20-7934

TRULINCS 14290003 - COUCH, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: REPLY Cover Page
DATE: 08/11/2021 12:32:49 PM

20-7934
No. 20-7924

Dr. John Patrick Couch,

-Petitioner

v.

United States of America,

-Respondent

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals For The Eleventh Circuit

---

REPLY BRIEF FOR PETITIONER

Filing Pro Se

John Patrick Couch, M.D.

August 10,2021

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: List of References
DATE: 08/11/2021 12:34:13 PM

TABLE OF AUTHORITIES

United States v. Hurwitz,
459 F.3d 463 (4th Cir. 2006).....passim

United States v. Moore,
423 U.S. 122 (1975).....passim

United States v. Arny, 831 F.3d 72596thCir.2016).....passim

United States v. Parkes (6th Circuit 2012) 688f.3d, 295,307

United States v. Solivan(6th Circuit 1991).....937F.2d.1146,1150

Trial Transcript.....Tr. Doc 722; V 1-40

Decision, U.S. COURT OF APPEALS FOR 11th Circuit, Doc.No 1:15-cr-00088-CG-B-2, filed 7/25/2020

FROM: 14290003
TO: Couch, David
SUBJECT: New First Page REPLY
DATE: 08/11/2021 12:33:54 PM

IN THE SUPREME COURT OF THE UNITED STATES
No.20-7924

REPLY BRIEF FOR PETITIONER

The legal foundation for this petition for writ of certiorari has been concurrently established by this Petitioner's codefendant, Dr. Xiulu Ruan and his legal counsel in separate filing of No. 20-1410, July 20, 2021. Defendant-Co-Petitioner John Patrick Couch, M.D. therefore adopts all arguments and supporting factual statements from the REPLY BRIEF of Co-Petitioner Xiulu Ruan, M.D. to the full extent any arguments, statements or facts that apply to Dr. Couch. See Fed Rl App.P 28(i); 11th Circuit R.28-1 (f).

Therefore Petitioner will address related issues related to the case and errors that have been presented by the Government Respondent in its REPLY BRIEF.

As at trial, to inflame the observer, and therefore the jury as well as the Court, the Government goes to great lengths to paint the defendants as interested only in the pecuniary aspects of their respective medical and surgical practices. Nothing could be farther from the truth as revealed after close inspection and examination of the facts. For example, in the [Government Reply, page 3], in states that "Between January 2011 and May 2015, each petitioner made more that $3.7 million from the clinic and more than $550,000 in prescription service fees from the pharmacy'. This was over a 4 1/2 year period and each Petitioner paid all applicable taxes to the IRS during the life of the practice and never had any troublesome issues with the IRS.

Agent White testified for the Government that C&R Pharmacy had paid $105,000 to each of the Petitioners between January 2012 and March 2014 and $450,000 to each in staggered payments to the Petitioners between April 2014 and January 2015, for a combined total of $550,000 total to each Petitioner.[Tr.Doc. 2/2/2017 pg 4159-60.] However, Agent White then testified that the Petitioners had to pay INTO the pharmacy the amount of $1,130,205.20 to "keep the pharmacy afloat". [id. pg. 4161-62] This means that the Petitioners LOST revenue from the company to the tune of $15,102.70 each.
As Agent White testified upon cross examination with Ruan counsel Mr. Knizley:
Q: "Did you show a payment to C&R Pharmacy, LLC?"
A: "Yes"
Q:"In what amount?
A: $1,130,205.20 (Id. pg. 4905)

The evidence therefore clearly shows that the pharmacy never made a profit for the doctors despite the Government's claims; it conveniently ignores this fact.
The pharmacy was initiated mainly as part of the multimodal, multidisciplinary clinic as a great convenience to the patients, many of whom were disabled, elderly, and battled significant transportation and logistical issues in getting to their monthly, bi-monthly, or tri-monthly appointments to see their doctor or to undergo diagnostic testing. It offered patients optional use and convenience.[Tr.Doc.722:V14:3143;V15:3604] The practice had three separate locations during the period of the investigation, and employed 57+ employees during the relevant time period. This required substantial 'reinvestment' of the doctors' earned income to improve the practice year over year.

The Petitioners were both very highly trained specialists with multiple board certifications and years of added training in this subspecialty of medicine and it is no surprise that they would earn more that their colleagues than if they had chosen to continue on in their primary specialties of medicine that they otherwise would have if they had remained in that field. Specifically, for Dr. Couch, as a practicing anesthesiologist, or Dr. Ruan as a practicing Physical Medicine and Rehabilitation specialist. Each doctor was also trained in and board certified in Addiction Medicine, as Dr. Ruan was only the 11th doctor in the State of Alabama to achieve this and Dr. Couch was the 12th in the state. Chronic pain is a disease in and of itself and is a severe problem for many individuals and often is not cured. [Tr.Doc. 722:V10:2258] The therapeutic goal of a interventional pain management physician is to control the patient's pain, improve their physical functioning, and provide an improved quality of life, and when possible, enable the patient to continue working. [Tr.Doc. 722:V26:6048]. PPSA was treating approximately 8,000+ active patients at its combined locations divided between three physicians, 6 nurse practitioners, and one Doctor of Nursing Anesthesia [Tr.Doc.722:V24:5560]. PPSA treated only patients who were referred from other physicians or surgeons who had seen the patient several times and the referring doctors were required to transmit patient files for the PPSA personnel to

evaluate whether patients were appropriate for chronic pain management. [Tr.Doc. 722:V5:877] The treatment plan many times included interventional procedures to treat the pain and in some cases to serve as part of the diagnostic work-up to locate the source of the pain including, but not limited to: X-Ray guided nerve blocks, facet joint blocks, epidurals, 'trigger point' injections, spinal vertebral percutaneous placement of 'bone-cement' for vertebral fractures resulting from osteoporosis, spinal cord stimulator implantation, and pain pump implantation. [Tr.Doc722:V19:4453; V23:5243-44;V26:6048-50]

The Alabama Prescription Drug Monitoring Program (PDMP) was checked daily on each patient seen in the office to avoid patients appearing to be "doctor shopping" seeking controlled substances.[Tr.Doc.722:V25:5842-43] Numerous patients were rejected.{Tr.Doc. 722:V20:4680,4683;V10:2264;V21:4966;V22:5164] The Petitioners could only check the PDMP databases of the states within which they were licensed. So they could only check the states of Alabama, Florida, Georgia, or California. Patients were required in every case on admission to the practice to sign an "Opioid Agreement" which was the standard of care, to take the medications as prescribed and to not seek controlled substances elsewhere and to get them from only one pharmacy of their choosing. [Tr.Doc.722:V19:4455] Random pill counts were utilized requiring patients to bring in their prescriptions to determine if the medications were being taken as prescribed. [Tr.Doc 722:V13:3073]. Tamper resistant medications were prescribed for some patients, including several relating to Government testimony. [Tr.Doc.722:V11:2492;V25:5819] Referral was made to psychologists and psychiatrists to ensure pain pump patients were psychologically prepared for implantation of a device. [Tr.Doc.722:V21:4921-22] PPSA only accepted patients with insurance and refused patients paying cash as the primary form of payment in an effort to keep out malingerers or those "seeking pills". [Tr.Doc.722:V22:5100]

The Petitioners had planned to close down the on-site pharmacy at the Airport Boulevard location in 2013, but due to patient response of those patients who pointed out to the Petitioners that the on-site pharmacy greatly reduced their burden of having to make two trips or more each month or every 60-90 days to the doctor and to a pharmacy in order to get their prescriptions filled. The pharmacy was staffed by a pharmacist who sat on the Alabama Board of Pharmacy, Dan McConahay, D.Ph., and was managed and operated by his own pharmacy chain that was not associated with the medical practice. Plus the clinic pharmacy kept in stock some of the special medications that a particular patient might need, that were not routinely stocked at community pharmacies. There were many advantages for the patients to have that as an option. No one was ever coerced in any way to use the pharmacy. They were always told that they had the right to get their prescriptions filled anywhere they chose.

Thus, the Petitioners were not involved in the day to day management or operations of the full-service pharmacy. The patients could also get their prescriptions filled there at that certain practice location that had been written by their primary care doctors for their other needs, such as their diabetic medications, antihypertensives, antibiotics, seizure control medications, and any other types of prescription, so that they would not have to travel to another location to complete their outing to see the doctor. The doctors made the substantial investment in the clinic pharmacy to stock all of the medications that they might need filled, not just pain management related meds. After all, if the patient had to also go to another pharmacy to get their other prescriptions filled, that would defeat the purpose of having the pharmacy in the first place. However, only one of the 3 locations of the PPSA practice had a pharmacy like this, and most patients got their prescriptions filled at an outlying pharmacy or in their own hometown anyway. A seperate location at Springhill Avenue housed the 'compounding pharmacy' to mix and prepare the special mixture of intrathecal, preservative-free medications, and opioids that were injected percutaneously into the patients that had implanted spinal drug delivery devices/pumps, and needed them refilled usually every 60 days or so. Again, the practice had over 700 of these special needs patients.[Tr.Doc.722:V21:4920-22]

Due to the inherent nature of a modern interventional pain management practice like the Petitioners', patients are typically seen every 30, 60 or 90 days depending on how well established of a patient that they are, and this helps to insure compliance with their medication regimens and to ensure that they are abiding by their signed "Opioid Agreement' that all patients within the practice were required to read, understand, and sign at their initial intake consultation. This was and is the standard of care in this subspecialty of the practice of medicine and is how the Petitioners were trained in their pain medicine fellowships. This frequent patient follow-up plan added to the raw number of office visits, and therefore the overall number of the prescriptions written to each patient over the 4 1/2 years of the investigation. So any claim that the pharmacy existed only to "line someone's pockets" , or that the number of prescriptions somehow indicated that the Petitioners were practicing "outside the usual course of professional practice" regarding the pharmacy operation and the number of prescriptions, is patently false. The doctors did indeed lose money on the pharmacy from day one as was, again, proven at trial by Agent White of the FBI, a CPA, in her testimony. Even though this was proven at trial, yet the government deliberately tries to perpetuate this falsehood about the Petitioners' practice.

This model was instituted by Dr. Couch based on the facility where he had trained at UCLA. The Pain Medicine Center there in Los Angeles had an in-house pharmacy, as well as an Open MRI, as did PPSA, as many multi-physician clinics and outpatient facilities have today, and it is in no way illegal. Many multi-physician practices today install on-site full service pharmacies. It is

Over 700, about 9% of the 8000+ active patients managed at PPSA, had implantable spinal drug pain pumps implanted, usually by Dr. Couch, although Dr. Ruan and Dr. Chen had implanted some. Some of the patients were "inherited" from other practices after the patients had moved to the area from distant states or areas of the country to the Gulf Coast area and needed someone to manage their pumps. These ingenious, totally implanted devices can be a lifesaver for these difficult cases and are ideal for patients that require higher dose oral or transdermal opioids or muscle relaxants for spasticity because they only require 1/100-1/200 or less of the daily oral dose and help to get the patients completely independent of oral opioids in many cases and greatly improve their quality of life and activities of daily living. They deliver the medication, including very, very low dose opioids directly to the spinal fluid in the low back, and block the pain at the spinal cord level. PPSA was the leader in this technology in the entire area from Houston,Texas to Jacksonville, Florida and indeed would manage the 'snowbirds' patients that would come down to the Gulf Coast beaches during the winter months or permanently to retire and needed a specialist to manage their devices. Dr. Couch tried to demonstrate this device to the jury but was dissallowed to by the court on Government objection to relevancy. PPSA also implanted and maintained hundreds of spinal cord stimulator devices for chronic pain, primarily for failed back surgery syndrome pain over the years and many of these patient simply got better and were only seen every few years when they needed battery replacement of their devices or device replacement for some reason.
So, a significant portion of the income to the practice, at least for Dr. Couch's practice was due in large part to the surgical implantation and mainly maintenance and refill of these devices about every 30-60 days in the office and PPSA employed at all times at least one full-time specially trained "implant nurse" to help the doctors to coordinate and maintain these special patients. Dr. Couch, through his legal counsel, tried to demonstrate this procedure to the jury, but was not allowed to after the government's objection and the court sustaining it.

The government states their REPLY that the petitioners had written "nearly 300,000 prescriptions for controlled substances, the majority of which were Schedule II drugs""The most powerful and dangerous drugs that can be lawfully prescribed"" (pg. 3 of REPLY). The actual number was about 280,000 and only 56% of this number were the Schedule II class, meaning 156,000 by both physicians over a four year period. In reference to Government chart titled "DR. JOHN PATRICK COUCH, Selected Drug Total January 1, 2011-May 19, 2015", they list the total number of prescriptions of Dr. Couch including both for the TIRF drugs and the other Schedule II drugs, the total was 18,631. (Gov't Exhibit 10-3, Case:17-12653, admt. to evidence 1/19/2015)The similar chart/graph shown for Dr. Ruan showed at full total of both TIRF and Schedule II medications as 8,910 under "number of prescriptions total". The 'pie chart' from chart labeled "DR. JOHN PATRICK COUCH Prescriptions by Schedule ,Selected dates, (Gov't exhibit 10-14 adm. to evid. 1/9/2017) shows that of that number, only 56% were Schedule II's with Schedule III's being 20% at 2,067 prescriptions, and 21% of the total being Schedule IV's and 3% Schedule V's. this includes drugs used for neuropathic pain or "nerve damage pain" which is difficult to treat, including Neurontin for diabetic neuropathy or Klonipin (sch.IV) for nerve injuries. For a practice of over 8,000 active patients,these are not an unreasonable number when the fact that the patients had to be seen often, every 30-60 days in most cases, and every 90 days in some of the patients that were long term, well established and lived far away. They insist on using inflammatory adjectives to describe the drugs like: "potent, "powerful" and "dangerous".

Dr. Couch is a board certified anesthesiologist who at the time had over 22 years experience and who had been extensively trained particularly with Fentanyl during his anesthesiology residency at the University of South Florida/Tampa General Hospital and affiliated hospitals to utilizing Fentanyl extensively in almost every one of the over 20,000 anesthetics that he administered during his successfully completed residency in 1995. Fentanyl, after all, is the most extensively used opioid in the operating room since it's introduction in 1961 due to its excellent cardiac stability. His training included 6 months of cardiothoracic anesthesiology where large amounts of Fentanyl are used on the patients undergoing heart and chest surgery in order to place them on cardiothoracic bypass during the surgery. Dr. Couch had served as a speaker for several companies that manufacture those medications and had trained medical students and residents during his tenure as Adjunct Assistant Professor of Neurology at the University of South Alabama.

Dr. Couch was therefore well aware and well trained in the use of Fentanyl and any inherent considerations or risks it has both inside and outside of the operative room and clinic and its showed in that there was not a single incidence of morbidity & mortality during his practice. The same simply cannot be said of the experts that the government put on to testify against the petitioners. None of them were anesthesiologist nor had ever worked with chronic pain patients or were well experienced in the use of Fentanyl in particular at any time of their practices. Dr. Greenberg actually had been dismissed from his anesthesiology residency due to his own fentanyl addiction, and never had returned and had never completed ANY residency in ANY field of medicine, and thus could hardly be called an "expert" on the matter by any standard. [Tr.Doc.1/12/17 p. 603, Id.pg.603-604]

The Galena stocks purchased by Petitioners was done so with personal after-tax funds and not with PPSA practice funds through their personal ETrade accounts; not an illegal activity.

FROM: 14290003
TO: Couch, David
SUBJECT: REPLY IV
DATE: 08/10/2021 05:55:43 PM

It was purchased due to the petitioners belief at the time in a pipeline drug that Galena Biopharma had at the time called NEUVAX, a promising breast cancer vaccine that had been in development by the U.S. Army at one time and the the company was testing for commercial use. They petitioners learned about this vaccine at their respective 3 day educational conferences that they were required to complete in order to be speakers for the pharmaceutical company. One learns not only of the medications of which they will be educating their colleague physicians about around the country or in their own areas, but also about all of the drugs in that company's pipeline and all of their COMPETITOR'S medications as well, so it is an excellent way to supplement one's continuing medical education while in busy private practice. The stock purchase in no way affected the petitioners prescribing habits and to believe that the petitioners believed that they could affect a stock price of a particular company on the New York Stock Exchange with a few prescriptions is unfounded. A few of the other employees at PPSA including government witness Justin Palmer also purchased some stock in the company after researching the breast cancer vaccine himself that was in the drug pipeline of the company.

As for speaking fees from any particular pharmaceutical company, it is not illegal to be a selected speaker for a pharmaceutical company. The petitioners had both participated in this for several companies over the years including for non-controlled substance medications (as well as several medical device manufacturers such as St. Jude, Medtronic, Stryker, and Johnson and Johnson/Codman-makers of spinal pain pumps, spinal cord stimulator devices, and spinal kyphoplasty devices for repair of fractured and compressed spinal vertebrae). These speaker agreements also included teaching about non schedule II medications such as Gralise (basically a time release neurontin/gabapentin), Vioxx (an anti-inflammatory medication for arthritis), Amrix (a muscle relaxant), Gabatril (for seizures and chronic neuropathic pain), Skelaxin (a muscle relaxant), Pristiq (an anti-depressant). But both petitioners were also speakers for competitors of Galena Biopharma such as for Fentora, and Actiq. So the petitioners wanted to be well educated on all of the different products in each drug class that could affect how they managed their patients and did so by being selected to be speakers for the different companies. A physician must be a noted in their field to be asked to be a speaker for their products and it is a privilege to be approached to do so. To allege that speaking for these companies is somehow lucrative or that profit motive drives one to be a speaker again misses the mark by being uninformed on the truth.
Speaking for a pharmaceutical company takes a significant amount of time away from the office which a physician has a number of employees on the clock (PPSA had around 57 employees on the clock which they were away giving a talk during office hours). This is time in which the physician could certainly earn more money treating patients than what he would receive in the $500 PRE TAX check that they would receive for the 2-3 hours away from the office that a daytime talk would require with travel, traffic and the rest is factored in. It can be disruptive to the daily schedule if attention is not attended to it, so it is not done for the fees that are paid. And to travel out of town to give a talk and therefore miss a whole day of clinic and/or surgeries performed is even worse, whereas the $1000 that petitioners receive after tax is not worth the hassle and loss of revenue for missing a day at the office. That that is not it either. It is done for as mentioned, medical education, to stay current of recent medications that have been developed and introduced, and to be able to associate with one's colleagues and to network and promote the services offered at ones own clinic and to learn what other doctors are doing in their offices and what the trends are.

Petitioners, as mentioned and suggested in the government REPLY on page 4, had no loyalty to Galena Biopharma whatsoever, and that fact has been shown, as the use by the petitioners of the Galena's "voucher program" allowing the petitioners' patients to receive FREE medication, actually harmed the companies bottom line to some extent, and shows that the petitioners were not focused on the stock price as it related to the Abstral prescriptions that were written. Indeed, as shown in "Government Exhibit 10-3", Dr. Couch had prescribed the competitors "Lazanda" a TIRF drug, to 16 patients, which clearly demonstrated that he chose from each drug in that class depending on the particular patient and neither. Those prescriptions were written for carefully selected patient who each had a clear indication for the rapid onset drug as part of their armamentarium to battle significant severe breakthrough pain that was becoming a problem and to help keep the patients out of the emergency room and off higher doses of the longer acting opioids that they otherwise would have needed. All of this is how each petitioner was trained in his pain medicine fellowship programs and was and is the standard of care. There was a well thought out REASON that each patient was prescribed the way they were. Dr. Couch had only 194 patients on Abstral during the 4 1/2 years, most all receiving the free voucher coupons to TRY the drug first to see if that delivery vehicle afforded them some improvement in their activities of daily living (ADL) and overall pain control. (Govt. Ex 10-3)

Petitioners do not see anywhere in the care of their respective patients where they could have fallen outside the course of the usual professional practice nor treated anyone in any manner without a legitimate medical purpose. These patients were very complicated. The petitioners did not usually receive patients on referrals with simple lumbago or sciatica for treatment of a

"slipped disc" who needed an epidural or such. That did happen, but the norm was the very complex post-surgical patient, or the patient who had undergone radiation therapy and chemotherapy for malignant cancer, or the post-trauma patient who had failed conservative therapies, or even from other pain management physicians.

The petitioners clinic was located along the southern Gulf Coast of the nation were there is concentrated a great deal of industry and military installations with a large base of blue collar workers and work related injury patients. They therefore were referred a large percentage of their patient population that was disabled, on workman's comp, or Medicare and the physicians in that area needed a multidisciplinary, experienced clinic where to refer their chronic pain patients, including, as mentioned before, the VA hospitals and it's clinics along the Gulf Coast from the panhandle of Florida to Biloxi, Mississippi and the VA clinics and military clinics that are there. Indeed, government witness patient David Riley was referred to the clinic from the VA hospital in Biloxi.

Dr. Couch's experts, including Harvard professor Carol Warfield, M.D. testified that the patients that she reviewed where "some of the most complicated that I could imagine." [Tr.Doc. 722-21 at 60-62]. Dr. Warfield also testified that each and every prescription issued by Dr. Couch was both within the standard of care and for a legitimate medical purpose.(same) The issue on the issue of "Good Faith" has already been settled by the Supreme Court in <United States v. Moore 423 U. S. 122(1975)> and by other circuits including the Fourth Circuit in 'United States v. Hurwitz' where that verdict was overturned by the Appeals Court of the Fourth Circuit for precisely that same thing as in petitioners trial: that 'Good Faith' was not allowed as a defense. (See "Hurwitz") The 11th Circuit has played and outlier with the rest of the nation on this issue and we ask this court to resolve the issue and bring all of the circuits into alignment on this very important issue so that medical professionals targeted can construct a valid defense for themselves which is after all their respective right. But this has been well covered by petitioners co -defendant's legal counsel in separate REPLY to the government's brief.

The government claims on page 23 of the REPLY that " that approach allowed petitioners' clinic to process ""upwards of ...150 to 200"" patients each day". This does not account for the 3rd physician on staff, and his patients that he saw, Dr. Chen, nor does it account that some of those patients that were 'processed' were at the clinic to have their MRI's performed (usually 12-15 per day) nor those that were there just to pick up their due prescriptions from the prescription nurse or for physical therapy when that was offered at one of the clinics until 2013. Nor does it account for the patients that were called in routinely for random "pill counts' and urine drug screens to monitor their compliance with their respective "opioid agreements". These would all have been on the electronic medical records' daily log. If one factors in the 3rd physician plus the fact that the clinic employed 6 nurse practitioners to assist the physicians in collaborative practice, which today is common practice in all medical specialties, among the 3 doctors 150 or even 200 patient a day is not unusual for a busy multi-member private practice. That, taken liberally even, would mean 50 to 65 patients per day for each doctor in that number including new consults, follow-up visits, and procedures performed in the office daily. Not an exorbitant sum. Dr. Couch had 'fired', or released over 250 patients during the January 2011-May 2015 time frame of the investigation. [Tr. Doc. 722:V25:5839]. This equates to approximately one patient per week in a 5 day work week over the 4 years. Each patient that was released by both Petitioners was mailed a form letter informing them that they were being released from care after the next 30 days and were given the contact information for the 'Mobile County Medical Society' in order to find another physician to preclude patient abandonment.

The government tries to blur and confuse the court in it's REPLY, is that the is no Federal definition and no Federal standard regarding the "usual course of professional practice " or "legitimate medical purpose", the DEA does not define the terms used in the CSA, these two terms that a jury is instructed on when a physician is charged under the Controlled Substances Act (CSA) [Tr.Doc. 722:V2:140, Doc 722:V4:807-08;V19:4457-58;V21:4785,4792]. Therefore, juries can be confused on what is the issue at hand, particularly when "the usual course of professional practice" is defined by the governments' medical experts during testimony, which in Petitioners case was flawed, therefore their testimony is the only basis that a jury has to describe or define what constitutes "usual course of professional practice". The government claims "overwhelming evidence" that petitioners dispensed dangerous and addictive drugs to serve their own financial interests rather that to further any legitimate medical purpose of adhere to any arguable, reasonable, or subjectively perceived professional standard" see REPLY page 23. Petitioners tried multiple times to introduce evidence to refute this type of outrageous claim duding the trial but was told by the Court "There will be no testimony concerning patient files not directly related to the allegations of the indictment; in other words, no testimony concerning patient files which were not allegedly criminal prescriptions written or dispensed";"there will be no evidence concerning good patients or the non-illegal patients, because that is not relevant to this case" [Tr. Doc. 722 at 4-5] id. at 17. And with that, and the fact that the government was granted pretrial an in limine ruling to limit evidence and testimony including from Petitioners' expert witnesses and any undercover videos favorable to the petitioners [see Tr. Doc. 400, Doc. 722 at 14-19], the Petitioners were barred from providing clear evidence to counter the governments sweeping claims against them. Again, despite the District Court's refusal to permit petitioners to introduce any other patients because the Government objected, the Government argued in closing that these five patients were all the petitioners could muster in support of their case: "We called for you 14 patients in comparison to the few patients the defense called". [Tr.Doc. 722-27 at 204]. Dr. Couch raised this issue, again, in his motion for a new trial which the Court denied. [Doc. 530 at 12-13;Doc. 703 at 13].

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: New Page III Reply
DATE: 08/11/2021 12:33:12 PM

After the Government closure of the practice, hundreds of special needs patients with implantable devices, suffering with highly documented chronic pain and disability, along with the other 8,000+ patients within the practice, were left with nowhere to go and no subsequent plan had been arranged by the Government to arrange care for these complex patients. Dr. Couch met with the FBI agent Amy White, and DEA agent Michael Burt the afternoon after DEA closure of the practice and was told that there was no plan in place to procure subsequent care for any of the patients. The Alabama State Medical Board contacted Dr. Couch a few days after the practice closure and asked him to assist them in finding other physicians and to provide care for the patients, particularly the spinal pain pump patients, and Dr. Couch assisted them the best he could. The Board was concerned that a public health crisis was brewing as the patients did not have readily availible other doctors to turn to in order to provide continuing care.

Seeing patients frequently in follow-up was and remains the standard of care in the subspecialty of the practice of pain medicine and is how the Petitioners were trained to practice in their pain medicine fellowships. This added to the raw number of office visits, and therefore the total number of prescriptions that were written by the Petitioners over the 4 1/2 years of the investigation.

The patients at PPSA were seen more often than patients would be in other fields, like internal medicine of family medicine, in order to closely monitor the medication usage and to help insure compliance. The 35 patients that the government had testify at trial all had legitimate medical purposes for their prescriptions. As the Government stated in the opening arguments:

"prescribing a controlled substance is illegal unless there's two things that happen:It's prescribed in the usual course of professional practice and it's prescribed for a legitimate medical purpose. So both things have to be there. You can have somebody that has a legitimate medical purpose for a medication--and you're going to see that a lot in this case. A lot of the patients that went to PPSA, the clinic there, had legitimate medical problems where pain medicine may have been appropriate. But just because there is a legitimate medical need for controlled substances does not make the prescription legal if it's prescribed outside the usual course of professional practice". [Tr. Doc. 722-1;pg.28]

So, the question remained then if any of the patients called to testify for the Government were treated "outside the usual course of professional practice." The thousands of patients that treated at PPSA were not treated outside of the usual course of professional practice and a total of three board certified pain medicine specialists who actually had been trained and practiced within the specialty for their entire careers, much like the Petitioners, and therefore were qualified to opine on the Petitioner's and their level of care and how they treated the patients and prescribed the medication to them, and in particular the controlled substance to their respective patients, testified in that regard. The patients that the Government called were by in large presented questioned and testified as if it were a malpractice case, and PPSA was portrayed to the jury as it it were some type of "Animal House", yet the Petitioners were not allowed to call anyone to refute that charge (either former patients or referring physicians) due to the sweeping pre-trial in liminae ruling by the court, which the Government took full advantage of, to disallow the Petitioners to demonstrate any examples of 'good faith'. Specifically, the Government told the jury:

"Instead of being a legitimate medical practice, it was almost like an Animal House" [Tr. Doc., pg 6174-day 27]

Thus, as the Petitioners were not allowed by the District Court to provide any examples of"good faith" or show any "good acts", or to build on "good faith" as a defense in the 11th Circuit, they were completely hampered in mounting a theory of defense against such ridiculous charges by the Government before the jury in their trial.

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: New Page VI
DATE: 08/11/2021 12:35:16 PM

The patients called to testify by the government may have voiced in some cases an unhappiness with the medications that they were prescribed or that they had some minor problem with them and they had been changed. [Tr.Doc.722-6 at 27-30] Not all patients that are treated in a medical practice, particularly in a pain management practice where the conditions that the patients suffer with are chronic, and they have routinely been treated by a litany of physicians and/or have undergone invasive surgeries that have even worsened their pain experince, they can generally be pensive and contemptual about anything that is has been tried to improve their conditions. That does not meet the level of proving beyond a reasonable doubt that the medications were prescribed outside the usual course of professional practice or that the course of treatment was outside the usual course of professional practice. Indeed, patient David Riley, the quad-amputee Coast Guard veteran of the year actually testified favorably for Dr. Couch, even though he was called as a government witness, saying in essence that he was still alive due to the treatment that he had received from Dr. Couch over several years and had no complaints about Dr. Couch's treatment. [Tr. Doc. 722-20 at 55-144] The Government chose 16 'cherry-picked' patients of Dr. Ruan's to testify who were described by defense expert, board certified Dr. Gudin as "very challenging", but that Dr. Ruan's treatment of them was 'exemplary" {Tr.Doc. 722:V26:6044-45]

All patients were seen and given an extensive initial evaluation, history taken, and physical exam, some required Open MRI imaging in an effort to identify the source of the pain. Many underwent interventional procedures to classify and hopefully treat their chronic pain. In some cases, reasonably low dose opioid prescription regimens were utilized all within FDA recommendations in every case. All underwent random urine drug screens to help ensure compliance which had essentially become the standard of care in the nation. [Tr. Doc.722:V21:4969] However, up to 40% of the screening cup tests could render false results, thus when appropriate, the screens were sent out for more reliable GC/MS testing. [Tr. Doc. 722:V9:2076;V102223-25;V25:5831-32] Alabama guidelines did not require this testing, but PPSA did it anyway. [Tr.Doc.722:V21:4787-91] Defense expert Gudin acknowedged that Dr. Ruan was board certified in addiction medicine and thus qualified to make that determination. [Tr.Doc.722:V23:5326-27]. There were no prescriptions written in any case of the patients shown at trial were the dosage was even near 100% or more above FDA recommended doses. Down the line, they all were on usually 20-50% of the FDA dosing recommendations with any of the drugs. It was just an inherent policy at the clinic to keep the doses themselves low in an effort to eventually wean the patient off using multi-modal treatment methods or in some cases implantable therapy to provide the patient a pathway to opioid dependence. But in a patient population like the Petitioners', in some cases that just wasn't a feasible alternative. The VA is on record stating that some patients may need to be on opioids for chronic pain treatment for life to improve their function, quality of life, and activities of daily living.

As stated, Mr. Bodnar for the government explained to the jury that PPSA definitely was not a "pill-mill". He told the jury in opening statements: "Now, I know a lot of you talked about in jury selection -- there's been a lot of talk about pill mills. And when at least I think of pill mills, the classic thing that comes to mind is people driving in from , say, Kentucky or Tennessee or Ohio of South Florida paying cash, getting prescriptions for Oxycontin, Roxicodone. That's not what this clinic was about. That's very, very, very different from how this clinic operated." [Tr.Doc. 722-1;pg.28] This despite the fact that the Indictment's primary theme asserted that the Petitioners operated "in essence a pill mill" and that prescriptions for controlled substances were "written for no legitimate medical purpose or outside the usual course of professional practice." [Doc:269, && 28,50.]
Paragraph 28 of the Idictment's introductory section alleged about PPSA:

"Members and associates of the PPSA Enterprise primarily operated the enterprise as a pill mill where numbers of prescriptions for Controlled Substances were written for no legitimate medical purpose or outside the usual course of professional practice."

Paragraphs 1-52 of the introductory section, including 28 and 50, were realleged and incorporated into every count. (Doc. 269)

PPSA was nothing of the sort at all comparable to a pill mill. What it was was a highly skilled, multi-disciplinary, multi-modal interventional pain management practice that was staffed by 3 highly trained medical doctors working in tandem in 'collaborative practice' with 6 nurse practitioners and a doctor of nurse anesthesia modeled after where Dr. Couch trained at UCLA Medical Center who admitted only selected, referred patients with medical records who had already failed more conservative therapies at outlying practices and clinics. At that facility in Los Angeles, there was an in-house pharmacy and Open MRI. PPSA had those too. In fact the pharmacy at PPSA was staffed by a standing member of the Alabama Board of Pharmacy to help ensure that all practices and procedures where up to date and within the current standard of pharmacological practice in the State of Alabama.

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: New Page V
DATE: 08/11/2021 12:35:31 PM

The practice was never found to have any irregularities in billing ever in all of the in-house audits that were performed by both Medicare and Blue Cross Blue Shield or any of the other insurance companies. The fact that the practice operated on a 'insurance only' basis precluding primarily cash paying patients, meant that each patient had to be "pre-authorized" for each and every visit, each and every prescription and each and every interventional procedure or surgery as well as any diagnostic tests including the urine drug screens and the Open MRI studies that any patient were to receive. This also proves added medical necessity as a third party had reviewed the medical record of each and every patient when approving each and every prescription, test, office visit, or procedure performed on the patients.

These studies included diagnostic nerve testing (Dr. Ruan was board certified in Neurodiagnostic Medicine and performed the tests on each patient indicated for that), physical therapy services (which ended in 2013), drug screen testing on site, and in-house Open MRI. All of these diagnostic services aided the doctors in making the correct diagnosis and in trying to identify the source of the patients pain problem, which in some cases was not always possible to locate, but attempts were made on a daily basis including 2 interventional procedural fluoroscopes and ambulatory surgery suites at each location where procedures were performed routinely on 30-45 different patients on a given 5 day work week among the three physicians and the one doctor of nurse anesthesia. The Open MRI serviced routinely 12-15 patients per day which were each read by board certified radiologist at one of the local hospitals off site. This greatly added benefit to the practice in guiding treatment decisions and improving patient outcomes.

The government also takes great issue with the fact that the TIRF (Transmucosal Immediate Release Fentanyl) delivery vehicles were used in some of the most challenging patients who for one reason or another had failed trials of other opiates. Many of these patients had come to the practice already on a fentanyl patch from their referring physicians who in some cases were other pain management specialists who had had less than optimal outcomes with the patients and referred them to us. Study and past experience shows that outcomes are best when the patient is kept on a single molecular formation of opioid or other analgesic preparation thus if they were on a fentanyl patch, logic dictated that if they needed something that worked rapidly and safely, the TIRF fentanyl option was often ideal and improved the patients quality of life and functional physical stamina and ability. Also, many of the patients were allergic or intolerant to morphine, codeine, oxycodone, or the other sister opioids, and in this difficult to manage population with the disease of incurable chronic pain, the fentanyl patch and or the fentanyl TIRF vehicle proved to be remarkably effective. During the life of the practice, there were no patient deaths related to prescribing and at no time was any doctor in the practice sued for "making someone an addict" nor were they accused of that. There were no 'pill sellers' or diverters shown at trial by the government except for patient Douthitt of Dr. Ruan who was terminated from the practice after 6 visits due to his prescribed medication not showing up in his regular urine drug screens.

On page 5 of the government reply brief, states "Suspecting that petitioners were operating a "pill mill", the Drug Enforcement Administration (DEA) launched an investigation in 2014". The investigation was actually launched in 2011 thus the 4 year investigation discussed at trial ensued after a former disgruntled med tech tried to purse a Qui Tam complaint against the practice, but the DOJ, after investigating, decided that it was without merit and did not pursue and the ex-employee claimant's case was dismissed on appeal.(See United States v. Lori Carver, No. 17-13402, United States Court of Appeals for the Eleventh Circuit. Judgment entered Oct.17,2018). But that triggered the ongoing investigation starting in 2011. As to the "Pill Mill" label placed on the practice by the government repeatedly in the second superseding indictment, the government was forced to admit to the jury in opening statements that the practice "was not a pill mill, but was a money mill". (App., infra 84a). There was a reason for that. The government admitted that Petitioners' patients were legitimate and each were carried a legitimate medical purpose. The Government took issue with the "in the usual course of professional practice" arm of the 841 statute and thus directed each of the three non-board certified, non-fellowship trained doctors with no experience in treating the type of patients that the petitioners were referred, that were paid large sums to testify that Petitioners had somehow operated "outside the usual course of professional practice" again stating in opening arguments: "just because there is a legitimate medical need for controlled substances does not make the prescription legal if it's prescribed outside the usual course of professional practice" (Tr Doc.722-1, pg. 28.) Prosecutor Griffin later during the trial specifically asked Dr. Greenberg about that in which this doctor stated that each patient identified was "outside the usual course of professional practice" without any medical or factual basis whatsoever. When Dr. Greenberg, who was not provided with the complete medical records for the patients by the government, was shown the full record while on the stand, he actually recounted his testimony and admitted that the petitioners HAD operated INSIDE the usual course of professional practice, and then on direct testimony, we went switched back his position and testified that they weren't. [Tr. Doc 722:V5:996] Greenberg's inappropriate testimony supports Couch's jury instruction argument. Several times, Greenberg testified Ruan's treatment was below "the standard of care", a civil term [Tr.

Doc. 722:V4:676,754.]. Greenberg's testimony, injecting the standard in civil cases, shows reversible error. None of these doctor/experts presented by the government had any professional experience with these types of patients and had never practiced in pain management, had never trained in pain management, had never taken or passed any board examination in pain medicine or pain management, nor addiction medicine for that matter. They simply should not have been allowed to testify as to our level of care.

Someone who did investigate this Petitioners level of care and found him to be practicing within the usual standard of care in Alabama and in the usual course of professional practice was the Medical Board of the State of Alabama. A few months after the raid in 2015, the Alabama State Board of Medicine investigators conducted an extensive investigation in to Petitioner's practice, Dr. Couch, including a demand to produce over 60 charts of patients that had been treated with Schedule II opioids long term, and found no objectionable evidence against him and RENEWED his licensure to practice medicine and surgery in the state of Alabama for the next (2015-2016) annual term (see Appendix). This again, included an extensive chart review of 60 patients including some that were identified by the government during trial. But for the outcome of this trial, Dr. Couch would still be licensed to practice medicine and surgery not only in Alabama, but Florida, California, and Georgia where he had been licensed in each of those states continually since 1997. However, due to the district court's sweeping decision, and due to the governments objections, this type of "good faith" and "good acts" evidence was precluded from the jury. So in effect, petitioners ability to mount any effective defense against the charges was completely curtailed from being constructed to tell the true picture to the jury of Physicians' Pain Specialists of Alabama, P.C. and how it's medical providers practiced medicine in the manner that they did. This is why it is so important for any practicing physician to be able to demonstrate "Good Faith" and "Good Acts" to the court and to the jury in providing for a viable defense. It is really all that any doctor can do and certainly what they can do to delineate the line for the jury between simple malpractice and/or negligence and criminal level offenses.

As to the Undercover Agent (UC) visit to Dr. Couch, the allegation by the government that it was a "one minute visit" as they state on page 5 of the Reply is simply untrue.

First, as discussed above, the agent was turned away twice, first because he wanted to pay cash and was told by the front desk staff that the practice did not accept cash as primary payment, and then he was told when he came back that he had to have a referral. So he left and called his boss Mr. Burt of the DEA who also testified that they didn't know that patient were non-cash and required a referral with medical records. They contacted a local chiropractor who then faxed over phony MRI findings and clinic records showing failed conservative treatments. [Doc. 722-9 at 71-71 and Doc. 722-8 at 202]. The chiropractor was very rude to the office staff when he was told that we did not accept cash-only patients and the petitioner himself, Dr. Couch, got on the phone to explain this to the chiropractor when he was met with reputational threat by the chiropractor and was quite rude, so petitioner, in an effort to help the chiropractor as well as the "patient" agreed to make a one time exception to the cash only rule. The UC was then taken in an vitals were taken and he filled out the usual extensive paperwork and signed the always required 'opioid agreement' in the event that he may by prescribed a controlled substance, and then was taken back to be seen.

A decision was made by petitioner to allow Dr. Madison, the on-staff doctorate of nurse anesthesia, to also evaluate the patient in an effort to gain experience and perform the history and physical examination which she did over a 30 minute time frame. Dr. Madison then presented the 'patient' to me in my office over a 10 minute period including her full length page hand written notes, and we discussed his 'bullying' his way into the office and the highly unusual way that he was referred for consultation. Petitioner, like any pain medicine fellow, is trained, when dealing with a hostile patient, to try and keep the visit as short as possible, and come back another day. I performed a "pain management targeted exam" of the "patient" Mr. Brennan (Agent Kelley), the UC, focusing on his lumbar region of the back and looking for clinical sins of mechanical lumbar pain as his MRI did show some degenerative changes of the lumbar facet joints at L5 and S1 level of whoever's back the MRI was of, which of course I was lead to believe falsely that it was his MRI that I was reviewing, but nevertheless would explain his symptoms. Kelley testified that he did not expect to be turned away from PPSA for not having health insurance, yet he was.

The initial plan as formulated at the UC's first visit, was to perform a 'Lumbar Facet Joint Block' under X-Ray guidance in the office, for diagnostic as well as therapeutic purpose both to try and identify the source of his pain, and to hopefully provide him some relief of his significant low back pain that was hindering his activities of daily living (i.e.. bulldozer operator on an important job in Mississippi as he stated that he owned the earthmoving company and needed to keep working). Again, he stated that he was 'afraid of needles' but would "think about it". Both Dr. Madison and Petitioner reaffirmed to him that he couldn't 'just get medicine' that he would need some interventional management but, of course, Petitioner Dr. Couch could not force him to undergo anything. Dr. Madison is actually on the UC video telling Mr. Brennan, the phony patient, that "if you came here looking for Oxycontin you came to the wrong place". Again, the decision was made, rightly to give him only 3 tablets per day and see him back relatively soon, in 30 days. It was planned to get a repeat MRI of the low back at a later date, which might have been complicated by his cash pay only status, again, another reason why the clinic did not accept cash pay primary patients.

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: New Pg IV
DATE: 08/11/2021 12:34:28 PM

Concerning the undercover agent (UC), Mr. Kelley, who presented to the office and was seen by Dr. Couch was an unusual visit and follow-up visits, because the "patient" was unusual. Never before had Petitioner experienced in any way a new patient like the UC agent that was referred by someone as belligerent and hostile as the chiropractor that referred him proved to be. Never before had the petitioner, Dr. Couch, been coerced into allowing into the practice, not just a cash paying patient, but a new patient where the referring physician, in this case a chiropractor Dr. Witzel, had knowingly and clandestinely forwarded completely fallacious medical records and MRI reports that were fabricated and did not represent that patient's physical status as was 'verified' by the chiropractor in that case. A physician assumes that the medical records that any referring physician, surgeon, or chiropractor, or any other type of healthcare provider sends to their office will by accompanied by valid and complete medical records and will not be 'hoodwinked' into believing something about that referred "patient" that is not true. The UC agent and the chiropractor lied to Dr. Couch about his identity and his physical status and the validity of his complaints on presentation. The MRI did indeed show some pathological changes in his lumbar spine (or whoever's spine that it was), as well as his physical examination by Dr. Madison, who was employed as a medical provider/student, and also the targeted spinal exam by Dr. Couch following that, that were suggestive of a certain working diagnosis that Dr. Couch formulated concerning the UC "patient" and that determined his plan of care for a lumbar facet joint block under X-Ray and low dose opioid analgesic with muscle relaxant to allow the "patient" to work in his usual job as a bulldozer operator.

This UC "patient" and the chiropractor were adamant that his symptoms needed to be adequately addressed in order for him to continue functioning in his blue collar job in the company that he owned. The UC "patient" repeatedly emphasized to Dr. Couch that he "had to keep working" and Dr. Couch was trying to help said patient to accomplish that and took the chiropractor who 'vouched' for his patient at his word. Now, with hindsight, it is easy to judge petitioner Dr. Couch, but he certainly did not know the true status of this 'phony patient' and certainly it did not occur to him that the referring chiropractor could be lying about the patient and his medical records that he was referring over, and Dr. Couch only intended to treat the patient's primary complaint and to hopefully allow that 'patient' to keep working at this physically demanding blue-collar job, by prescribing the lowest dose available Oxycodone at only 15 mg per tablet, 3 tablets per day maximum, at much lower a dose that it would have been for 'Oxycontin', and not to support anyone's drug habit or for the medications to be diverted to someone other than the patient presented. [Doc. : 269 pg.11] This was not "knowingly and intentionally pushing drugs".

The UC agent, again, was requesting"Oxycontin" but was told that he was not a candidate for that long acting opioid and would not be prescribed that and was not prescribed that, and Dr. Couch personally signed the two prescriptions that the "patient" was prescribed and that is clearly shown on the UC video. As mentioned, it was decided by Dr. Couch to give him instead Oxycodone 15 mg only up to 3/day until his next visit 30 days later as he complained that he had to get back on the job as a bulldozer operator on "an important job in Mississippi " and that he was the owner of the company. Branded oxycodone is available in 15 mg and 30 mg strengths. The UC agent was prescribed the lower of the two. Thus, for these reasons he was treated the way he was. Of note, 4 separate videos showing petitioner Dr. Ruan not prescribing any controlled substances at all to the UC agents that visited him with phony medical records and subversive referrals from other physicians were not allowed into evidence by the District Court for the jury at all as the Government successfully moved to exclude undercover DEA videos which revealed good and legitimate medical practices exercised by Ruan and his staff. [Doc. 400;Doc. 441,442; Doc.722-pp 5,14-17] This as a situation analogous to the government placing a bag of cash in the parking lot of a bank and then charging with bank robbery the person who undoubtedly picks up the bag of cash and walks off.

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: New Page II
DATE: 08/11/2021 12:33:37 PM

The Government alleged that false information was submitted to insurers for approval of TIRF drugs. [Indictment 114b.] These include fentanyl products the FSA approved for breakthrough cancer pain. Before an insurer covered TIRF prescriptions, prior approval was often required.[Indictment &30]. Approximately 15% of PPSA's over 8000 active patients were cancer patients, either with active cancer, or with chronic pain resulting from the treatment of their previous tumors.[Doc.722:V17:3872] Of the "Top 25 patients" for whom Petitioners had prescribed the TIRF medications Subsys and Abstral, 44%, or eleven for each doctor/Petitioners were cancer patients [Tr. Doc 722:V8:1612] The Government alledged during the trial that false information was submitted to insurance companies by Petitioners in an effort to procure approval of the insurance coverage of said medications without any concrete proof to support that charge. For example, the Government claimed that false information was submitted to the insurance company Cigna in an effort to have coverage gained for patient 'Burns' of Dr. Ruan for a TIRF medication. Initially, coverage was denied [Doc.:Tr.Doc 722:V13:2866.], but Petitioner Dr. Ruan appealed this decision of behalf of the patient, submitting information reflecting medication which had failed in treating the significant breakthrough pain of the patient related to her lumbar radiculitis and back pain, including the conditions CPT of 'diagnosis code'.[Tr.Doc:722:V13:2865-66]. Contrary to the charges,DEA Agent Mr. Burt offered noevidence showing submission of false information sent to insurance company Cigna.

Regarding the treatment of cancer by the Petitioners, the court, the government and the government experts simply did not understand that a patient can suffer with chronic pain, in many instances for the rest of their life, as a result of the highly invasive TREATMENT of that cancer. Such treatments would include, but not limited to: radiation therapy, chemotherapy which both can be highly toxic and injurious to nerve plexuses, in addition to highly destructive surgeries for embedded tumors in the body which can lead to restrictive scar tissue in and around nerves and nerve bundles resulting in very disturbing neuropathic (nerve pain) again for years and years. A percentage of these patients would in some cases eventually turn to suicide in order to escape their painful existences. [TR.Doc 722:V173872]. Dr. Ruan prescribed TIRF products only to approximately 77% of his cancer patients (G.Ex.10-1;Doc:724-48). Both doctors also prescribed TIRF products off label to their most difficult to treat non-cancer patients with intractable breakthrough pain. Many of these patients were also concordantly treated with the fentanyl patch (Duragesic, a fentanyl based skin patch, came on the market for not cancer pain in 1996), and therefore took advantage of that to fact to utilize the TIRF medication for intractable breakthrough pain. The Government and its experts conceded that off -label prescribing is in fact legal. (Tr. Doc:722:V5:716-17;V19:4454-55) However, the Petitioners were charged, convicted, sentenced and were subjected to substantial asset and forfeiture provisions in addition to decades long prison sentences as if off-label prescribing was illegal.

TRULINCS 14290003 - COUCH MD, JOHN PATRICK - Unit: FOR-W-B

FROM: 14290003
TO: Couch, David
SUBJECT: NEW PG VIII
DATE: 08/11/2021 12:34:44 PM

'United States vs. Moore' essentially held that doctors illegally prescribing were the equivalent of 'drug pushers', and the doctors are not exempt from CSA prosecutions. [See 423 U.S.at 138-39, 143]. Therefore, a jury instruction equating bad doctors to 'drug pushers' is not an incorrect statement of the law. The District Court's instructions on this point were fatally wrong and incomplete.

The unfounded assertion that the "trial evidence thus overwhelmingly demonstrated that each petitioner, like the doctor in 'Moore', ""in practical effect *** acted as a large-scale 'pusher'--not as a physician'" by the government simply ignores the evidence if one objectively assesses what PPSA was about and does not account for, or understand the type of patient population that was referred to this multi-disciplinary practice.(see Government REPLY page 24). The petitioners where specially trained over years to provide care for this complex type of patient population in the practice within this subspecialty. In the case of Dr. Moore, he prescribed Methadone to patients on a "sliding scale" cash bases where any patient was taken, and referrals were not required and the physician Moore was not a specialist in Pain Medicine, very much unlike what happened at PPSA regarding Petitioners.

Thus, this was totally contrary to what was repeatedly asserted in almost each and every count of the second superseding indictment, which included substantial forfeiture provisions. Between the time period of the Second Superseding Indictment and the 7 week trial, the Governments claims against petitioners evolved from being a "pill mill" to a "money mill". [Doc. 269] This was clearly constructive evolution of the indictment. Other Circuits have ruled that a pain management physician must be able to introduce patients from their practices who had faired well with the doctor's treatment to show the jury that successfully treated patients existed and that the doctors had "established doctor-patient relationships". In U.S.v. Arny, 831 F.3d 725(6th Cir. 2016), the court in that case ordered a new trial in the prosecution of a pain management physician based on ineffective assistance of counsel.
Such testimony as in the case of United States v. Arny for Petitioners would have rebutted evidence that prescriptions lacked a "legitimate medical purpose" or were "outside the usual course of professional practice". In that case, the appellate court stated:

"Trial counsel could have called former patients to testify that they were not drug abusers but rather had a legitimate medical need for pain medication...Evans also could have testified that he was examined monthly from September 2010 through September 2011 and that Arny adjusted his medications as necessary, which would have countered the Government's theory that Arny did not establish legitimate doctor-patient relationships. From this one witness, the jury would have been left with an impression that not all of Arny's patient were similar to the drug abusers and dealers called by the Government".

Although, in Petitioners' trial, not a single drug abuser or drug dealer was identified by the Government in their investigation, nor presented during trial except for the aforementioned patient Douthitt of Dr. Ruan, who was quickly terminated by Dr. Ruan in January 2013 for violating his opioid agreement.[Tr. Doc.722:V15:351 1,3537.) He, again , was discharged by Petitioner Dr. Ruan for the medication not showing up in the drug screens performed at the office. Douthitt's testimony was insufficient to show that Dr. Ruan failed to prescribe for a legitimate purpose or outside the usual course of professional practice. Petitioners were trained to listen to patients and treat pain as the fifth vital sign. [Tr.Doc. 722:V21:4803-04]

Petitioners were indicted, tried, convicted and sentenced as well as having substantial asset forfeiture and seizure provisions and large restitution amounts placed on them equating 'off-label' prescribing as illegal and outside the usual course of professional practice. This despite Government expert testimony establishing that it is completely legal and often done, and that the Food and Drug Administration (FDA) does not regulate the practice of medicine. Agent Young of the DEA testified as follows: [Tr. Doc. 722-7, pg. 1596-1597]:

Q: "Isn't it true or are you aware, Agent Young, based on your education and your experience, that the FDA does not regulate how doctors practice medicine?"
A: "That is correct"

Government expert Dr. Aultman on the question of 'off-label' prescribing being legal testified to this as follows:
Q:"So there's nothing unusual or inappropriate about a doctor prescribing off-label; right?"
A: "It's really not. So there's many, many, many older medicines that we use today that are indicated for other things other than what we use them for."[Tr.Doc. 722-19,pg.4454-Aultman testimony]
On that note, fentanyl came on the United States market in 1961 having been invented in Belgium by Dr. Jansen, founder of

Jansen Pharmaceuticals which still exists today.

Nowhere in the indictments was PPSA equated to a 'money mill", but that is what the jury was told that the Petitioners were and that is what the evidence focused on along with, through their flawed experts, attacking their treatment choices of the patients that were presented by the government as if it was a malpractice case. It is not illegal for medical doctors, and thus busy private medical practices to earn money, but petitioners where treated that way and that was implied in the Government's case to the jury. Petitioners remain incarcerated for decades due largely by the fact that they were not allowed, in the 11th Circuit, to demonstrate a defense based on "good faith" nor demonstrate ANY "good acts" as part of that non-available defense, like other circuits allow as shown in co-defendant Ruan's REPLY, which is thus allowing no real defense at all.

Drug diversion is a current problem in the nation and the Petitioners were well aware of this as it was shown that they went great lengths to first avoid accepting patients that could be malingering in their pain complaints, and they took significant steps as shown to 'root-out" any patients that were admitted into the practice that were not indicated to have any controlled substances as part of their treatment plan (random urine drug screens, opioid agreements, random pill counts, PDMP online checks of their prescription fills in the states where Petitioners were licensed, frequent office follow-ups, diagnostic testing and radiographs). Indeed, both Petitioners frequently discharged from the patients what amounted to hundreds of patients for non-compliance during the relevant period. [Tr.Doc. 722:V25:5839]. Both Petitioners went the extra step of becoming board certified in Addiction Medicine to help them in managing these complex patients, even a few who had a history of drug abuse, but still suffered with true chronic pain issues. Those patients can be successfully treated if done appropriately, and one must be very experienced in this as the Petitioners were, and that is what was done in Petitioners' practices. The Petitoners were not afforded the ability to mount a defense bases on "good faith" nor allowed to present any "good acts" in the foundation of that defense. PPSA was "very, very, very different from a pill mill" as the Government admitted as above.

Conclusion

The petition for a writ of certiorari should be granted.

Respectfully submitted.

J. Patrick Couch, M.D.
Filing Pro Se
July 31,2021