein the DEA Administrator determined that the practitioner issued controlled substances in violation of the CSA and 21 C.F.R. § 1306.04; and *(2)* they are cases against pharmacies where the DEA Administrator alleged that the pharmacy distributed drugs despite "obvious warning signs," *i.e.,* "red flags."[208] The DEA's decisions from 2008 to 2012 have caused an echo chamber effect, ultimately causing a DEA created standard to bleed into the common lexicon of physician prescribing. The term "red flag" is a law enforcement created concept that has been adopted by the medical profession in an effort to remain in compliance with DEA regulations. Despite this fact, "red flags" have been applied in cases against physicians as a quazi "standard of care" and physicians have been charged and even convicted for prescribing in the face of one or more "red flags."[209] However, there is no empirical evidence that exists to support the theory that "red flags" are signs of diversion. As such, "red flags" should not be entitled to any deference – as Justice Scalia noted, "The Justice Department, of course, has a very specific responsibility to determine for itself what [criminal statutes mean], in order to decide when to prosecute; but we have never thought that the interpretation of those charged with prosecuting criminal statutes is entitled to deference."[210]

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[207] *Id.* (citing United States Drug Enforcement Administration; *Practitioner's Manual*, p. 30 (2006); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy,* Nos. 219 and 5195, Decision and Order, 77 FR 108, 62, 315 (Dept. of Justice, Oct. 12, 2012); *East Main Street Pharmacy,* Affirmance of Suspension Order, 75 FR 207, 66149 (Dept. of Justice, Oct. 27, 2010); *Holiday CVS, L.L.C. v. Holder,* 839 F.Supp.2d 145 (D.D.C. 2012); *Townwood Pharmacy*, 63 Fed. Reg. 8, 477 (Dept. of Justice, Feb. 19, 1998); *Grider Drug 1 & Grider Drug 2*, 77 Fed. Reg. 44, 069 (Dept. of Justice, July 26, 2012) (Decision and Order); *The Medicine Dropper,* 76 Fed. Reg. 20, (Dept. of Justice, Apr. 11, 2011); *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 363 (Dept. of Justice, Jan. 2, 2008); *Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409 (2008)).

[208] *See e.g., Medicine Shoppe-Jonesborough,* 30 Fed. Appx., *supra* note 207, at 413.

[209] *United States v. Lovern,* 590 F.3d 1095, 1102 (10th Cir. 2009).

[210] *Crandon v. United States,* 494 U.S. 152, 177 (1990).

Unfortunately, for physicians, the "red flag" model can easily ensnare honest and well-meaning physicians. The characteristics used by law enforcement to portray "drug seeking patients" are also qualities exhibited by legitimate patients that are undertreated.[211] Deception is difficult to detect and physicians as healers have an inherent truth bias.[212] The lack of empirical data to support the theory that "red flags" are signs of drug seeking patients and not legitimate patients places physicians in an untenable position. According to Dineen and DuBois, "labeling physicians as mis prescribers for merely being fooled is improper…physicians have inappropriately faced sanctions simply for being fooled."[213] In fact, recent research has determined that even after training to detect fake pain complaints, people could not detect real pain versus faked pain more than 55% of the time.[214] When it comes to something as intangible as "pain", deceiving physicians and playing on their inherent "truth bias," and punishing physicians for not recognizing law enforcement created, non-medical signals exhibited by undercover officers posing as legitimate patients creates fear in the medical profession and does nothing to resolve the real cause of the "opioid epidemic."

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[211] K.K. Dineen & J.M. DuBios, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42(1) AM. J. LAW MED. 7-52 (2016) (citing Beth Jung & M.M. Reidenberg, *Physicians Being Decieved,* 8 PAIN MED. 433 (2007) ("[o]ur review of [DEA] . . . actions against physicians who prescribed opioids found that some of these actions were based on prescriptions given to undercover agents. In several high-profile prosecutions of physicians for prescribing opioids, prosecutors claimed that the doctors should have known the individuals were feigning pain solely to obtain the prescriptions") (citation omitted); M.M. Reidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients,* 81 CLINICAL PHARMACOLOGY & THERAPEUTICS, 903, 904 (2007) [PUBMED] (finding that in many of the cases they reviewed between 2004 and 2005, the focus was on the fact that undercover officers had "fooled" the physician); Hailey Branson-Potts, *Woman Says Doctor in Murder Case Provider Her Hundreds of Pills Weekly,* L.A. TIMES: BLOGS (Jun. 15, 2012, 6:11 PM), http://latimesblogs.latimes.com/lanow/2012/06/doctor-charged-with-murder-supplied-addict-with-hundreds-of-addictive-pills-each-week-former-patient.html [perma.cc/U5B2-6WB9] ("[i]n two weeks of testimony, prosecution witnesses have said they exaggerated or lied to [the doctor] about suffering pain and walked away with their desired prescriptions after little or no examination")).

[212] *Id.*

[213] *Id.*

[214] M.S. Bartlett, G.C. Littlewort, M.G., Frank, & K., Lee, *Automatic Decoding of Facial Movements Reveals Deceptive Pain Expressions,* 24(7) CURR BIOL. 738-43 (Mar. 31, 2014).

## VIII. THE CDC GUIDELINES: A CHILLING EFFECT ON THE MEDICAL PROFESSION

In addition to "red flag" evidence, the abrupt left turn of recent "opiate epidemic" guidance and regulations presented by government agencies has had a direct impact on the standard of care for prescribing nationwide. The roots of the opioid epidemic can be traced back to a 1986 study propped up by the opioid industry that concluded that opioid maintenance therapy can be a "safe, salutary, and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[215] In the 1990's, the management of chronic pain was a significant health care policy concern and practitioners were advised by the Joint Commission, an accrediting body, to treat pain as a fifth vital sign.[216] Since the "pain as the fifth vital sign" movement, physician opioid prescribing surged.[217] This was principally because Centers for Medicare and Medicaid Services (CMS) tied post-hospitalization patient survey questions about the effectiveness of a patient's pain management to physician reimbursement and performance rankings. Only recently has the tide turned in the opposite direction. A proposed rule to remove the policy was only proposed in 2016.[218] This reversal was done contemporaneously with a sweeping change to drug policy and the implementation of the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain.[219] It

[215] Bob Tedeschi, *A 'Civil War' Over Painkillers Rips Apart the Medical Community - and Leaves Patients in Fear,* STAT (Jan. 17, 2017), https://www.statnews.com/2017/01/17/chronic-pain-management-opioids/ (citing R.K. Portenoy & K.M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*. 25(2) PAIN. 171-86 (May 1986)).

[216] Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions,* 16(5) EXP. CLIN. PSYCHOPHARMACOL. 405 (2018) ("During the 1990s, a major change occurred . . . . The use of opioids for legitimate medical purposes has been accompanied by a substantial increase in the prevalence of nonmedical use of prescription opioids"); Kristina Fiore, *Groups Call on JC and CMS to Re-Evaluate Policies that Could Lead to Opioid Overprescribing,* MEDPAGE TODAY (Apr. 13, 2016), https://www.medpagetoday.com/publichealthpolicy/publichealth/57336.

[217] *Id.*

[218] 81 C.F.R. § 45603

[219] Centers for Disease Control and Prevention, *CDC Guidelines for Prescribing Opioids for Chronic Pain,* (last updated Aug. 29, 2017), https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

appears as if the government "woke up" in 2016 and steered too hard in the other direction with the implementation of a substantial number of policy changes, including the CDC Guidelines.

The CDC Guidelines, implemented in 2016, were intended as a guideline, but recommended limits to prescribing by primary care physicians. The guidelines contain 12 recommendations for primary care physicians:[220]

> 1. Non-pharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
> 2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
> 3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.
> 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
> 5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.
> 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
> 7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

[220] *Id.*

> 8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.
> 9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
> 10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
> 11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
> 12. Clinicians should offer or arrange evidence-based treatment (usually medication assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

The guidelines themselves read like a "standard of care" for prescribing physicians that was created by the government. Since their implementation, the guidelines have been highly controversial, and some have argued that they have been used to form a government created "standard of care" which was created under dubious circumstances.[221]

For instance, Drs. Michael Schatman and Stephen Ziegler argue that the composition of the board responsible for drafting the guidelines was "not balanced" and public comment was a charade because the guidelines were not made publicly available for comment.[222] Schatman and

[221] Doug Campos-Outcalt, M.D., M.P.A., *Opioids for Chronic Pain: The CDC's 12 Recommendations*, 65(12) J. FAM. PRACT. 906-909 (Dec. 2016) ("given the prominence of the CDC, this clinical guideline will likely be considered standard of care for family physicians").

[222] M.E. Schatman & S.J. Ziegler, *Pain Management, Prescription Opioid Mortality, and the CDC: Is the Devil in the Data?* 10 J. PAIN RES. 2489-2495 (2017); M.E. Rose, *Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts,* 19(4) PAIN MED., 793-807 (Apr. 1, 2018), https://doi.org/10.1093/pm/pnx048 (interestingly, of the 17 members of the CDC guideline expert panel, 15 were emergency medicine, addiction, public health, or state regulatory professionals; the remaining two members with pain profession backgrounds were members of a group called "physicians for responsible opioid prescribing," an activist group dedicated to limiting the use of opioid analgesics, and one was also a paid consultant to a law firm that litigates against opioid analgesic manufacturers).

Ziegler argue that over 100 million Americans suffer from chronic, long-term pain and the CDC conflates the opioid epidemic by assuming that overdose deaths are connected to the "over treatment" of chronic pain.[223] They further argue that pain patients in America are undertreated and efforts to reduce opioid prescribing confound this problem. [224] Schatman and Ziegler are not alone in their criticism. Mark Rose authored an article in Pain Medicine heavily criticizing the conflicts of interest apparent in the implementation of the CDC Guidelines and argues that the public participation touted by the guidelines is largely a charade and "perpetuate the misperceptions of opioid analgesics."[225]

Data from the CDC indicates that, prior to the implementations of the CDC guidelines, the amount of opioids prescribed in the United States decreased by more than 18%.[226] Another study found that 2017 saw the largest annual decline of opioid prescriptions in the last 25 years when opioid prescriptions dropped 12% in 2017 – immediately after the implementation of the guidelines.[227] The essential question is whether or not this decrease represents better decision-making by providers or the knee jerk reaction of providers limiting their prescribing arbitrarily to meet federal demands. Indeed, in April of 2018, the *Washington Post* reported that, despite the drastic decrease in opioid prescribing, deaths from heroin skyrocketed with over 42,000 deaths in 2016.[228] Certainly, this may be the result of previously addicted patients turning to the streets

[223] Id. (citing Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,* WASHINGTON, DC: THE NATIONAL ACADEMIES PRESS (2011).
[224] *Id.*
[225] M.E. Rose, *Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts,* 19(4) PAIN MED., 793-807 (Apr. 1, 2018), https://doi.org/10.1093/pm/pnx048.
[226] G.P. Guy Jr., K. Zhang, M.K. Bohm, J. Losby, B. Lewis, R. Young, L.B. Murphy & D. Dowwell, *Vital Signs: Changes in Opioid Prescribing in the United States*, *2006-2015,* 66(26) MMWR MORB. MORTAL WKLY. REP. 697-704 (JUL. 7, 2017).
[227] Megan Brooks, *Opioid Prescriptions See Largest Annual Drop in 25 Years*, MEDSCAPE (Apr. 19, 2018), https://www.medscape.com/viewarticle/895419.
[228] Katie Zezima, *Study: Despite Decline in Prescriptions, Opioid Deaths Skyrocketing Due to Heroin and Synthetic Drugs,* WASHINGTON POST (Apr. 10, 2018), https://www.washingtonpost.com/news/post-

because illegitimate doctors are being prosecuted and are no longer able to treat patients. However, it may also be the result of a risk adverse populations of physicians fearful of prescribing to legitimate pain patients who are forced to self-medicate.[229]

In a 2016 *New York Times* article, University of Maryland Law Professor Diane Hoffmann predicted that the unintended consequence of the "war on opiates" would likely be many undertreated chronic pain patients. Professor Hoffman correctly pointed out that the medical community "is generally a risk averse population, one easily put off by the threat of government investigation or sanctions" and that "fear of criminal liability is only one side of the legal pressures physician may face." Dr. Daniel B. Carr, President of the American Academy of Pain Medicine, agrees and believes that "there is a civil war in the pain community" where one group "believes the primary goal of pain treatment is curtailing opioid prescribing [and] [t]he other group looks at the disability, the human suffering, the expense of chronic pain."[230] Dr. Sean Mackey, a past President of the American Academy of Pain Medicine who oversees Stanford University's pain management program, also agrees and believes that "there's almost a McCarthyism . . . that's silencing so many [physicians] who are simply scared."[231] Carr believes that the CDC Guidelines have led some to take a zero-tolerance approach to opioids while insurance companies and the government have done little to support opioid-withdrawal efforts or help physicians learn how to manage pain or enable access to alternate therapies.[232] The *New York Times* and *ProPublica*, the independent, nonprofit investigative journalism organization, jointly reported in 2017 that "at the

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nation/wp/2018/04/10/study-despite-decline-in-prescriptions-opioid-deaths-skyrocketing-due-to-heroin-and-synthetic-drugs/?noredirect=on&utm_term=.9aa3bfcd1e10

[229] M.E. Rose, *Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts,* 19(4) PAIN MED., 793-807 (Apr. 1, 2018), https://doi.org/10.1093/pm/pnx048.

[230] Bob Tedeschi, *A 'Civil War' Over Painkillers Rips Apart the Medical Community - and Leaves Patients in Fear,* STAT (Jan. 17, 2017), https://www.statnews.com/2017/01/17/chronic-pain-management-opioids/.

[231] *Id.*

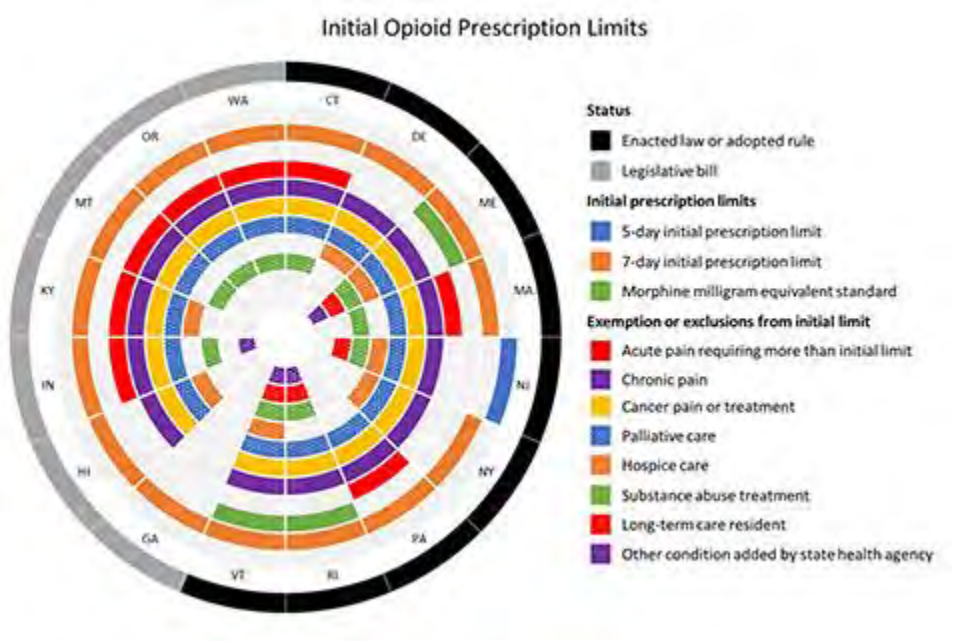
[232] *Id.*

same time the United States is in the grip of an opioid epidemic, many insurers are limiting access to pain medications that carry a lower risk of addiction or dependence, even as they provide comparatively easy access to generic opioid medications."[233] With limited access to insurance funding for alternative therapies, physicians are faced with the decision between prescribing risky opioid medications or refusing to treat pain patients; however, recent regulations have limited the supply of traditional opiates. In 2018, Medicare provided notice of a proposed rule that would deny coverage, in certain circumstances, for opioid prescriptions issued for more than seven days and over a 50-morphine milligram equivalent dose.[234] Finally, several major pharmacy chains have recently enacted limits on doses of pain medication for chronic pain patients.[235] The dosage limits put in place by CMS and major pharmacy chains were derived from the highly disputed CDC Guidelines.[236]

We are seeing a pyramid of regulation built on the unstable foundation of the highly contested CDC Guidelines. The changes in regulation are fast paced and providers are unlikely to keep the pace with the myriad of fast changing regulations. In 2017, nine states added statutes that limit the initial amount of opiates a provider may prescribe, and the limits follow the CDC

[233] Katie Thomas & Charles Ornstien, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, NEW YORK TIMES (Sept. 17, 2017), https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html.
[234] CMS, *Advance Notice of Methodological Changes for Calendar Year (CV) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter,* (Feb. 1, 2018), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf.
[235] CVS Caremark, *Opioid Quantity Limits Pharmacy Reference Guide*, (2018), https://www.caremark.com/portal/asset/Opioid_Reference_Guide.pdf; BCBS of Texas, *Standard Dispensing Limits (DL)*, (2018), https://www.bcbstx.com/pdf/rx/rx_dispensing_limits_std_tx.pdf; Vanessa Romo, *Walmart Will Implement New Opioid Prescription Limits By End of Summer*, NATIONAL PUBLIC RADIO: THE TWO-WAY (May 8, 2018, 7:28 PM), https://www.npr.org/sections/thetwo-way/2018/05/08/609442939/walmart-will-implement-new-opioid-prescription-limits-by-end-of-summer.
[236] *See* source cited *supra* note 234, pp. 143 and 203 (CMS will re-assess including these measures in the Star Ratings once the PQA updates their measures to better align with the CDC guideline and/or OMS).

Guideline's opioid limitations.[237] Seven other states are considering initial limits with legislation pending. Below is a chart depicting the complicated web of state regulations in 2017:




[Image Credit to Association of State and Territorial Health Officials]

As a direct result of the circuit shift to anchor violations of 21 C.F.R. § 1306.04 to "standard of care," the practice requirements necessary to avoid the potential for criminal lability are heightening, becoming more complex, and difficult to follow.

## IX. CONCLUSION

Courts simply cannot agree about the most basic elements of 21 U.S.C. § 841(a) and 21 C.F.R. § 1306.04.[238] Over the last 40 years, the courts have drastically shifted to the approach that Justice Potter Stewart feared when he pointed out during oral argument *in United States v. Moore,* that we are embarking on dubious grounds when we begin prosecuting physicians for professional

[237] Andy Baker-White, *A Look at State Legislation Limiting Opioid Prescriptions,* ASTHO (Feb. 23, 2017), http://www.astho.org/StatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/.
[238] *See Feingold*, 454 F.3d 1001,1008 (2006); *see also United States v. Hurwitz*, 459 F.3d 463, 480 (4th Cir. 2006).

disagreements.[239] Despite this ominous warning, this is exactly what we have done. Misinterpretation of the phrases "legitimate medical purpose" and "course of professional practice" have led some courts to embark on an exploration of civil malpractice issues when determining whether a physician should spend years, if not decades, in jail.

Lack of consensus about the criminal standard to be applied has somehow survived vagueness challenges notwithstanding the fact that courts cannot agree over whether the standard is objective or subjective, disjunctive or conjunctive, and even whether "legitimate medical purpose" and "usual course of professional practice" mean the same thing. While we patiently wait for the long overdue return of the Supreme Court's voice on this topic, the practice of medicine hangs in the balance. Pain management physicians and family practice physicians alike are waiting on the sidelines, fearful of prescribing, until some definitive standard is set forth so that this "risk adverse" population can know the limits of their liability.

Somehow, despite the clear ruling in *Gonzales v. Oregon,* that state standards drive the standard of care, the federal government has continued to pump out practice standards that have been adopted as the standard of care.[240] The CDC Guidelines and the "red flag" standard used by DEA agents and prosecutors alike are federally created standards that lack empirical data and are misplaced in a medical community where advancement comes at the form of sometimes pushing boundaries and attempting new modalities.[241] Physicians have a tendency to overreact to such standards for fear that violating them may trigger licensing action, audits, or place them in handcuffs.

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[239] *Hurwitz,* 459 F.3d at 480; *see also* oral argument in *United States v. Moore,* 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.
[240] *Gonzales v. Oregon,* 546 U.S. 243, 269 (2005).
[241] M.E. Schatman & S.J. Ziegler, *Pain Management, Prescription Opioid Mortality, and the CDC: Is the Devil in the Data?* 10 J. PAIN RES. 2489-2495 (2017).

The Supreme Court was clear in *United States v. Gonzales* that a physician should only be prosecuted when his or her conduct departs from the practice of medicine and delves into the realm of drug dealing.[242] Given the split amongst the circuits pertaining to the applicability of the standard of care in this analysis, whether an objective or subjective approach is necessary, and the plain meaning of both statutory phrases "legitimate medical purpose" and "usual course of professional practice," the Supreme Court must act and either declare 21 U.S.C. § 841(a) vague, or pronounce an interpretation of 21 C.F.R. § 841(a) and 21 C.F.R. § 1306.04 consistent with *Gonzales* and *Feingold*.[243] The court must hold that "legitimate medical purpose" means what it says – a physician is protected if he or she prescribes for what he or she subjectively believes to be a legitimate medical purpose and the federal government is prohibited from regulating the practice of medicine unless a doctor is stripped of his or her statutory protection by prescribing for a non-medical purpose and outside the course of professional practice.

Malpractice has no place in this analysis, as Justice Stewart warned:

> And is it not true that historically most, if not all of the great breakthroughs and advances in medical science are made by people who did not follow the conventional way of doing things. They followed a new way, their way, and most of the conventional physicians of their day would have disagreed with them because this is not the way it has always been done . . . . It bothers me that this kind of evidence . . . is the basis for criminal liability. This man was a physician, he was not a fraud.

What Justice Stewart means is that prosecuting physicians for violations of federally created "standards of care" places too much power in the hands of the federal government to regulate the practice of medicine and usurps the power of physicians to advance the field of medicine and attempt alternative approaches for the benefit of our republic.

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[242] *Gonzales, 546* U.S. at 269.

[243] *See Gonzales,* 546 U.S. at 243 (the Supreme Court analyzed the interpretation of "legitimate medical purpose" to determine if the attorney general may interpret it as prohibiting physician assisted suicide); *see also United States v. Feingold, 454 F.3d 1001 at 1008 (2006).*