Case No. 23-130

In the Supreme Court of the United States

Saad Sakkal, MD
Petitioner,

v.

UNITED STATES OF AMERICA
Respondent.

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

PETITION FOR REHEARING

Saad Sakkal, MD (*Pro se*)
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Updated October 24, 2024 (from original 1/29/2024)

QUESTIONS PRESENTED

A. WHETHER THE GOVERNMENT QUESTION RAISED, IN RESPONSE TO THE PETITIONER'S CERTIORARI IS A DIVERSION?

B. WHETHER PLAIN ERRORS, EVEN IF NOT RAISED PREVIOUSLY, ARE REASONS TO VACATE?

C. WHETHER THE DISTRICT COURT JURY INSTRUCTION VIOLATED SCOTUS' RUAN 2022 DECISION, AND ITS OWN RECENTLY MODIFIED JURY INSTRUCTION GUIDELINES, IGNORING MENS REA, AND PERPETUATING CIRCUITS CONFLICT?

D. WHETHER THE GOVERNMENT LAWYERS AND THE COURT(s) LEGISLATED ENCROACHING ON CONGRESS' INTENT, WHEN MISAPPLIED 21 U.S.C. SECTION 841, VIOLATING SEPARATION OF POWERS DOCTRINE? AND WROTE THE SENTENCING COMMISSION DRUG CONVERSION TABLES ARBITRARILY BIASED AGAINST PHYSICIANS?

E. WHETHER THE INEFFECTIVE ASSISTANCE OF COUNSEL CHANGED THIS CASE TO NEGATIVE OUTCOME?

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STATUTORY AND REGULATORY FRAMEWORK

"841 Prohibited Acts A

(a) unlawful acts

Except as authorized.. it shall be unlawful for any person knowingly or intentionally_ (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

"21 USC # 841" (a)(1). This subchapter authorizes persons, who have registered with the Attorney General to dispense, according to 21 USC 822(b). The CSA also directs the Attorney General to "accept the registration of medical doctor if he is "authorized to dispense.. controlled substance under the law of the state in which he practices "21 USC 823 (g)(1). [The CSA never included "prescribe" as unlawful. Sakkal only prescribed; he did not "dispense" to end user, or "distribute" according to 21 U.S.C. 802 et seq. definitions. as explained below]

"1306.04 Purpose of issue of prescription

(a) 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.. A prescription issued not in the usual course of professional treatment ..is not a prescription within the meaning and intent of section 309 of the Act

Other Related Acts

A) 21 U.S.C. 802 (8) defines: Deliver and delivery as the actual, constructive or attempted transfer of a controlled substance. (Constructive in dictionary means: fabricative, able to fabricate, concerned with manufacture)

B) 21 USC 802(10), defines:

"dispense": "to deliver a controlled substances to an ultimate user, or pursuant to the lawful order of, a practitioner, including prescribing and administering of a controlled

substance".. so the term "dispenser" means: a practitioner who so delivers a controlled substance to an ultimate user". (Dictionary definition: expense, supply, to weigh out)

C) 21 U.S.C. 802 (11) defines:

"distribute": to deliver (other than by administering or dispensing) a controlled substance".

"distributor" means a person who so delivers a controlled substance" (Federal Rules and Codes 2014, Page 1198).

(see also 2023 Revised Model Jury Instruction:

14.02C: Dispensing or distribution of a controlled substance by a practitioner 21 U.S.C. #841(a)(1))

(Dictionary definition give, provide, handle, prepare and distribute medicine to the sick, deal)

D) "Practitioner"

"Practitioner" means: a physician, dentist, veterinarian, pharmacist, hospital or other licensed, registered, and permitted by the United States or the Jurisdiction in which he practices" (Id. at 1199).

(Both dispenser and distributor HANDLE physically the controlled substance, the distributor to an intermediary like a drug store, or another distributor, and the dispenser is the one who dispense to the ultimate user: either legally like pharmacist, or illegally like a small drug dealer/peddler). (all dictionary definition are from Webster's International Dictionary unabridged)

INTRODUCTION TO THE CASE

1) "Lengthy incarceration without proving criminal intent is tyrannical. A 20-year imprisonment for medicating pain (is many physicians' painful experience that) deters all physicians against fully treating any patient who suffer. Undertreatment of pain will inevitably results when a robust good faith defense (In the District Court) is denied. Dr. (Sakkal) acted in good faith as shown by unsubstantiated witnesses' testimony that revealed not a single illegal act, his supportive patients were withheld from the jury, his exculpatory evidence was suppressed from the record by his defense counsel, and his jury instruction did not include a viable Mens Rea that comport with Ruan 2022 SCOTUS decision. The Jury also was misled by the government and its expert witness and misled that (Sakkal) could have any witness he wanted when his counsel refused to allow any to come to his defense." (Brief Amic. Curiae Association of physicians and Surgeons, in support of Ruan 12/27/2021)

2) Under the Sixth circuit decision process, nearly any physician who treats pain is at risk of an arbitrary 20-year imprisonment or more, based on a very small fraction of his prescriptions. In Sakkal case this was 20 cherry-picked patients out of 4000, or less than 60 prescriptions out of 63.000 prescription (<1/1000). By eliminating bona-fide good faith defense, the approach taken by the Sixth Circuit misleads juries regarding what constitutes legitimate medical practice.

3) The Circuit Ruling begins by stating that "Saad Sakkal prescribed controlled substances to help his patients manage pain" a truly beneficial legitimate purpose, then on its seventh page contradicts itself to accept the premise the prescription was 'not for legitimate medical purpose". The trial degenerated into scapegoating and eliciting jealousy of doctors by unfounded speculation that "Sakkal made money off drugs making his patients high and killed in the process 40% of his patients" as the prosecutor proudly claimed in his closing argument. The prosecutor miscalculated the fraction/ratio by using 8 deaths in relation to the twenty small sampled, cherry-picked indictment cases in plain calculation error. Instead, the correct calculation is by relating the total practice's death of 8 to the total number of practice patients of

4000 (which makes the ratio only 0,002%, compared to the national average of 1-2% in primary care, and 5-10% in addiction clinics). It is sad fact that the prosecutor made such a prejudicial error in calculating fractions, of a third-grade elementary school student without Court's objection.

4) "Mischaracterizing a doctor based on non-representative prescriptions (of his most challenging complicated patients who have multiple disorders and a multiple medications) does not make him a drug dealer or reduce overall abuse of prescriptions. Instead, eliminating the (well versed experienced) high-volume prescriber has the effect of dispersing those medications among many smaller practices with fragmented care, less experience, with an increase in the potential for misuse, duplication and doctor's shopping. The denial of good faith defense (by the Sixth Circuit) exacerbates the problem it purports to address. Allowing a robust good faith defense would safeguard legitimate practices and help patients in pain to become productive in their lives. Incarceration of physicians who treat pain does not eliminate the pain and the need to treat it." (Id, supra)

5) Thus, "A robust good faith defense is essential to protect patient access to prescriptions written in good faith" (Id.). This opinion was explained extensively in five pages by Justice Alito and Thomas in their concurrence in Ruan 2022, of which the following paragraph is quoted:

> "We have previously held that the CSA incorporates settled understandings of the "exemption given to doctors" to dispense controlled substances "'in the course of professional practice"' under the Harrison's Act (1913). Moore, 423 U.S. at 139-140, 96 S.Ct 335, 46 L. Ed 333. The language of the CSA supports the same conclusions. As our CSA precedents explained, to act "in the course of professional practice" is to engage in the practice of medicine-or, as we have put it, to "act as a physician"'. For a practitioner to "practice medicine he or

> she must act for medical purpose-which means aims to prevent, cure, or alleviate the symptoms of a disease or injury." (United States v. Ruan at 17).

Although Justice Alito and Thomas did not agree with the need to go any further than this plain statement, they narrated the other reasons the majority corrected the lower court and vacated/remanded Ruan, Couch and Kahn in the same decision:

> "the Court provides four reasons for this conclusion: " the language of # 841 (which explicitly exclude a 'Knowingly or intentionally' provision); the crucial role authorization plays in distinguishing morally blameworthy conduct from socially necessary conduct; the serious nature of the crime and its penalties; and the vague, highly general language of the regulation (1306.04(a) defining the bounds of prescribing authority" Ibid.

6) "Juries lack the training necessary to delineate or establish the boundaries of a highly skilled profession like Medicine and the complicated web of the many statutes and regulations involved in building the prosecution scheme in #841 cases, to be able to convict all. Yet that is the approach taken by most court(s) (including the Sixth Circuit),-contrary to the teaching of SCOTUS in Moore, 423 U.S. 122 (1975), and other circuits like the 7th and 9th circuits. States, not federal juries should assess the local boundaries of medical treatment of pain as a part of the medical practice Jurisdiction. Rather than draconian 20-year incarceration for prescribers, a more sensible approach would be simply to suspend the DEA registration while providing full due process for the physician, including allowing access to his records, and listening to his supportive patients and expert witness that was denied to Sakkal. The (Sixth circuit) usurped state authority over regulation of medicine, contrary to federalism, then contravened the due process".

7) "A dystopia results when the most basic individual right-innocence amid lack of criminal intent-is infringed upon under the guise of a so-called "War on Drugs". The Federal government can revoke the DEA registration at any time to stop a physician's prescription of controlled medications. State Medical Boards can and do impose summary suspensions of physicians licensed to practice. A 20-year incarceration of a physician by denying him the basic defense of good faith is not justifiable on any rationale. Benjamin Franklin famously said, "those who would give up essential liberty, to purchase a little temporary safety, deserve neither liberty nor safety" (House of Representatives 1756, P 19. Philadelphia 1756). Safety is not enhanced by sacrificing liberty to convict physicians who TREAT PAIN. (See also Katherine Goodman, Prosecution of Physicians as drug traffickers: failed USA under the CSA, and South Australia's Alternative Regulatory approach. 47 Colum. J. Trans'l L. 210 (2008) and Kelly Dineen et al. between the Rock and Hard Place: can physicians prescribe opioids to treat pain adequately while avoiding legal sanction? 42 Amer.J. L& Medicine 1 (2016).

8) "The USA continues to face two intertwined crises: 1. substance use disorder alongside an increase in fatal poisonings and, 2. the under-treatment of pain. Prescription opioids have been falsely mixed with street drugs. While illicit opioids are driving the nations' overdose death rate and are distinct from the (innocent) prescription opioids that are used to treat pain and opioid use disorder (Puja Seth et al. Quantifying the epidemic of prescription opioid, Amer. J Public Health 2018, 108:500-2). Opioid prescription has been influenced by a variety of factors including availability, affordability, and health insurance coverage and treatment options. Prescription opioids occupy an important role in medical care as attested by a plethora of medical literature and the regulatory Section #801 for its benefit to treat pain stemming from surgery, accidents, cancer, and other legitimate disorders." (Brief amici curiae, Center for US Policy, in support of Ruan 12/27/2021)

9) "Few providers have contributed to the uncertainty by medical error, negligence, recklessness and rarely criminal intent for illicit profit. The last group is very small (<1/10.000) but enormous resources are dedicated to enforcing the CSA. make it reasonable to expect that

many more prescribers who lack any criminal intent will be caught up in the government massive effort to prosecute for crime, like Sakkal and similar cases as revealed in a study by a prior prosecutor, and DEA task force member Stephen Ziegler et al., Pain relief, prescription drugs and prosecution: a four state survey of chief prosecutors, Jour. of Law, medicine & ethics, 31 (1), 75-100, 2003."(Id.)

10) "But when it comes to prescription medications law enforcement is hampered by their limited knowledge regarding medical practice and the fact they view the problem and the solution through the singular lens of enforcement, not public health. Consequently, healthcare professional are at high risk of being investigated, indicted, and criminally prosecuted for false accusation of drug trafficking, irrespective of whether the prescribing was legal and legitimate, or stemmed from a medical error, negligence, recklessness, or the rare criminal intent. Thousands of physicians have been as such convicted because they accepted a plea bargain to avoid the merciless trials, since the Harrison's Act 1913, and the CSA."Id.
Here is one example of a DOJ Press Release warning devised to instill terror:

> "The DEA has teams of investigators specialized in finding "negligence" when writing perilous prescription, which can cause.. a potential overdose, The DEA will investigate the doctors who conduct this kind of practice; Special Agent in charge, Dallas field office.
>
> The Department of Justice will use every available tool to stop doctors who fail to prescribe controlled substance "properly". Assistant Attorney General. Press release 19-511, 5/19/2019.

The negative impact damages prescriber's reputation, livelihood, family, or loss of liberty stemming from wrongful conviction based on DEA finding of 'negligence when writing perilous prescriptions' or "properly"! Just as frightening is the millions of people who need their controlled medications responsibly but face significant barriers to access. These barriers led to contrary

dire consequences like increase in substance abuse, drug overdose poisonings, and suicide" Id. (see Lynn R. Webster, Pain and suicide, Pain Medicine, 15(3):345-46, 2014)

11) At the time of Sakkal's trial and conviction, "the government used the standard of care as a proxy for the CSA violation that 'the prescription was prescribed for no legitimate medical purpose 'and thus 'outside the usual course of professional practice', leading to wrongful jury instruction, and wrongful conviction. In this scheme, if the jury accepts the government expert's witness claim that the prescription fell outside the standard of care, then the government had to prove only one thing and that is the "defendant" wrote the prescription! Not that he KNEW that the written prescription was unlawful, or unauthorized. But this is NOT the law" Id.
This effective removal of the Mens Rea was wrong when decided in Sakkal's trial at the District and at the Appeals Courts, and as a result vacated and remanded by SCOTUS after Ruan 2022. Yet the Sixth Circuit denied the second appeal, ignoring Ruan's mandate, under the guise that it believed that the Mens Rea and mental state were covered well in the instruction of "deliberate ignorance" which was refuted by SCOTUS AS AMBIGUOUS. SCOTUS's mandate is being accepted by other judges in the Sixth Circuits (Judges white in Anderson, and Cole in Hofstetter) as well as Hargrave, Purpera, among others, and most USA circuits except for the Sixth Circuit in the second Sakkal appeal denial. The worst tragic farce was that the so-called government expert witness announced that the standard of care was what "was acceptable to an expert like myself in the USA at the time under consideration" and this was accepted in the Court without objection. This unknown, unpublished standard, without fair notice was the only standard the jury heard and had to accept.

12) The better jury instruction states the law as "in United States v. Feingold, 454 F.3d 1001 (9th Cir. 2006) where the government had to prove the defendant distributed the controlled substance 'outside the usual course of professional practice and without legitimate medical purpose' and to make a finding with respect to the intent to act as a pusher rather than a medical professional" Feingold at 1008. This was also confirmed in Gonzales v. Oregon at 269 "whether the defendant was engaged in illicit drug dealing".

Violation of the standard of care is relevant to malpractice civil cases, or administrative actions by a Medical Board, or suspension of DEA registration. In Re Roth, 60 Fed. Reg 62262 (1995) the physician was subject to administrative sanctions regarding his pain medicine prescriptions. Dr. Roth's appeal finally prevailed, but if he was charged today he would have been imprisoned by a court that went outside the usual expected course, as in Sakkal's case.

13) "Although opioid was not considered optimal therapy for fibromyalgia, clinical treatment guidelines indicate it is justified when combined with other therapeutics. (Don L. Goldenberg et al., Opioid use in fibromyalgia, Mayo Clin. Proc.91 (5): 640-48 (2016). However the reality is that 60% of fibromyalgia patients are prescribed opiates because it is needed" in a very chronic disease as a last resort. Government experts in other cases claimed that "opiates were precluded ever from being used in fibromyalgia, thus it is not a legitimate medical purpose" Id, and precluded from use in Migraine, opioid use disorder or other maladies.

This claim contradicts acceptable medical practice and is unethical and dangerous. Sakkal's extensive experienced research on fibromyalgia proved it was hypothalamic dysfunction found in 33-35% of clinic patients, associated with a spectrum of associated disorders related to mood, energy, sleep, metabolism, hormones and many other neurotransmitter disturbances that each need its own therapy with central combination medicines for opiate dose to be minimized to the smallest safe dose. Yet the government expert who has no experience with this disease spectrum announced that prescriptions were for "not a legitimate medical purpose, and thus outside the usual course of professional practice", which converted Sakkal from forty years experienced, successful medical practitioner into a drug dealer/trafficker, in one sentence.

14) "Urine Drug Tests (UDT) are another example.. Different types of tests have varying degree of accuracy, and if a patient lacks insurance or cannot afford a co-payment (estimated at $211 to $300), a UDT may be prohibitive. This poses a dilemma for the health care practitioner. Legal pressure demands a test, but patients will decline many times because they might forgo other essential life needs in order to afford the test" Id. Poor population will never submit to any

test if they had to pay anything. "The point is, decisions that lie outside the standard of care are not matters for prosecution; they may be the result of lack of resources, absence of affordable health care, and the reality that pain and complex conditions are treated by general practitioners with limited tools and resources available to them or their patients. Clinical care inherently difficult" Id, and it is not a crime to miss some guideline standards which are always changing and described as advisory and not obligatory as the government or its expert claim. At the end, risk exists in every treatment, allowing physicians many alternatives, and among the government's experts a myriad of ways exist for how chronic pain is treated, a minefield practitioners must navigate, but no one size standard fits all.

Sakkal did UDT on each patient as a policy, did the interpretation in light of the clinical setting, as explained supra. His insistence on using the best possible system he tested three different kits for accuracy and sensitivity while paying an outside reference laboratory to compare the result, at a high cost (> $20,000) before settling on the best clinically relevant system. Yet it is sad he was accused of doing no testing, ignoring all tests results, and counted outside the standard falsely as the jury was told by prosecutor and his expert, without objection. 15) Even not following any standard at one point was not an adequate reason for prosecution. Remarkably, a decade after the CSA and 1306.04 became law, Stephen Stone, Associate chief of the DEA wrote:

> "Act pf prescribing or dispensing done within the registrant's professional practice are lawful. It matters not that such acts are terrible medicine or malpractice, misconduct or negligence. they are nevertheless legal (Investigation and prosecution of professional practice cases under the CSA. In Drug Enforcement, 10:1, spring 1983, P 21-28." Id.

Yet decades later the government and court are still using the standard of care when it prosecuted Sakkal. The decision of SCOTUS in Ruan was hoped to change the attitude of the Sixth Circuit since the legal basis of physician's conviction has been reversed, and as a result

Sakkal's conviction itself should be reversed. Any such matters should be handled administratively at the state level, but not the unlimited federal government enormous resources, that overwhelm defendants, juries and courts. Please, See why this re-hearing is needed next.

INTRODUCTION: WHY PETITION FOR REHEARING

I. Petitioner Saad Sakkal (hereinafter "Petitioner"), proceeding pro se, respectfully petition for rehearing of this court 's January 8, 2024, order denying his petition for a writ of Certiorari. This Court previously 10/11/2022 granted a petition for a writ of certiorari, vacated and remanded to the Sixth Circuit Court of Appeals in light of its decision in Ruan v, United States, 597 U.S. 450 (2022) ("Ruan").

On remand, the Sixth Circuit affirmed, applying plain error review (Appeal Ruling at 2), rejected Petitioner argument that the "district Court's scienter instruction [did not] comply with the holding of Ruan." (Certiorari at 2). Petitioner argued consistently that the district court's jury instruction was defective because it tied the "knowingly and intentionally" Mens Rea to the act of dispensing (instead of authorized prescribing), but not to the requirement that a prescription be prescribed knowingly and intentionally "for legitimate medical purpose in the usual course of HIS professional practice" (United States v. Saad Sakkal, U.S. Dist. Lexis 79675 at 5, 2020; Appeal Brief at 61; Appeal Reply at 5-8).

The Sixth Circuit found that its decision in United States v. Anderson, 67 F. 4th 755 (6th Cir. 2023)"forecloses this negative implication argument" (Appeal Ruling 2023 on remand at 11), because as in Anderson, the district court elaborated on the MENS REA requirement through a 'deliberate ignorance' instruction. It added that the "more detailed instruction" provided to the jury went beyond an objective view of the usual course of professional practice and directed the jury's attention to [petitioner's] subjective mindset [Mens Rea] in issuing prescriptions" (Id at 12), and the 'deliberate ignorance' instructions "ensured that the instruction comported with Ruan holding (Id at 12), and accordingly saw no basis for plain error relief (Id at 13), citing Anderson F. 4th at 766. Petitioner will explain below why the Sixth Circuit got it all wrong, it plainly erred.

When petitioner had to go back to this Honorable Court for remedy, for the second time. His counsel asked this Court to review pending Ruan and Anderson's and resulted in a denial after Anderson's certiorari failed, inviting the petitioner to request a rehearing immediately, in

timely manner. However a post mail mishap prevented this petition from reaching the court until the date of this note (see Appx. F: communications with the Court Clerk).

Preliminary Statement

II. The Sixth Circuit, on first appeal, plainly erred when it affirmed the petitioner's conviction by contradicting itself: In its Ruling first sentence the Appeals Court admits that "Sakkal prescribed for managing pain" (Appeal Ruling at 1), the primary legitimate medical purpose, then stating later "he prescribed for no legitimate medical purpose", in violation of the doctrine of judicial estoppel. The Sixth Circuit also declined dealing with many issues of ineffective assistance of counsel or the merits of the case, and Instead applied a plain error standard, regarding the counsel error (Appeal ruling on remand at 7). Although the defense counsel failed to preserve an objection for a defective jury instructions, (Id. at 4) and refused the government's proffered plea unilaterally, on his own, without conferring with his client, the petitioner maintains that these two serious counsel failures are more important in the case. (District Court Opinion at 19).

But the district court concluded, and the appeal court affirmed, that "In sum, the court is satisfied that Mr. Goldberg gave the defendant competent advice as to whether to accept the plea offer" (District Court Opinion at 22).

III. When this court, 10/11/2022, vacated petitioner's conviction, with government agreement, and remanded the case to the Sixth Circuit in light of Ruan 2022, this Court did so to reclarify its old decision by including the new "Ruan" standard that reinforced the "except as authorized" doctrine and the MENS REA/SCIENTER requirement in the application of F.C.R. 1306.04 (a) to 21 USC 841 cases, which was absent in the district court defective jury instruction. While the government in this Court waived its objection, too, the government reversed its position at the Sixth circuit, in violation of the doctrine of estoppel and contradicting the Supreme court/government agreement/decision to remand, thus the Appeal court refused

to accept the Supreme Court Grant, Vacate & Remand, denying the appeal again based on the "plain error review" — regarding the counsel failure to object — insisting that the petitioner alone waived his right by his counsel failing to object in the district court, but not the government Solicitor General's Office that also did not object in the Supreme Court, agreeing with the remand. This is another example of Appeal Court plain error and violation of Due Process.

IV. Either the Counsel assistance failed by his lack of objection, as the government implies in its argument at the Appeal Court, or he did not as the government insisted in the District Court! Two contradicting arguments cannot both be correct at the same time. The government has to decide which is which! This Court needs to make a choice applicable to all lower systems, including the District and Appeals courts. Moreover, the Sixth Circuit is by the doctrine of Stare Decises, not expected to resist the Supreme Court decision.

V. In Petitioner's case, during trial, the district court provided the jury with ambiguous and confusing instruction that immutably caused the jury to reach a finding of guilt. The use of this ambiguous and incorrect language to replace the "except as authorized" requirement of the CSA, which precedes a finding of "willful blindness and deliberate ignorance", (both don't satisfy the "beyond reasonable doubt" standard), are inconsistent with The Supreme court "Runa" guidance. This is the true heart of the legal constitutional matter at hand. Indeed, the district court confused the CSA intent with a misapplied regulatory rule by the Attorney General, rule 1306.04 (a) which replaced the MENS REA/SCIENTER standard with unconstitutionally ambiguous language, as This Court held in Runa.

VI. Moreover, the district court used a modified "but-for" argument from Burrage clause (see infra) equating inappropriately, unauthorized rogue drug trafficker with authorized physicians, misusing the Burrage clause intent in another serious plain error.

VII. As explained, then, the Sixth Circuit first erred in its affirmation of conviction, when it refused to review the case on its merit, contradicting its own ruling, contradicted the USC # 841CSA, the CFR 1306.04, and a second denial plain error after this Court's remand following "Ruan".

VIII. This Court's Rule 44.2 authorizes a petition for rehearing based on "intervening circumstance of a substantial .. effect". With regards to the complex circumstances driving this case and the concomitant application of rule 44.2, a number of intervening circumstances occurred REQUIRES a rehearing, notwithstanding the fact that Anderson's certiorari was recently denied, supra_ the case upon which the Sixth Circuit relied in finding of "no basis for plain error relief" in this case. Note the following circumstances:

i) The Anderson's decision was derived from a divided panel, with one justice (Judge white) strongly dissenting, based clear evidence the jury instruction did not comport with Ruan (Id.at)

ii) A judge on the panel that decided another case-United States v. Hofstetter, 80 F. 4th 725, 733-34 (6th Circ 2023)- also criticized the same appeal's court Anderson's ruling as deviating from the reasoning espoused by this court in Ruan.

iii) The Sixth Circuit itself modified its own Jury instruction model to comply with Ruan on 3/1/2023, yet it denied the petitioner's remand capriciously on 5/23/2023, 2 months afterward! The change in the text is a plain admission by the Sixth Circuit that its Sakkal's trial instruction was defective, and violated the Ruan mandate, was unacceptably ambiguous in its letter, structure and spirit requiring change. The new corrected text reads closer to what Sakkal requested in trial, inviting to vacate the conviction. The new text reads:

> "(14.02C dispensing a controlled substance by a practitioner (21
>
> U.S.C. # 841 (a)(1)
>
> (1) the defendant is charged with the crime of dispensing [distributing]
>
> a controlled substance. For you to find the defendant guilty of this

crime, you must find that the government has proved each and every one of the following elements beyond reasonable doubt:

(A) the defendant knowingly [or intentionally] dispensed [distributed] the substance.

(B) the defendant knew at the time of dispensing [distributing] that the substance was a controlled substance.

(C) the defendant's dispensing [distributing] was unauthorized, that is to say the dispensing [distribution] was not for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice; and

(D) the defendant KNEW [or intended] that HIS DISPENSING [distribution] WAS UNAUTHORIZED.

The term "practitioner" means a physician [dentist, veterinarian, scientific investigator, pharmacy, hospital or other person] licensed ..

The requirement that the defendant KNEW or intended is based on RUAN, 142S.Ct 2370, 2382 (2022). This change requires exoneration.

iv) Add to the aforementioned reasons that many Circuits are beginning to apply this principles. as a plain error losing confidence in the jury outcome which renders it unacceptable, here are two recent examples:

A. In United States v. Hargrave, 2024 U.S. App. Lexis 14271 (4th Cir.), the 4th circuit held:

"The government argues that Hargrave invited error by proposing some of the language in the jury instruction. We disagree with the government on invited error, but we agree on plain error.. the government does not dispute that:

(1) there was an error; (2) the error was plain, and in light of Ruan and our decision in Smithers (2024) we agree.

"[A] district court errs when it applies an objective standard, or fail to convey that a subjective analysis is required"

(Id at 3). "The error [have to] actually affect the outcome"

The Court in Hargrave vacated three counts related to #841 based on plain error argument in light of Ruan, because the Mens Rea/Scienter was not strong enough to make subjective standard clear. Sakkal's First Certiorari at SCOTUS 2022, WAS VACATED BY SCOTUS WITH THE GOVERNMENT AGREEMENT, WHICH LATER REVERSED ITS POSITION IN ESTOPPEL at the Appeals Court and this Court.

Hargrave holds that any jury instruction which did not account for the heightened Scienter standard, that correctly inform the jury it must find beyond reasonable doubt that Dr. Sakkal subjectively acted outside HIS usual course of professional practice and prescribing authority-not merely, that any of his actions were improper by objective medical standards-is inconsistent with Ruan.

Thus, it makes Sakkal's jury instruction similarly in doubt, as a plain error, especially when it was more vague than the now unacceptable regulation vague language (as held by this Court in Ruan 2022) asking the jury to "INFER KNOWLEDGE" if it finds the defendant "deliberately ignored the obvious" or "aware of probability that controlled substances "WERE Distributed" outside authorized practice, etc. without explaining how to define any "inference", "knowledge" of what, how to prove "deliberate" or what is the "Obvious" that is truly unobvious, or how to prove in-mind "awareness", or how to define "probability" and using the passive "CS WERE DISTRIBUTED", without indicating who distributed and to whom, which could be anyone unknown to anyone unknown outside the doctor office, without the doctor "awareness" of space or time or material distribution.

Only the Sixth Circuit still insists on this charade of ambiguity, despite changing its jury instruction in 3/1/2023, and denying in error 2 months later the defendant appeal on 5/31/2023.

B. In United States v. Purpera (4th Cir. 5/30/2024) the court pointed out that the record contained the physician statement that he prescribed for "legitimate medical purpose" which was adequate to balance the government expert witness claim that the prescription was "not legitimate", and as a result the 4th circuit vacated 56 counts related to #841.

Similarly, Sakkal have stated more than once in the post-conviction hearing in the district court and in every appeal that all his prescriptions were for legitimate medical purpose and have proven this fact based on each patient diagnosis, history and physical examination. Thus, to vacate all #841, 843 for Sakkal is the appropriate course for this Court, to erase Circuit conflict which only persist at the Sixth Circuit.

IX. In this Sakkal's case even though the jury instruction replaced incorrectly the CSA's "except as authorized" principle with this Court called ambiguous 21C.F.R 1306.04(a) as this Court explained In Ruan, the Sixth circuit denied the defendant appeal again after this Court remand and after the Sixth circuit changed its jury instruction to fit, on 3/1/2023, but violated it immediately when it denied the petitioner's appeal, 2 months later, on 5/31/2023.

Therefore in consideration of an increasing case load validating this Court decision in Ruan, vacating Ruan and Couch and Kahn, Dissention of Judge white in Anderson. concurrence critique of Judge Cole in Hofstetter, government agreement on plain error in Hargrave, and the acceptance of the physician's statement of legitimate medical purpose in Purpera, and many other cases, it makes clear that Sakkal's conviction was in error, and he continues to be incarcerated as a result of a false interpretation of the CSA, CFR, and SCOTUS held mandate. This incarceration criminalized good faith behavior, which was outlined well by Justice Alito in Ruan argument, it perpetuate poor judgment, district court error, and treat good faith as an intentional criminal conduct, without Mens Rea, necessary to distinguish a wrongdoing from a socially beneficial act like treating the ill, the sick, the poor by prescription, conflating drug

dealing/trafficking/ distributing or dispensing as defined in 802 (10) et seq with "legitimate prescribing", lowering the bar in a way that whimsically transform innocuous acts into nefarious criminal offenses.

This unfair approach should be stopped by the SCOTUS, who need to confirm to the Sixth circuit the need for subjective state of mind of the actor, to avoid circuit conflict or inconsistent contradictory outcome in future #841 cases, as in the underlying petitioner's case, if the sixth circuit continue the ambiguity in its transactions.

X. The ensuing result that these medical 841 cases, like Sakkal, continued to be prosecuted under a false interpretation of the CSA, CFR, and Supreme Court guidance, in a manner that criminalizes good faith behavior, or poor judgment, error, or negligence as intentional criminal conduct, without having established MENS REA, which is necessary to distinguish a wrong from a socially beneficial act like treating pain by prescription, and by conflating drug dealing with "legitimate medical purpose in the usual course of provider's professional practice", lowering the bar in a way that whimsically transforms innocuous acts into nefarious offenses. This unfair approach, that violate the 4th, 6th, the 8th Amendments, that does not confirm the subjective state of mind of the doctor, will lead to criminalization, to inconsistent contradictory outcomes in future CSA medical practitioners' cases, that present similar unadulterated #841 charges, as in the underlying case, as long as ambiguous 1306 govern the 6th Circuit. This change in the jury instruction alone is an indication that Sakkal's Jury instruction was incorrect, mislead the jury, making the conviction itself unwarranted and need to be vacated.

E) Prescriptions:

"it is unlawful to dispense controlled substances without valid prescription" Gonzales v. Oregon 546 U.S. 243 (2006).

"A valid prescription can be found in two places in the CSA:

"# 829 Prescriptions

(2) As used in this subsection:

(A) The term valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice.

#830. Regulation of listed chemicals..

(3) mail order reporting_'(A) As used in this paragraph:

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to.. prescribe the drugs acting in the usual course of professional practice."

"Section 829, 830, and 1306.04 make reference to the two well-known prongs of "legitimate medical purpose, and usual course of professional practice. However these two phrases do not appear in the CSA 21 U.S.C. #804, and their meaning was never defined in the statute or regulation. This phrase is recognized as a generality, susceptible to more precise definition and open to varying

constructions, and thus ambiguous in the relevant sense" (Gonzales v. Oregon at 258)

F) The Sixth Circuit added another description for distribution to include the sale of a controlled substance according to United States v. Robbs, 75 F.App'x 425, 431 (6th Cir. 2003). And it added the act of writing a prescription according to United States v. Johnson, 831 F. 2d 124, 128 (6th Cir. 1987). The 2023 revised Jury instruction covers the conduct of writing prescriptions under the definition of "dispense"! (2023 Revised Jury instruction 14.02C, at 4 see supra)

G) 21 U.S.C. 824 (a)(4) defines Suspension of registration if

"registrant committed such acts as would render his registration.. inconsistent with public interest"

(b) May limit the practitioner Controlled substance

(c) proceedings.. Attorney General (DEA) shall serve upon the registrant an order showing basis thereof.. and for the registrant to show cause why not to revoke..

(d)..The Attorney General may suspend any registration in cases where he find an imminent danger to the public health or safety (Id.P 1219)

H) Any controlled substance today is generally "authorized" by physicians, according to specific liability outlined in 21 USC 829 (a), civil penalty in 824, and according to A.G regulation 1306.04 (a) three elements. The controlled substance is "dispensed" by a pharmacist, who have a corresponding responsibility standard, and only after "authorization by prescription". (Federal Rules and Codes, 2014, Page 1218)

FRAMEWORK BACKGROUND:

Language interpretation of this statute from the Oxford Dictionary, the Webster dictionary, and the 21 USC 802 (10) statute itself then imply:

1) Both distribution and dispensing, in English dictionaries, involve physical HANDLING of a controlled substance, which was the clear intent of the Congress when it issued the CSA (Congressional Record 9).

2) "Distribution" is done by manufacturing pharmaceuticals and other intermediaries like their wholesale's vendors, who supply other "distributors" like pharmacies chains, and may apply to larger drug dealer/distributors who supplies illegally smaller street dealers/peddlers who dispense.

3) "Dispensing": "To deliver a controlled substance to an ultimate user, and "dispenser" means the person who so delivers, like Pharmacists, pharmacy chains, or the street peddlers who dispense illicitly directly to the end user.

4) Doctors today only "authorize" by "prescribing". In the 'old days' they used to authorize and dispense medications, but no longer do (except in giving free samples to needy patients.) Their function today is "authorizing" pharmacists to dispense by "prescribing" as the present usual course of professional practice, and in compliance with 21 U.S.C. 829 (a), the Attorney General regulation 21 F.C.R. 1306.04 in its three well known elements.

There is no dictionary, or legal statute, regulation, or otherwise that defines doctors as "dispensers" or "distributors" of medicine/drugs today. Today any controlled substance is "prescribed" by an "authorized" physician, and "dispensed" by a pharmacist. The prosecution of physicians as "distributors" or dispensers" is unsupported by foundational legal text!

5) There are few exceptions: Encouraged by some pharmaceutical companies and wholesale suppliers, who offer discounted prices, very few providers still dispense as retail vendors, by selling medications in their offices, 'for a profit', as the old system of State authorization still allow them, and where the above regulations (21 USC 822, 823, 829) of dispensing then will apply, but the vast majority today, including the petitioner Sakkal do not.

6) In the present defendant's case: he was approached by pharmaceuticals to "dispense" for huge cash 400% profits, but he declined, and he never "dispensed" in "His professional practice", to abide by his main intention/Mens Rea of practicing medicine for only the patient benefit, and not his own enrichment. The government and the Court used the term "distribute/dispense" in an incorrect manner, contradictory to the plain English Dictionaries definition, and the federal code legal definition, abandoning Congress's intent in the CSA where the profit motif by drug trafficking

was specifically named (Id.)

7) Note that the Sixth Circuit unilaterally added "prescriber" and "prescription" to the law, as "distribute/distribution" in 1987. The 2023 Revised Jury Instruction "covered the legal action of prescribing under the definition of "dispense""!

REASONS FOR GRANTING/List

A. WHETHER THE GOVERNMENT QUESTION RAISED, IN RESPONSE TO THE PETITIONER'S CERTIORARI IS A DIVERSION?

B. WHETHER PLAIN ERRORS, EVEN IF NOT RAISED PREVIOUSLY, ARE REASONS TO VACATE?

1. Errors In the District Court
2. Errors In the Appeals Court
3. Errors After SCOTUS remand
4. New Jury Instruction Model violation post-Ruan
5. Recent 6th Circuit cases post-Ruan including Hargrave, Purpera

C. WHETHER THE DISTRICT COURT JURY INSTRUCTION VIOLATED SCOTUS' RUAN 2022 DECISION, AND ITS OWN RECENTLY MODIFIED JURY INSTRUCTION GUIDELINES, IGNORING MENS REA, AND PERPETUATING CIRCUITS CONFLICT?

1. Contradicting SCOTUS Ruan decision
2. Contradicting C.F.R. 1306.04(a)
3. The Burrage Clause and Jury Instruction

D. WHETHER THE GOVERNMENT LAWYERS AND THE COURT(s) LEGISLATED ENCROACHING ON CONGRESS' INTENT, WHEN MISAPPLIED 21 U.S.C. SECTION 841, VIOLATING SEPARATION OF POWERS DOCTRINE? AND WROTE THE SENTENCING COMMISSION DRUG CONVERSION TABLES ARBITRARILY BIASED AGAINST PHYSICIANS?

1. encroachment on the CSA
2. encroachment on C.F.R. 1306.04(a)
3. Moore connected the CSA and C.F.R encroachments
4. Lower court(s) decisions are difficult to reconcile with SCOTUS
5. The petitioner was in complete compliance with the law in the CSA, CFR and SCOTUS
6. The 6th Circuit insistence on violation of the constitution has dire consequences to health
7. Whether the sentences commission Drugs Conversion Tables are arbitrary and biased against physicians

E. WHETHER THE INEFFECTIVE ASSISTANCE OF COUNSEL CHANGED THIS CASE TO NEGATIVE OUTCOME?

CONCLUSION

A. WHETHER THE GOVERNMENT QUESTION RAISED, IN RESPONSE TO THE PETITIONER'S CERTIORARI IS A DIVERSION?

I) The government raised a new procedural question, in response to the petitioner certiorari of 8/4/23 (Saad Sakkal v. United States), which is a diversion from the petitioner raised constitutional questions regarding the lack of jury instruction compliance with Ruan 2022 SCOTUS decision, and physicians' liability. The government is attempting to divert this Court attention from the ambiguous jury instruction relying on terms like "deliberate ignorance", "willful blindness" which are standard tradition in the Sixth Circuit, which contradicted for years This Court decision in Ruan v. US 142 S.Ct. 2022 (Ruan), as well as the "except as authorized" doctrine in the Controlled Substances Act (CSA). The convoluted government question raised, in This Court reads:

> "Whether the court of appeals was required to vacate.. following a remand of this Court based on a theory NEVER raised by incorporating the language of 21 C.F.R. 1306.04(a) that define the scope of authorization" (Respondent Brief P.1).

a) This question, in response to the petitioner's raised question regarding the jury instruction completely ignore the plain requirement of this Court in its remand, which was exactly directed, "in light of Ruan" question of 1306.04 (a) "ambiguous" language, as this court determined, and nothing else.

b) It is a fallacy to state "the theory was NEVER raised" regarding the court 1306.04 (a) "ambiguous" language, because the petitioner's Appeal brief specifically argued this was unclear language in defining the scope of authorization, quoting US v. Feingold (2006). But the government declined to accept the argument, and the Appeals Court agreed with the government position, in plain error. Thus, the Appeals Court was required to correct its own error, in light of Ruan universal SCOTUS instruction. Here is how the original petitioner's Appeal Brief read:

> "The underlying question is.. whether this court and counsel for both parties misunderstood, the issue, as to all patients generally and specifically in the context of patient 1, who passed away as a result of overdosing (Verdict RE 59,

Page 382)". (Appellant Brief at 54)..(overdose suicide unrelated to Sakkal low dose treatment).

"8) FAILURE TO OBJECT TO JURY INSTRUCTION WHICH FAILED TO PROPERLY STATE THE NECESSARY FINDINGS OF Dr. Sakkal's INTENT:

This Court has not previously ruled on the question of intent on an allegation of violation #841 as discussed in United States v. Feingold, 454 F. 3d 1001, 1008 (9th Cir. 2006), in which the Ninth Circuit held that:

Simply put, to convict a practitioner under #841, the government must prove (1) that the practitioner distributed controlled substances, (2) the distribution.. was outside the usual course of professional practice and without a legitimate medical purpose, and (3) that the practitioner acted with INTENT to distribute the drugs and with INTENT to distribute them outside the course of professional practice.

In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor's INTENT to ACT AS A PUSHER rather than a medical professional".. But the trial court in this case improperly broke that out into two issues, misinterpreting the issue. The failure of Dr. Sakkal's counsel to address this issue in the jury instructions, especially when that was the very crux of this argument to the jury that Dr. Sakkal was negligent but not criminal, shows 'counsel' ineffectiveness."

(Appellant Brief at 60-61) (definitions of "distribution" or "dispensing" to the end user, _like pharmacists do not apply to physicians, who authorize or issue a prescription according to 21 USC 802 language. Drug trafficker could be either

a "distributor" to other drug dealers, or "dispenser" to the end user. Federal Rules and Codes, 2014. P. 1199).

More elaboration on the error of the jury instruction followed in the Appellant's Reply Brief:

"The Trial court plainly erred.. The assignment of error is useful to illustrate the point that applies to all counts.. that a number of serious errors throughout the trial converged to produce an incorrect and unjust outcome.. Dr. Sakkal's position is straight-forward:

1) He did not knowingly prescribe medication to his patients for other than a "legitimate medical purpose, in the usual course of his professional medical practice".

2) His trial counsel failed to call him to explain why his treatment protocols.. were appropriate.. for "legitimate medical purpose in the usual course of his medical practice...

4) His trial lawyer failed to object to a jury instruction that was defective insofar as it would allow the jury to find that Dr. Sakkal had violated # 841 without a finding that his actions.. were knowingly and intentionally done without legitimate medical purpose.. (Appellant Reply Brief at 5)..

5) ..With regard to the elements of 21 U.S.C. # 841(a)(1), the jury instruction in question reads:

'In order to find Defendant guilty.. the government must prove beyond reasonable doubt each of the following elements:

(1) Defendant distributed or dispensed a controlled substance as alleged in these counts of indictment.

(2) Defendant acted knowingly and intentionally in distributing or dispensing that controlled substance.

(3) Defendant's act was not for a legitimate medical purpose in the usual course of his professional practice [Doc #57, P. 24, Page ID 292.] (Note always that the definition of distribute or dispense did not apply to Sakkal who only prescribed or authorized according to # 802 (10) definition).

Reading this jury instruction exactly as written, it states that the distributing or dispensing.. must be done knowingly and intentionally, but that the act of doing it.. could be done with some other, unspecified, state of mind such as negligence. So the jury could have convicted Dr. Sakkal of numerous violations of # 841 (a)(1) for ..writing a prescription for medication for which he mistakenly BELIEVED was beneficial... In other words, the jury may very well have criminally convicted Dr. Sakkal for medical malpractice". (Appellant Reply Brief at 6)

These quotes from the petitioner appeal brief show petitioner Appeal clearly presented the subject forcefully, and the government's claim that the theory/subject was never raised is false.

c) The government, here, reduced the question to the Appeal Court right to deny remand, for failure of the defense counsel to preserve objection to defective jury instruction at a lower court level. The government argued the same, in their Appeal response, proving ineffective assistance of counsel, twice, the same counsel whose performance the government defended in the post-trial hearing of the lower court, as very effective! a violation of estoppel. If we all agree the defense counsel was ineffective, then the crucial SCOTUS question, and the reason for the remand is not the ineffective counsel but remains the plain error of the jury instruction "in light of Ruan". When SCOTUS remanded, it wanted to ascertain exactly if the jury instruction was fundamentally consistent with Ruan holding or Not, and thus with the law.

II. This Court in deciding Ruan, in effort to correct a past error and remove pre-existing circuit conflict, confirmed that jury instruction based on 1306.04 (a)'s ambiguous text should define more clearly Intention, "knowingly and intentionally" in each element, not only of "dispensing" as the district court instruction held, and to be clear that "the defendant KNEW the prescription were unauthorized". If the practitioner KNEW the prescription was unauthorized, then the prescription has no "legitimate medical purpose" and "outside the course of HIS professional practice", Id. In the district jury instruction both statements were false, and did not address the Mens Rea requirement. The government/District court instruction knowingly and willfully omitted the crucial element of "knowledge" from the element "legitimate medical purpose and outside the course of HIS professional practice". As a result, the jury instruction failed to comport with Ruan's needed requirement as explained by Judge White's dissention in the 6th Circuit case United States v. Anderson, 67 F .4th 755 (6th Cir 2023):

III. The petitioner's argument is further supported by more recent cases in the 6th and 4th circuits including Judge Cole's opinion in United States v. Hofstetter, 80 F. 4th 725 (6th Cir. 2023) and in United States v. Purpera, (4th Cir. 5/30/24), see detail infra. In a clear departure from the old pre-Ruan inadequate jury instruction the 4th Circuit took a bald step in United States v. Hargrave 6/12/2024 U.S. App. Lexis 14271 at 3 (4th Cir. 2024). The 4th circuit decided WITH GOVERNMENT AGREEMENT, that 1306.04's-based jury instruction is a "plain error", hopefully breaking the camel's back regarding circuit conflict. So, now:

a) The government wants this Court to ignore the major question of circuit conflict about the defective jury instruction which is the major constitutional concern by exploiting triple errors that occurred:1) by defense counsel, 2) compounded by the district and 3) affirmed by the appeals court, as the ground to decline the petitioner's certiorari in this Court.

b) And to do so based on a technicality in procedural error, diverting this Court from its constitutional mandate regarding compromised 1306.04 (a) text, with dire consequences to physicians, and

c) Ignore to correct plain errors in the lower courts, even if not raised previously according to Rule 52(b). If 1306.04(a) language, which is considered recently by the 4th Circuit as a plain error is ignored here by SCOTUS then harm could deprive any innocent citizen such as Sakkal from any chance at justice and government Duty of Protection, which is a constitutional government duty, and specifically any practicing physician because of this perpetuated error(s).

IV. To sum this point

a) The government diversion cannot keep SCOTUS from enforcing Ruan standard, and recognize this case for what it is:

A case of constitutional error in defective jury instruction, resulting from misapplying the triple hybrid of criminal liability standard (1.CSA/841, 2.CFR/1306.04, and 3. Moore 1975 case law), which created the unresolved circuit conflict that persists only in the Sixth Circuit, even after Ruan, as in the denial of Sakkal case after SCOTUS remand to review in "light of Ruan". AND failure to correct ambiguous erroneous jury instruction, which led, in turn, to convicting thousands of physicians, in the last five decades.

b) Moreover, this case is a clean, simple #841 question, without any other complicating charges, as in other cases (like fraud, kickback, RICO, conspiracy, money laundering, firearms, premises, interstate commerce, etc.). Thus it is an easy model with which to enforce Ruan, re-establish clarity to physicians' prosecution, conviction, and sentencing.

This Certiorari will still deal with the issue raised by the government regarding the ineffective assistance of counsel in its proper constitutional role, as another ground to vacate. (Affidavit, App. D)

B. WHETHER PLAIN ERRORS, EVEN IF NOT RAISED PREVIOUSLY, ARE REASONS TO VACATE?

Can SCOTUS avoid its role as the ultimate guardian of the Constitution and the law? Can SCOTUS correct the plain errors in the shifting government and court(s) position in violation of estoppel? Was the defense counsel ineffective or not in the government's eyes? Here are only four of more than 40 errors of the defense counsel and supported by the District Court, thus becoming court's errors:

i. Counsel did not object to the defective jury instruction prejudicing defendant chances for acquittal at the Courts.

ii. Counsel unilaterally refused the plea offer presented, without informing Sakkal, 11 days prior to trial, as proven by his E mail.

iii. Counsel refused to permit the petitioner to testify and present an expert witness, And.

iv. counsel suppressed material evidence, keeping the exculpatory evidence off the record.

As for the government, its question in the instant certiorari claims that the Appeal court is correct in refusing the remand, as a result of defense counsel error, thus the government admits counsel was, in fact, ineffective. But contrast this with the Government claim at the district court post-trial hearing, by their vigorous defense of the counsel by stating he was effective, the reversal of which is violation of estoppel. The defendant will outline first how the District Court and government supported the counsel errors, then reversed their positions in the Appeals Court, to deny justice:

I) Errors in the District Court post-trial hearing of 3/2/2020:

1) The government defended vigorously the defense counsel to extract a false contention that defense counsel did the most outstanding effort, with the intent of affirming the defendant's guilt. After which the District Court adopted the government argument, exonerated defense counsel from being ineffective, and erroneously affirmed the conviction. This prejudicial COURT error will be explained in some detail first, then followed by more specific examples. Here are first only a few pertinent quotes from the published Court Opinion. US. v. Sakkal, 2020 U.S. Dist. Lexis 79675:

a) Regarding Refusal to allow defendant to testify: "This decision was a reasonable one, not subject to challenge" (Id.at 15) A violation of the 6th Amendment and Strickland.

b) Regarding Keeping material facts of exculpatory evidence (Graphic charts, practice and financial statistics, etc.) off the records: The decision not to introduce the Graphs and bar charts.. Mr. Goldberg notes dated October 24/2018 (6 months before trial) defendant explained ratio of controlled substances to total prescription was 15% when he started at Lindenwald, but six months later, had reduced to 7% (Gov. Exh 12 at 1), and average dose of controlled substance decreased by 50-70% (Opinion at 17).

(When defense counsel did not prepare the graphic charts discussed in October 2018, petitioner sent graphic charts 1/18/2019, 10 weeks prior to trial, but counsel never presented them. The court summarized some slides at post-trial hearing on 3/4/2020, but defendant was never allowed to explain the full content and meaning of each graph and its exculpatory conclusion. The court erroneously concluded the following:)

> "As the United States correctly points out, the errors contained within the 'graphic' charts would have been exposed during cross examination" (Id.at 17). (Cross examination cannot show errors, because the numbers were correctly copied from the government's own discovery documents. The government never challenged the charts statistics or data, at any time because the numbers were the government's own numbers!).

c) Regarding the Unilateral Plea refusal by counsel independently:

> "The court is satisfied that Mr. Goldberg gave defendant competent advice" (Id.at 22).

d) Regarding Jury instruction: "Goldberg proposed several instructions.. taken verbatim from Volkman.. and proposed other instructions as well based on United States v. Feingold (Ninth Cir.2006)..the court did not use the additional related instructions, and Goldberg did not object to this decision" (Appellee brief at 23).

"The jury instruction Mr. Goldberg proposed were in accord with Volkman. Additional instructions indicate NOT INEFFECTIVE ASSISTANCE" (Court opinion at 25) (Another erroneous conclusion).

2) During the reading of the instruction, the defendant knew the instruction was prejudicial, and will certainly end up with a conviction, without any supportive material evidence. The defendant, sensing the danger, vigorously protested to his counsel, with uncharacteristic force, informing counsel that he will not return to the court if the instruction was adopted.

a) "These instruction will hang me, without any evidence, they will convict me 100%, although I committed no crime.. and I always intended only my patient's best benefit. I made no extra profit, received no reward, or received any illegal pay. My patients always loved my service, sent their family, and children. They had the best results as the pharmacists used to tell me, and returned to a worthwhile functioning lives, working and making a living. Yet, with these instruction which is designed to take from the jury any choice, but to convict, with vague, and 'hard to understand' language, that I even find it hard to comprehend, except that anything wrongful happened from any patient is my crime.

I cannot return to the court tomorrow if these instructions were given, because I think it is more dignified to the Court to judge me in absentia without deceived jury than go through sham biased trial with biased jury, a jury which has none of my peers to start with, had no one on any medications like my patients, to know what illness is like. The jury will agree with a confusing instruction, which convict in every word, and on top of it all now they will be brain washed by poisoned stuff from the prosecutor who played a dirty ugly game, blackmailing the judge, during the bond hearing, by reminding him of his past error, just to prevent my release on a bond and thus prevent access to most crucial exonerating evidence from my patients medical records or monthly individual patients surveys that show my strict pain management policies or office audit administrative records, weekly staff policy instruction, monthly personnel performance review to enforce policies, quarterly community education, all about pain, addiction and other diseases. All needed to defend myself. I have never seen anyone deprived from bond without access to his own defense materials, in "out of order injustice". I have no chance if I return to court."

b) The counsel warned the defendant of contempt of court, losing the case instantly, if the defendant did not return. Counsel approached the bench after he promised to object, but the court

record shows no objection regarding the intention in 1306.04 (a), but only an objection regarding the But-For Burrage language as it relate to patient's suicide after a prescription, which is clearly another issue.)

c) The defendant first heard about the missing lack of objection during the Appeal, after the Government Reply Brief. Only then, the defendant realized the counsel mislead him, believing the counsel made the objection at the trial.

d) The resulting prejudice from the lack of objection became clear at appeals when denied, twice, as a result.

e) Now the government is requesting this Court to deny again, using the same false argument of ineffective counsel, as it did in the Appeal court, in contrast to its favorable position in the District court, in violation of estoppel

f) It should be noted that Volkman Instruction which the Sixth Circuit considered the "Model Gold standard" did not comport with Ruan decision, and should be considered defective, and in error.

g) In summary: the District Court erred in its jury instruction, missing the Mens Rea in the third element, violating Ruan 2022 SCOTUS decision, and the counsel did not object to the defective jury instruction. The government and the court committed the same erroneous argument that ignore this crucial fact. The government and the District Court vigorously enforced Mr. Goldberg's exoneration and defended him at the post-trial hearing, from every shade of ineffective counsel of the following errors:

1. Not allowing the defendant to testify "over my dead body"; 2. Not allowing any expert witness to testify despite multiple requests by defendant; 3. Conflating unfounded unrelated facts; 4. Suppressing exculpatory material evidence; 5. Keeping the exculpatory facts off the records; 6. Refusing unilaterally the government plea offer, on his own, without consent of the defendant or the family, and 7. Not objecting on the record against the jury instruction (for more errors see Affidavit Appx F).

The result of these counsel mistakes the petitioner, Sakkal was deprived from the opportunity to be heard in full.

(For more errors see Affidavit, App D)

II) In the Appeals court:

a) The government, as explained, reversed its position in the Appeals Court, to deny Sakkal's appeal, stating in its brief:

"The record is not developed as to Goldberg's decision not to object. Nevertheless, it is clear even on the existing record that the decision not to object .. neither constituted deficient performance nor prejudiced Sakkal, because the objections were unlikely to be sustained" (Appellee Brief at 61).

"Moreover, even if such objections had been made and sustained, they would have not affected the results of trial given the evidence against Sakkal". (Id at 62). "Sakkal contends that Goldberg rendered ineffective assistance by not objecting to the jury instruction on the lack of Mens Rea for the 841 counts (Id. 60-61.) while this claim was not raised below, the record is adequate for review.. establishes that the district court correctly stated the law on this issue" (Id.at 64).

"Sakkal suggests that Goldberg should have proposed an instruction modeled on the Ninth Circuit's decision in United States v. Feingold, 454 F.3d 1001 (9th Cir.2006)..which the court declined to use. Because the instructions given were correct, approved by this court in Volkman, Sakkal cannot show that his counsel was ineffective in not persuading the district court to include the instruction he requested, much less a reasonable probability that including the additional instructions he requested would have altered the outcome" (Id at 65).

b) The government defense of Goldberg, in their Appeal reply brief, further included the following:

"Goldberg provided effective assistance at trial (Id.54), in his

1."decision not to retain a rebuttal expert (Id.55), 2. decision not to file pretrial motions (Id.58), 3. decision not to object to certain testimony (Id.6), and 4. decision not to object to jury instruction (Id.64)" (see detail in Affidavit Appx F).

c) Based on this government's position above the appeal court affirmed. The government effort succeeded in denying Sakkal's appeal, a prejudicial result for sure. While the government claimed none of these arguments caused Sakkal harm, or could change the outcome, or had a chance of success, the Supreme Court Ruan decision and its aftermath proved, on multiple appeals later, in a number of other circuits, that the government was 100% wrong:

i. Because counsels for Ruan, Couch, and Kahn, in the 10th and 11th Circuits, preserved the objection to defective jury instructions, they all received relief from 841 charges. As a result, so Sakkal also should have been relieved of 841 charges after remand, to be consistent with other cases mentioned, if the defense counsel had preserved the objection.

ii. Instead, the result was the petitioner is incarcerated for 20 years, (a life sentence at his age), with destruction of his medical practice, his beloved family and grandchildren, his life savings, and his future end of life years. At his age of 77, an ethical, innocent, advanced research and clinical expert will die alone in prison as a victim of cruel punishment for no wrongdoing, except delivering to his poor patients the best care anyone in the best academic centers could have, as a result of blind and overzealous prosecution.

iii. Similarly Hargrave further proved an alternate favorable outcome is expected contrary to government speculation, that "the error is harmless and unlikely to change outcome"

d) The Appeals Court Ruling also contradicted itself:

i. The first Ruling sentence starts by:

"SAAD SAKKAL PRESCRIBED CONTROLLED SUBSTANCES TO HELP HIS PATIENTS MANAGE PAIN".

This is the clearest statement of the "legitimate medical purpose, in the usual course of professional practice", of the defendant act, or any physician, which is the relief of suffering from pain, improving the quality of life, and well-being, as the hallmark of medicine as a profession, and its reason to exist.

ii. Furthermore, it correctly describes the act of physician's as "prescribing", not using the incorrect definitions of "distributing" or "dispensing", used by the government outside the bounds of the terms defined by the federal code according to 21 U.S.C 802 (10) definitions, where: "a 'dispenser' is the one who so delivers to the end user".

This dispensing is done today by pharmacist, not Sakkal, who only authorized or issued prescriptions but never distributed or dispensed controlled substances, although the government commonly uses these terms as a court tradition.

iii. After this respected beginning, the Appeals Court made 180-degree U turn, accepting the government claim that the defendant wrote prescription not for a "legitimate medical purpose and outside the usual course of professional practice", which fully contradicts its initial admission of the legitimacy of Sakkal purpose of HELPING his patient manage pain!

iv. So, which is which? two contradictory opinions cannot be both correct in the same ruling. Either he prescribed for other reasons, like profitable cash, sexual favors or other personal benefit, which the government never mentioned any material evidence. Or he truly prescribed for the only legal purpose of managing pain, which is the only purpose

proven so far in the record, thus no crime exists.

v. The Appeals Court plainly erred in its denial of Sakkal's appeal, an error within the purview of the SCOTUS to review.

III) After SCOTUS Remand:

1) Another plain error after SCOTUS Remand:

SCOTUS Remanded Sakkal case to decide, in light of Ruan, if the jury instruction was compliant with Ruan decision or not.

a) Ruan 2022 new standard was related to the Mens Rea requirement in the jury instruction derived from 1306.04 (a),

which was not fulfilled in the District Court instruction, as Judge White correctly argued in United States v. Roger Anderson 6th Cir. 2023, supra).

b) This was the only reason for the remand, not any other technical procedural error of the counsel, which today is nearly universally accepted by most courts to be a plain error (see United states v. Hargrave at 3, 4th Cir. June 2024, supra).

c) In Sakkal case there was no other criminal charges like fraud, kickback, RICO, money laundering, firearms, or anything else as in other Section # 841 cases, which need to be considered, thus acquittal was the only reasonable course.

d) Contrast this 6th Circuit defiance with all other circuits, who are now unanimous in including the Mens Rea requirement in their Jury instruction. Prior to Ruan, the 9th, 7th, 8th were ahead, and after Ruan the 10th, 11th, 5th have joined.

The 10th Circuit vacated Kahn, the 11th vacated Ruan and Clough from all #841 charges, proving not giving the same chance to Sakkal is NOT HARMLESS, but prejudicial.

e) Only the Sixth Circuit continue to ignore SCOTUS, in staris decisis, believing that old Volkman's model instruction was correct, which is not. And when in reality it does not comport with Ruan mandate as Judges White and Cole in their dissention and concurrence in Anderson and Hofstetter in the 6th Circuit and Hargrave and Purpera decisions in the 4th Circuit so well held, supra.

f) The staris decisis defiance of the Sixth Circuit is inconsistent with Equal justice under the law, and Due process. The Sixth Circuit alone is unique in its position and requires the attention of This Court, one more time, to abolish Circuit Conflict, maintain a single justice standard through the USA circuits.

g) Not correcting this egregious persistent error is a dangerous dereliction of duty of protection, which is the requirement of allegiance of citizenship, that will leave, as a consequence, two tiers of justice-one is informed, legally sound, favor lenity when ambiguity exists, and compatible with common sense in applying the pertinent law (CSA/1306.04, and Ruan), as explained by Judges White and Cole in the 6th Circuit, Hargrave, Purpera decisions in the 4th Circuit; the other is uninformed, illegal, harsh favoring cruelty when ambiguity exists, and therefore violate the Fifth and Eighth Amendments of the Constitution.

2) A recent new and improved Sixth Circuit model jury instruction was not applied in Sakkal's case:

a) The petitioner described briefly how the defendant found the new improved model of jury instruction regarding section #841, in the Sixth circuit commentary, published 3/1/2023 was closer to Ruan mandate, which add clearly a new element stating:

> "14.02C Dispensing or Distribution of a controlled substance by a PRACTITIONER under 21 U.S.C 841(a)(1):

(1) the defendant is charged with the crime of dispensing a controlled substance. For you to find the defendant guilty of this crime, you must find that the government proved each and every one of the following beyond reasonable doubt:

(A) The defendant knowingly [or intentionally] dispensed [distributed] the controlled substance (CS):

(B) The defendant knew at the time of dispensing [distribution]that the substance was a controlled substance:

(C) The defendant knew that his dispensing was unauthorized, that is to say the dispensing was not for a legitimate medical purpose by an individual practitioner acting in the usual course of HIS professional practice; and

(D) The defendant KNEW [or intended] that the dispensing [distribution] was UNAUTHORIZED.

(2) Now the details of the terms.

(A) "Dispense" means to deliver a CS to an ultimate user.. pursuant to the lawful order of a practitioner..

"Dispenser" means a person who so deliver a CS to an ultimate user..

(B) "Distribute" means to deliver (other than by administering or dispensing) a CS ..including actual, constructive, or attempted transfer of a CS [including the sale of CS] "Distributor" means a person who so deliver a Controlled Substance.

(C) "Legitimate medical purpose by an individual practitioner.. practice" means acting in accordance with generally recognized and accepted professional standards in the field in which the individual practices.

(D) "Practitioner" means a physician [or dentist, veterinarian, investigator, pharmacy, hospital, or other person] licensed [registered, or permitted] by the US or the jurisdiction in which he practices, to distribute or dispense a CS.

(3) If you are convinced that the government has proved all these elements, say so by returning a guilty verdict.. if you have a reasonable doubt, about any of these elements, then you must find the defendant not guilty.

Use Note

If the defendant is not a practitioner use Inst. 14.02 A or B Instruction should be given only after the defendant produces evidence that he or she "authorized" "acting In accordance with generally recognized and accepted professional standards.." Standards are set by various organizations. THE LAW DOES NOT DEFINE THIS PHRASE. "Practitioner" is based on the statutory definition in #802(21), if not listed use "other person" Committee Commentary Instruction for 14.02C ...

A very detailed important commentary ends with:

"In paragraph (1)(D), supra, the requirement that the defendant KNEW OR INTENDED this dispensing or distribution was unauthorized is based on Ruan, 142 S.Ct. 2370, 2382 (2022).

"Definitions of "dispensing, distribution, etc." are drawn primarily from 18 U.S.C. ## 802(8); 802(10); 802(11); and 802(21) EDITED TO FIT the usual case! The Court may need to consult the full definitions."

"SOME ISSUES REMAIN UNCERTAIN IN THE WAKE OF RUAN: GOOD FAITH AND DELIBERATE IGNORANCE. As no authority from SCOTUS or the Sixth Circuit, the committee took no position.

"As to the word "purpose", we look at the "reason", rather than the patient's underlying conditions!

"Evidence of "circumstances" surrounding a prescription allows juries TO INFER the purpose other than legitimate medical treatment, the underlying conditions are not dispositive"

b) The defendant concludes the following:

i) The 6th Circuit made what it believes to be a necessary change in its defective Sakkal's jury instruction, admitting error. And "the change was directly in response to Ruan SCOTUS" guidance, a hopeful sign. Alas, the Appeals Court on Sakkal's remand DID NOT apply it, in a second denial on 5/31/2023, to the defendant's case, two months after this new model jury instruction became effective, when the defendant appealed for the second time after SCOTUS remand. THIS IS A PUZZLING ERROR.

ii) The new jury instruction is much clearer than the Court old convoluted poorly understood language by the lay jury. It will improve jury performance.

iii) It appears an honest effort to define the undefined terms, which was one of the defendant's main concerns in the past. It defined dispensing, distribution, dispenser, distributer, and practitioner to be consistent with 18 USC 802 (10) et seq.

iv) Unfortunately honesty did not prevent the fall into some major deviations from more important concepts in 802(10).

A careful reading of the text still show the Circuit edited the regulatory terms incorrectly: There is not a single sentence in 18 U.S.C. 802(10) that defines physicians as either distributor or dispenser, both

terms are specific to others involved with controlled substances physical handling which is not applicable to physicians.

v) 18 U.S.C. 802 (10) is clear that the role of physicians is prescribing, issuing a prescription, to authorize the dispenser to the end user, the pharmacist, to fill the prescription, but not distribution or dispensing in any way or form. Carefully looking at the letter of the law: there is nothing at all in the law related to physicians, a defect in the original law, the Circuit said it wants to remedy, by "editing to fit the usual case"!, Thus, incorrectly, added physicians to the list of persons targeted in the law!

vi) For the Sixth Circuit to add or omit from a statute would be "legislation from the bench". If the Court sees ambiguous or uncertain law it must return to Congress for legislation, to avoid separation of power violation (see infra).

vii) defining legitimate medical purpose as the legal reason as separate from the medical standard (diagnosis, symptom, or disease entities) is absurd, not the reverse as the Court indicates. The term must be defined by medical legal experts once and for all, in Congress, which issued the statute (CSA) in the first place for drug trafficker and excluded physicians.

viii) Similarly the Sixth Circuit attempt to define " the usual course of professional practice.." is vague as "the law applicable to this offense does not define this phrase"!

ix) Infer "Deliberate ignorance" in Sakkal's instruction has no basis in the law statute or regulation but a court innovation.

c) Should denial error be considered intentional or not is unclear to the petitioner, but SCOTUS WILL have the wisdom to correct in this petition, especially in light of another recent 4th Circuit in Hargrave's quoted below.

3) Hargrave v. United stated sets plain error review correcting pre-Ruan Jury instruction. The argument is not complete without the recent 6/12/2024 4th Circuit case of US v. Hargrave U.S. App. Lexis 14271. In this case the 4th Circuit made it clear that Ruan implication make every older jury instruction in the 6th and 4th circuits a plain error in light of Ruan, and the post-Ruan instruction had to include Mens Rea Scienter requirement in each of its elements to be acceptable. It reads:

> "Hargrave relies on SCOTUS decision in Ruan v. United States, 579 U.S. 450,
>
> 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022) to argue that the district court's jury

instructions were erroneous because they applied an objective, rather than subjective standard to the requirement that Hargrave's actions were outside the scope of professional medical practice. The government argues that Hargrave invited any error by proposing some of the language in the jury's instructions. Alternatively, the government contends that plain error applies. We disagree with the government on invited error but agree on plain error."

"Under the invited error doctrine "a court can not be asked by counsel to take a step in a case and later be convicted of error, because it has complied with such request". United States v. Herrera 1994..We have applied the doctrine in the context of jury instructions Id 76. However Hargrave's "requested instructions 'relied on settled law that changed while the case was on appeal'". Thus we will consider Hargrave's challenge on the merits, employing plain-error review.. a district court errs by instructing a jury to apply an objective standard to the usual course of professional practice requirement or failing to convey that a subjective analysis is required..

The government cannot meet its burden by proving that the physician lacked objective good faith in issuing the prescriptions, Ruan 597 U.S. at 465.." (US v. Hargrave at page 3).

"As for counts 4 through 7 (841 charges only) the government introduced an expert who testified that these prescriptions were not justified by Hargrave's written notes, but Hargrave called his own expert to testify that they were.. Thus, on this record, we believe that a properly instructed jury could at least be hung, Nicolau 180 F.3d at 570, (4th Cir. 1999), and the instructional error undermines our confidence in the outcome of the trial" Duldullao.. "(quote omitted)

> Accordingly we believe it prudent to exercise our discretion to correct the plain error and vacate Hargrave's convictions on counts 4 through 7..and remand for further proceedings" (Id at 4).

What are Hargrave implications for Sakkal case?

A quick analysis of Hargrave's, which parallels Sakkal's case in some features, as it relates to jury instruction reveals:

a) The 4th Circuit Court felt it is appropriate to drop 841, 843 charges, and keep other charges related to sexual or other matters. Sakkal has no other matters charges: no cash money, money laundering, RICO, Medicaid or Medicare fraud and abuse, firearms, premises for drug interstate commerce trade, or sexual counts. Based on Hargrave's, Sakkal case could be vacated because the jury instruction used objective rather than subjective standard, and his only alleged crime is "prescribing".

b) Counsel contribution to jury instruction does not allow the court to claim "invited error" review. Although Sakkal's counsel suggested INITIALLY few jury instruction, the court refused to include the most important part related to SUBJECTIVE standard, issuing its own OBJECTIVE standard instruction which the 4th Cir. found inconsistent with Ruan.

c) The 4th circuit reasoned:

> "We believe that a properly instructed jury could at least be hung.. Instructional error undermines our confidence in the outcome of the trial.. accordingly we.. vacate.."

This is exactly the correct conclusion in Sakkal's as well, an equal justice under the law.

d) The government must now accept, and the Court must agree, that the jury instruction that applied the so-called objective standard, like in Sakkal's case, is unacceptable after Ruan. "Red flags" "inferences" "high or low probability" "ambiguous 1306.04 language", Court's omissions of Mens Rea are all unacceptable standard in USA Courts today and at the time the petitioner's case was vacated, remanded to the Sixth Circuit in May 2023, thus denying the appeal by the Appeal's Court is simply named now a "Plain error." Almost all Circuits agree except the Sixth Circuit!

e) A change during appeal, in so called settled law, cannot be ignored, as in this case Sakkal's appeal came after Ruan standard changed the landscape of objective to subjective standard. This

deliberate ignorance or willful blindness, using its own language, by the Sixth Circuit is a contradiction to SCOTUS.

f) A VERY DISTINCT DIFFERENCE BETWEEN SAKKAL AND HARGRAVE WAS THE FACT THE JURY IN HARGRAVE HEARD ANOTHER MEDICAL OPINION OPPOSING THE GOVERNMENT EXPERT WITNESS REGARDING THE LEGITIMATE MEDICAL PURPOSE OF THE PRESCRIPTION. THIS ALONE WAS ENOUGH TO LEAD TO POTENTIAL HUNG JURY AND OR ACQUITTAL, AND THE 4TH CIRCUIT VACATING THE CONVICTION.

g) Either an expert witness was needed at any cost, or at least Sakkal should have explained the correctness and superiority of his protocols, prescriptions, and patient's outcome, neutralizing the poisoned pill the prosecutor handed to the jury. This correction alone would have led to a completely different favorable outcome: vacating all 841 related charges (see Affidavit, Appx F). This is a major flaw in the counsel performance (see IAC Affidavit for detail). This was proven by many other post Ruan cases including Ruan, Clough, Kahn, etc.

h) Preservation of the objection to the incorrect jury instruction was also operative in Hargrave, confirming the simple plain error that a jury instruction, like Sakkal's, which is inconsistent with Ruan is an adequate foundation to vacate.

4) In United States v. Purpera (4th Cir. 5/30/2024) a jury convicted Frank C Purpera among other charges, of 56 counts of distribution of Controlled Substance "without legitimate medical purpose and outside the scope of professional practice". The record contains Appellant's testimony that he believed there was a legitimate medical purpose for his prescriptions.

A jury record contains Appellant's testimony to reach a contrary finding on the scienter element. Accordingly, we vacate Purpera's 56 convictions for unlawful distribution of controlled substances.

This case benefit Sakkal in three ways:

It was adequate for the Court to hear Purpera testimony that he had a legitimate medical purpose, to cancel the government witness impact. Like Purpera, If Sakkal testified, his case would have been vacated as well.

The defense counsel failed as a result, making a double error: He missed his duty of finding an expert witness, or he could have Sakkal testifies, with equal impact. If both were pursued he would have a double beneficial effect.

The scienter is best described by the accused, to show the intention clearly regardless of the government red flags/herrings and regardless how many the counts were (56 in Purpera, 39 in Sakkal's).

5) Thus, the amorphous, ambiguous, arbitrary, and inclusive hybrid standard formed by the CSA 841 statute, Section 1306.04(a) and the Moore case law has allowed to government to prosecute Sakkal as a drug trafficker, merely for unusual but better practices based on the government's misperception, without requiring the government to prove whether or not the defendant physician truly harbored malicious intent/Mens Rea or caused harm to plaintiff. This prosecution formula has resulted not only in Sakkal's conviction, but massive incarceration of medical professionals in violation of Due process of the Fifth Amendment, as well as the Cruel and unusual punishment clause of the 8th Amendment, especially with wrong Drug Conversion Table DCT, Below)

IN SUM,

a) All above factors regarding the plain errors of the District, Appellate court, each requires SCOTUS review and correction.

b) Changing the jury instruction model to comply with Ruan is the right step in repentance of the 6th circuit, and the admission that its own jury instruction, applied to Sakkal, prior to Ruan was incorrect. Its own model jury instruction with its commission commentary of its use, all confirm the validity of vacating Sakkal's conviction, but the question is why the Appeals court failed to vacate after these new instructions were published on 3/1/2023, when it denied Sakkal's appeal for the second time on 5/31/2023, 2 months later, after SCOTUS remand? Double error or what?

c) This is the best proof that the prior Sixth Circuit was inconsistent with the correct Mens Rea, although it claimed in its denial that it was, despite using the twisted unintelligible vague expressions “deliberate ignorance”, when Sakkal had no "deliberate misconduct" proven in anyway, "willful blindness to what is obvious" when nothing was obvious, and could have been thought of many possibilities nonobvious until now, and "reckless, foolishness", etc.

d) It is not then a surprise the new Sixth Circuit jury instruction model removed all these terms in the explanation and commentary and made it even in doubt if used, stating

> "The requirement that the defendant KNEW or intended that his dispensing or distribution was UNAUTHORIZED IS BASED ON RUAN, 142 S.Ct. 2370, 2382

(2022). Some issues remain unclear in the wake of Ruan. One is 'good faith'. A second issue is ..'Deliberate ignorance'. The committee took no position." (14.02C instructions, 3/1/2023)

e) To accept the government diversion question, on procedural technicality, and ignoring Sakkal's constitutional arguments would:

i. Shift SCOTUS from its fair justice, under the law, purpose in correcting the triple law hybrid liability old standard (CSA, CFR 1306.04, and Moore's case law from Moore to Sakkal and Purpera), and ignoring its recent wise Ruan new standard.

ii. Shift from correcting the multiple plain errors at the Sixth Circuits described supra, including contradicting itself in the first appeal ruling, and their own rules, the old and the new.

iii. Shift from making Mens Rea subjective standard the acceptable standard that is consistent with a long tradition from Morrissette until Rehaif and Ruan. This important doctrine which differentiates wrongdoing from beneficial legal act, criminality and innocence, as was described eloquently in Ruan SCOTUS argument commentary, and.

iv. Allow the Sixth Circuit to keep circuit chaos, in #841 prosecution, and conviction/judgment inequality under the law.

v. It would not solve the puzzle why the Appeals Court denied the second Sakkal's Appeal after remand on 5/31/2023, 2 months after it corrected its own jury instruction standard somewhat to comport with Ruan on paper, but did not apply in fact. Was this another reversal by estoppel or plain error. SCOTUS COULD ANSWER NOW.

C. WHETHER THE DISTRICT COURT JURY INSTRUCTION VIOLATED SCOTUS' RUAN 2022 DECISION, AND ITS OWN RECENTLY MODIFIED JURY INSTRUCTION GUIDELINES, IGNORING MENS REA, AND PERPETUATING CIRCUITS CONFLICT?

Further analysis of the jury instruction reveals more errors, contradicting the present criminal liability standard in its triple components (CSA, CFR and Moore 1975 case law), in addition to Ruan, and even commonly accepted English language.

I) Contradicting SCOTUS Ruan decision:

Petitioner explained how the jury instruction did not comport with Ruan 2022 Men Rea intention text. This was amplified by Judge White in United States v. Anderson 67 F. 4th (2022), supra, where she concluded that similar instruction did not comport with Ruan. Id at 766. She further noted that the ambiguous terms used by the court to replace the Mens Rea, as in the Sakkal jury instruction, by "telling the jury that carelessness, negligence, or foolishness is insufficient is not tantamount to instructing what mental state is required" Id. Extra confirmation came from Judge Cole in United States v. Hofstetter 80 F.4th 725; (6th Cir. 2023), where he stated:

> "I write separately to highlight how Anderson conflicts with the Supreme Court's opinion in Ruan v. United States 142 S.Ct 2370, 213 L. Ed 2d 706 (2022) In Anderson Judge White penned a forceful dissent.. I will not spend much space reiterating her arguments.. but the instant case cast further doubt, where the panel ordered supplemental briefing on Ruan Impact, in which the government conceded that "the #841 jury instructions here likely fell short of conveying the requisite Mens Rea" (Appellee Suppl. Br.6)"(Id.)
>
> "The issues with the instruction begin on its face. Grammatically, the "knowingly and intentionally" Mens Rea applied directly to the "distributed" clause, but (not) the following clauses, so it is not clear it properly instructed the jury that the knowledge requirement applied to the "outside the scope of

> medical professional practice" clause"... They did not make clear, that to be found guilty, Hofstetter had to KNOW that the prescriptions were "unauthorized". Yet, under Ruan, the jury must explicitly be told that "knowledge of the prescription illegality" is an element of the offense. (Id. at 2375-76). Understanding this the government therefore argued that while the district court likely abused its discretion by providing erroneous instructions, any such instruction was harmless"! The record supports the government concession that the instructions were, in fact, erroneous." US v. Hofstetter"

In #841(a) prosecutions, what commonly

> "separates lawful acts from unlawful ones is whether or not the "distribution" was "authorized". The fact that the doctor issued an unauthorized prescription that render his/her conduct wrongful, not the fact of the dispensation itself.. Authorization plays a 'crucial role in separating innocent conduct.. from wrongful conduct." (Ruan at 2377)
>
> Here (Hofstetter), the jury was never instructed that Hofstetter had to have the "Knowledge or intent" to illegally distribute controlled substance in an unauthorized manner, and a deliberate indifference instruction cannot cure that initial error. The government agreed that the deliberate indifference instruction did not remedy the error in the jury instruction, and I agree" (from Judge Cole in Hofstetter).

There are a number of crucial conclusions from Judge Cole opinion:

a) The government is right in its concession the instructions are erroneous. But dead wrong that the error was harmless, because the 10th and 11th circuit have relieved # 841 charges, based on the jury instruction erroneous error in Ruan, Couch and Kahn, and most recently Purpera (5/30/24) and Hargrave (6/12/24) but led to Sakkal incarceration for 20 years. The harm is clear, in the 6th Circuit willful

blindness, deliberate indifference. So exactly was Sakkal jury's instruction missing the intention/knowledge of being unauthorized, and harmful by its ambiguity and jury misleading by deliberate indifference or ignorance.

b) The multiple contradictions to Ruan is well documented by Judge Cole in the above opinion, and not cured by the vague "deliberate ignorance" deliberate indifference", or willful blindness" instructions used in Sakkal Jury instruction.

c) Multiple judges are beginning to realize the harm experienced by innocent physicians, and adapting to the new truth, repenting from the past ignorance, (Anderson, Hofstetter Purpera, Hargrave are few examples), but some, in the 6th Circuit, are still very resistant and recalcitrant, frozen in the past age.

II) Contradicting C.F.R. 1306.04 (a):

The jury instructions were inconsistent even with the DEA/AG regulatory 21 C.F.R. 1306.04 (a) in many ways:

a) The Court claims in the jury instruction that, the word "Knowledge" means voluntary, but the dictionary describe "Knowledge" in other ways including acquaintance with the truth, awareness of a fact, which is the 1306.04 intent, but certainly it is not equivalent to the innovative term "deliberate ignorance", as used by the Sixth circuit court. It is clear that Sakkal who did not know that any patient was selling his medication, until the patient testified at trial, have truly factual lack of knowledge, and has no intention of performing any of the vague concept such as "deliberate ignorance", "ignoring what is obvious" or should incur any guilty burden.

b) Vagueness is unconstitutional. This Court in United States v. Davis (2019), 139 S.Ct 2319 held:

> "When Congress passes a vague law, the role of the Courts under the constitution is not to fashion a new, clear law to take its place, but to treat the law as nullity and invite the congress to try again. The doctrine prohibiting vague laws rests on the twin pillars of due process and separation of powers.
>
> Vague laws contravene the first essential due process of law that statutes (and regulations) must give people of common intelligence fair notice of what the law demands of them.. vague statutes threaten to hand responsibility of defining

crimes to relatively unaccountable police, prosecutors, and judges, eroding people ability.." Id at 766

c) It uses "distribution and dispensing" as if they relate to physician, but we found supra that physicians only authorize by prescribing and don't "distribute or dispense". However, If the "Distribution/Dispensing" was done by another person--say a patient in this case- outside the medical practice office, and without the physician's knowledge or approval, that the patient was breaking his professional contract with the physician, a contract represented by receiving his legally signed prescription, his instructions, warning three times in the office, with a written copy in his chart, how is it possible it would become the crime of the victim of contract breaking and not the one who broke the contract ? By which law?

It is clear to the court that a physician has control only over his office encounter time with the patient- normally less than 10 hours/year- but the physician cannot be responsible about any and every act outside his office which is around 8750 hours/year. The prosecutor attribution of the patient crime to the physician is reverse justice unheard of in the civilized world. The Court would not support this injustice or take a part.

d) The Court used two different terms in the same jury instruction: outside the "usual course of professional practice", or "Scope of medical practice", while 21 U.S.C. 1306.04(a) uses "the usual course of HIS professional practice", with clear difference between the two:

i. "usual" defined in the dictionary as customary, but "unusual" does not make a course unlawful, which is what the jury instruction imply or want to convey. People may use a different unusual courses, in any field including medicine, and still be lawful, even they may break barriers of common habit, and the usual, from Einstein to Picasso. Imagine If the concept was extended to any profession, like law, architecture, or art, then the world of justice will be turned on its face in complete chaos: every unusual course in the wide range that exist in medicine or law become unlawful, The jury instruction is clearly using the term incorrectly, and inconsistent with 1306.04 (a).

ii. Usual and unusual medical course: in Medicine there is not only one single course, but, many "usual" and "unusual" pathways to deal with patients treatment, because each patient is different, and not every patient is usual, regardless of what non-clinician thinks, which make medicine an 'Art' in a true sense, in addition to being an applied "science". The Court understand that patients have unique features that demand adaptation of physicians to many of these pathways dictating variance in almost every patient, because every patient is unique or unusual, contrary to the government and the court

insistence on one standard size fits all, named the "usual course of professional practice" which is a misnomer or oxymoron contained in the jury instruction, inconsistent with 1306.04 (a) as explained infra.

iii. not all patients the same: We have to believe it is self-evident truth that patients come with their own natural or induced diseases to their physicians to be treated, and physicians are not the creators of these unique collection of diseases in the same patient, yet physicians are obligated to treat them all by many drug combinations. This create unique patients' variation, most apparent in pain medicine where there are many triggers, and associated diseases, that may coincide with the pain, forcing the physician to treat each and every symptom to reach wellness with necessary combinations, because treating pain alone is unsatisfactory to patient's health and wellness.

iv. Sakkal's protocol of Mini-Dose-Combination-Therapy (MDCT) is today the best standard of acceptable care, although it may not be universally the most common practiced by the untrained or the unfamiliar with the Art of Therapeutics or have learned the Art of holistic medicine from "Masters" in micro-dose therapy (like Jacque Le Coz), like Sakkal had. MDCT is best because it uses the lowest dose opiate for pain treatment, in combination of treating the debilitating associated diseases that relate to pain in USA citizen.

v. Pain Associated maladies are many, and often need combination medications; few will be mentioned next:

a) Anxiety/phobias are treated with benzodiazepine (50 million Americans daily),

b) Depression, melancholy, dysthymia: need SSRI's for depression (50 million daily),

c) Dependency/Addiction to chronic opiate therapy: need short or longer opiate derivative like Methadone, suboxone or vivitrol

(60 million daily),

d) Anti-Psychotic for personality, Schizophrenia paranoia spectrum (30 million daily),

e) ADHD with amphetamine or methylphenidate (20 million daily), and so on.

As expected many of these diseases need their own separate and necessary medications, and MDCT is best to serve them. These unavoidable necessary well-tried combinations in their lower doses are safe, effective, and superior to a single large dose medication as the government, the court and few specialists insist, without experience, or by support from well-paid so-called experts, who speak the government opinion in medical therapeutics: "usually" a family practitioner testifies against pain specialist, and a pain specialist against a primary care physician, a Rheumatologist against

Endocrinologist, etc. in exploitation of these well-paid expert professional ego and jealousy and divide to conquer strategy, and sometimes just for the money.

vi. A world authority in Pain Medicine, a Textbook author, and a Harvard Medical School Professor, has testified to the fact there are many "usual" pain practices in United States v. Lopez No 17-12653 Lexis (11th Circ 2020): Dr. Carole Warfield testified:

> "First, There is a fierce debate within the medical arena about the best practice in pain management.. with lack of consensus.. and there is no specific regulation or requirements of pain management doctors exist."
>
> "Second, the terms 'best practice' 'standard of care' 'the usual course of professional practice' and 'standard of practice' are all used in civil malpractice cases and not applicable to criminal cases, thus if used it is a conflation."
>
> "Third, as such, most physicians' cases prove to be within the wide range of the usual course of professional practice based on the facts they have established a provider patient relation, and had a medical history, conducted physical examination and toxicology testing, and obtained patient responsibility agreement."

vii. More on Sakkal's case usual course of professional practice:

There are today as many usual and unusual acceptable courses of therapy protocols as there are medical organizations, societies, guidelines (around 80 at last count). In additions authorities, anecdotal experience, one or more case reports, as well as ongoing pre-clinical and clinical researches enriches the medical arena non-stop with better clinical outcomes, including the petitioner's own ongoing quest to find the best tool to diagnose and treat in his real life clinically oriented research practice, based on the best and latest in the field from "harm reduction" which he practiced for years as a goal, "Sakkal Scale and Score", as the best diagnostic tool, to "MDCT" as the best answer to treating multiple overlapping associated disorders, as best practice.

The petitioner has experienced great success for years, in thousands of patients, with the hypothalamic paradigm , which understand the association of pain, addiction, cravings, depression, anxiety, ADHD,

psychosis, metabolism, energy etc. as disturbances in the hypothalamic neurotransmitters and receptors set-point (threshold) and thus their treatment is successful when neurotransmitters modulators are used in small doses to re-establish synergy, which is the natural intuitive, and logical treatment, used in the petitioner Mini-Dose-Combination-Therapy used in the practice. While, on the other hand the government and its well-paid so-called expert think any combination is dangerous, and prohibited, forgetting that most medical conditions today are treated with combinations from Asthma, cancer chemotherapy, to pain and zoster (shingle).

Some physicians are not trained on the successful Micro-dose therapy, like Sakkal had, under the mentorship of the French Master in Mesotherapy, Jacque Le Coz, which may explain inability, in some physicians, to accept other alternatives.

viii. This hypothalamic paradigm is summarized in an easy language to give to patients at their departure from the office visit, as a pain therapy foundational comprehensive plan in detail, documented in each patient's chart and was not presented in court as evidence, that include many steps: natural, pharmacological and intellectual (App.G).

Briefly it includes anti-inflammatory antioxidant, dense superfood diet, progressive exercise (stretch, balance, aerobic), stress reduction, sleep hygiene, braces and prosthesis, helping the MDCT medications, instructions, warning of misuse.

The government and its expert who may not be familiar with this hypothalamic paradigm and MDCT as their opinions reflect in the courtroom, should have explained by the defense counsel or the petitioner. The defense counsel was familiar with this evidence, expressed his utmost admiration.

ix. Defense counsel failure in edifying the jury was puzzling:

a) When counsel read the pain management plan and the instructions related summarizing it he was very impressed, he opined, expressing his admiration: "this is the best plan and instructions I have seen, It is so much better than my own doctor, and the government cannot come through, just reading this will prove they have no case".

b) Yet he failed to explain it to the jury, ignored it, despite multiple requests from the defendant to explain the pain treatment protocol, or at least permit the defendant to testify to explain it, but he refused in the strongest possible term, finally exploding in a tantrum "Over my dead body" (Court Opinion at 13). The harm caused by the counsel erased any chance of acquittal because the jury did not hear

these facts as a result of the counsel ineffectiveness. The damage of the defense counsel action was immense and irreparable at any appeal level.

c) The defendant had every right to be heard, but never could, hoping now these facts will put lights on the truth. The petitioner/defendant right to testify was scarified, as will be explained next.

d) RIGHT TO TESTIFY WITHELD FROM SAKKAL

1) "The decision to testify ultimately rests with the client". Demaro v. US 2009 U.S. Dist. Lexis 18191 (3rd Cir.).

Unless it can be shown that the decision was the result of coercion" Atale v. Winchester, 8th Dist. No 79739, 2002-Ohio-2180 citing Hutchins v. Garrison (1983), 724 F. 2d 1425, 1430 and Lema v.US (1993), 987 F. 2d 48, 52-53.

2) The doctrine of the right to testify has been repeatedly affirmed.

> "Clearly, the decision to testify is a determination that the client ultimately gets to make". Florida v. Nixon, 543 U.S. 175, 125 S.Ct 551, 160 L Ed 2d 565 (2004)
>
> "With the respect to the right to testify, and several other rights, whose ultimate decision regarding those rights is up to the client. Concerning these decisions an attorney MUST BOTH CONSULT with the defendant AND OBTAIN CONSENT to the recommended course of action" Id 1t 187, 125 S.Ct at 560.
>
> "Trial counsel always informs a client it is [client]'s decision, and he can only provide advice". Alexander v. Cartledge, 2017 U.S. Dist. Lexis 15057 (4th Cir.).

The decision not to have Sakkal testify was not Sakkal's decision but the counsel's.

3) (Mr. Goldberg) coerced Sakkal into not testifying, by being "placed under undue pressure when the counsel made that decision" Hixon v. US 2023 U.S. App. Lexis 417 (6th Cir. 2023). When Sakkal insisted on testifying the counsel coerced him by screaming "over my dead body", (Opinion at 13) threatened him not to say a single word that may anger the judge, saying that would make him in contempt of court, lose his case, and "don't blame me then, but blame yourself for losing".

4) "The Eleventh circuit made clear that a defense counsel would be considered ineffective if he failed to inform the client that the ultimate decision to testify rests with the defendant" Gonzales v. Elo, 233 F. 3d 348 (6th Cir. 2000)

5) Sakkal was depending fully on the counsel's advice, and the court role as a fair gatekeeper, who should be responsible about keeping basic rights of the accused, on the record, including the right to testify, calling on medical expert witness, and signature analysis expert to verify the potential forgery in 6 prescriptions among others. This is also a basic function of the counsel according to Strickland. In Sakkal's case the counsel coercion was obvious and well documented in the court opinion (Id). But the court silence made no comment about it.

6) The counsel's decision made in Sakkal's case was not of a sound trial strategy (Strickland 466 at 689): the decision to not call an expert witness or Sakkal, prejudiced Sakkal when Sakkal was the best expert witness to explain HIS own sound superior protocol of therapy in HIS usual course of professional practice, with its proven outcomes, minimizing opiates use, decreasing addiction, diversion and abuse, when compared to the traditional pain specialist's protocol. Lee v. US, 2022 U.S. App. Lexis 30940 (6th Cir.)

7) The 6th Circuit Appeals Court amplified the error by not upholding Sakkal's claim of ineffective assistance of counsel which warrants SCOTUS correction on plain error review. As the decision not to have Sakkal testify was not "free and unhampered" but made under counsel's coercion to the point that Sakkal, nearly fainted, and threatened at one point not to show up to court if he could not testify. See US v. Thomas, 488 F.2d. 334, 336 (6th Cir. 1973).

8) Every defendant has the right to an expert witness, appointed by the Court if necessary. Sakkal 's defense was clearly prejudiced by the Court not appointing an expert witness pursuant to 18 USC 3006A.

9) Sakkal met his burden to identify an error, so obvious that the District court should have corrected Sua sponte. see US. v. Frody; 456 U.S. 152, 163, 102 S.Ct 1584.

In sum, the defendant was deprived of his rights to testify and to have an expert witness by Intentional Counsel's ineffectiveness and court error.

x. C.F.R. 1306.04(a), wisely recognized the need to allow more than one practice style to be respected according to patients' unique needs, and each physician expertise and professional competence by using the crucial word "HIS" when describing the nature of professional practice. The 1306.04 text reads: "a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of HIS professional practice". Although it had some other concerned discussed infra, the regulation meant the word "HIS" to be exactly that: "HIS". And the usual course of "HIS" differs from one physician to the other without being unlawful. HIS means HIS standard of care, his style, as Dr. Warfield testified, supra, and not a generic universal or one single standard.

a) In contrast the District Court jury instructions contained once the generic sentence "Boundaries of professional practice" although when it quoted the regulation it used the full sentence (HIS professional practice" a guarantee to jury confusion. The text implies only one single universal standard exists, which is untrue, like using the word "unicorn" which does not exist in nature, as a real animal, although the word exists. So is "professional practice" a common term that no one knows exactly what it is in the court room of the #841 prosecution world. At least we know no statutory or regulatory definition exists so far, and SCOTUS never defined it either.

b) it should be accepted however, to consider the deviation of the practitioner from HIS usual course for criminal intention a base for suspicion, when the patient benefit is uncertain, and the activity benefit the practitioner in money profit, abuse of ethics, or other personal rewards, none of them proven in Sakkal case: no cash, no sex, no arms, no trade, sport cars, condos, real estate owned, no money laundering, bribery, conspiracy, fraud or abuse or kickback, and the government did NOT CONFISCATE FROM SAKKAL A SINGLE DOLLAR AS DRUGS MONEY OR OTHERWISE.

xi. Court jury instruction complicated THE CLEARER LANGUAGE DERIVED FROM 1306.04 ELEMENTS rather than to simplify it:

a) The regulation 1306.04(a) had a simpler direct language, easier to understand, although still difficult to define some of its terms which were ambiguous, as explained earlier. Yet, the court jury instruction complicated it, using very unusual structure.

b) The court text usurped the jury right to make a free decision, compatible with the simple truth, or plain law. Instead, the court used vey convoluted text, with unintelligible wording, reversed sentence structure, with innuendo, inferences, speculation and mysteries, but the most prejudicial in every word to the medical profession and its providers. Only reading the full text in the transcript will make this fact understood. The defendant read the long-convoluted text more than 100 times so far, and each time the mysterious meaning gets more confusing, complicated, and absurd.

c) Some vague words have been explained supra, but each time they are read the more the confusion; ambiguous terms like "deliberate ignorance, willful blindness to what is obvious, the many mythical red flags, etc. none of them appeared in 1306.04(a). The court might have tried to simplify the text but in reality made it more confusing and unintelligible.

d) Its language imply that physicians are responsible about every rogue acts by an employee in the office, a patient outside the office, even if the provider was unaware of any of these acts, as if their acts are the physician's acts. At the same time knowingly and intentionally it ignored the definitions in section 802(10) et seq and called the physician's "prescribing" a different false terms, "dispensing or distributing", a double jeopardy.

These jury instruction errors led to conviction of thousands by making physicians criminals if they made an error, if a rogue patient abused his medication outside the physician office, against his warning, and even if a computer glitch caused a typographical error of another person DEA number as Sakkal case had all these features, causing his counts to stack at accelerated rate.

In sum, the jury instruction in violation of SCOTUS, CFR, CSA, AND THE ENGLISH LANGUAGE have caused major harmful court(s) errors to petitioner, his family, his life, liberty, honor, and future livelihood. This petition is only a cry for justice, under the Constitution.

The petitioner pleads to the Court to exonerate an innocent man, vacate all charges, restore full honor, licensures, human and citizen rights, and repair the damage incurred as a result of zealous prosecution, shifting court(s) and ineffective assistance of counsel.

III) The Burrage Clause in Jury instruction:

Although Ashley Adkins (AA) death was a self-inflicted overdose by ingesting a lethal amount equal to forty times the prescribed dose, Sakkal was convicted for (AA) death and received sentence

enhancement. To reach this conviction the prosecutor introduced in trial jury instruction the "Burrage clause" which has not been used previously in this court. This selective partiality in Judge Barrett's court, different from his prior # 841 cases, produced a different treatment for Sakkal under the law, by the prosecutor's misrepresentation of "Burrage's" intent.

1) The Court's application of the Burrage clause implied to the jury that any death after a drug ingestion is a form of murder, regardless of who was the source of the drug: an indicated legal prescription like Sakkal or a drug trafficker distribution in the street. A CDC overdose statistics audit for the last decade revealed that the implementation of "Burrage" in the lower court(s) since 2014 coincided with a 200% increase in overdose death rate in the population, correlated with an increase in physicians' conviction rate. While association is not always synonymous with causation, there is strong speculation that "Burrage" helped incriminate more providers, with resulting deterrence of all providers prescribing, leading to a patients shift to street polluted source of controlled substance, leading to more overdose death rate since 2014 (see CDC statistics in Appx. G). Sakkal's case is another example of misapplied "Burrage" effect on physicians' prosecution, compounded in Sakkal's case by the fact it was applied first in this court as a selective injustice.

2) "Burrage clause" does not correlate to patient's misuse or abuse of the legally prescribed medications and patient's self-induced suicide. Burrage's basic original intent was benign; that is to be certain a death cannot be attributed to a drug if the drug was not detected in the body as the primary cause of death (A "But-For" clause: is usually given to the jury to decide, although it is a very hard to comprehend term). But, prosecutors and judges misapply it, as in Sakkal's case, where the jury instruction language implied that death after a prescription was a murder rather than a suicide, as in Adkins' case. The government's "expert witness" falsely claimed the prescription was for "no legitimate medical purpose or outside the usual professional practice", (despite documented ten diagnosis) equating a doctor to a drug dealer. Here, the questionable opinion of one non eyewitness, so called "expert", became the false deciding factor for judgment and a life sentence.

3) However this opinion of equating two opposites of drug use/abuse is false, and counterintuitive for many reasons:

i. A Patient seeks the doctor for help in a licensed medical care office. A Drug dealer chases and seduces addicts in shadowy dark streets.

ii. A Doctor prescribes legal FDA approved medication. A Drug dealer sells smuggled prohibited illegal drugs.

iii. A Prescriber intent is to help pain suffering, improve healing and quality of life. A Drug dealer gives for "Recreational Harm" pure profit, often destroying lives.

iv. Both "knowingly and intentionally" are aware of their conduct goal: legitimate beneficial purpose serving people ills v. malicious money greedy purpose exploiting subjective addict's habits.

v. A Prescriber offers a service valued more than the meager Medicaid reimbursement, paying income taxes, benefiting the common good of society. A Drug dealer gives a product for huge profit much more than its real value and launder the money in more illegal activities increasing social ills, injuring society.

vi. A Doctor hands the "prescription" after extensive objective evaluation including history, physical examination, diagnosis, therapy plan, according to the scientifically acceptable standard of professional practice. Drug dealer "distribute" the illicit drug without any evaluation but standardless thugs' rules.

vii. A Prescriber have the patient sign a drug contract, informed consent. Drug dealer has no documented contract.

viii. A Prescriber gives full oral and written instructions, warnings, precautions repeated by Sakkal medical assistant at discharge, for three stages in the office, then pharmacist repeats extra oral and written instructions for a total of five stages. A Drug dealer does not give any instruction, warning or precaution.

ix. A Prescriber documents every part of the encounter in extended medical records, making him an easier target for prosecutors' zealous indictment with hundreds of counts, with long sentencing, since everything is recorded. A Drug dealer avoids any documentation of the encounter which makes it harder to prosecute until material evidence is confiscated, usually with one or two counts only and short sentencing. This explains why prosecutors prefer to prosecute doctors who have easy evidence, more to plunder, and confiscate, with better career advancement and return on invested time rather than small drug dealers.

x. A Doctor schedules a follow-up surveillance visit for drug effects or side effects monthly. A Drug dealer follow-up ignore side effects and depends on the need for drug supply driven by emotional cravings.

xi. A Prescriber adjusts follow-up dose based on OBJECTIVE findings, drug testing, drug effect/side effects and OAARS reviews. A Drug dealer adjust to addicts demand.

xii. If a patient death occurred after doctor's good intention and ignoring these 10 safety guardrails, as used by Sakkal, it would be reasonable to conclude that the death was self-induced/suicide against altruistic medical advice, the written prescriptions and all instructions, precautions taken for life preservation and Harm Reduction described above. But if death occurs after drug dealing it would be reasonable to conclude it was related to the malicious conduct that supports greed, recreational harm and disregard to human life and morality

xiii. Thus, death must not be and should not be attributed to the Good Samaritan physician as the District Court falsely concluded. But Burrage should be applied only to a drug dealer. How the two are equated through "Burrage" is puzzling.

xiv. Sakkal's practice has extra periodic audits, published outcomes/cost effective statistics studies/patients' surveys helping others. Drug dealers only audit their street distributors in their territory to account for the money, street supply and demands, and never publish their results to help any other.

xv. Providers are convicted at 97%. Drug dealers at less than 40% rate!

xvi. Equating the two conducts of physician's prescribing and dealer's distributing in case of death is incomprehensible.

4) Equating physicians with drug dealers in "Burrage" is a crime against humanity's goodness servers, in favor of socially rogue evil forces. It is not the court(s) best mission. Here is a realistic perspective: while death may occur in both situations after ingesting a drug or medication, the difference legally is stark: from intention to action to consequences. The circumstances and context are contradictory where one side (trafficker) has all elements of a criminal act, and the other (physician) has all elements of a beneficial act. To equate one with the other is the ultimate conflation and poor judgment used to prosecute doctors falsely. In Sakkal's case it took only one so-called "expert" to announce that "prescriptions were for no legitimate medical purpose" to make Sakkal a drug trafficker.

Sakkal, an experienced authorized licensed physician, issued a legal prescription, for a legal FDA approved medication, in the correct indication, for the benefit of AA, to relief her suffering, without cash

profit, with good faith purpose, after extensive medical history, physical diagnosis, and therapy plan, with surveillance follow-up to readjust according to a well-proven objective signs (Tender points and nerve vibration perception), documented in the medical records (ignored by the court), according to the best superior hypothalamic paradigm, in the smallest medication dose in Mini-Dose-Combination-Therapy (which is the standard today in all fields of medicine). Yet he was convicted for 37 counts in a travesty of "Burrage" injustice. On the other hand, a dealer of 1 kg of heroin had one conviction for one count.

5) In Sakkal's prosecution the prosecutor insisted on using "Burrage" clause convincing the Court it was the latest "modern" instruction from the Supreme Court on the subject (although it existed for 5 years). The honorable judge, who never used this clause before in his court, submitted to the prosecutor's false conflation scheme, after 24 hours of review, despite Sakkal's recorded objection. This was a first misapplication of Burrage clause" in his court, on Sakkal, instead of a drug trafficker's. Thus falsely extended to include physicians, only by one witness' statement that Sakkal's prescription was for "no legitimate medical purpose", an error like Moore 1975

6) The above described is based on the following facts in Sakkal's case that resulted in a false death conviction:

i. Sakkal was indicted on three counts for the same patient Ashley Adkins ("AA"): counts # 1, 2, for her two prescriptions under 21 USC 841 (a)(1), and count # 31 for her death under 21USC 841(b)(c), stacking 3 counts for one act.

ii. Her visit to petitioner was 12/28/2015 after release from incarceration, with many complaints and many diagnosis, that included: severe pain, depression, OCD, muscle spasm, anxiety, extreme fatigue, lack of energy, gastrointestinal and genitourinary symptoms, sleep disorder, fibromyalgia, myofascial pain syndrome, hypothalamic hypopituitary dysfunction, and many others ending with more than 12 prescriptions (almost two medication for each). On physical examination she had 26 objective tender pain points of hypothalamic origin documenting the most extreme degree of severe pain (mild 8-12, moderate 12-16, severe 16-20).

Sakkal prescribed for her no opiates preferring to start with ibuprofen, Tylenol, local OTC pain patch Salonpas, and mild non-opiate mini-dose-combination therapy with small dose-1 mg klonopin- (a new benzodiazepine without cardiac respiratory side effects and many proper indications like an

adjuvant pain modulator, stress, nervousness, anxiety, panic, phobia, and obsessive compulsive trait, all of which exaggerate pain) and Soma (a gentle anti-spasm to relieve her spasm which also exaggerates her pain and vice versa). She denied an ideation of suicide, but admitted that after her incarceration she was still miserable with her medical issues, and many social stressful issues like homelessness, lack of income, resources, etc. As with all Sakkal's patients she received her instructions and foundational pain treatment plan including a return follow-up review visit in one month. Prescribing two mild synergistic medications has the least side effects, and the better response, reducing the dose of both medications to the smallest chemical load possible.

iii. Her second and final visit on 1/18/2016, one week earlier than her appointment, was triggered by flare-up of her fibromyalgia pain. She ran out of medications a week earlier than her appointment, because she was trying to relieve her pain but to no avail. She started self-medicating by drinking alcohol "to kill the pain" and appeared "under the influence" of alcohol as she admitted. She requested a much stronger pain therapy because her pain was intolerable. She still had challenging social medical issues, with lack of meaning in her life. Her examination still revealed 26 tender pain points, reflecting extremely severe pain needing high dose level 4 pain therapy.

A frank discussion with her culminated in signing a drug agreement and an agreement with the doctor to stop alcohol. She promised not to mix her medications with alcohol, and to continue her multi-modal therapies, and in return she received a small dose Xanax (1 mg) to replace klonopin, and the smallest dose of opiate (Percocet 5 mg). Soma was stopped because Xanax has also some anti-spasm features and redundancy was not needed.

iv. Her housemate/living companion/uncle-in law/boyfriend/significant other, Chris Norvell, testified she filled her prescription on 1/19/2016, played video games, told him she "wanted to get high", started to swallow her tablets for few hours, passed out, found dead in the morning. The counsel did not ask if he shared her or other drugs, if he encouraged her, why did he let her do it, or if he had an explanation!

What is clear however that Norvell did not stop her, or called for help from her doctor, the hospital emergency room, the poison control center, or if she left a suicide note. He admitted she had in the past attempted suicide but failed in her attempt. What is also clear he was the last to see her alive, the closer person who have access to her in her last hour to influence her Suicide Crisis Syndrome as described in APPX. G. And he is the only one who could have saved her, and HE is the one that was recruited by the prosecutor to testify against the doctor who tried to save her but could not.

v. The petitioner felt that titrating AA according to MDCT (Appx G), was the responsible pathway. In the first visit, with her extreme symptoms and 26 tender pain points, the petitioner prescribed her the smaller than indicated standard dose Soma, for spasm and smaller than indicated dose klonopin for anxiety, phobia, panic, OCD, spasm, pain fixation as adjuvant pain trial. These two medications are a good starting combination to see if benefit will occur, before using stronger medications.

In her second visit the petitioner replaced the inadequate therapy combination with a better more effective combination, strongly indicated in this type of extremely severe pain (with persistent 26 tender pain points), and anxious mood.

The Petitioner prescribed a Small 1 mg dose Xanax, a new benzodiazepine without respiratory effects, with wider spectrum symptoms coverage, replacing 1 mg klonopin. The petitioner also prescribed the smallest dose available in the market of Percocet 5 mg (a fourth line medication in MDCT) replacing Soma, as the most sensible next step in her conservative titration to improve the dismal response of the first combination.

There was no other alternative in a patient who have used opiates for years, after a non-opiate therapeutic trial have already failed. The new combination was much better than sending the patient away in desperation to seek illicit drugs from the black market on the street, as the government, who offered no better alternative treatment, seems to imply.

vi. The chosen combinations in its smallest dose was extremely safe, is not a dangerous combination by any standard, as speculated by the prosecutor who is unfamiliar with Mini-Dose-Combination-Therapy. Her Percocet 5 mg dose was 1/25 the dose (more than 120 mg) prescribed by a pain specialist (like Drs. Ruan and Couch) her Xanax dose was less than 1/5 the maximum daily dose of 10 mg prescribed by other physicians (see www.drugs. com)

This low dose combination deserves praise not an indictment in triplet; one for each conservative safe low dose combination prescribed by the doctor, and one extra enhancement for a patient's self-induced overdose death, which was perpetrated against the small dose prescription, the doctor verbal and written warning and instructions and against common sense, just for pleasure's sake, and despite her denial of suicide ideation. A triple indictment is a prosecution over-kill.

vii. The lethality of her ingested medications amounts is easily explained by three indices:

a) The number of Percocet 5 tablets she ingested intentionally over few hours, as reported by her living companion, was huge (At least 60, not counting other friend's supply which could add up to 86 tablets). A 60-80 times of what Sakkal prescribed is certainly a lethal dose.

b) The extremely high blood level in her autopsy, as reported by the coroner in court, was shocking even to the government "expert witness" who did not hear about the levels prior to court, since the prosecutor did not give him the report before the "expert" wrote his report: Oxycodone level was 545 ng/dl, ten times the therapeutic range of 20-60); Xanax level was elevated at 80 ng/dl (normal 20-60). This proves that her death was Oxycodone related 100% without the clinical influence of Xanax. Thus her death is related to opiate overdose, pure and simple and not related to opiate/Benzo combination.

c) The acetaminophen ingested was also certainly lethal by taking sixty times Sakkal's prescribed dose. Her total acetaminophen ingestion was at least 40.000 mg or ten times the 4000 mg lethal dose by liver toxicity.

viii. The coroner testimony was clear "she must have ingested huge amounts of her medications". The government "expert witness" concurred and added "if she took her small dose medication as prescribed her blood level would be normal". calculation of blood level if she took the medications as prescribed would be 15 ng/dl for oxycodone, and 3 for Xanax. The first level is at the lower edge of therapeutic range, and the second is below the therapeutic range, neither would be lethal.

In sum, Sakkal' prescription did not cause AA death, her own self-induced massive ingestion overdose did. All These counts should be reversed and vacated.

6) SCOTUS should consider this time an opportunity to clarify the "Burrage" clause intention, context and application as it is designed for drug dealers. This will correct another major error in the Sixth Circuit. Sakkal and defense counsel objected in court, which did not agree with Sakkal objection, ignored reasonable common sense. If this practice continues thousands more physicians will be falsely indicted, hundreds of thousands more will be deterred, and millions of patients will suffer deprivation of their necessary daily medications. This will lead patients to seek illicit drugs in the street, with more overdose death rate increase and worse public health crisis.

SCOTUS action is so important for the public health, as reflected by some early moderation of prosecution after Ruan 2022 decision which started to have an impact on overdose death. For the first time in 10 years overdose death began to decrease this year by 10% after 10 years of persistent steady

double fold increase. Association is not a proof of causation, but the experts can't explain the death rate decrease this year, and the petitioner's experience makes him believe this is exactly the reason until a better explanation is proven.

This welcome new decrease trend could be the mirror image reversal of the increase trend noted after "Burrage" 2014, which is further confirmation of the powerful impact on public health from SCOTUS decisions. (see: Jacob Sullum, A Mysterious decline in overdoses, The Week, October 11, 2024, Page 12: "Drug deaths are finally declining, and nobody really knows why". The Center for Disease Control and prevention released data indicating a 10% drop in overdoses over the past year, to 112,470. Researchers pointed out the government war on drugs cannot explain it. The street price of drugs is actually declining, indicating either greater availability, or lesser demand which is more likely. Naloxone may be partly responsible, but it has been introduced 2017 without prescription. Prohibition of drug sales and use (or their restriction by limiting prescription drugs) has never been effective, and in fact contributed to the overdose epidemic 'by creating a need for a black market in which quality and purity are unpredictable'. The failed war on drugs deserves "a large share of blame for creating a situation in which an annual toll of more than 100,000 drug deaths looks like an improvement").

D. WHETHER THE GOVERNMENT LAWYERS AND THE COURT(s) LEGISLATED ENCROACHING ON CONGRESS' INTENT, WHEN MISAPPLIED 21 U.S.C. SECTION 841, VIOLATING SEPARATION OF POWERS DOCTRINE? AND WROTE THE SENTENCING COMMISSION DRUG CONVERSION TABLES ARBITRARILY BIASED AGAINST PHYSICIANS?

The "shotgun" approach to convict physicians is flawed, built around the hybrid triad of (1) the CSA, (2) #1306.04 (a), and (3) the Moore 1975 SCOTUS decision; and each of these components, has been misapplied in Court for the last five decades, with a cascade of cases that started with Moore and delivered, afterward, many precedents that became the scheme for #841 conviction, with incarceration of thousands. Here is a brief synopsis:

I) THE CSA SECTION 841(A) WAS ENACTED TO COMBAT DRUG TRAFFICKING

The CSA section 841(a) was enacted to combat drug trafficking, regulate "distribution", and excluded physicians who "prescribe" for a socially beneficial and necessary public health service to US citizen, as a part of the Government Duty of Protection. Congress intended to distinguish between criminal behavior for "profit" (Congressional record 1970,19), and authorized medical practice by excluding "registrants authorized physicians". Thus, The CSA cannot be used to convict physicians, and, therefore, the CSA contained no penalty component for violation because of the "except as authorized" clause. Any noted violation was to be treated under # 822, 823, 829 and 309 rules, which is civil in nature, leaving #841 for Its exclusive domain for the conventional drug traffickers, charging the DEA with diversion prevention regulation. (Sakkal v. US 143 S.Ct. 20221011v27l Leagle.com)

II) THE C.F.R. #1306.04 (A)(1) WAS CREATED TO MANAGE REGISTERED PROVIDERS

The C.F.R. #1306.04 (a)(1) was created as a regulation, by the DEA under the highest lawyer in the Executive Branch (the Attorney General) to manage registered providers, bypassing the #841 exclusion, according to their registration as outlined in 21 U.S.C. 802 et seq. 1306.04 (a) requires that "prescriptions, to be effective, be made for legitimate medical purpose",
but prescribing does not create a criminal offense by itself. Instead, the offense arises explicitly after proving, beyond reasonable doubt, the intent to prescribe was unauthorized unlawful prescription. The regulatory 1306.04 (a) was written in unusual, vague, ambiguous language, as Ruan decision described, in detail.

Vagueness is unconstitutional, defined in Webster's as fuzzy, not clear, murky, obscure. In United States v. Davis (2019). SCOTUS held:

> "When Congress passes a vague law,.. role of court is to treat the law as nullity
>
> and send it to congress to retry again"

The Court(s) applied an "objective standard" (whether the prescription was written according to unannounced medical standard(s)) without proving that the doctor, like Sakkal, had the required "subjective intent or knowledge" that the prescription was unlawful or unauthorized. Vagueness is manifested in many ways:

A) "LEGITIMATE MEDICAL PURPOSE IN THE USUAL COURSE OF HIS PROFESSIONAL PRACTICE"

1) The two prongs used, namely, legitimate medical purpose' and "the usual course of his professional practice" have never been defined in universally accepted meaning by SCOTUS and have been misinterpreted by the lower Court(s), to mean, in court application, anything the Court holds. The Sixth Circuit plainly announce that it would deal with it "on case-by-case basis, in a broad approach, rather than a narrow, specific approach. (see Volkman 2015, Kirk 1978).

It is very surprising that there is no statutory or regulatory definition anywhere, of these two terms, which renders the regulation vague, unusual, as described in Ruan Court analysis, and should be returned to Congress for clarification.

See United States v. Birbrapher, 603 F. 3d 478 (8th Cir. 2009). What this means, then, that physicians do not have an advanced notice with failure of fair warning of the boundaries of the law, another unconstitutional error, violating the Fifth Amendment.

2) The Sixth Circuit in this case and before, as well as many other Circuits, have replaced "HIS professional practice with the generic "Professional practice, transforming 1306.04 (a) language when it omitted the law's specific wording, "HIS". Omission is an error as prejudicial as addition, or vagueness. The difference is plainly clear: HIS means exactly that: "HIS" in the English dictionary-the specific style the provider follows in HIS professional practice in "HIS usual course" of practice, on a daily basis with HIS patients, and does not deviate from it except for a CRIMINAL INTENT.

3) For example, a dentist's usual course of professional practice will not allow her to prescribe pain medicine for a heel pain, or for a podiatrist to prescribe for toothache. Different Pain specialists may prefer using specific brands, with long or short acting opiate or both in combination, and all are within the legal "HIS usual course of professional practice".

While some pain specialists prefer only pharmacologic pain therapy at higher doses as tolerated, like Dr. Ruan, the defendant Sakkal, follows the hypothalamic paradigm which treat all central nuclei involved with the constellation of symptoms, as a well-trained-Endocrinologist, the Mini-Dose-Combination-Therapy as a trained-Geriatrician, and natural/psychological interpersonal cognitive therapy, for the mental component, as a holistic Complementary Medicine-trained physician. Sakkal's approach to treatment then, combines unquestionably the best integrated benefits of many fields (see infra), and he is well within the legal boundaries of "HIS best course of professional practice". The defendant style-with world experience of the Art of Therapeutics- is not familiar to the government or its own "well-paid" expert witness, as could be "inferred" from their opinions.

All these are legal examples of "the usual course of HIS professional practice" but each in a specific field, in which pain prescription is fully legal, while the jury in Sakkal's case heard only the "well-paid" expert states "the standard of care acceptable to an expert like myself in the USA at the time of the events in question", as the only available standard. This was absurd but truly happened in the court without objection (Affidavit). If either practitioner deviated beyond the boundaries of 'Their' professional practice for criminal intent, and self-profit as the congress intended (Congressional Records, 1970, 19), then criminal suspicion is reasonable until proven guilty or innocent.

4) This regulation was not meant to be one single standard, a one size fits all, making any physician that oversteps the Court, or prosecutor, or their expert undefined unpublished standard, liable, as the Sixth Circuit wants it to be.

In medicine there are many protocols to treat pain in real life medical care system characterized by first do no harm, freedom of choice, without a single payer, or enforcer of medical protocols, and duty of advocacy and protection to patient's rights, all recognized and all valid.

5) Although many guidelines and standards have been published by more than 80 medical societies and organizations, none is considered the only and universal rule of law, and the defendant, Sakkal, has chosen from these guidelines what fits best his holistic comprehensive approach, which was

ignored by government, the court, and even his own counsel who later perjured himself. The difference in practice style was explained in one citation by a world authority of pain Medicine, Chairman of the Pain Therapy unit and a Professor at Harvard Medical School, Dr. Carole Warfield, testifying in United States v. Lopez 2019, U.S. Dist. Lexis 62760:

> "First, there is a fierce debate within the medical arena about the best practice in pain management.. with lack of consensus.. and there is no specific regulation or requirements of pain management doctors exist anywhere.. including patients who have a history of substance dependency or abuse."
>
> "Second, the terms "best practice" "standard of care", "usual course of professional practice" and "standard of practice" are all used in civil malpractice cases and not applicable to criminal cases, thus if used it is a conflation."
>
> "Third, as such, most physicians' cases prove to be within the wide range of the usual course of professional practice based on the facts they have established a provider patient relation, had a medical history, conducted physical examination and toxicology testing, and obtained patient responsibility agreement."

The government has resisted Dr. Warfield testimonies in many cases, but her opinion represents the overwhelming majority of pain providers in the USA, contrary to 1306.04 interpretation in the Sixth circuit. supra. So, In sum the terms "usual course of HIS professional practice" is vague, misused in the Sixth Circuit, incorrectly applied beyond its letter or intent.

6) The Sixth Circuit jury instruction had ambiguity about the terms "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" which is even more problematic. The Committee commentary defines it "to mean "acting in accordance with generally

recognized and accepted standards of that individual professional practice.. which are set by various organizations". But announcing its inability to be specific:

"The law applicable to this offense does not define this phrase further"! This commentary dogma was contrary to SCOTUS decision in Ruan which advised to replace the "objective" evidence standard by the "subjective" intent. The commentary however points to the resistant stand of the Sixth Circuit, although in fairness, it observes the "individual" practice wording Another unfortunate part of the committee commentary states that "Circumstances surrounding a prescription allows juries to "INFER" that a physician's purpose was something other than 'legitimate medical treatment' ; the underlying conditions (diseases or symptoms) a patient may have had are not dispositive". This sentence implies that the unskilled uneducated jury in any medical art "inference" (which means guessing in the dictionary)to carry the burden of judging rather than the highly educated judges and prosecutors or than the sound clinical judgement of physician medical record diagnosis, which is binding legally for billing under fraud and abuse laws, but not here, and it assigns to the jury the impossible function to read the mind of a physician intent rather than his written medical record. This is logically and medically too much (see Neurocognitive Sciences Textbook, Supra).

B) "KNOWINGLY AND INTENTIONALLY"

This term should be specified in each element of the jury instruction devised from 1306.04 (a), according to the Ruan SCOTUS decision, to make this regulation effective and to cover the MENS REA regulation requirement. In "Sakkal" the district Court instruction did not fully incorporate this heightened scienter requirement, thus, the instruction violated "Ruan". The jury was instructed to convict based merely on objective standard (i.e. that Dr. Sakkal's prescriptions were not in line with general medical standards). The sixth circuit ignored the scienter requirement in the third element, and used it only in one element, rendering the instruction incorrect. Therefore, it did not comport with the Ruan decision which requires clarity about the "state of mind" and the intention that "differentiate beneficial from wrongdoing", crime from innocence. The error is crucial, as it fundamentally alters the burden of proof regarding intent. This was well explained by Judges White and Cole, supra, in the 6th and 4th Circuits, respectively, and will not be repeated here for space limits.

C) Not defining these terms by SCOTUS, led to widespread confusion for nearly five decades, which explains the contradiction among appellate and district courts as to the actual term's meaning,

leading to divergent interpretations and contradictory decisions, resulting in multiple wasted appeals in many cases, leading to more cases being appealed to SCOTUS than necessary, wasting its time, because of the circuits deep contradictions, even after Ruan, as in this case, which could be resolved now by a unified terms DEFINITIONS by SCOTUS.

The already noted conflict among circuits in how they apply Mens Rea in cases under #841 persisted in the Sixth Circuit Jury instruction, in Sakkal's case, adhering to the pre-Ruan standards (objective recklessness, deliberate ignorance, etc.), but was inconsistent with Post- Ruan standard. Comparing the Sixth circuit and other circuits post-Ruan can reveal this discrepancy. Sakkal's case reflects an outdated approach to jury instructions, that perpetuate existing conflict, undermining the uniform application of the law across different jurisdictions. (www.supremecourt.gov/docket/doc..)

D) 21 C.F.R. 1306.04(A) VIOLATES THE DUE PROCESS NOTIFICATION AND FAIR WARNING REQUIREMENT GENERALLY, AND AS IT WAS APPLIED TO Saad Sakkal

> "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of HIS professional practice" 21 C.F.R. Section 1306.04(a).

The government expert Dr. Timothy King testified that a "legitimate medical purpose in usual course of professional practice" was " defined by an expert such as myself based on my perception and understanding of the standards of care as practiced in the United States at the particular time frame that's under examination" Transcript. RE 73, Page ID 1553.

1) Using CFR 1306.04(a) for criminal prosecution of Sakkal (and similar physicians) is unfair because the standards are undefined and subject to the perception and understanding of an expert only divulged at trial. The expert then testifies the doctor is "outside the usual course of professional practice" without saying what the usual course is for each patient, so it is unreviewable for fact error. This regulation fails to provide the requisite notice and fair warning required by Due Process.

2) 1306.04(a) was originally promulgated to authorize doctors to prescribe controlled substances rather than serve as a basis for criminal prosecution and so was crafted as clearly as necessary to serve

as a criminal statute. When Dr. Moore in 1975 challenged whether doctors could be prosecuted for violating the Controlled Substance Act, SCOTUS logically indicated that since he practiced outside the usual course of any minimal professional practice, the rogue doctor could be prosecuted under the CSA. The problem now that "outside the course of professional practice" means whatever the government says it does; it is now the crime of violating the expert's perception of his standard of care, divulged ex post facto during trial, even if the "proof" was unregulated, unrequired, or unrelated conduct, as will explain infra.

3) The Regulation above contains the terms "for a legitimate medical purpose" and "by an individual practitioner acting in the usual course of HIS professional practice". 1306.04(a) authorizes doctors to prescribe for a diagnosis which the substance is approved to treat (opiate for pain, benzodiazepine for anxiety/panic/phobia/spasm/sedation). And authorizes a doctor to prescribe the substance if it is within the scope of his practice. Hence, a doctor may not prescribe oxycodone for allergies when antihistamine is indicated, and a dentist may prescribe oxycodone for his patient's maxillofacial pain or toothache but not for her lower back pain. The regulation had two prongs, that evolved into just one under the present standard, and have legal false "inverses", so anything deemed "outside the usual course of professional practice" is also deemed to be "without legitimate medical purpose", although this is not always correct since atypical patients can have atypical but legitimate medical needs and atypical treatment.

4) The medications used have undergone a special FDA process for approval before they are released into the market, including controlled substances. The FDA provides an elaborate long process for pharmaceutical manufacturers to get their drugs approved for a specific medical indication use based upon their demonstrated efficacy for that use, and safety.
For most practitioners the go-to- guide for prescribing is the Physician's Desk Reference (PDR), or similar sources. The PDR informs practitioners what is a drug is indicated for and warns of dangerous interactions and specify contraindications. Physicians are authorized by 1306.04(a) to prescribe controlled substances, as long as they authorized by their state medical boards, even if they are not pain specialists, so long as the substance is indicated for the symptom and within the scope of the doctor's practice.

5) The government has not passed legislation that specifically forbids Internists (or family practitioners) from prescribing these controlled substances so that only specialized practitioners ay prescribe, nor has it passed legislation which specifically forbids prescribing certain combinations of drugs, such as the one called by the government the "holy trinity" (a combination that has nothing holy about it) in many cases including Ruan, Couch's cases or the combinations of drugs at issue here in Sakkal's case here. The government had the ability to clarify this standardless standard for five decades to do so, but it did not, and it took SCOTUS in Ruan 2022 to pronounce it "vague and ambiguous". Yet, the government still uses it for prosecution after Ruan, subject to the whim of the government and its exerts during trial. The government is exploiting this vague standard and won't take steps to fix it even it is within the discretion of the AG to do so, because it makes easy prey of hapless, unarmed doctors, allowing the government to confiscate their life work ESTATE/Trust.

6) What matters is Dr. Sakkal was authorized, well educated, highly regarded Internist, versed in innovative clinical research of successful methods to treat pain, addiction and minimizes the use of opiate. Sakkal published his excellent results, contrary to the expert witness, and most importantly he acted within his discretion when treating HIS patients, especially since there no legislated protocols to follow. HIS conduct adhered at all times to the recommendations made by and for the medical community at WWW. Drugs.Com. The Court is urged to review http://www.drugs.com/pro/percocet.html, which is consistent with the PDR. This site explains how to recognize substance abuse and explains to doctors that seeking pain treatment, even for an addict, is an appropriate patient behavior, prescribing is a normal response, and recommends counseling patients about dangers of abuse, as Sakkal did, as documented in Sakkal's/patients drug contract, his verbal and written instructions and printed warning on each discharge instruction sheet at each patient's encounter. WWW.drugs.com does not instruct doctors to turn away addicted patients and send them to street dealers and drug traffickers. Only the government and its expert witness call this a recommended "protocol/standard".

7) "As a physician at Lindenwald Medical Associates, defendant Saad Sakkal prescribed various controlled substances to help his patients mange pain" (Appeals Court Ruling 1st sentence Page 1). This is a clear declaration from the Appeals court regarding the "legitimate medical purpose" of Sakkal's conduct, yet at page 7 it reverses itself to state but "prescriptions were for not a legitimate medical

purpose"! Dr. Sakkal has been a law-abiding citizen of the USA for fifty (50) years with no history of drug abuse, trade, or any legal brush with the law ever. Former receptionist Robbi Mott testified that "Sakkal was a good doctor who cared about his patients, and he was not selling prescriptions for cash" (District opinion at). If Sakkal were a dope dealer, as the government claims he would be much wealthier and the stingiest prescriber one ever, because he only prescribed the lowest available dose.

8) Sakkal employed a protocol called "Mini-Dose-Combination-therapy" (MDCT) which simultaneously treats other symptoms and disorders that exacerbate patient's perception of pain, thereby permitting him to efficaciously mange patient's pain using less of the most dangerous and addictive component, the opiate, by also treating the patient's anxiety, depression, muscle spasm and tension, with the medications approved for those exacerbating symptoms. MDCT requires a substantially smaller dosage of opiates analgesic in combination with the other drugs to be more efficacious than opiate alone. The use of this MDCT protocol is evident from the low doses of drugs Sakkal prescribed, and all drugs were prescribed as indicated by the PDR. The government and their so called "expert witness" called this a "dangerous combinations", while it was the least dangerous. (Sakkal's counsel presented no expert witness; whenever the term "expert witness" is mentioned here, it means the government "expert witness, although he was not designed as such in court).

9) In addition, Sakkal employed simple specific tests he learned during his long well-versed clinical experience, before even expensive MRI's came into service (which some specialists depends on excessively to diagnose and treat):

a) "Vibratory sensory perception" is the most sensitive clinical bedside tool to measure neuropathic pain, by placing a "tuning fork" over the nerve pathway to examine its condition.

b) "Tender pain points counts" by acupressure applied gently through specific hypothalamic points is the best measure of generalized pain to objectively determine the lev4el of pain experienced.

c) Hamilton Anxiety Scale: a numerical tool to measure anxiety at diagnosis and progress follow-up.

d) Zung depression Scale: a numerical tool to measure depression at diagnosis and progress follow-up.

These tests are reliable, inexpensive, and very easy to perform by an experienced practitioner, which guide therapy in 80% of patients making MRI not needed for most patients. Sakkal recorded the results of each test when he examined his patients in each medical record (ignored by the government and court) and could monitor and track his patients' progress.

Sakkal orally warned his patients of the dangers of abuse, his staff reiterated the oral and written instructions and warning at discharge of each patient and handed the patient a copy for their home use, as he recommended. let us see an example.

Counts #1, 2, 31

10) In count #1, Ashley Adkins first came to Sakkal's clinic 12/26/2015, with more than 10 ailments as many patients do, resulting in prescribing more than 15 medications. Adkins' chronic pain, treated with opiates for years, was very acute at her visit with Sakkal, and he prescribed initially a non-opiate analgesics (Salonpas locally, ibuprofen-anti-inflammatory, Tylenol-a common OTC analgesic, a standard dose carisoprodol/Soma-an anti-spasm muscle relaxant, and new benzodiazepine klonopin-which has no cardiac respiratory risk at its low dose of 1 mg). The PDR indicates that klonopin is used alone or with other medications to treat a number of symptoms including anxiety, panic disorder, phobia, Obsessives Compulsive trait, insomnia, convulsion and spasm, as all existed in Ashley. OCD and anxiety exacerbate a patient's perception of pain and klonopin has therapeutic value for some chronic pain sufferers. Sakkal is convicted now for prescribing klonopin and Soma to Adkins which were strongly indicated and within the scope of HIS professional practice, within the guidelines of the PDR (count #1).

11) In count #2, Ashley returned before her next scheduled visit because she could not wait for her appointment from excessive pain on 1/18/2016, complaining the pain was intolerable, and she was medicating herself with alcohol "to kill the pain", and was note by Sakkal in his history note as "being under the influence" of alcohol, and was desperate for relief. Sakkal appropriately titrated her up from a failed non-opioid analgesics to a lowest dose opiate analgesic (Percocet 5 mg) and small dose Xanax at 1 mg with a patient/doctor agreement that Adkins would stop alcohol abuse. Adkins died of a drug overdose shortly after filling her prescriptions 1/2/2016 by swallowing her bottle content over few hours next to her living companion, proven by lethal very high blood level of opiate of 545 mg/dl (Ten '10' times the therapeutic level of 20-60), and moderately elevated level of Xanax of 80 mg (therapeutic is 20-60), which is not lethal. had Adkins "taken the medications as Sakkal prescribed, her blood level would be

normal" as testified by the government's expert witness, and her levels would have been at the low level of 15 for oxycodone, and 3 for Xanax, both are extremely safe, but synergistic in combination.

12) The pathologist coroner witness testified that Adkins died from "mixed drug overdose", but interactions were probably not the real issue here-The Xanax level was slightly elevated but not lethal, however the oxycodone she self-ingested was reflected in a very high lethal level, which was certain to cause Adkins' death. Sakkal is now convicted of prescribing Percocet and Xanax -as if this combination was not prescribed more than 10 million times in the USA daily- although both were plainly indicated by her pain, anxiety-panic, phobia, spasm, and insomnia-, without misdiagnosis or mistreatment. Sakkal titrated her up from her previous failed prescription, within the guidance of the PDR, and within the scope of his practice (Count #2).

13) Furthermore, Sakkal was also enhanced for Adkins' death, which was caused by her excessive ingestion of a huge amount of prescription medication, because "she wanted to get high" as her living companion reported, rather than the very low dosage Sakkal prescribed for her (Count #31).

14) Percocet Oxycodone is produced in 5, 7.5, 10 mg, in addition to 20 and 30 mg available in the market. Sakkal prescribed 5 mg; the lowest dose available (pain specialist often prescribe 120 mg daily). Sakkal prescribed 5 mg tablet, but the patient Adkins ingested more than 80 tablets which is eighty times Sakkal's low dose prescription. Xanax is produced in 0.25, 0.5, 1 and 2 mg tablet (Psychiatrist often prescribe up to 10 mg daily); Sakkal prescribed a low dose of 1 mg, but Adkins ingested many times the low dose Sakkal prescribed. Sakkal's prescribed doses were low, within the lowest therapeutic range (oxycodone) or below the therapeutic range (Xanax), and both even in combination were nowhere close to the "dangerous" limits the government and its "expert witness" claimed (see https://www,drugs.com/dosage/Xanax/html, which indicates up to 10 mg Xanax dosage). The reverse was true Sakkal doses were at the lowest possible risk and extremely safe, as shown in "Millions" of patients in the USA year after year. In all counts Sakkal conformed to the PDR, was well within the recognized safe limits, and DID NOT PRESCRIBE ANYTHING CONTRAINDICATED.

15) To establish Sakkal's guilt, the government criticized him for a number of unregulated actions and inactions: The government criticized falsely Sakkal for failing to give or look at drug confirmation

tests, even though Sakkal gave the tests routinely and interpreted them, initialed them before filing in each chart, and even though the tests are not required in primary care practices by any regulation, and even though there is no consensus amongst doctors what to do with those results anyway (As testified in US v. Lopez, by Dr. Warfield, an authority in the field).

The government falsely criticized Sakkal for not firing patients, although he fired on many occasions for unacceptable abuse, and although that firing patients only drive them to the illicit market and the fentanyl-laced look-alike, which is certain to be lethal.

The government falsely criticized Sakkal for not using OARRS (Ohio reporting software for controlled substance survey), which was designed for law authorities, to check on doctor's shopping, which is not required by primary care practices. Yet, it is a fact that Sakkal opened an OARRS account as soon as he started at Lindenwald, assigned two Medical Assistants to retrieve the report, through his account, for each patient each visit and reviewed it before seeing patients as testified by Alesha Hayes in court, and as seen by his initials on the report. Still, it is better to give patient medication in the clinical setting than dying from street dealer's fentanyl.

Sakkal was criticized for prescribing pain medication when he was not a pain specialist, but he was an internist, a primary care provider with a duty to treat his patients to the best of his knowledge and he was authorized under 1306.04(a) to do so. Primary care providers prescribe today more than 97% of controlled substances. Only less than 3% of prescriptions are written by pain specialists, so Sakkal represents the norm and not the exception. If only pain specialists are to prescribe they would not be able to keep pace with the patients' medical needs, and it would be against anti-trust laws.

16) Sakkal was criticized for diluting his prescriptions profile by writing six prescriptions for a single medication to treat a number of medical illnesses like Adderall for ADHD, an FDA drug specifically approved for that purpose, and used off-label for lethargy, depression and cataplexy, and he prescribed more than 63,000 prescriptions to 4000 patients.

It is difficult to say how six prescriptions (1/10000) diluted the other 63,000 to allegedly conceal his other "prescribing habits" as the prosecutor concluded. Sakkal now has six more convictions stacked against him for prescribing Adderall using someone's else DEA number. But just as that former Nurse Practitioner had to log onto the computer EMR to enter data about the patient and print prescriptions, so did Sakkal. This appears to be a beta software glitch in which the wrong DEA number field was

referenced by the software, and it went unnoticed, rather than intentionally diluting prescriptions to further criminal activity.

After Sakkal left the practice, the government did not prosecute the next provider when Sakkal's DEA number appeared on those prescriptions, so the government prosecuted Sakkal SELECTIVELY for this in order to further the prosecution for allegedly violating other counts of the CSA. Aside from the DEA number errors, Sakkal's purported misconduct was not regulated or forbidden. Sakkal was authorized to prescribe the medications, and he did so in accordance with the recommendations of the PDR, www.drugs.com and the best in medical practice in pain and addiction therapeutics.

17) Sakkal substantially differs from Moore (and most other convicted doctors) in the most important ways typical of rogue doctors. Sakkal provided low dosages and incremental monthly titration based on examination of objective physical signs (Tender pain points number for generalized pain and vibratory sensory perception for neuropathic pain). He examined every patient personally, not as a supervisor of other surrogates like RN/PA, etc. A visit to his office occurred monthly to survey patient's medical progress, and in accordance with insurance rule to avoid excessive utilization. There were no unwarranted, too frequent prescriptions, and never large dosage like other pain specialists (described in Volkman's case as "scary").

he counseled each and every patients, according to their unique clinical state, about the dangers of abusing their medication prescriptions verbally and had his staff reiterate the instruction and warning verbally and handing the patient a written full-page copy for their guidance at home, with specific warning printed on each discharge instructions, after signing a drug use contract kept in the chart EMR. Sakkal did not have any financial ties with any pharmacy and was frequently invited by drug companies to sell medications in the office, for exuberant profit but he declined many offers, and did not take cash for prescription ever. Because of all these clean operational rules there was no way for Sakkal to turn the practice into a pill mill and no incentive to do so. Sakkal was merely a practitioner that "prescribed controlled substance to help his patients manage pain" as the appeals Court announced in its first ruling sentence.

18) Another part of the government unfairness is that it ignored the fact that patients come with their personal set of acquired diseases and symptoms, to be treated by the physician who has no role in creating their illness. So NOT all patients are "typical" and treated by a cookbook recipe. Each patient

comes with "Unique" combinations and degrees of issues and comorbidities that need to be addressed by a combination of medications. Because the "usual course of professional practice" standard is still elusive, atypical patients must be shoe-horned in, using some magical form of precognition, into some unknown "government expert's" secret mold of the "usual course", which the expert in Sakkal case refers to ex post facto during the trial but never defined.

This is a conundrum for the good doctor- in the ethical performance of his duties the doctor must be more concerned with watching over his shoulder for the USAO and its unknown expert with his subjective personal standards instead of treating the doctor's most challenging complicated patient's medical needs to the best of his ability, because under the present law there is no clear legal guide for treating his usual typical patients, let alone his unusual or atypical patients, while the PDR, which is the most reliable guide, is ignored by the government in favor of their "well-paid" expert's (as the district court called him) perceptions and his opinion of 1306.04(a).

19) The sixth circuit acknowledged that "Sakkal was helping his patients manage pain", so the circuit noticed that Sakkal was acting for a legitimate medical purpose in the usual course of professional practice of his profession by diagnosing and treating real patients pain. Yet, the Circuit found Sakkal's practice was illegal, rather than it differed by some margin or degree from what the other doctor, the "expert witness", would have done. Of course no one knows what is exactly the "expert" would have done because the expert never examined any of the patients, and he has a different standard that he announced Ex post facto during trial only, and the expert never explained definitely what that standard in the USA he was referring to except to say: "the standard acceptable to an expert like myself. Sakkal did not trespass over any imaginary line the expert mythically alluded to. A different expert, with experience and training similar to Sakkal's, and not motivated by government finance but by an altruistic desire to be fair and just, may have said that what Sakkal did was the reasonable and acceptable practice within his discretion. Thus, Sakkal's guilt is grounded in the subjective opinion of the well-paid "expert's perception and understanding", as he said, rather than clear published standards that were not given "fair notice"

20) Sakkal's medications combinations here are not specifically contraindicated by the PDR, statute, or regulation, although the government could have easily regulated it through clear legislation and had a long chance to do so. Each substance was indicated and prescribed at the lowest dosage

possible, and therefore justifiable as Mini-Dose-Combination-Therapy. the PDR indications AA medications included klonopin which treat certain anxiety, panic, phobia, spasm, OCD, and pain adjuvant in combination with other drugs. Here the justification for klonopin was clear that it helps reduce her anxiety, and OCD which would reduce her pain, just as Xanax does, and the decrease in pain perception would decrease anxiety and OCD fixation, in a virtuous cycle helpful without the needed opiates. Klonopin as one of the new Benzodiazepine is FDA approved for anxiety and can be used in combination to relief pain perception.

21) In sum, the court should take this opportunity to hold that 1306.04(a) is unconstitutionally vague, as SCOTUS has held in Ruan 2022, because it criminalizes a doctor's discretionary decisions ex post facto without fair notification or warning. Even if the Court considered that Sakkal was close to the line of validity, the rule of lenity applies to him, with an ambiguous text.

E) 21 C.F.R. 1306.04(a) CRIMINALIZES UNREGULATED CONDUCT AND THERFORE LACKS SCIENTER OR MENS REA, AS SCOTUS HELD

"In order to find the defendant guilty of violation of 21 USC section 841(a), the government must prove beyond a reasonable doubt the following elements: (1) Defendant distributed or dispensed a controlled substance as alleged in these counts indictment; (2) Defendant acted knowingly and intentionally in distributing that controlled substances; and (3) Defendant's act was not for a legitimate medical purpose in the usual course of HIS professional practice" Appellant reply brief page 6 quoting Sakkal jury instruction, and District Court opinion. *(first)

> "But you must be convinced beyond a reasonable doubt that the defendant was aware of a high probability that the controlled substances were distributed or dispensed outside the usual course of professional practice, and not for a legitimate medical purpose. and that the defendant closed his eyes to what was obvious. Carelessness, negligence, or foolishness on his part are not the same

as knowledge, and are not enough to find him guilty on any of these counts. This, of course for you to decide.." Sakkal jury instruction *(second)

"When a statute "prescribe the kind of culpability that is sufficient for the commission of an offense, without distinguishing among the material elements thereof, such provision shall apply to all the material elements of the offense, unless a contrary purpose plainly appears". Rehaif v. US, 139 S.Ct 2191, 2195 (2019)

"The regulatory language of 21 C.F.R. 1306.04(a) is ambiguous written in generalities, susceptible to more precise definition and open to varying constructions.. thus difficult to distinguish from the gray zone of socially acceptable conduct (issuing valid prescription).. The Court of Appeals.. evaluated the jury instruction under an incorrect understanding of Scienter requirements.. judgment is vacated and remanded. 9-0 decision"

"The hypothetical scenario is unacceptable.. the government standard would turn a defendant's criminal liability on the mental state of a hypothetical reasonable doctor, not the mental state of the defendant herself.. we rejected.. in criminal context." (Ruan v. United States, 2022)

1) Congress intends to require a defendant to possess a culpable mental state regarding each of the statutory elements that criminalize otherwise innocent conduct. In the first jury instruction above, the scienter of "knowing" was applied to the dispensation or distribution of the controlled substances (Sakkal did neither according to #802 et seq, explained supra). But this was not applied to the third element "Not for a legitimate medical purpose in the usual course of professional practice".

In the second instruction, Sakkal's alleged "guilt" rested on the jury believing the "expert" that for every practitioner to be legal, he must possess the expert's "perceptions and understanding of his standard of care", as if the standards were published somewhere or were common knowledge.
But if that were the case, the prosecutor would have simply opened the Federal Register and showed the legal standards from it, rather than hire a "well-paid" expert to pronounce that Sakkal was OUTSIDE his standards to the jury. If this second instruction made logical sense, the government would not even need an expert to prove Sakkal's alleged guilt, because the published standard would make them "obvious", as the court seems to suggest, that Sakkal closed his eyes to what was obvious (although this ambiguous term itself may be open to many interpretations). As it is now, the so called "obvious" standard must be ferreted out through an elaborate process at trial with many expert witnesses, opinions, and much testimony, so it is obviously not that "obvious".

2) Notice that the PDR was not consulted or opened for the medications' legitimate indications, the jury was not even made aware of the PDR, and that no court wants to talk about the extremely low dosages Sakkal used, or even the diagnosis for which the medications were legitimately prescribed, as the medical purpose.

3) Oxycodone comes in a number of dosage' range in the market from low 5 mg to high 30 mg tablet, and Xanax comes in many dosages as well from 0.25 mg to 2 mg tablet. Thus, there is a wide range of discretionary medical care available, and Sakkal was at the lowest end of the range, where the upper therapeutic range always far exceeded what Sakkal prescribed. There is no one size fits all standard in therapeutics. Sakkal prescribed the lowest safe dose to AA, the deceased patient, (5 mg oxycodone compared to a 120 mg/day commonly prescribed by the pain specialist, and Sakkal prescribed her 1 mg Xanax compared to a maximum daily dose of 10 mg prescribed by psychiatrists and other providers).

Sakkal low dose combination is not contraindicated by the PDR, is 100% safe when taken as directed, and Sakkal is a far under the larger doses the manufacturers make, or specialists prescribe as a maximum daily limits. The irony of this is that Sakkal would be unassailable for titrating up and prescribing much more of the highly addictive oxycodone at 120 mg daily alone without Xanax, but with his safer MDCT combination is criminalized without any clear, published legislation, medical guideline prohibition, or PDR contraindication. How could this be so "obvious"?

4) Sakkal has been serving Medicine as a low abiding citizen for fifty years, and he actually examined well all his patients in question, so his opinion is the more qualified than the expert who did not. Sakkal did not transgress any clear legislation that forbids low dose combination because there is none. There is no legislation even for even a high dose, because it was never under the government's jurisdiction. Nor did his purported "a first year medical student's examination" violate any statute or regulation; he learned long time ago, before MRI existed, that a comprehensive full examination from head to toes is the best prevention against missing an important clinical diagnosis, and thus helped his holistic comprehensive hypothalamic paradigm, not like the pain specialist "expert" who limits his examination to pain findings, and "avoids even treating addicts or any patient until they stop all their other mental health medications", as he testified.

Thus, with his objective bedside tests (TP, VSP, H, and Z scales) Sakkal is able to manage 80% of patients without the imaging that the "expert" depends on, which has 40% false positive or negative results (see supra).

5) Sakkal did drug tests routinely, read and initialed them before filing in the chart. The government and court built a mythical case alleging willful blindness to their results. Drug tests may be administered for detecting the presence or absence of prescribed drug, but as mentioned supra, there is no legal requirement for primary care providers to give them, and their results open to interpretation, on case-by-case basis, and there is no consensus on how to react to the results, so they are an overrated tool clinically, irrelevant to alleged guilt. Moreover, there is no legal requirement to fire patients based on a single drug test result, or even doctor's shopping. Common sense would counsel against driving patients, especially addicts, out of the clinical setting and force them to go to the street market. At least in the clinical supervised setting, drug purity standards protect addicts from fentanyl with a certain death. CDC statistics analysis, for the last 10 years, reveals that the more the legal restriction on prescribing the higher the overdose death rate rise (Appx G).

Drug testing was not even an issue with Adkins; Adkins had only two visit. Drug test was done but was meaningless because she was not given Percocet until her second and last visit, and drug test was irrelevant in her case. But the drug tests were used certainly to build a false case for Sakkal conviction in count 1, 2, and other counts, bundled together, for allegedly violating the CSA via 1306.04(a).

6) This standardless standard, criticized by SCOTUS for its ambiguity and unconstitutional vagueness permits unrelated and discretionary issues like drug tests to be conflated to construct the appearance of the alleged "guilt" for any particular count, even though the government cannot and did not prove that Sakkal KNEW he was "outside the usual course of HIS professional practice" because it cannot show he knowingly violated a clear standard since none exist on these issues regarding urine drug tests, OARRS, doctor's shopping, combination medicines or the low dose therapy. All these elements that the prosecutor described as red flags (warning signs), and the court claimed that "no one can avoid responsibility for deliberate ignorance or that Sakkal closed his eyes to what was obvious."

7) The government constructed unregulated, unrequired, and unrelated action or inaction as a proof of alleged "guilt" without ever proving Sakkal possessed the Mens Rea to violate the "legitimate medical purpose" and "scope of practice" prongs, which neither was ever defined in court, although physicians unanimously use the patient's diagnosis as the obvious medical purpose, and the court continues to ignore the consensus of physicians, medical societies, medical boards, and authorizing state agencies without offering an alternative!

Sakkal acting within his sound discretion treating Adkins pain, could not KNOW that he went outside the government's or court's bounds because he was not informed or knew what those bounds are, since they have yet to be announced by the government's "expert" in court. One would think that Sakkal exercising HIS discretion, using his many long years' experience in vulnerable population, HIS low dose skills learned from his elderly geriatrics practice, and micro-dose learned from masters in Mesotherapy with micro-dose inoculation, when he treated HIS real life patients conditions, in "HIS usual course of professional practice" so long as he adheres to what is taught and published by the medical community, is "legitimate".

8) Sakkal alleged transgression can't possibly be "obvious" because the government had to pay someone to create this alleged "guilt" from the "expert" "perception and understanding of what acceptable to an expert like himself of unregulated, unrequired, and unrelated acts rather than open any source or reference and reads those bounds, which the "expert" never defined anyway in court, and the court, the jury, the defense all submitted to the unknown masquerade, to demonstrate the alleged Sakkal's "guilt" No clear prohibited act was shown, or shown that Sakkal went afoul of published standards demonstrate just how absurd the second jury instruction is, and as a consequence the

outcome reached. Notice that the government only relied on testimonies rather than showing the jury those standards which are published by the medical community or the PDR, or www. drugs.com at least. Sakkal did not violate any published statute, regulation, the manufacturers of the drug make and recommend much larger doses which are OBVIOUSLY LEGAL, and he did not even come close to prescribing any dosage level that would be unsafe.

9) Sakkal could not know that he allegedly transgressed 1306.04(a) because his actions were authorized, were an exercise of his discretion, and only later criminalized through another doctor's ex post facto perceptions at trial. Deeming a mix up with the previous provider's DEA number as a proof of another CSA violation is untenable, and none of the alleged transgressions clearly violate any part of 1306.04(a) terminology. Defendant did not close his eyes to what was obvious, there is nothing obvious about unknown expert's perception and understanding of unclear, vague, unpublished standard and unregulated conduct.

10) In sum, this Court should take this opportunity to hold that using 1306.04(a) as a standard for prosecution violates Due Process notification, fair warning requirements, the Mens Rea requirement (as held in Morissette, Elonis, Rehaif, Ruan and many other SCOTUS cases narrated in details in Ruan 2022 ruling), thus it unconstitutional to prosecute those authorized doctors who act within their discretion generally, and as it applies to Sakkal.

F) IN UNITED STATES V. SADRINIA 2023 U.S. DIST. LEXIS 98166 (6TH CIR.6/6/2023)

> "Sadrinia makes three arguments in support of his Motion to dismiss..each focuses on 1306.04(a)..First, that it violates Due Process Clause of the Fifth Amendment. Second, that it exceeds the DEA statutory authority. Lastly, that the 'as authorized' clause violates the separation of powers."

1.Vagueness and Due Process

a) "Sadrinia argues that 1306.04(a) fails to give a defendant fair notice and leads to abuse because, prior to "Ruan v. US, judges and prosecutors 'turned the language of the regulation into an objective standard for criminality with no legitimate basis in the law" (Id at 3). He further argues that medical practitioners have no way of knowing what conduct is authorized as legitimate and in the usual

course of professional practice, leaving practitioners at the Mercy of the decision maker. (Id) including individual judges and prosecutors.

The Due Process Clause bars enforcement of a criminal statute for vagueness if it fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standard-less that it authorizes or encourages seriously discriminatory enforcement" (United States v. Williams, 553 U.S. 285, 304, 128 S.Ct 1830, 170 L. Ed.2d. 650 (2008).

b) The Sixth circuit has further clarified that the "void-for-vagueness doctrine requires that a statute define the criminal offense with such definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement "United States v. Kerns, 9 F. 4th 342, 351 '6th Circ.2021'. This makes sense as 'written laws are meant to be understood and lived by. If a fog of uncertainty surrounded them, if their meaning could shift with the latest judicial whim, the point of reducing them to writing would be lost". Wisconsin Cent. Ltd. v. United States, 138 S.Ct 2067, 2074, 201 L. Ed. 2d 490 '2018'.

c) However the district court refused Sadrinia above argument by an 'interesting' interpretation:

> "In the criminal context with no first Amendment implications, the defendant bears the burden of establishing the statute is vague as applied to his particular case, not merely that the statute COULD BE construed as vague in some HYPOTHETICAL SITUATION, United states v. Krumeri, 258 F. 3d 535, 537 (6th Cir. 2001).

Sadrinia made no arguments specific to his case.. Sadrinia has failed to meet his burden.."(Id.at 3)

d) The Sixth Circuit district court then elaborates by a most convoluted vague arguments misquoting SCOTUS Ruan, using also pre-Ruan 8th Circuit's Birbrapher; -both refute its argument-, and it quotes a post-Ruan case from a "sister court".

i) SCOTUS Ruan corrected Moore's objective standard, advising subjective standard. The Sixth Circuit quotes correctly: "Tellingly, SCOTUS noted the ambiguity.. went to illuminate the scienter requirement (Id 1t 2377-78)" "the regulatory language defining an authorized prescription is ambiguous, written in generalities.. open to various constructions".

Indeed SCOTUS clarified the subjective standard because applying #841

"knowingly and intentionally" MENS REA thus helps advance the purpose of scienter, for it helps to separate wrongful from innocent acts" (Id quoting Rehaif v. United States, 139 S.Ct 2191, 2197, 204 L. Ed 2d 594 (2019)".

ii) SCOTUS quote just mentioned actually contradicts the district court's argument. But the district court misreads Ruan's intent: "Ruan colors this Court's view.. because SCOTUS refined (truly re-defined) what was necessary.. did not see a substantial issue with ambiguity" (?!). The fact is that Ruan's decision criticized exactly the 1306.04(a) ambiguity, but the district court continued to quote pre-Ruan cases, in violation of stare decisis, closing its eyes to what was "obvious" in Ruan's, and continued to mis-define "dispense" "distribute" and to conflate them with "prescribe" while # 802 et seq clearly define them differently, see 2.b infra.

iii) It also quotes post-Ruan "sister court's" decision in United States v. Bodwoin Smith (M.D.Tenn.4/4/2023) and based on that it: "likewise reject Sardinia's challenge on vagueness" (Id). This is another sister court's mistaken decision, explained by un-informed judiciary, in a transitional court period after Ruan, where some courts were still in Pre-Ruan a stare decisis (see next).

iv) Sadrinia's rejection ignores many other more significant court(s) favorable opinions noted in many "sister courts" afterward, as explained supra, including, but not limited to: Judge White in Anderson, Judge Cole in Hofstetter, in addition to, Purpera, and Hargrave cases, among others.

v) A keen eye courts observer will note that in the first half of 2023, the Sixth Circuit district and appeal courts were still lost in a pre-Ruan old style fog, in violation of stare decisis, including Sakkal's Appeal Court denial 5/31/2023, that contradicts the new model. When Ruan's clarity opened the court(s) eyes to the new standard after a new clear change of Jury instruction Model, opinions applied Ruan.

vi) The new instruction was re-modeled to comply wih Ruan and published in March 2023. Some courts understandably, took few months to follow, but it became clearer in Hargrave that any

language that is not "fully reflective of the subjective standard is not compliant with Ruan", as Hargrave stated, and now by the agreement of the court and the government considered a "plain error" (Id.). Petitioner and all physicians who were scapegoats on the altar of un-repenting court(s) hope this is clear to all prosecutors and courts by now, and it is not excusable to deny appeals based on Court(s) lack of knowledge of their own new Model, or overt violation of stare decisis.

e) In Sadrinia the court got it all wrong about vagueness:

i) It asks the petitioner "to bear the burden of establishing the statute is vague as applied to his 'particular case', not merely that the statute could be construed as vague in some HYPOTHETICAL SITUATION". Clearly this is a higher bar than anything else in the law, clearly Sadrinia's situation is not hypothetical, but real and specific, and most of the terms "could be construed" "hypothetical situation" are not relevant because 1306.04(a)'s language has been announced loudly by SCOTUS to be 'VAGUE' in SCOTUS's Ruan decision. it is a done deal, complete with no if's or but's. It needs no further 'could be', or construed as vague', or 'some hypothetical situation', except if the court(s), in denial, does not accept reality, and still live in mythical hypothetical situation, exemplifying its 'before Ruan's' "deliberate ignorance."

ii) The Sadrinia district court's ruling itself admits SCOTUS confirmation of vagueness in principle but does not apply it in reality as could be "inferred" from its text:

> "Tellingly, SCOTUS noted the ambiguity.. went to illuminate the scienter requirement, because the regulatory language is ambiguous, written in (unacceptable) generalities,.. open to varying constructions.. and clarifying the subjective standard will separate wrongful from innocent acts". (Sadrinia at 3)

What more is needed to prove 1306.04(a) vagueness? If the basic general foundation is so vague, ambiguous, and unacceptable, then, its applications to any "particular case" is vague, ambiguous and unacceptable. It needs no further imaginary, or impossible proof.

iii) If the Sixth Circuit still insists on individual proof in Sakkal's "Particular case" there were many vague terms used in this "particular" case like " dispense, distribute, willful blindness", some were explained in II.A.3. supra.

iv) In sum, the Sixth Circuit describes in Sadrinia all the correct language of SCOTUS Ruan decision regarding 1306.04(a)'s vagueness and ambiguity BUT still reject cases based on residual pre-Ruan incorrect mentality, as when it denied Sakkal's case 5/31/23 after its new jury instruction became operative 3/1/2023, which was expected to exonerate Sakkal, Sadrinia and similar cases, but it did not in violation of stare decisis.

2. Statutory Authority

The Sadrinia's District court refused his argument that the Congress did not authorize the AG and DEA to define the word "authorize". The argument is open for discussion, but the petitioner finds it more significant that two important arguments were omitted from Sadrinia:

a) It is inconsistent with the Constitution to allow the highest attorney in government to legislate, which contradicts the separation of powers, mentioned in the next Sadrinia argument, but here we will limit our discussion to b).

b) The government lawyers, DEA and prosecution have mis-defined in 1306.04(a) the terms used in the application of the CSA statute, in regard to physicians, in what is fraudulent definitions on the court, language and law: they equated "authorized prescribing" (in 21 USC #829) with "dispensing" to the end user, like a pharmacist (#802 (10)), which doctors don't do, and with "distribution" which is a "physical handling" of the controlled substance like manufacturers, wholesalers and retailers, (#802(11)) which most doctors don t do either.

c) Either dispensing or distributing is illicitly accomplished by drug traffickers and dealers, but none of these relates to "prescribing". How this violation of clear text of the statute's English language could pass for five decades is a shame.

d) the Sadrinia court quotes the correct statute, and regulation in its text, but makes the wrong interpretation:

"The actual distinction between authorized and unauthorized conduct still lies at state level decision making, see Gonzales v. Oregon, 546 U.S. at 270 AND 21 U.S.C. #823(f).

"The CSA defines a 'valid prescription' as a prescription that is issued for a 'legitimate medical purpose in the usual course of professional practice' of a qualified 'practitioner'. 21 U.S.C. #829(e)(2)(A). The at-issue regulation tracks this exact language: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in the usual course of HIS professional practice" 21 C.F.R. 1306.04(a) (Id. at 3).

Note that both describe "prescribing" and not "dispensing or distributing", and the regulation makes it clear that individual practices are recognized, by the emphasized word "HIS", and not as one generic standard of care that fits all, as we explained previously in vi. In sum, Sadrinia's used an argument the court refused in violation of stare decisis, while the court should have admitted that the statutory authority was that the statute and regulation were related to prohibition of drug traffickers exercising dispensing and distributing and not related at all in letter or intent to including the prohibition or penalties for "authorized prescribing". Applying the statute and the regulation to prescribing is still an overreach fraudulence and legislation by executive beyond Congress's delegation.

3. Separation of powers

Again in this discussion the court describe the correct statutes and regulation, but with its own wrong interpretation:

"Sadrinia's final argument is that 'the DEA is exercising legislative authority through its application of #1306.04(a) which requires Congress to have provided an "intelligible principle" with which the DEA must act in accordance, but Congress did not do so here.'

The US Constitution's Article I, section 1 permits no delegation of Congress' legislative powers. Whitman v. American Trucking Ass'ns 531 U.S. 457, 472, 121 S.Ct 903, 149 L. Ed 2d 1 (2001). The court finds that Congress articulated an intelligible principle for the Attorney General, and subsequently the DEA. The court has invalidated a statutory provision for lacking an intelligible principle on only two

occasions in 1935, but the CSA is not one of them. [The Court finds] Congress provided the Attorney General and DEA. Consequently, the court rejects this argument as well" (Id. at 4).

a) The court got wrong again. The CSA delegation truly was on "intelligible principle". BUT was not a Carte Blanche for the AG or DEA to legislate whatever they wanted, but was limited to defining better:

i. CSA "excepted as authorized registrants" with the DEA (#822(b));

ii. Accept the "registration" of medical doctor if he is authorized by the state (823(g)(1);

iii. Civil penalties, "suspension" of registration (824 (a)(4);

iv. "Prescriptions" (#829), and prescriptions legal effectiveness (1306.04(a) was derived as such;

v. "Practitioner" taken from the Federal Rules and Codes Manual (see 2014 edition, page 1199).

b) All after defining delivery/deliver in 21 USC # 802 (8), dispensing/dispenser in # 802(10), distribution/distributor in 802 (11), where all three possess and handles physically the controlled substance in the legal and illicit manner described supra. Nothing in this "Mesh" included "criminal liability" as we know it today. Moore's 1975 was the catalyst that let the genie out of the bottle, built the bridge between the CSA, 1306.04 and criminal liability, and became the prosecutor's favorite tool, to crucify the medical profession in the public eye. see next argument.

c) As expressed by judge Ely in United States v. Rosenberg at 206:

> "It is inconceivable that an unconstitutionally vague and ambiguous penal statute can be cured by a regulation by a prosecuting agency" "To permit the Attorney General to answer that question, in the guise of issuing an interpretation would be to countenance an intolerable violation of the doctrine of separation of powers.
>
> Indeed in their brief of Pacific legal foundation supporting Ruan Certiorari, C Kruckenberg, et al reasoned:
>
> "Only Congress may create mew criminal offense; allowing the DEA to do so violates the non-delegation doctrine (Id at 8); a regulatory agency, particularly a prosecutorial one, cannot decide, on its own, that such conduct should be

unlawful. Fair notice, the separation of powers, and our constitution's essential desire to maximize liberty must not be casually cast aside" (Id. at 19).

They cited Justice Gorsuch opinion in Gundy v. United States (2019) 139 S.Ct. 2116, 2131:

"A delegation that purports to endow the nation's chief prosecutor with the power to write his own criminal code scrambles the design of the Constitution, which promises that only the people's elected representatives may adopt federal laws restricting liability".

Even that Congress may have delegate some of the administrative function is not an excuse to challenge the Constitution. As we will argue infra this delegation was limited and focused.

d) Not only we have doubt about the DEA legislating, by usurping the Congress' role, but there is some controversy about the Congressional statute itself being a subject to review if it contradicts the Constitution. The Constitution Article VI, clause 2 known as the Supremacy clause, established the supremacy of the Constitution over any who shall be bound by an oath to support the Constitution in the government in all its branches including the Congress. This was recognized by SCOTUS in one of its earliest decisions in Marbury v. Madison, 5 U.S. (1 cranch) at 177 and 2 L Ed. at 73, 74 (1803)." An act of Congress repugnant to the Constitution cannot become law. The supremacy of the Constitution is absolute, but a statute enacted by Congress is not." If the CSA/CFR dyad was suspected of being a Congressional infringement on State rights of medical practice it could become a subject to cancellation if not congruent, as SCOTUS opined in Marbury.

e) In the same vein, some scholars have suggested another potential controversy: that even the jurisdiction of the present United States District Courts are themselves not an Article III constitutional courts, but Article IV legislative courts with no jurisdiction to prosecute US statute violators! This was recognized by Mookini v. United States, 303 US 201 (1938) which made clear the difference between the two courts systems where it reads:

"The term 'District Court of the United States' as used in the rules.. has its historic significance. It describes the constitutional courts created under

> Article III of the Constitution. Courts of the territories are legislative courts and not District Courts of the United States". The opinion originated in Balzac v. Porto Rico (1922).

Thus "United States District Court of Southern Ohio", in Sakkal case, is not an Article III "District Court of the United States". It is an Article IV legislative court limited to hearing civil suits.. but not civil suit masquerading as a criminal prosecution under #841 violation, by the corporate United States against Saad Sakkal. It also has no jurisdiction under 3231 which does not empower the US district court in any way to prosecute practitioners for a number of reasons.

f) Furthermore, some scholars believe the court jurisdiction in doubt because it did not follow the first rule for all federal judges and "affirmatively established on the face of the record the standing of the government and the jurisdiction of the court before addressing the merits of the case--A rule that is inflexible and without exception" pursuant to Mansfield C&L. M.R.Co. v. Swann, 111 US 379, 382, 28 L.Ed 462, 463 which reads in part:

> "On every writ of error or appeal the first and fundamental question is that of jurisdiction, first of the court, then of the court from which the record comes. this question the Court is bound to ask and answer for itself, even when not otherwise suggested, and without respect of the relation of the parties to it".

This principle has been affirmed in more than 10 other citations, that are omitted because of space limit here. The petitioner humbly needs to leave the last three assumptions to experts to contemplate but mentioned here to suggest that physicians' prosecution is taken very lightly against more foundational constitutional issues need resolution first.

g) In sum, the fact is that CSA delegation to the DEA is unconstitutional based on an argument different from what Sadrinia suggested and was refused. Sakkal's argue for the unconstitutionality of CSA/1306.04(a) delegation itself violating the dereliction of duty doctrine and separation of powers by inappropriate delegation of penal code. The penal code should be resubmitted to Congress to write separate physicians' specific law, while in the meantime the court need to suspend all #841 prosecution until congress design a law for the excluded physicians from #841.

(III). Moore Connected the CSA and 1306.04 (a) liability

The bridge that connected the two (CSA section #841(a), and 1306.04 (a) that deal principally with non-registrants traffickers) was SCOTUS Moore 1975 decision in which SCOTUS held that a licensed physician could be criminally liable under the CSA, which excluded physicians, for "dispensing" (dispensing is a term reserved in 802 for non-physicians) controlled substances outside the bounds of the professional practice, which was a landmark erroneous case with caveats:

Moore V. Ruan

In Moore 1975 This Court ruling "registered physicians can be prosecuted under Section 841 when, as here, their activities fell outside the usual course of professional practice" eliminated the government's burden to prove a requisite guilty intention (Mens Rea), contradicted the CSA, 1306.04 that were designed for non-registrants, and even deviated from Moore 1974 jury instruction in the District court (Moore 1974, 505 F 2d 262) which reads in relevant part:

> 'it had to find beyond reasonable doubt that a physician who knowingly or intentionally did dispense or distribute Methadone by prescription, did so other than in good faith for "detoxification" in the usual course of professional practice and in accordance with a standard of medical practice generally recognized and accepted in the USA"(Moore 1975 at 139.) (MD's don't dispense)

1) A quick view reveals that the 1974's instruction had restricted the question to a)"Methadone for detoxification", b) Dr. Moore confession of profit motive, c) true dispensing or distribution, d) other than good faith, e) "a" (or any) standard of medical practice (not THE standard's').

This instruction stayed clear from erosion of the "except as authorized". Using the "A" standard of medical care could be any physician's standard acceptable in medical practice, but not limited to official standards of care, which is applicable instead in medical malpractice cases. Said in another way, this instruction allows for any of a wide range of variation that exists in medicine today, including Sakkal Hypothalamic paradigm, (which is not the most universal known standard, but is still the best). It does not constrict "The standard" to what "an expert like myself accepted in the USA in the time of

events"(Appeal Brief at), as the well-paid government expert in Sakkal trial announced. This latter government definition contradicts the CSA, 1306.04, and Moore 1974 jury instruction, which became the basis of SCOTUS Moore 1975 decision.

2) The problematic deviation started at the district court Moore's 1974 which replaced dispensing with prescribing. Then In Moore 1975 This Court used for the first time the new different terms:

a) "When physicians activities fell outside the course of professional practice"

b) Moore 1974 jury instruction contained the Mens Rea (knowingly and intentionally). But SCOTUS in Moore 1975 used objective activities rather than subjective intention, thus Moore 1975 was inconsistent with the CSA, 1306.04, and Moore 1974 Jury instruction

c) Switched from an exclusive exceptional case of a "bad faith" Methadone for detoxification" to any "medical practice" in pain or anxiety, insomnia, etc.

d) Switched from "a standard course of professional practice" to restricted "The course". This opened a Pandora's box for any potential disagreement about types of medical practices, to become criminal liability, subject to a battle of the experts, where brain-washing the jury's mind with the sweetest eloquence, in the lower court(s) render the law intent corrupted

e) it also changed 1306.04 specific word of "HIS professional practice" to generic "Professional practice", which covers all providers, not only addiction detoxification, or only sellers who "hands" Methadone/drugs, for cash or sliding scale payments, as Dr. Moore did, acting clearly as a drug dealer, distributor, dispenser and not a registrant prescriber. A bridge too far.

3) This error, of many switches from specific to generic, was most likely UNINTENTIONAL as we could see from This Court long tradition from Morisette 1952 before Moore, and at later SCOTUS decisions in Elonis 2015, and Rehaif 2019 and, many others described in the Ruan 2022 opinion, the doctrine of Mens Rea was emphasized more than once, The court always enforced Congressional law intent rather than changing it, or creating a new law, like in Moore.

> "If the statute was ambiguous, in need of a change, the court refers the statute back to the congress for modification according to the doctrine of separation of powers. Only Congress may create a new criminal law".

(C. Krunckenberg et al. Pacific Legal Foundation AMICUS CURIA brief in support of Ruan, quoting SCOTUS).

4) The key issue in Moore was whether Dr. Moore who "dispensed" Methadone without adhering to the regulations governing "addiction" treatment, could be prosecuted under the CSA. The Court concluded that even though Moore was registered, his actions without legitimate medical purpose violated the CSA. SCOTUS set a precedent that a doctor can be criminally liable for prescriptions made outside the bounds of professional practice, without specifically requiring an in-depth analysis of the doctor's subjective intent, or proof of INTENTIONAL wrongdoing, which contradicts many earlier and later SCOTUS DECISIONS. (Morisette 1952; Elonis 2015; Rehaif 2019, etc.). It allowed loose prosecution automatically for a deviation from a medical standard. Mens Rea requirement in Moore did not focus on the subjective intent as a critical factor, although a fair trier recognizes that Dr. Moore actions did not need an analysis of intent as he confessed to it, being purely for cash "profit" motive, with a stark sliding scale cash payment scheme rather than the medical service itself. Dr. Moore was an extreme exceptional aberration as plain crime and to generalize it was an error.

5) In contrast, the recent Ruan 2022 decision, fifty years later, dealt with the intent question, because the physicians in the case had more than one motive, and the subjective intent needed to be analyzed and dissected, enforcing the "state of mind" question in #841 cases. Ruan provides appropriate protections ensuring that a mistake in judgment or a difference in medical opinion does not automatically lead to criminal liability without proof of intentional wrongdoing, setting more stringent standard for prosecuting doctors under the CSA: namely, the prosecution must prove beyond a reasonable doubt that the physician "KNEW" or "INTENDED" that their action was unauthorized outside the bounds of legitimate medical practice. This heightened the burden on the government to show that the doctor was not merely negligent or mistaken, but had a specific criminal intent (scienter), which was described in the original congressional hearing as "Profit", monetary or otherwise.

Dr, Moore was truly a drug trafficker, outside any professional practice ethics or standard, he was a criminal from medical perspective before he was prosecuted, and to make his case the model for judging all authorized physicians was a plain error. Moore, in a detoxification clinic, SOLD Methadone for sliding scale, in exchange for incremental CASH based on quantity "sold", not on service given, a typical distributor, dispenser, trafficker description. These crimes fit perfectly with the CSA intention and letter

for non-registrants without the need to consider his registration, and thus Moore decision was correct, but it was wrongly generalized to any doctor.

SCOTUS error in Moore

6) SCOTUS generalized from "detoxification in addiction" case to all pain therapies; from a trafficker, dispenser, distributor like Dr. Moore, to all prescribers/issuers of authorization to dispense by pharmacists, even though the overwhelming majority of physicians today do not dispense to the end user or distribute in any constructive manner.

SCOTUS was right to judge Moore for distribution and dispensing, because HE DISTRIBUTED AND DISPENSED the controlled substance like a dispenser and a distributor, but SCOTUS was wrong to extend this to every "prescriber" and issuer of authorization, since they don't dispense or distribute as the CSA, 1306.04(a), 802 and seq, and all regulation are clear in intention and letter. CSA 841 was designed for non-registrants and directed only for manufacturers, distributors, dispensers, or any person who HANDLE the Controlled Substance, AND NO ONE ELS. It did contain "registrant" and Not "prescribers" for sure, because the Congress had no intention to include them.

7) All that was needed is to check the Federal Regulations and Codes Manual these clear definition described earlier:

In 802(8): to deliver is the actual constructive or attempted transfer of a controlled substance

In 802(10) (2)(a): Dispense is to deliver to the end user a controlled substance.

In 802(11) (2)(b): Distribute is to deliver (other than by administering or dispensing) a controlled substance.

The Sixth Circuit also refers to sale as "distribution" as used in many precedents, but then it added using the same term for "prescribing" without any basis in the statute (CSA) or regulation (1306.04, 802 and seq) or any basis in the law, except its own precedents that started with United States v. Kirk 584 F 2d 773, 784 (6th Cir. 1978), and continued since.

Comparing Moore to Ruan

8) Key differences exist between Moore and Ruan. Some believes medical practice issues are only state concern, In a similar parallel to Rowe v. Wade, which was reversed to the states, for lack of constitutional basis, so is the CSA. However, there is one major difference, namely that Moore has not

been pronounced dead yet. Here are the key differences that should make Moore obsolete: Mens Rea view, The doctor's state of mind, implications for physicians' prosecution.

9) Some scholars believe "Ruan did not directly correct the Moore decision or criticize it but clarified and refined its application of criminal liability for doctors, and adjusted the framework for how the CSA should be applied.

While Ruan and Moore deal with similar issues, they approach the legal standards differently, especially concerning the mental state (Mens Rea): Moore focused on objective illegitimate actions of Dr. Moore prescribing (although he cannot be considered a prescriber but a dispenser/distributor/trafficker to the end user for cash, which differentiate Dr. Moore from any other doctor 's case fundamentally. By confusing his dispensing to the end user with prescribing). It did not look at his subjective intent as the central issue (because the intent was clear and stark: money) . Ruan added an important clarification: that the Physician subjectively "KNEW" the action was unlawful. Ruan required then a more appropriate stricter demonstration of criminal intent, with better protections for physicians, ensuring they are less liable for good-faith medical judgement that might fall outside standard practices."(Ruan v. United States. Justia SCOTUS center,

https://supreme.justia.com/cases/federal/us/579/20-1410)

The petitioner believes that the Sixth Circuit in denied his second appeal after Ruan because it made an error by treating Moore as still the prevailing precedent, ignoring Ruan completely, as a minor clarification. What's needed now is for SCOTUS to make it clear that Moore is no longer viable.

Is Moore constitutional?

10) Moore was not considered unconstitutional by the court(s) but was a problematic decision, which needs to be reconsidered in light of the evolution of Mens Rea jurisprudence in SCOTUS, in many cases and precedents, enforcing the doctrine of criminality as relate to intention requirement, which was well detailed in SCOTUS Ruan opinion, which need not be repeated here. But Moore was an interpretation that did not arise from the CSA legislation, but from the DEA 1306.04 regulation, with "ambiguous vague language", according to Ruan opinion commentary, thus violating due process, despite its mention of legitimate medical purpose, an issue left to the court)s) to decide, and the court(s) left it to the jury, and the jury received it from the prosecutor/and his expert in Sakkal's case. The jury who is least qualified to decide guilt or innocence, life or death, ended carrying the heaviest burden that was

expected from the most highly qualified Justices, judges and even prosecutors! Moore case law in lower courts ended making penalties for registrants more severe than drug traffickers, with higher conviction rate, higher Controlled Substances Table Conversion amounts, leading to higher sentence years (see infra), thus violating equal protection, violating avoidance of cruel and unusual punishments doctrine, and legislating from the bench violating "separation of powers".

11) Moore led to a dangerous increase of convictions when providers were identified as drug traffickers.

a) The DEA shifted its effort from pursuing the hard-to-catch drug traffickers with one or few counts, to physicians who were easy catch sitting ducks, with potential hundreds of counts because each prescription was a count, even if it was the same maintenance medication for the same patient. This shift alone improved the DEA statistics in the public eyes, and in congressional scrutiny, giving it more budget allowance to do more. Government prosecutors developed an excellent track record with more than 98% conviction rate, compared to less than 40% conviction rate for drug traffickers.

b) The outstanding prosecutorial mythical conviction rate, like no other in the justice system, was caused by:

i. 95% pleading guilty from sheer fear, and to avoid facing a blind illiterate jury decisions, which was easily manipulated by the prosecutors "red flags", a constellation of unactual signs, to "infer" crime out of thin air, by indirect unactual evidence, easily fed to the jury by well-paid expert witnesses, and "full time generously-paid professional prosecutors devoted to the nuances of the (mysterious ambiguous) statutes, regulations, definitions, and case law terminology," as described in a California AG "warning to physicians", of what satisfy the court and public thirst for conviction.

ii. While in contrast, the defendants (naive physicians), who have never been in court like Sakkal, have the "curse" of hiring inefficient criminal defense counsels who were often more successful in defending hard-core killers but know nothing about medical practice and more naive about criminality in #841. And who play by the government playbook for a total unheard-of conviction rate of 98%, Only 2% of physicians reach exoneration.

More Consequences of Moore's decision

iii. Moore had dire consequences to physicians' prosecutions in the last five decades: Jury instruction built from fragments of the defective application of #841(a)(1) and 1306.04(a) in the Sixth Circuit, was so well constructed that it always fulfilled one function: conviction. Especially when the defendant, Sakkal was not allowed to describe his treatment plan for each patient, to explain the medical therapy sequence, the only way to understand the true evidence, not the manufactured red flags by the prosecution. This was arranged by the court "bundling" the counts based on artificial groups of drug collections, without describing at all the associated diagnosis, The "bundling" was in response to the prosecutor request, with court agreement, and naive counsel acquiescence, making the jury thinking only of drugs rather than patients, and the physician appear as a trafficker dealing with a collection of drugs, not as healer prescribing for a documented real disease patients. The jury's capture was complete right at that moment.

iv. The court accepted the jury instruction suggested by the prosecutor, adding few sentences from the counsel, but refused to add to the jury instruction any hint of Mens Rea healing intention or relieving suffering or patient's benefits, or even "good faith", in contrast to drug trafficking activities. The outcome was guaranteed.

v. At the end, this petition will plead to this Honorable Court to correct these dire errors described above so far, define the undefined terms, stop using #841 and 1306.04 until they are sent back to congress for clarification, while Ruan is applied as a stop-gap measure, and plead to the court to save medicine before its complete destruction

vi. If this serious error called Moore is not corrected soon the petitioner will hold hope that calamities will CONTINUE as in the following:

a) The USA will continue to be the leader in physicians' imprisonment in the advanced or underdeveloped world.

b) Overdeterrence will prevent 50 million Americans (on maintenance pain therapy) from receiving supervised medicine.

c) Fear of innovation, like MDCT, Sakkal Score, Scale (see App.G) and aversion to try new modalities will strangle future benefits in advanced healthcare.

d) Restriction of access to safe prescriptions, for needy poor population, will drive patients to street drugs.

e) The opiate epidemic fire will be further inflamed non-stop from diversion to street polluted fentanyl.

f) Overdose death will continue to skyrocket, as documented by the CDC. (described in App.G)

g) Public health crisis will expand, overwhelming the health system

h) Violation of State Rights regarding medicine regulation, violation of the 4th, 5th, 6th, 8th, 14 Amendments, presently widespread in # 841 prosecutions, will become permanent.

i) Public confidence loss in government ability to perform its Duty to Protect will strain citizen Allegiance.

j) Dark doubt will cast on the American dream of life, liberty and pursuit of happiness, in this exceptional nation.

(IV). THE LOWER COURT(S) DECISIONS ARE HARD TO RECONCILE WITH THIS SCOTUS

At trial, petitioner offered jury instruction compatible with SCOTUS Mens Rea emphasis in Ruan, good faith intention, and "authorized physicians" prescribing to distinguish from drug trafficker, but the court refused the instructions, WITHOUT objection of the defense counsel. The Appeals court affirmed that the Sixth circuit instruction were appropriate, despite repeated request for relief in THREE APPEALS. Many decisions at the district and appeals court(s) are contradictory to the CSA, 1306.04 and SCOTUS decision in both Moore and Ruan. Here are few examples:

1) The district court bundled counts, for expediency, ignored its original "bundling" until sentencing.

a) Allowed prosecutors to argue one issue to imply a crime, then extend the criminal suggestion to cover all counts in one blanket, as if each was argued separately.

b) The prosecutor argued counts 1, 2, 31(patient1, AA) as one issue related to death caused by the defendant prescription and then implied that each one of the other 36 counts were similar in nature, ignoring its own bundling, in one crime fits all process.

c) Another example in counts 33-39 under section # 843 (using another person DEA number) were combined in one separate group or "bundle"; they brought the prior provider to testify that she did not recognize her signature on the prescriptions, but she thought the signature on only one prescription "looks like Sakkal' signature", without certainty, yet the prosecutor and the court extended this "impression" to all other signatures without material evidence or specific documentation, as a "fact". The hidden truth was that Sakkal himself did not recognize the signature either, as his own, (the signatures were missing some letters from his usual signature) on any of these prescriptions, because he was forbidden to speak the truth in the courtroom. Moreover, the defense counsel did not ask for a signature analysis expert to disprove those signatures were not Sakkal's signatures either.

d) A third example is that the prosecutor and his well-paid expert witness considered one or two combination as dangerous, unsafe, illegal, for no legitimate purpose, then considered any and all combinations the same in many counts (1-10, 12,, 13, 15, 17-30).
The hidden truth was the fact this unfounded claim was not supported by Pharmacology and Therapeutics textbooks, or the Physician Desk Reference, or any website reference, which do not describe any of these combinations as contraindicated, but only states these should be prescribed cautiously under physicians' supervision. This is exactly how Sakkal did, cautiously, in using the smallest available dosage in the market, the monthly supervision followed by incremental titration up or down, as clinically valid, using only FDA approved medications, according to the best protocols, and the best outcomes (App. G).

e) In another stark example the prosecutor reversed tactics, attacking single medications too, as being illegal; even though the petitioner prescribed only the lowest possible dose in the lowest therapeutic range for each diagnosis and symptoms, for legitimate medical purpose; the Court "bundled" many in one group, ignoring the diagnosis, as the legitimate medical purpose to cut legitimate defense potential, but then ignored the "bundling" and separated each for the guilt assignment, and for the sentence calculation. /fairness requires either to "lump/bundle" for prosecution and sentencing in smaller number of counts, or deal with each count separately in prosecution and sentencing. But to prosecute in groups avoiding individual count argument of criminal activities proof, then separate individually the highest number of counts for sentencing only is hypocritical and patently unfair, unusual and cruel punishment.

The hidden truth is that each one of these single medications' counts were some of the most prescribed medications by most physicians to millions of patients daily through the USA.

f) The list included

i. Ambien the standard prescription for insomnia (count 38),

ii. Adderall the standard prescription for ADHD (counts 33-35, 39),

iii. Alprazolam (count 14),

iv. Carisoprodol (count 11),

v. Phentermine the standard prescription for extreme Morbid obesity (combined with Topiramate, not mentioned by the prosecutor list) (count 36),

vi. Methadone the standard long-acting opiate for pain (count 16),

vii. Methylphenidate another standard therapy for ADHD (count 37).

All of these counts are for normal common single prescription per patient, that should have been never prosecuted ad abinito and were stacked just to increase the convictions and sentencing years in a malicious prosecutorial misconduct.

It is very difficult, from medical (or even legal) perspective, to understand the prosecutor logic in these charges for the most common standard medications; none of them was discussed separately for its medical indications. But the Court counted them for the purpose of guilt and sentencing as if they are proven by the generality of the prosecutions and medical expert testimony simply saying the petitioner "prescribed for no legitimate medical purpose and outside the bounds of the usual course of professional practice", without the defense counsel pointing out that none of these counts have been discussed or argued in court because they were lumped in one group, that was argued only in light of one witness (for example in counts 33-39) stating she did not recognize her signature as described in the last paragraph. But at the time of sentencing each count was added separately one by one, as if each one was a crime proven in the courtroom on its own, when they were not even mentioned one by one.

2) The Court allowed the expert witness without any prove of methodology, or specifying the standard. When he was asked which standard he uses he answered: "the standard acceptable to an expert like myself in the USA at the time of the events under consideration"

a) The counsel failed in dealing with each one of these court deficient performance, which is hard to reconcile with any standard of justice or SCOTUS prestige. Yet, in the direct post-trial hearing for

ineffective assistance of counsel and lack of sufficient material evidence, it considered the counsel effective despite multiple deficiencies and perjuries, challenging to describe here, for limited space but described in the appendix (Affidavit: Ineffective Assistance of Counsel))

b) The district court refused direct appeal, despite overwhelming evidence that the counsel did not preserve objection and proven his inefficiency.

3) The Appeals court refused to consider ineffective assistance of counsel in 9 other separate elements; refused to look at the merits of the case, which is puzzling, and contradictory to due process, leading to further appeal at SCOTUS, when the issue could have been resolved easily at the Circuit level.

4) The appeals court denied a second appeal after remand from SCOTUS, resisting to admit that its jury instructions were defective according to Ruan, and further by Judge White in United States v. Anderson (2023), and Judge Cole in United States v. Hofstetter (2024) in the Sixth circuit. Then more recently in United States v. Hargrave (6/12/2024), which considered the Sixth Circuit jury instruction plain error in light of Ruan. At the same time the 10th circuit vacated Kahn and the 11th circuit vacated Ruan and Couch for all # 841 charges, but not Sakkal in the Sixth Circuit, another double system of justice, and unequal treatment under the law between the 6th and other circuits, even the 10, 11 the circuits.

What will take the Sixth Circuit to vacate Sakkal now but another clear order from SCOTUS!

(V). THE PETITIONER, SAKKAL, WAS IN FULL COMPLIANCE WITH CSA, CFR AND SCOTUS

The petitioner, Sakkal, followed fully the letter and intent of the law by its three components: CSA, CFR and SCOTUS, developed the best usual course of HIS Professional practice accordingly, although the constitutional basis is still in flux, with the Court(s) often contradicting some tenets of these statute and regulations as explained supra. The evidence for Sakkal compliance will be partly summarized here:

1) the petitioner prescribed only for a legitimate medical purpose as amplified many times in each patient's medical record.

a. Each record had a full history of the nature of pain, and associated complaints, symptoms, and mental/physical disorders

b. Each record had a full physical examination, with extra specific determination of the count of all tender pain points for generalized pain (Sakkal Score), and vibratory sensory perception for neuropathic pain (Sakkal Scale).

These two objective methods guide therapy adjustment in more than 80% of patients, regardless of the patient's unreliable complaints, preventing malingering, avoiding diversion in almost 100% of cases, and save health resources, which made Sakkal's practice highly distinguished from any other.

c. Each record had the appropriate Radiology, Lab, drug tests, OAARS CS surveillance, and other ancillary tests, in a long-standing medical records that extend for many years in the office in hand-written manner, which was ignored completely by the prosecutor, the expert witness, and the Court. Some patients were on their medications for more than two decades, when the petitioner renewed the prescriptions for which he was charged as a criminal. Unbelievable but true.

d. Each record had multiple diagnoses for pain (often more than three), as well all associated disorders, mental or physical (often more than 10 diagnosis).

e. Each record had very comprehensive instructions for pain management plan, wellness, holistic natural therapies, anti-inflammatory, anti-pain nutrition, exercise, stress release, sleep hygiene, massage, and all needed pain self-management.

f. Each record contained the Mini-Dose-Combination-Therapy medication, at the lowest safe dose, least side effects, least addiction potential, diversion or misuse; with detailed instructions about the time to take, precautions.

g. Each record had a full-page signed patient contract for controlled substance use, precautions, alcohol avoidance, driving heavy equipment, with three-line summary each encounter with the patient.

h. The building co-tenant was a chiropractic clinic which received constant automatic referral for manipulation, ultrasound, hot packs, physical therapy and orthotics when needed, supplementing our protocol.

2) Each medication was appropriately "prescribed", without any physical dispensing or distribution for its legitimate medical purpose of associated disorders, carefully titrated in a comprehensive monthly visit, based on metric objective findings:

a) Anxiolytic for anxiety, phobia, Panic, PTSD (small dose New Benzodiazepine: Ativan, clonazepam, or alprazolam);

b) SSRI's for depression, dysthymia, Melancholy (small dose escitalopram, Prozac, Trazodone);

c) Mild Hypnotic for sleep hygiene, insomnia, fibromyalgia unrefreshing sleep (small dose Ambien)

d) ADHD medications in small dose (Methylphenidate or Adderall)

e) Muscle relaxant for severe primary or secondary muscle spasm (Flexeril, Baclofen, Soma)

f) Anti-inflammatory Analgesics for severe inflammatory pain, articular and extra articular (Ibuprofen, Meloxicam, etc.)

g) Anticonvulsant Na channel blocker for neuropathic pain (Gabapentin, mexitil, etc.) or trazodone.

h) controlled substances (small dose opiate) were prescribed if all fail, or patients have been on prior maintenance (one third of patients in this long-standing clinic since 1945).

This profile represents the best legitimate medical purpose in the best usual course of professional practice.

3) Petitioner had an extremely well-structured superior style, in the top 3% in the USA in its efficacy, safety, success in weaning off controlled substances and steroids.

a) Petitioner used to get referrals of the most difficult cases because of his expertise as an Endocrinologist, Geriatrician, Complementary holistic medicine practitioner, and Micro-dose Mesotherapy learned directly from world masters like Jacque Le Coz, who was the French soccer team pain management physician, and exchanged wide peer experiences in the USA and overseas (App.G CV).

b) The petitioner had applied the NIH (National Institute of Health) protocols in every sphere of his practice, for pain, diabetes, osteoporosis, thyroid, adrenal, stress, nutrition, cardiovascular metabolic syndrome, obesity, etc. which he outlined scientifically in two letters sent to authorities to explain to them the legitimate medical purpose in the best course of HIS professional practice: one was sent to the Ohio Board of Medicine, and the other letter to the DEA, which the prosecutor incoherently used against him during trial for lack of comprehension of his protocols.

c) The petitioner had done extensive research on cravings, pain related to neuropathy (the most painful localized pain), fibromyalgia (the most common generalized pain), and their relation to Hypothalamic dysfunction, Central Control, with many publications, and presentations in national, international and regional peers attended medical meetings, which testify to the petitioner emphasis on patient benefit and finding the best diagnostic and therapeutic resource saving measures, regardless of how little reimbursement he received from Medicaid (See Appendix G: CV)

4) The petitioner's investigations led him to develop two of the most objective, easily documented quantitative pain evaluation in medicine today, namely the "Sakkal Score" for fibromyalgia pain, and the "Sakkal Scale" for neuropathy pain:

a) Sakkal Score: With gentle acupressure on specific target pain points, the number of points determines in numerical fashion the severity of real pain experienced, not imagined, by patients: 8-12 points mild, 12-16 moderate, 16-20 severe, and more than 20 points extremely severe pain. These counts, done each visit, will guide the best therapy in most cases.

b) Sakkal Scale: detection of vibratory sensory perception for neuropathic pain is done each visit by the bedside with metric classification from grade (1) to grade (10), determining the level of neural involvement from the toes to the umbilicus, with its progress, improvement or deterioration which determine the change of medication dose, confidently every time, avoiding malingering, patient subjective unrealistic pain sensation, manipulation for merely getting pain prescription, and any diversion or drug misuse, because these physical signs don't lie.

c) These two clinical maneuvers will obviate the need for excessive Radiology, EMR, CT scans, to determine the source of pain, and save large amount of healthcare dollars for the government and the health care system. The prosecutor and his expert witness who never used these techniques, claimed I have done less than other physicians of these expensive procedures, which has false negative and false positive up to 40%, while I was in fact able to manage more than 80% of patients by my two objective documented clinical scale and score, by investing more of my time with the patient, rather than in the expensive radiology department. This is what I mean by superior course of MY professional practice.
A different style perhaps, which made the prosecutor, the expert witness and later the defense counsel think I was practicing outside the guidelines, but I was within the guideline 100% only better, and for sure much better than the expert witness standard that he said, "the standard acceptable to an expert like myself in the USA in the time frame of the events". (Tr.)

5) Knowingly and intentionally, the petitioner restricted the dose of opiate, the most powerful and addictive substance, to the lowest dose possible, cutting the dose, in the first visit, for many of these chronic maintenance patients by 50%-70%.
Within few months the petitioner decreased the total number of Controlled Substances prescriptions from 15% down to 7%, cut ER/hospital visits, and total expenses by 30%. This is the ultimate compliance

with the CSA, 1306.04, SCOTUS Ruan and Moore guidance, and all medical ethical standards, while improving patients' outcome, decreasing their morbidity and mortality, and any form of criminality, fulfilling the letter, intent and the consequences of the law, with high caliber and impeccable record. The morbidity decrease was noted in all clinical parameters, including quality of life, Zung and Hamilton scales for anxiety and depression, and patient's satisfaction surveys monthly in each visit, documenting more than 90% satisfaction rate: with two specific question for pain documenting the strictness of our prescription protocol.

Mortality decrease was documented by the DEA investigator, who confirmed that only 8 death out of 4000 patients, occurred during the two years the petitioner worked in the clinic. This rate of %002 is much lower than the national death rate of 1-2% in primary care practice, which Lindenwald clinic was, and definitely lower than the 5% rate noted in addiction and pain clinics.

6) Section 1306.04 makes it clear that the physician is responsible for HIS usual course of professional practice, and I humbly agree and feel proud of my accomplishment under the regulation. The Petitioner performed this feat in HIS office, with each one of HIS patients for anywhere from 5-10 hours/per year per patient, during the physician-patient encounters, and did it perfectly well while the patient was in HIS professional practice.

a) But the regulation does not require the physician to be responsible about the patient in the other 8750 hours per year of patients' daily life, with its unlimited activities, ups, downs, positive or negative behaviors, emotional outbursts, or deviation, use and abuse, life and death. No one is able to do that, not physicians, lawyers, prosecutors, judges, and any professional.

b) Yet, the petitioner was alleged to have caused the death of a patient who violated her contract with him, a sacred contract based on his full evaluation, understanding of her suffering, her background, her extreme pain causing poor quality of life, with miserable existence, and prescribed for her incrementally a muscle relaxant and medication for anxiety depression first, then titrated her when treatment failed-had more than 24 tender points on physical examination, documenting persistent extremely severe pain-to the smallest dose Percocet which she took in lethal dose on her own outside professional practice, far from the physician's control, but next to her romantic lover who she told she "wanted to get high". Her lover watched her die, then came to testify against the petitioner under duress to avoid being accused of murder, (surely because he was the last to see her alive). Petitioner knew this only in retrospect, and so everyone else in court at the same time.

c) The deceased patient prescribed dose was the lowest, but ingested amount was lethal as the amount of acetaminophen she took was more than 20 grams, while the lethal dose is anything above 4 grams, and the amount of oxycodone she took was more than 400 mg while the lethal dose is anything around 150

d) The jury instruction demanded a guilty decision if the jury felt that the death prescription was outside the professional practice, and the jury complied with assigning the death outside the professional practice to the prescriber of the smallest dose in the market, not the person who shot the drug into her own flesh, exactly as if Walmart was sued for selling a gun or bullet rather the one who loaded the gun and did the shooting!

e) The violator of the contract is here considered the victim, not her own self-abuse, and the criminal is the physician who tried to help the sick. But it is clear the petitioner has used the best common sense medical judgment, the highest ethical guidelines and standards, and the letter and spirit of the CSA, 1306.04 regulation.

7) As for Sakkal compliance with SCOTUS it is enough to compare Sakkal's to Moore 1975:

a) Dr. Moore confessed he SOLD methadone for cash by sliding scale, to enrich himself, with illegal profits, violated many laws, acted as a drug dealer, and not as a registered physician, had no history and physical, often no medical record at all, no drug testing, no provider-patient relation, no planned therapy and follow-up. He acted outside the boundaries of any ethical medical duty, inviting SCOTUS to consider him a drug dealer correctly, not protected from prosecution, at that time. Unfortunately the Court generalized his specific aberrant case to become a generalized precedent for all other physicians, incorrectly stretching the CSA beyond its intention and letter, with following misapplication by the lower courts imprisoning's thousands of providers illegally.

b) Sakkal, on the other hand, had none of the behavioral features of Moore during HIS practice:

i. No selling for profits scheme, despite multiple tempting offers by wholesaler suppliers to "dispense" medication in the office, to make 400% profit margin.

ii. No overprescribing, or dispensing/distributing for pay, because he did not deal with cash as the basis for service.

iii. Accepting the lowest reimbursement from Medicaid in legally sound billing practice, without fraud or kickbacks.

iv. Opening the practice to the poorest of the poor, the sickest of the sick, needy patients as a form of charitable approach.

v. With extensive history, comprehensive physical examination (which was described by the expert witness as a medical student type medical examination, because of its details).

vi. And based on the best ethical practice with scientific paradigm, that led to superior patient benefit, without enriching himself as Moore did.

c) Petitioner treated every patient according to scientifically sound protocol,

i. with holistic approach, based on the highly effective Hypothalamic paradigm, Mini-Dose-Combination-Therapy,

ii. with fully comprehensive medical history and physical, complete medical record (ignored in the Courtroom, in trial), iii. extremely useful objective signs of the number of tender points for generalized pain and fibromyalgia, based on expanding to 28, the American Rheumatologic Association 18 well recognized points (Sakkal Score), and vibratory sensory perception for neuropathic pain (Sakkal Scale), which guided, objectively, dose adjustment in more than 80% of cases,

vi. multiple pain diagnosis documenting the legitimate medical purpose, full page pain therapy plan by natural and pharmacologic modalities

v. according to the best cost-effective usual course of HIS professional practice,

vi. with the strictest pain prescribing, only after monthly physical examination to determine level of pain, objectively by physical signs, each office visit,

vii. after review of OARRS record generated by the medical assistant, and with drug testing all interpreted and initialed by Sakkal before filing in the medical record which was ignored completely in the courtroom!

viii. and full-page treatment plan, instruction, warning, and a contract.

ix. perfect the first time and every time in a continuous quality improvement program.

x. with high satisfaction rate, in a strict prescribing documented by monthly surveys.

d) The outcome results of this targeted, goal oriented, multimodalities superior pain therapy program

i. were published and presented in national, international, and regional peers attended medical meetings with feedback for continuous quality improvement, especially in Fibromyalgia (the most common generalized pain syndrome in any clinic), and neuropathic pain (the most resistant localized pain)

ii. The reduction in opiate dose was 50-70% in the majority of patients

iii. total weaning off controlled substance in 25%, result than the gold standard VIVITRL which helps in 22-24%, with a major cost difference ($32 v. $1300/monthly)

iv. decrease healthcare resource utilization by 30% from ER visits to hospitalization, etc.

v. and high satisfaction quality of life and well-being rate more than 90% (All were summarized in graphic chart evidence that was suppressed by the counsel and kept off the record)

e) This is complete contrast to Moore actions, and even many other cases of #841 which has been tarnished with other illegal activities:

cash transaction, money laundering, confiscated cash.

RICO, conspiracy, fraud, kickback, coercion, sexual misbehavior

Firearms, probands, interstate commerce violation, etc.

Splitting fees, Medicaid or Medicare abuse, abnormal billing, bribery. etc.

8) The compliance of Sakkal extended to his post arrest response, while many DOJ divisions exercised incremental abuse:

a) The moment of his arrest 6/28/2018 Sakkal instantly complied although the arresting officers did not read his Miranda rights, or informed him about his charges, or why he is been arrested for!

b) The instant arrest cut his beloved wife from her only support and companion with his sudden disappearance without a trace, cut his dear children and grandchildren from his love, cut badly needed service in a underserved shortage area in a rural Florida community depending fully on his expertise as the only Specialist in Diabetes, Endocrinology and Metabolism in a 250.000 population area, where patients life was threatened, creating a potential public health crisis, with service interruption, because some were on insulin infusion pumps, some had brittle diabetes with complications, and some very complicated endocrine urgent disorders in the hospital acute care unit and in the clinic, all the medical

challenges seen in a consulting tertiary care practice, supporting more than 60 primary care practices, who could not do without his service as
an expert consultant.

c) When Sakkal requested he be released on a bond in the federal court in Pensacola, Florida, while awaiting his hearing, to stay close to his needy patients in the hospital and office, close to his residence and wife who could not live alone without him, and close to the federal court system in Pensacola, his official domicile, he was told he had to appear only in the United States District Court of Southern Ohio, as if the federal system has no building, judges, prosecutors and personnel in Florida where he offers an indispensable crucial health service to the large community citizenship, a service that does not include controlled substances which HE HAS NOT PRESCRIBED FOR TWO YEARS, thus pausing not a shred of public threat to anyone.

d) His compliance took a proactive form when he offered to the federal magistrate in Pensacola, FL. to fly immediately to Cincinnati with two US Marshalls, to appear for arraignment immediately, with full payment of expenses, so his patients are not compromised, his duty of service not interrupted, the offer was refused, as if flying held by/with US Marshalls was too risky for a cuffed man in chains, and if the government wants only to treat the innocent accused as a criminal before being even proven guilty.

e) Instead, the US Marshalls took him, even before any court trial, to experience the most terrifying trip of a lifetime:

i. offering the unique "Diesel Treatment Service", a specialty of US Marshalls Con Airlines, that is offered to manslaughters, drug lords and serial killers, a flying system of the most inhumane transportation protocol in many unannounced stops.

ii. During this "unique" transportation he was placed in counties jails, that treat people like animals, where he was abused in solitary confinement in a freezing cell, with untreated seizures, nearly naked on the floor, after physical assault, and religious discrimination 'God does not exist here'. Petitioner placed in the famous Atlanta Penitentiary, a huge near
medieval castle of dungeons, and demonic criminals, where he had to sleep as third inmate in two men bunk-bed cell, who forced him, after 'eraser' wound/cut and killing threat, to sleep on the floor, with cockroaches running all night around his one-inch mattress and living in four-letter words painful noise for more than two weeks- the penitentiary was closed since then for 'rebuilding'!

iii. As a result of these abuses of human rights, individual rights, and citizenship rights, the petitioner:

a) Asked for a quick judge hearing, to no avail, thus, he proceeded with a hunger strike for full 18 days to see if that would bring a court appearance, until he was told he will be, as soon as he arrives to Oklahoma City federal center.

b) Ok was a clean triangular indoor facility without sun or fresh air, where he had to spend three more weeks, but was able to have an E mail service to communicate finally with his family, who finally were assured he was truly alive.

c) then a final loop through Kentucky until arriving to the notorious Butler County jail in Hamilton, Ohio, a one-hour drive from the closest Federal court in Cincinnati, nearly 8 weeks later, instead of the two hours flight he offered to pay for on his first hour of arrest. The jail was "run" by three different gangs, threatening Sakkal who was not included with any gang.

iv. The consequences of this miserable dangerous trip were extreme:

a) Petitioner was mentally drained from state terror and psychologic warfare, became debilitated, disillusioned with justice.

c) Wife and family were living a nightmare scurrying for any help without resources.

d) The Hospital was furious for sudden dangerous service interruption.

e) 250.000 community citizen stayed without needed medical consultant care in Diabetes, Endocrinology and Metabolism.

f) Insurers were unhappy with unfulfilled contractual obligations and claims.

g) Reputation and dishonor from mouth-to-mouth slander and defamation spread like fire to everyone who knew him.

h) Multiple bodily injuries, threats, and uncalled-for four letter-word nefarious insults, persistent fears, experiencing nakedness of body orifices search for drugs.

i) while the accused is being treated as the worst drug king lord of the south, the prosecutors and DEA agents spent few more days on Pensacola Beach in the bright Florida sun, proud of their hunt.

v. While this ferocious prisoner's transfer was running the petitioner lost all his medical licenses in the last five states he worked so hard to pursue and keep for years. To get a license someone had to pursue many months procedures of legal work, had to pursue continuing medical

education of 150 hours at least, through medical conferences for continuing medical education, to submit to each state special extra requirements, satisfy each state Board of medicine criteria, and to pay yearly fees that range from $ 200-600, investing in time and resources.

To lose a license is so much easier: As soon as the arrest became public, with the AG TV proud announcement about the largest sting operation, there was a race to suspend and remove the petitioner's name from registered providers. Only one state needs to do it, according to its criteria for the rest to follow in reciprocity. Kentucky was first with its own rule that suspend license upon arrest, not conviction. As soon as Kentucky cancelled the license in each one of these states was cancelled. The effort that took years in education, hard work, medical expertise, licensure, was lost in few weeks with cruel DOJ attitude in violation of the 8th Amendment.

9) The compliance continued during every step of the legal proceedings with reciprocal cruelty from the government prosecutors, who advanced every day a new unusual and cruel punishment:

a) Every drug lord who may have been violent many times, and familiar to the court systems from past history, gets released on a bond to prepare for his defense, with blood money, hiring lawyers experienced in their common violation.

But not Sakkal, the physician who had the most ethical impeccable past, never been in a court for any brush with the law. The prosecutor insisted Sakkal stay in prison for many manufactured myths without basis, too extensive to explain here.

b) the magistrate judge weighing all the factors, listening to all witnesses concluded Sakkal may be bonded under extremely restrictive requirements., which Sakkal complied with. But this was not enough to satisfy the blood thirsty cruelty of the prosecutor, who appealed to Judge Barrett who did not see any witness or read the magistrate report that was published a week after judge Barrett's decision. To coerce the judge, the aggressive malicious prosecutor reminded the judge by one of his past mistake, shaming him "The judge understood the intention: 'are you trying to shame me'?' -'Your honor I just wanted to be sure it is on the record'". Suggesting he not repeat the error, the blackmailing by this unrelated past case error pushed the embarrassed judge to cancel Sakkal Bond.

c) The consequences of cancelling the bond and keeping the petitioner in jail were immense:

i. Petitioner could not get any access to the cloud-based patient's medical record, for each patient, to study after three years of hiatus, and rebut the prosecutor or his expert unfounded claims to practice violations.

ii. Could not reach his office policy manual which has all the policies that instruct employees about each disease management including pain, addiction, diabetes, etc. which prove the existence of a very comprehensive pain plan in policy and practice.

.iii. Could not get the administrative office records which contains exculpatory evidence of sensitive nature.

iv. could not reach his patient's monthly surveys which prove, by patients' words, without a doubt, how strict was the physician prescription style for any controlled substance — thousands of these statements, surveys, and materials.

v. Could not reach his weekly staff meeting minutes where discussions and instructions were given for the best practice in -how to treat pain, addiction, diabetes, stress, mental disorders, etc.,

— how to get OARRS reports for controlled substances state record,

— how to do the drug testing, how to take the H/P, the verification of the patient's medication list and the bottles counts, the inclusion in the record the present medicines that need renewal or not, and

— how to do Brown bag review for all medications once every six months, and much more..

vi. Could not reach the monthly employees individual review sessions to view their performance, reminding them of deficiencies, receives their list of services which has monetary incentives, including their OARRS retrieval, drug testing, etc., and to measure their progress or regress in each function

vii. Could not reach the quarterly community public educational sessions records which included variable subjects including pain, addiction, diabetes, nutrition, exercise, stress, etc., which were held in the local public library, as awareness session for the community to prevent drug abuse, addiction, overweight, etc.

viii. And the six-monthly retreat for the full staff to review the office practice achievement for its goals in all the areas described above and the plan for the next six months goals. Dose any of these activities appears to be the acts of the criminal mind the government is alleging? which drug dealer would be prepared to put all the efforts into doctor's role?

ix. These records, in totality, are crucial exculpatory evidence suppressed, and a proof that the Sakkal usual practice was in FULL COMPLIANCE with CSA, CFR and SCOTUS legal framework. Sakkal's was an advanced, progressive, well informed practice, in achieving drug prevention, addiction awareness, and contrary to the prosecutor allegations of malfeasance or illegal forms of intentions or actions. The practice was a "superior usual course of His professional practice" the achieve the highest level of "legitimate medical purpose," which was unfairly rewarded with undeserved malicious out of line, prosecution, conviction, and incarceration for a total of 20 years, Ten (10) year for every year he has been in Lindenwald practice. This is truly unusual and cruel punishment, inconsistent with the 8th Amendment.

x. Instead, the prosecutor, the judge, and the court refused the plea for a bond not understanding the need for this access to the exculpatory evidence, assuming that the issue was access to the defense counsel, which could be accomplished in jail without internet access, or access the physical materials in storage areas in the office, the house, and storage space.
The defense counsel failed to explain the rationale, refused to initiate a legal full Motion for release, and instantly rebuffed by the court when he asked for a minimal adjustments on the conditions, as unacceptable while it was extremely crucial, for exoneration of incarceration. This was extremely frustrating, but the accused complied anyway.

d) The petitioner was fully compliant also with his defense counsel, during trial, an attitude that backfired:

— When he disagrees with the defense counsel, he complied out of respect to the professional experience of a legal expert!

— When the counsel explained to petitioner he could be in contempt of court and forbid the petitioner of speaking ever in front of the judge he complied, especially when he threatened him he could lose his case.

— When petitioner was shocked by the sudden plea offer, the day of the trial he complied asking to negotiate a lower term.

— When he wanted to make a statement to the jury, and was forbidden he complied, regretting in hindsight.

— Then he complied with every step of the following steps the court system exercised against him afterward till now, filing appeals on time, taking all rehabilitation steps while incarcerated, like every drug criminal, while the court denies his appeal one by one, in error each time contradicting the statutes, regulation, and its own rules as explained.

e) The first direct appeal at the district court, for ineffective assistance of counsel, lack of sufficient evidence, the illogical split jury decision regarding two similar death cases was denied claiming the government "presented ample evidence" while the evidence was a collection of unfounded "red flags or herring"; the second request at the Appeals Court for ineffective assistance of counsel, court bond hearing error, and defective jury instruction was denied for procedural excuse as a plain error; the third request at the Appeals court after Ruan decision remand by SCOTUS was denied with the unfounded excuse that the court used a jury instruction that comport with Ruan when it was not as explained supra. Each Court was out of step with justice, each court was incompliant with intent and letter of the law, forcing the petitioner to return again to SCOTUS for a final determination according to the law, and not to the erroneous case law since Moore that govern the Sixth Circuit decision process, ignoring SCOTUS Mens Rea emphasis as if it does not exist.

f) In sum, the petitioner has been in compliance with the CSA/CFR and SCOTUS, while the Sixth Circuit insists on continuing to be out of compliance, without constitutional basis in its verdict, jurisdiction and authority.

(VI). SIXTH CIRCUIT VIOLATIONS HAD DIRE CONSEQUENCES TO PUBLIC HEALTH

Physicians who are recognized as potential pioneers (in contrast to aberrant doctors or drug pushers), who intend to alleviate suffering by adopting new modalities of treatment, like Sakkal's effective holistic Hypothalamic paradigm and Mini-Dose-Combination-Therapy, will lose their enthusiasm and become inhibited from innovation by overreaching prosecution. This innovation strangulation will dampen the progress achieved in the last few decades, with regression of American leadership in medicine and related fields. Scientists involved with design and production of medications

for pain, addiction and mental health will reconsider their time and effort investments in basic and applied research.

1) "Pain is a widespread and consequential public health problem, and care for patients with pain is a primary duty of healthcare providers. (One of three Americans have hypothalamic dysfunction/Fibromyalgia spectrum which is treated in 50-60% with opiate despite uncertainty regarding opiate use). One in Six Americans, or 50 millions in 2016, suffered from significant pain daily, which is more than that are affected by cancer, diabetes, stroke or heart disease. It is the primary cause of disability, increasing with older population, and worse after the covid epidemic. People seeking pain healthcare accounts for 115 million emergency room visits yearly, (and more than 300 millions are seen in providers' clinics). Pain also occurs in 50 million after surgery every year. At the end of life it effects 70% of the population. It is still poorly managed and undertreated in the USA, at a cost of $700 billion yearly in medical expenses, disability and lost productivity." (Brief Amici Curiae, National Pain Advocacy Center in support of Ruan 12/27/2021)

2) "Unlike in the treatment of conditions such as sepsis or heart attack, there is no unitary standard or broadly applicable protocol for treating pain. The medical view on opioid, the mainstay in many types of pain, is in continuous flux, and medical science is still unable to reach a unified protocol to treat the 10 million disabled. Recent attempts by government agencies to present a protocol backfired, requiring these agencies to course correct including the DEA in 2004, CDC 2016, among others." (see more detail at Br. Amic. Curiae, NACP, Id). Sakkal followed the major acceptable guidelines devised by the FDA (2009), The Institute of Medicine (2011), and the NIH (2016), yet he was convicted.

3) Although it appears only a legal concern related to deprivation of life, liberty and property without due process of law and fair notice (5th Amendment), limited to a small segment of the USA population who are healthcare providers, in the Sixth Circuit or Supreme Court with no impact on the justice system or the general public, However, in real life "The legal uncertainty, with unclear standard for prosecution (like the department of justice issuing a series of highly publicized letters to providers who prescribe US Attorney Office 2/5/2019), had a chilling effects on care, leading good providers to fear when they exercise their best judgment" (Id.), leading to increased insecurity of prescribing (see reference , infra), punishes physicians who practice to serve interest of their patients, as they are

ethically bound to do (Ref.2), instill fears from prescribing necessary medications to needy patients (Ref.3), leading to overdeterrence of providers from doing their jobs, deprive 40-50% of patients from receiving clean supervised medications (Ref.4, 5, 5a), pushing patients to illicit street source polluted with fentanyl, increases overdose death rate, making the government appears unable to deal with the epidemic, eroding public confidence in government, DOJ, science, and medicine, allowing for more superstition, conspiracy theories, speculation about evil forces controlling government and society, disturbing the meaning of thriving living in the USA, the most advanced country in the world, taking away the liberty to live healthy, happy, and productive, and destroying the American dream for millions of the population.

4) This poisoned medical-legal environment "discourages medical students from going into pain medicine when there are already very few providers and increasing need" (Br. Amic Curiae, NPAC, Id.), and discourages young people from enrolling in medical and nursing schools. "Overdeterrence has predictable and significant effects on patients healthcare"(Id), leading to abandonment and breakdown of healthcare relationships (Ref.6) leading to further shortage in health care providers, building a higher need for more foreign medical graduates to fill the gaps in urban cities downtowns, scant rural health in the Midwest, and underserved areas which are already facing health care service shortages which are presently only filled by international medical graduates who serve up to 21% of the population.

5) Physicians who are recognized as potential pioneers, (contrary to the drug pusher, or aberrant physician described in Brief NPAC amic curiae Id. who intend to alleviate suffering by adopting new methods of treatment, like Sakkal in his effective holistic hypothalamic paradigm and Mini-Dose-Combination-Therapy, will be inhibited from innovation, dampening the progress experienced in health care over the last few decades leading to stagnation or regression of American leadership in medicine and related fields (Ref.7). Scientists who were motivated to design and discover new treatment modalities in pain, addiction and mental health will reconsider their investment in time and effort outcome before proceeding in their basic or applied research in these fields.

6) Pharmaceutical manufacturers will avoid production of newer and better drugs, which are badly needed today, and will take longer years to be approved when discovered with increasing costs. Wholesale distributors, pharmacy chains and pharmacists will incur higher operating expenses,

insurance premiums, and will pass the costs to consumers, who will have to pay more out of pocket co-pay, and suffer further from spiraling drug prices, and healthcare costs, which will increase inflation, and place financial pressure on every part of the health sector which represent 18% of the GDP, leading to unforeseen cycles of depression, unemployment, followed by more sedentary living, stress and disease with more misery, suffering, unhappiness and disillusion, culminating sooner or later with social upheaval, political instability and violence.

7) Many of these predictions became realities and the lack of consensus within the medical field led the medical community (8) other agencies (9) and the AMA to criticize the 2016 CDC guidelines (10) leading finally the CDC to reverse itself from its own 2016 guidelines (10.a) and the FDA to sound the alarm (10.b, 11) about opioid withdrawal risks, which was documented in many studies(Id.) and more alarming increased death rates as a result of the above sequence (12, 13, 14, 15).

8) In Conclusion:

The space in this petition will not allow here detailed citations of all recent studies that has proven these dire predictions have already became realities as well as the other issues resulting from the federal intervention in state rights to control medical service, the overreach of law authorities on personal freedom and choices, and other political ramifications, but further detail could be found in a reference list for each one of the above facts in Appx G/Consequences, predictions, and painful realities.

Proper interpretation of the CSA and clarifying its intent by Congress and SCOTUS is vital to PREVENT THE DIRE CONSEQUENCES DESCRIBED ABOVE FOR TENS OF MILLIONS OF AMERICANS WHO MUST CONTEND EVERY DAY WITH SEVERE AND CHRONIC PAIN. IT MUST PROTECT GOOD PROVIDERS AND THE PATIENTS IN THEIR CARE, NOT TREATING THEM AS DRUG PUSHERS EXCEPT WHEN THEY ACT LIKE ONE: SELLING DRUGS OR EXTORTING PATIENTS FOR THEIR SELF- BENEFITS.

References:

(1) Cara L. Sedney et al. "The DEA would come in and destroy you": a quantitative study of fear, unintended consequences in West Virginia, the epicenter of opioid crisis. Research Square (10/25/2019)

(2) AMA patient-physicians relationship code of medical ethics 1.1.1. requires physicians to place patients' welfare above the physician's own self-interest or obligations to others including the government, and to advocate for their patients.

(3) Kate M. Nicholson and Deborah Hellman, Opioid prescribing and the ethical duty to do no harm, 46 Am. J. L.& Med.297, 299 (2020). 50 million suffer from daily pain, severe in at least 40 millions, and debilitating disabling in 20 Millions.

(4) Pooja A. Lagisetty et al., Access to primary care for patients with chronic pain receiving opioids, JAMA Network open (2019). 40.7% of clinics refused to make an appointment for currently opioids taking patients.

(5) Industry DX, MHealth Lab Blog, https://timyur.com/2p85msjm. accessed 2021. nearly 50% refused to take patients.

(5a) Jay G. Wohlgemuth et al. Health trends: drugs Misuse in America 2019 at 6, QuestDiagnostics (11/2019) 80% reluctant to take opioid patients.

(6) Hector R. Perez et al., Opioid tapering is associated with subsequent termination of care, 35 J Gen. Internal med. 36 (2020). more interruptions of patient-provider relationship, abandonment and lack of service.

(7) Brief of Amici Curiae Professors of Health Law in support of Ruan v. United States 5/7/2021. comprehensive review of the legal and public consequences of misapplication of the CSA, 1306/04(a) and the SCOTUS decisions, and fear of scrutiny.

(8) Challenges with implementing the CDC opioid guidelines: A consensus Panel Report, 20 Pain Med. 724 (2019).

(9) Pain Management best practice inter-agencies task force, HHS, 5/9/2019) another attempt to look at consequences.

(10) Julia Mc Donald, Do no Harm or injustice to them: indicting and convicting physicians for controlled substance in the age of opioid crisis. 72, Me. L. Rev. 197, 221 (2020). The AMA resolved that CDC guidelines should not be utilized, physicians should not be subject to criminal prosecution solely for prescribing at level above the DC guidelines.

(10a) Deborah Dowell et al No short cut to safer opioid prescription, 380 NEJM 2285, 2287 (2019). Highlights the low evidence for its misapplied provisions

(10b) FDA virtual public workshop. Individual patient and medications factors (6/7/2021)

(11) FDA identifies harm reported from sudden discontinuation of opioid.. and requires label changes. FDA. (4/9/2019)

(12) Jocelyn R. James et al., Mortality after discontinuation of primary care-based chronic opioid therapy. 34 J Gen Internal Med. 2749 (2019). An increase in mortality because of tapering or withdrawal from fear of continuing opioid

(13) Hannah T. Neprash et al., Abrupt discontinuation of opioid among Medicare beneficiaries 2012-2017, 36 J. Gen. Intern Med, 1576 (2021)

(14) Elizabeth Oliva et al. Association between stopping prescriptions for opioids,.. and overdose or suicide deaths among veterans, 368 BMJ m283 (2020). remarkable increase

(15) Alicia Agnoli et al. Association of dose tapering with overdose or mental health crisis, 326 JAMA 411 (2021). Tapering was associated with increased risk of death and mental health crisis.

(VII). THE SENTENCING COMMISSION DRUG CONVERSION TABLES ARE ARBITRARY AND BIASED AGAINST PHYSICIANS

I. The Drug Conversion Tables "DCT" in the Federal Sentencing Guidelines, as applied to physicians, including Sakkal, is arbitrary, wrong, without any scientific basis, medical explanation or legal benefit, violating more than one Amendments. Because it is easy to prove a disparity between physicians, and drug traffickers, as well unequal medications conversion values, it violates the equal protection of law, of the 5th, 8th Amendments.

The DCT is based on drug type and quantity. Prescription opioids, except Fentanyl, are not listed or included, raising the question of lack of validity of using any conversion, because prescription medications were not intended to be included in the DCT. if either Congress or the original writer in the Sentencing Commission intended to include them he/she would have included them.

II. At any rate, the amounts of drugs are converted to another metric such as Marijuana or Heroin equivalent. From 1987 until 2018 it has been in the Federal Sentencing Guidelines Manual (FSGM), and since 2018 the DCT replaced the older system, as the Sentencing Commission has chosen by irrational, unaccountable, arbitrary and not agreed upon rule or regulation!. However the CDC, another government scientific agency, had a different formula (infra)

a) Example 1: Here is a simplified Opioid conversion ratio:

i- Based on the 2016 version in a simplified form: 1 gm Heroin = 1 kg Marijuana; 1 gm Fentanyl= 2,5 kg Marijuana; 1 g hydroxymorphone = 2.5 kg Marihuana; 1 g oxymorphone = 5 kg Marijuana; 1 g Oxycodone, or hydrocodone = 6.7 g Heroin.

ii- So if drug trafficker was sentenced for 1 gm of Heroin it would be converted to 1 kg of Marijuana

iii- But if a physician was sentenced for 1 g of Oxycodone/hydrocodone, the most widely used opiate it would equal 6.7 kg of Marijuana, that is more than 6 times the drug trafficker, vilifying prescription opiates for truly harmful disparity.

iv- It is easy for the Court to see the disparity of how a street drug pusher of the "Brown heroin" will receive a lighter sentence, although he knowingly and intentionally distributed with the intention of harm. Is this not absurd and cruel?

b) Example 2: Here is a different confusion that result from duplication between the CDC and FSGM:

i- In the FSGM 1 mg hydromorphone or fentanyl= equals 2,5 mg Heroin; 1 mg oxymorphone+ 5 mg Heroin.

1 mg oxycodone or hydrocodone (most prescriptions) = 6.7 mg Heroin (highest conversion rate).

1 mg Methadone or Morphine+ 0.5 mg Heroin (lowest conversion rate) (From FSGM 2D1.1, cmt. n8 (D)

ii- In the CDC, the scientific Morphine equivalent is used to do conversion:

1 mg oxymorphone=3 mg Morphine; 1 gm Methadone=4.7 mg Morphine (From the CDC website)

iii- The difference will be exemplified in the following:

If Dr. A prescribed the usual 30 mg of oxymorphone daily or 1.8 gm in 60 days it would equals 9 gm of Heroin. If Dr. B prescribed the usual 90 mg Morphine daily or 5.4 gm in 60 days it equals 2.7 gm of Heroin.

So, Dr. A heroin equivalent is more than three (3) times of Dr. B (9 v.2.7), although they prescribed almost same effect drug.

iv- If Dr. C prescribed the usual 30 mg oxymorphone daily or 1.8 gm for 60 days, which equals to 6 gm Methadone; and Dr. D prescribed Methadone 18 mg daily or 1.08 gm in 60 days it equals 0,54 gm heroin equivalent.

So, the difference here is even more drastic by eighteen times (9 v. 0.54)

v- Taking all four prescribers the base offense is highest for Dr. A& C (9 gm), followed by Dr.B (2.7), and least for Dr. D (0,54), and the sentencing as a result would be very different for similar amount of opiate pain relief prescriptions.

c) The examples show the legal dilemma for physicians, who faces a difficult decision:

i. If Sakkal followed the DCT guidelines by prescribing Methadone, the lowest offense conversion ratio, with the lowest sentencing risk, he could be sued for malpractice for not following the CDC instructions, or the government standard.

if he prescribed oxymorphone he would be following the common usual course in practice, but face the higher offense weight, and higher sentencing years. The dilemma is clear, and relates directly to arbitrary, confused conversion basis in the DCT, without well proven scientific basis in Pharmacology or Therapeutics textbooks.

iii. The legally FDA approved drugs all carry higher sentencing risk than the illicit street heroin (up to 6.7 times more), and longer imprisonment years, an unfair, cruel punishment under the 8th Amendment! This scheme vilifies safe medically supervised opioid prescriptions by physicians, in comparison to polluted street drugs distribution by drug traffickers, turning physicians into worse criminals than traffickers. This aggressive attack on medicine as a profession, physicians as professionals have dire consequences to public health and safety, while violating Due Process of the 5th Amendment, with equal protection guarantee under the law! SCOTUS should request the Sentencing Commission to equalize penalties in DCT, that presently favors drug traffickers for whom the CSA was designed in the first place.

iv. SCOTUS need to reverse this absurd outcome where the court(s) is punishing physicians harshly under the CSA designed to punish drug traffickers and exclude physicians. If the court insists on punishing physicians it should ask Congress to write a designed law after consulting reliable medical legal and public health experts to save medicine, public health, patients, providers and other stakeholders in this nightmare of injustice. This a major court tragedy with many innocent victims.

E. WHETHER THE INEFFECTIVE ASSISTANCE OF COUNSEL CHANGED THIS CASE TO NEGATIVE OUTCOME?

When the defendant is totally innocent from any criminal act, false convictions still may happen as a result of overzealous prosecutor misconduct or biased unfair court, but it definitely happens after Ineffective assistance of counsel, who cannot or will not defend appropriately intentionally or incompetently. In this section the question raised will be answered from the court proceedings to include legal errors, procedural failures, even perjuries in the post-conviction hearing, later.

> "The only means by which the defendant can defend against expert testimony by the state is to offer expert testimony of his own" Barnard v. Henderson, 514 F. 2d 744,746 (5th Cir. 1975)
>
> From the Honorable Judge Michael Barrett's opinion, District Court 5/6/2020:
>
> "Q: [Dr. Akbik] also looked at the death cases, and he said that Dr. Sakkal was in trouble on them because the levels were extremely high?
>
> A: the toxicology level, yes.
>
> Q: and he indicated that he thought Dr. Sakkal had a good heart and wanted to help his patients, but he should not have been prescribing the drugs and drug combinations that he was doing because he was endangering them by not following any of the protocols?
>
> A: Any of the appropriate protocols, yes.
>
> ...
>
> A: I told [Sakkal] that [Dr. Akbik] looked at the charts, particularly the death cases, and that the toxicology reports were damaging to our case.. The experts said that.. these are dangerous combinations.. that Dr. Sakkal was not a pain doctor

...

A: having been a former employee of a state medical board, [Michael Staples]..felt the same way I did and Dr. Akbik.. that the best defense would be that Sakkal was not a pain doctor, he was in over his head, he had good intentions, and he acted in good faith, and he made mistakes, but he did not have criminal intent" (Opinion 5/6/2020)

1) One of the counsel's most obvious error was to conflate the toxicology levels of the deceased patient with Sakkal's conduct. The toxicology level reflects the patient's conduct-her choice to ingest intentionally too many tablets-, while Sakkal's conduct was writing his prescription. The blood levels from Sakkal's prescription have been set forth previously (15 for oxycodone, 3 for Xanax, with acceptable range 20-60) reflect Sakkal's low dosage of Percocet and Xanax. The patient Adkins conduct was to ingest a massive amounts of those substances in a manner substantially contradictory to her small dose prescription.

2) The nominal levels reflecting Sakkal's conduct were at the low end of the therapeutic range. The toxicology level was considered by Sakkal's counsel (and the lower court) as reasonable basis to determine whether counsel should obtain an expert for Sakkal, and he did not. This is a major error of conflation (high toxicology related to patient conduct, in contradiction with low dose related to Sakkal's conduct) that substantially informed and influenced counsel's wrong decision not to obtain an expert. Sakkal needed his own expert to explain this simple fact, defending him since he was not one of those rogue doctors that were so far over the line of validity that a defense expert would not make a difference in the outcome of the trial. Even The "phantom" unseen witness, Dr. Akbik, admitted Sakkal wanted to help his patients.

3) Counsel made many errors, (see Appx E for extended details), of which few are mentioned next:

a) Counsel sought the advice of government experts and accepted their biased opinions without question instead of seeking bona-fide defense experts.

b) Counsel failed to investigate the protocols to be discussed during trial, including the range of care, medications dosages, that are available at the discretion of the doctor, and how Sakkal's

combinations were beneficial, and not dangerous, at the low level prescribed, general information that are readily available on www.drugs.com, or any PDR, and on the dangers of firing patients with abrupt withdrawal or death.

c) Counsel failed to investigate particular facts which Sakkal informed him of, or of which he otherwise had reason to know or investigate such as Mini-Dose-Combination-Therapy, the maximum recommended daily dosage, which was very far from Sakkal's low end safe prescribing habits

d) Counsel failed to explain to jury why these combination were not outlawed in the regulations, or contraindicated in the medical community literature, like the PDR, and they are safer therapeutics for their low chemical burden.

e) Counsel failed to make sure prosecutor's conflation, in closing argument, of the ratio of patients dying under Sakkal's care were not 40% as the prosecutor claimed (dividing, in error, 8 over the selected 20 counts patients), but was actually 0.002% (dividing, correctly, 8 by 4000 total clinic patients), the lowest ratio in the USA for primary care (1-2%), or for pain and addiction's clinics (4-8%), proving Sakkal's protocol minimized controlled substances and prevented mortality

f) Counsel failed to make sure that matters did not remain conflated during trial on more than one occasion, and at closing, so that the jury could differentiate fact from falsehood, one count from another, without being influenced by the errors of repetitive conflation.

4) Those errors culminated in a bigger error; rather than consult with a bona-fide defense expert and investigates dosages and mount an adequate defense, counsel chose "to concede to the government's position", and worse he misinformed the jury that Sakkal was sloppy, careless, and negligent bordering on reckless and even foolish! Once the counsel told the jury this negative description of his client, the possibility of the jury finding that Sakkal acted within his discretion and in good faith was diminished to zero. He handed Sakkal to the jury to be slaughtered like the lamb on the altar. The recommended maximum daily dosage would have been sufficient to change the outcome of the trial, if only counsel investigated this among other things.

5) Aside from obviously conflating the toxicology levels with Sakkal's prescriptions, The phantom unseen witness, Dr. Akbik, told counsel that "Sakkal had a good heart and wanted to help his patients." On this last point the Sixth circuit agreed when it accepted employees witness statements like Robbi Mott, Deborah Clowers, and Alesha Hayes also told the same to the jury. Counsel followed the advice of

the government's experts he consulted, but the proper thing to do was to have them testify about Sakkal's good intention and good faith prescriptions, or find a better doctor willing to say this on Sakkal's behalf, rather than tell the jury falsely Sakkal was sloppy and careless, when Sakkal detailed practice policies and habits proves the reverse because he was very organized, meticulous, comprehensive, and careful with every prescription: Sakkal modernized the medical records as the sole provider, from a hand written to electronic, a herculean job for 4000 patients; decreased controlled substance prescriptions from 15% to 7%, weaned off 30% of patients, prevented death by 100 times fold from the national average, made Lindenwald the most progressive practice in the community, responding to the need of the sickest of the sick, the most complicated challenging patients, in the poorest section of an urban slum, at a very high satisfaction rate, all documented by audits, weekly staff quality improvement program, monthly surveys, quarterly community service education sessions, at the most cost effective safe protocols.

6) Counsel did the prosecutor's job for him, just as counsel did in Buck v. Davis. But sakkal's counsel first confused the toxicology level with sakkal's prescription before making up his mind that a defense expert and defense other than "sloppy and careless" was pointless and harmful. It would have been his job, instead, to bring defense expert who could explain to the jury the truth, assure the jury that Sakkal acted in good faith, with below the allowable dosage in each prescription, rather than defame Sakkal in front of the jury, adding to the prosecutor's slander, and character assassination by a variety of unrelated prejudicial red herrings, irrelevant to the merits of the case, but tarnished Sakkal's impeccable image.

The expert was needed to point out: a) that the government's standard of one size fits all is unrealistic in medicine today, but there is a range of care available, and it is subject to differing opinions, of which Sakkal had the best, so not just one correct course of professional practice in every patient; b) that Sakkal was being prosecuted for his atypical patients, and their atypical needs which Sakkal did not cause, but responded according to his oath of service, so he was certain to treat them differently than the average patients; c) that there is no legislation requiring one protocol, or drug testing, or using OARRS; and d) that there is no agreement on what to do with these ancillary information anyway, and that firing patients from a supervised clean clinical setting was more dangerous because they end up shifting to fentanyl polluted street drugs with certain death. e) This expert could have explained that combining opiate (like Percocet) and benzodiazepine (like Xanax) was permissible by the PDR, when

prescribed with caution under supervision, not inherently "dangerous" and; f) that they are used in millions in the USA daily, as the norm, the usual course of professional practice, for a varieties of symptoms, diseases, and indications and not the exception) let alone the fact Sakkal used the lowest possible safe dose compared to 99% of physicians. h) The expert could have stressed that Sakkal was acting within his discretion as authorized physician, when he prescribed his low dose combination. i) Explaining all these things, instead of defamation, would make the jury reach a different favorable outcome.

7) Counsel testified in post-conviction hearing that Sakkal lied to him about not being the first to prescribe opiates to one patient, referring to the woman to whom Sakkal prescribed 20 mg Methadone four times daily (since Methadone comes in 10 mg tablet she received a month supply of 240 tablets naturally), as described in the court opinion that ordered denial of new trial. This was the same woman who made a bet with her father that she could get her usual long-term maintenance of 400 mg of Methadone, a much larger dose than her father received from Sakkal, when her father complained that Sakkal was too stingy with his prescription. The woman informed Sakkal she was on $800 income monthly, while her methadone clinic charged her $500 and she could not afford it with her extreme need for her severe pain medication. Sakkal reduced her dose to 80 mg daily (20% of her pre-existing dose) taking a risk of some withdrawal transitional stage until he could reduce the dosage later further but could not go any lower because of fear of withdrawal and death, which was plainly a legitimate medical purpose. The counsel erred but not to locate an expert to explain this clinical encounter is inexcusable.

The government made much from the fact this woman was addicted to Methadone, as if addicts don't ever experience severe pain, while Sakkal contends he was treating her extreme pain in the best safe protocol possible within his discretion.

Either way, treating her addiction or pain or both, in the clinical supervised setting with pure safer drugs is far superior from legal perspective, and the reason d'etre of medicine as a profession, than driving the woman to street dealer and those associated risks. An objective medical expert would be needed to make this point, or an engaged attorney willing to research the matter, and Sakkal had neither, handing him a conviction.

8) Sakkal explained to his counsel many of his office policies regarding pain management and his effort to get his staff to comply with his clinic's protocols. So, Sakkal instituted a $0.50/per service item

completed as a bonus incentive program to fulfil these policies like drug testing, OAARS report generation to detect doctor's hopping, being sure of adherence to the planned medications surveillance office visit, preventive visit scheduling, etc. Many of his staff received a monthly bonus for performing these tasks, signaling his insistence on getting the service done.

Counsel was ineffective for failing to set the record straight by permitting the jury to belief the falsehood that some of these tasks were not performed or corrective actions were not implemented to insure they were performed.

9) More than anything else Sakkal needed counsel to convey to the jury that the dosages he prescribed were lower than anyone else, and no danger compared to the high dosages used by the traditional pain specialists, especially within the wide range of care available, whether the counsel did it himself, or through an expert, or by putting Sakkal on the stand to testify. Counsel kept telling Sakkal that he would be an excellent witness, and then changed his mind, claiming the testimony was not needed, the government had no case, and his fear Sakkal may make any single error.

If he felt so strongly against Sakkal testifying, announcing "over my dead body", he had a duty to seek a defense expert, disabuse himself of his errors of conflation, investigate allowable dosages and Sakkal protocols and explanations. But to do this with the alacrity and vigor it deserved he had first to believe in his role as a defense counsel, and that an expert was a necessity, and his misapprehension prejudiced him to the point of eschewing an expert and instead informing the jury that Sakkal sloppy, careless, reckless or negligent. Exactly what is not expected from a defense counsel, and not even an ethical prosecutor.

10) Everyone knows that the only way to defend against a government's expert is with an expert of his own, and the counsel must not start and end his defense with misunderstanding of the difference between the defendant's actual benign conduct (a pain relief prescription) and another person/patient choice to abuse her prescription medication, and so resort to informing the jury that his client was sloppy, careless, reckless instead of mounting a proper defense with an expert. Ruan and couch had three experts, and one of the counts dropped in Ruan was the one he explained his rationale in treatment to the jury. For Ruan who is a pain specialist it took three experts and his own testimony to justify his practice on one count the court allowed him to explain. The harm done to Sakkal was immense.

11) Given that the government generous money purse to pay experts who specialize in prosecuting doctors, and those experts' job is to find fault with any practice of the accused, even in contradictory prosecution terms: prosecuting high dose in Ruan and Murphy specialized practice and prosecuting Low dose combination in Sakkal primary care practice. The expert in Sakkal's prosecution received more than $35,000 for this case and more than $ 1,200,000 in the last few years, just to announce the legal terms "no legitimate medical purpose" and is always prepared to not objectively inquire into the diagnosis and therapy protocols or develop favorable facts. The defense needed an expert to refute these falsehoods, or there is no chance of edifying the jury that:

a) The government expert is biased because he has to do a pre-arranged job to condemn

b) That one expert does not possess the only possible acceptable opinion of the standard of care, of which there are more than 80 issued by many medical organizations, state boards, federal agencies, and specialties and primary care societies, pointing that there is more than one range of acceptable care protocols, including sakkal's superior hypothalamic paradigm

c) Most of what the government presented as a proof of alleged "guilt" is discretionary and not actually legally regulated or medically required, or else portrayed incorrectly by the government. For example, the government insists that the dosage prescribed to Adkins were both dangerous combination and extended this representation to all counts as a suggested fact.

d) But that is "deliberately misleading" because the dosages were:

i. actually quite lower than what patients receive in most other clinics.

ii. well below the maximum dosage.

iii. would have been below the therapeutic range if taken as prescribed, a fact admitted by the government "expert". and

iv. concordant with textbooks of pharmacology and therapeutics, the real acceptable reference, as extremely safe because of the low chemical load involved in Mini-Dose-Combination-Therapy.

There was no basis to the falsehood perpetuated on the court and the jury.

12) The government had also claimed Sakkal started his patients on opiates, as if this was a crime, ignoring the reality that hundreds of thousands are started on opiates every day single day after any surgery, injury, burn, or fracture, or even a heart attack. But more significant here is that all patients were on controlled substances prior to the first visit recorded in the EMR, because these patients were long term clinic patients for many years and some for decades who had their older medical records in the

clinic in traditional charts, filled with handwriting, that were ignored by the government, when it received only the electronic records, on which Sakkal might have been the first provider in the new EMR.

But the patients received the controlled substances before in the same clinic or from other sources, and Sakkal simply filled out their prescription, titrated their dose in his most objective clinical tools :tender pain points number for generalized pain and vibratory sensory perception for neuropathic pain, in addition to Hamilton scale for anxiety, and Zung scale for depression, in each office encounter, recorded these most crucial results that guided therapy successfully in more than 80% of patients without expensive imaging. Sakkal needed engaged, diligent counsel, an objective fair defense 'expert' to point out this to the jury and change the outcome.

13) Counsel also failed to question WHETHER THE UNITED STATES DISTRICT COURT HAD ARTICLE 3 JURISDICTION TO HEAR A CRIMINAL CASE?

I. WHETHER THE DISTRICT COURT, ACCORDING TO ITS NATURE OF JURIDCITION, AS AN ARTICLE 4 COURT (not article 3) FOLLOWED THE FIRST RULE FOR ALL FEDERAL JUDGES AND "AFFIRMATIVELY ESTABLISHED ON THE FACE OF THE RECORD THE STANDING OF GOVERNMENT AND THE JURISDICTION OF THE COURT BEFORE ADDRESSING THE MERITS OF THE CASE-'"

A RULE THAT IS INFLEXIBLE AND WITHOUT EXCEPTION"? These related questions -regarding the standing of the government, Jurisdiction of the court, and the federal judge compliance with federal rule- relates to the district court authority are crucial to answer, for addressing Sakkal's case merits. Furthermore, the government suit has violated its

Duty of Protection

II. DISTRICT COURTS OF THE UNITED STATES V. UNITED STATES DISTRICT COURTS

1) The United States Constitution, Article 1, section 8, clause 17 states in part, "the Congress shall have the power.. to exercise exclusive legislation in all cases, over such district (not exceeding ten miles square) as may by the cession of particular States, to become the seat of Government of the United States, and like Authority over places PURCHASED by the consent of the Legislature of the State in which the same shall be for the erection of.. needed buildings"

The territorial limitation of this Article 1, section 8, clause has NOT been amended.

2) Article VI, clause 2, is known as the "Supremacy clause" established the supremacy of the Constitution over any who shall be bound by Oath to support the Constitution in the government in all branches including the Congress. This was recognized by SCOTUS in Marbury v. Madison, 5 U.S. (1 cranch) at 177 and 2 L.Ed. at 73,74 (1803); "The Supreme Court recognizes the Supremacy of the United States Constitution"." An act of Congress repugnant to the Constitution cannot become law," including 18 USC 3231, which gives jurisdiction to district courts within several states.. or so they allege. In Carter v. Carter Coal Company, 298 U.S. 238 (1936) "The United States Constitution speaks for itself in terms so plain that to misunderstand their import is not rationally possible". The supremacy of the Constitution is absolute, but a statute enacted by Congress is not. Judicial power is required to ascertain the law and.. reject the inferior statute whenever the two conflict."

3) In USC # 3112, at 40, three conditions are required before the United States ACQUIRE jurisdiction within a state:

A. A notice of acceptance filed with the Governor..

B. Land must be PURCHASED from the state, not loaned or ceded..

C. The State legislature must consent to the federal jurisdiction within the enclave.

4) U.S. statute 18 U.S.C. #3231 empowers "District Courts of the United States" and NOT "United States District Courts":

> "The District Courts of the United States shall have original jurisdiction, exclusive of the courts of the states, of all offenses against the laws of the United States". June 25, 1948.

5) Pursuant to Adams v. United States, 319 U.S. 312, 63 S.Ct.1122, 87 L. Ed. 1421 (1943); Article 1, section 8, clauses 17-18 of the Constitution, the Acts of Congress at 40 USC 3112; In Federal Jurisdiction, No district court has the authority to sentence anyone on federally owned property, located in any state.., that has not been.. ESTABLISHED AS AN ENCLAVE for the purpose designated".

6) Neither the United States Congress, nor Department of Justice have any lawful authority to exercise territorial jurisdiction over any land LEASED within a State.. See Geyser v. United States, 2010 U.S. District Lexis 149421 (C.D.CA). Until now the statutes and laws of the U.S. Congress [at 40 USC

#3112; and 18 USC #7(3)], did NOT expand the territorial Jurisdiction beyond the original 10 miles scope of Article 1, section 8, clause 17 of the Constitution, or any has been amended.

7) Article 3 extends federal power to all cases in law and equity arising under the Constitution, laws and treaties of the United States.

8) However, # 3231does not empower "United States District Courts" in any way, which are Article 4 civil legislative courts, WITH POWER TO AWARD plaintiffs THREE TIMES DAMAGES, with no jurisdiction to prosecute US statutes violators. This was recognized by the Supreme Court in Mookini v. United States, 303 US 201 (1938) which made clear the difference between the two courts system where it reads:

> "The term 'District Courts of the United States' as used in the rules, without an addition expressing a wider connotation has its historic significance. It describes the constitutional courts created under Article 3 of the Constitution. Courts of the territories are legislative courts and not District Court of the United States".
>
> See Reynolds v. United States, 98 US 145 (1938); The City of Panama, Re Mills; Mc Allister v. US; Stephens v. US; Summers v. US; US v. Burroughs.

9) This was originally decided in Balzac v. Porto Rico, 258 U.S. 288-298 (1922):

> "The United States district court is NOT a true United States court, established under article 3 of the Constitution" "It is created by virtue of the sovereign congressional faculty, granted under Article 4 #3 of that instrument..." "The resemblance of its jurisdiction to that of true United States courts in offering an opportunity.. does NOT change its character as a mere territorial court"

10) In sum, the United States District Court of Southern Ohio is not an article 3 "District Court of the United States", It is an Article 4 legislative court limited to hearing civil suits.. but not a civil suit masquerading as a criminal prosecution by the Corporation of the United States v. SAAD SAKKAL, an artificial corporate entity, and not Dr. Saad Sakkal, MD, a live born sentient American. Sakkal was sued civilly under the guise of criminal prosecution.

The defense counsel did not challenge the District Court jurisdiction betraying his duty, and betrayed Sakkal's right under the 6th amendment. The Appeals Court did not verify the District Court jurisdiction either, depriving Sakkal of his rights according to the 5th Amendment. Both need SCOTUS review and remedy.

The District Court has no jurisdiction to prosecute Dr. Sakkal, and the government had no standing to initiate an indictment/True bill (a billing) to attach to his ESTATE/Trust known as SAAD SAKKAL ESTATE/Trust, as the accused in this case is NOT one and the same as the artificial corporate defendant. The government prosecution destroyed the private citizen Sakkal, for no justifiable reason, violating its Duty to Protect

III. Federal Judges Rule

The Sakkal's trial judge did not follow the first rule of all federal judges to "affirmatively establish on the face of the record the standing of government and the jurisdiction of the court to prosecute Dr. Saad Sakkal, MD.

1) Pursuant to Mansfield C&L.M. R. Co. v. Swann, 111 US 379, 382, 28 L. Ed 462, 463 (year missing), in part:

> "The rule springing from the nature and limits of the judicial power of the United States, is inflexible and without exception, which require this court, of its own motion,.. to deny its own jurisdiction. And, in the exercise of Appellate Power, that of all other courts of the United States, in all cases where such jurisdiction does not affirmatively appear in the record on which this exercise of that power, is called to act. On every writ of error or appeal the first and fundamental question is that of jurisdiction, first of the court, then of the court from which the record comes. This question the Court is bound to ask and answer for itself,

even when not otherwise suggested, and without respect of the relation of the parties to it".

"This principle of law has been reaffirmed again and again by: Capron v. VanNorden, 2 cranch 126, 2L.Ed.229 (1804) and its progeny (Brown v. Harris 1903; Morris v.Gilmer 1889; Hancock v. Holbrook 1883; Brown v. Harris 1903; Kentucky v. Powers 1906; Steel Co. v.Citizens for Better Environment 1998;) through Patchak v. Zinke, 138 S.Ct. 897 (2017)"

2) Pursuant to Caha v. United States, 152 US 211, 215, 38 L.Ed.415 (1894), in part:

"The laws of Congress..[.except.].. do not extend into the territorial limits of the States, but have force only in the District of Columbia.. (which nullifies 18 USC 3231 within the states)

3) In cooper v. Aaron (1958) "No.. judicial officer can war against Constitution"

As a result of the meaning of these accepted decisions, the United States District Court of Southern Ohio is an article 4 civil legislative court that had no jurisdiction to criminally prosecute Saad Sakkal, MD, with the judge failing to follow the first federal judges' rule, this case should be vacated ab initio

IV. MUTUAL DUTY OF PROTECTION AND ALLEGIANCE

1) In Filipino American Veterans & Dependents Assoc. v. US 391 F. Supp. 1314 (1974) posits:

"defining nationality as denoting the relationship between an individual and a nation involves the duty of allegiance on the part of the subject and protection on the part of the state"

2) Every American citizen has a duty of allegiance to the United States of America to be faithful to its laws, pay their taxes, respond when called upon for duty. The reciprocal is true-in that the U.S. has a duty of allegiance to the protection of the members of society-yet Sakkal has been deprived of said

"protection" by his unlawful prosecution when accused without proof of being a "drug dealer" and unlawfully placed in dishonor, BEFORE being tried

3) This principle was outlined in US. v. Wong Kim Ark., 169 US 649, 42L.Ed.890 (1898) where it reads that each citizen "is subjected to the duty of allegiance, which is claimed and enforced by the sovereign of his native land, and becomes reciprocally entitled to the protection of that sovereign and to the other rights and advantages which are included in the term "citizenship"

In Gardner v. Ward (1805) 2 Mass 244; and Fleming et al. v. Page, 9 Howard 603, 13L.Ed 276 "the duty of allegiance is reciprocal to the duty of protection"

4) It should be noted today every born American and every naturalized citizen are treated equally under the Constitution, and the Laws of the United States, without their permission, or consent every time.

5) Saad Sakkal's Prosecution violates the government Duty of Protection, when no crime or harm was caused by the accused, to either plaintiff, the government in this case, or the people, who never complained about Sakkal's treatment in any suit The petitioner quotes another Interim Decision:

> "A more reasonable interpretation of the phrase 'subject to jurisdiction' is that it connotes a duty or obligation on the part of both the government and those domiciled in the United States territory. On the one hand the government owes the DUTY OF PROTECTION, or grant of benefit and rights available to other (and all) citizens; and on the other hand. the citizen owes the duties which every citizen owes to this government if and when he is called upon to perform them. That the debt may not have been called in, does not mean it does not exist."
>
> Interim Decision # 2748: Matter of CANTU, 17 I.+N. Dec.190 (BIA, A.G.1978)

In one Deportation Proceeding, the following reads:

> "..When a state has-'by word and by deed', ante, at 197,103L Ed 2d, at 260- announced an intention to protect certain class of citizens and has before it

facts that would trigger that protection under the applicable state law, the constitution imposes an affirmative duty of protection" DeShanney v. Winnebago Soc. Serv, 489 U.S. 189, 103 Led 2d 24 (1989). "Except for the eligibility to the presidency, naturalized citizens stand on the same footing as do native-born citizens. All alike one allegiance to the government, and the government owes to them the DUTY OF PROTECTION. These are reciprocal obligations, and each is a consideration for the other." See Luria v. US, 231 U.S. 9,22,58L Ed.101, 105, 34 S.Ct Rep10 (1913); Minor v. Happerset 21 Wall.162, 165, 22L, ed.627; Elk v. Wilkins,112 U.S. 94, 101, 28L Ed. 643,645, 55 S.Ct Rep 41 (?); Osborn v. Bank of US, 9 Wheat.738,827, 6 L Ed.204

V. Conclusion:

The petitioner is a loyal American citizen since he pledged allegiance in September 1981, served jury duties, paid all taxes, served at National Institute of Health and Wright Patterson Airforce Base, who offered him a full-time job. He is entitled to Protection right, need SCOTUS to enforce Government Duty of Protection, Not to deprive him by prosecution, and incarceration, losing his life, and five states medical licenses.

14) the court should hold that counsel was ineffective with these few examples of errors, intentional or unintentional miscalculation. because of limited space more errors are explained in appendix E.

As expressed by Judge Ely in United States v. Rosenberg at 206:

> "it is inconceivable that an unconstitutionally vague.. and ambiguous penal statute can be cured by a regulation by a prosecuting agency." "To permit the AG (Attorney General) to answer that question, in the guise of issuing an interpretation would be, in my view, to countenance an intolerable violation of the doctrine of separation of powers".

Indeed in their brief of Pacific Legal Foundation supporting RUAN certiorari, C Kruckenberg, et al reasoned:

> "Only Congress may create a new criminal offense; allowing the DEA to do so violates the non-delegation doctrine (Id at 8); a regulatory agency, particularly a prosecutorial one, cannot decide, on its own, that such a conduct should be unlawful. Fair notice, the separation of powers, and our constitution's essential desire to maximize liberty must not be casually cast aside." Id at 19.

They cited Gorsuch opinion in Gundy v. United States (2019) 139 S.Ct. 2116, 2131:

> "A delegation that purports to endow the nation's chief prosecutor with the power to write his own criminal code scrambles the design of the constitution, which promises that only the people's elected representatives may adopt federal laws restricting liability."

This doctrine was recently further affirmed in Loper Bright Enters v. Raimondo 144 S.Ct 2244, 6/28/2024, and the petitioner hopes SCOTUS WILL EXTEND its wise doctrine, as well to 21 U.S.C. #841(a) physicians cases for affirmation of this commonsense doctrine.

CONCLUSION:

This humble accused physician -who was not allowed by his counsel to testify to defend his honor and life, despite intense requests- had presented himself to your wisdom, mercy, and integrity after having spent more than 45 years of his life in human

ethical service, education, research, innovation of better therapies, without ever committing a crime. Yet he is imprisoned wrongly for the last 7 years, despite multiple appeals in the 6th Circuit where he has no chance of fairness.

For the above forgoing reasons stated in this petition for a writ of certiorari rehearing: Court(s) plain errors, defective Jury instruction regarding Men Rea and Burrage clause, unconstitutional legal basis, biased drug conversion table, the petitioner respectfully pleads to This Honorable Supreme Court of United States to grant ORAL rehearing of the petition, or vacate ad abinito, expunge the record, restore petitioner previous civil and human rights, court order restoration of his Medical Licensure in the all States where he was licensed, because this is the only way to restore his pre-prosecution rights for livelihood, life, liberty and the pursuit of happiness, as a government's Duty of Protection due to his Allegiance to his beloved nation.

Updated 10/24/2024

Respectfully submitted,

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