CASE NO. 12-3212

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff,/Appellee,

vs.

PAUL H. VOLKMAN,

Defendant/Appellant

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO AT CINCINNATI
No. 1:07-cr-60-3—Sandra S. Beckwith, District Judge

ON REMAND FROM THE SUPREME COURT OF THE UNITED STATES
No. 13-8827—Justice Alito, with Whom Justice Thomas Joins,
concurring, (October 20, 2014)

DEFENDANT/APPELLANT'S SUPPLEMENTAL BRIEF, BY LEAVE OF COURT, ORDER (April 03, 2015)

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STATEMENT OF JURISDICTION

Jurisdiction was invoked by the Appellee below, pursuant to 28 U.S.C. § 132(c), 18 U.S.C. §§ 2, 924(c), and 3231, and 21 U.S.C. §§ 841(a), 841(b)(1)(C), 846, 856(a)(1) and (b). The District Court entered its "judgment," pursuant to Fed.R.Crim.Proc. 32, on February 14, 2012.

This Court assumed jurisdiction, pursuant to 28 U.S.C. § 1291 and 18 U.S.C. § 3742, in United States v. Volkman, 736 F.3d 1013 (6th Cir. 2013), and has jurisdiction, pursuant to 28 U.S.C. § 2106, to remand the matter to the District Court, pursuant to the the Supreme Court's remand order of October, 20, 2014, in the matter of Volkman v. United States, 190 L.Ed.2d 286 (2014).

ARGUMENT PRESENTED

A GENERAL REMAND DE NOVO TO THE DISTRICT COURT IS REQUIRED UNDER THE FIFTH AMENDMENT GUARANTEE TO "due process of law" FOR ADJUDICATION OF THE JURISDICTIONAL QUESTIONS AND GROUNDS CLARIFIED IN UNITED STATES v. BURRAGE, 134 S Ct. 881 (2014), AND UNADJUDICATED IN THE INSTANT MATTER.

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STATEMENT OF THE CASE

This is a review of the scope of the remand required by the Order of the Supreme Court issued on certiorari, October 20, 2014, directing a jurisdictional review of the enhanced punishment imposed below, pursuant to 21 U.S.C. § 841(b)(1)(C), in light of United States v. Burrage, 134 S. Ct. 881 (2014), after

a jury trial in March and April 2011 and direct appeal in 2011 to 2014, of 18 federal felony counts, including conspiracy to distribute, and distribution of controlled substance, in violation of 21 U.S.C. § 846, § 841(a)(1), § 841(b)(1)(C), and 18 U.S.C. § 2, maintaining a drug involved premises, in violation of 21 U.S.C. § 856(a)(1) and (b) and 18 U.S.C. § 2, causing the death of another by unlawful distribution, in violation of 21 U.S.C. § 841(a)(1), § 841(b)(1)(C), and 18 U.S.C. § 2, and possession of a firearm in furtherance of a drug trafficking offense, in violation of 18 U.S.C. § 924(C)(1) and (2).

Appellant was sentenced to serve life in prison. (R240, Judgment, #6242). On remand from the Supreme Court and appeal, the appellant seeks a further general remand of the entire case in light of United States v. Burrage, 134 S. Ct. 881 (2014), to the District Court for a full and fair adjudication of the issue of the lack of jurisdiction below and on direct appeal.

STATEMENT OF THE FACTS

From April 2003 until September 2005, Dr. Volkman, a pain management specialist, worked at Tri-State Health Care, a pain management clinic, owned and operated by Denise Huffman, in Portsmouth, Ohio. (R447, TT-Day 6, D. Huffman, #8394-6396, 6401, 6436) The Controlled Substances Act, 21 U.S.C § 801, et seq., does not, nor was it the intent of Congress to, proscribe criteria to regulate the medical practice of doctors who issue prescriptions for patients exhibiting symptoms of pain and suffering. The case of the Government and jury instructions of the trial court impermissibly relied upon the regulations of the Attorney General, 21 C.F.R. § 1306.04(a), to arbitrarily charge federal

common law elements of crime in the indictment, and instructed the jury, accordingly, contrary to congressional intent under 21 U.S.C. §§ 823(f)(4) and 903 to leave regulation of the medical profession and doctors in prescribing pain medication for patients exhibiting symptoms of pain and suffering to state government. (R84, Def's Mot. Dismiss, at 301; R322, TT-Day 21, #4838; R482, TT-Day 25 (jury instructions), #9593-9594)

Gov't's witness, Denise Huffman testified that she "opened [Tri-State Health Care clinic] for a pain management facility for chronic pain patients" in 2001-2002 (R447, TT-Day 6 (morning), p. 3), and that approximately 18-20 patients were treated for pain per day until the facility was closed by the DEA in 2006. (R477, TT-Day 7, #8320-8321)

DEA agent Kyle Wright testified that prescriptions for pain medication in the amount of 222,600 pills per 6 month period, or an average of 22,0000 per month, had been issued at the Tri-State Health Care clinic for approximately 500 patients, and therefore an average of 73 pills per month or 2½ pills per day per patient. (R414, TT-Day 3 (afternoon), pp. 39-40)(hydrocodone only)

DEA agent Nicole Bowie testified generally about 1 million pain pills being prescribed at the clinic from 2003 until 2006, without having reviewed the "sign out log" of the dispensary. (R452, TT-Day 9 (afternoon), pp. 61-62)

DEA agent Kyle Wright later testified that the average number of pain pills prescribed for each patient was 1.4 per day. (R414, TT-Day 3 (afternoon) Mar. 3, 2011, p. 43 (Oxycodone only)

Ms. Huffman also testified that she suffered from medical

conditions and pain, and had been motivated to set up the pain management clinic, after discovering that doctors had become fearful of wrongful prosecution by Federal authorities, and thus would not meet her medical needs for pain medications, nor that of many other pain suffers, regardless of genuine medical need and legitimacy. (R477, TT-Day 7, p. 31); see also United States v. Ilayayev, 800 F.Supp.2d 417, 435-448 (E.D.N.Y. 8/5/2011)(discussing studies and fear among doctors to prescribe opioid painkillers and state government role in regulation thereof since 2001)

Of the 500 patients treated by Dr. Volkman under Ohio law, the indictment names 13 as having died after receiving prescriptions from Dr. Volkman for pain medication on separate dates from October 21, 2003, until December 28, 2005, all of which patients had documented medical conditions warranting their treatments and the prescriptions for pain medications within the criteria for pain management outlined in the Ohio Revised Code 119.032, Ch. 4731-21, et seq (1998-2008) and contemplated by 21 U.S.C. §§ 823(f)(4) and 903. The legitimacy of the prescriptions issued by Dr. Volkman for all of the patients was confirmed by expert witnesses, Dr. Forrest Tennant (R322, TT-Day 21, 4834-4843), Dr. Harry Bonnell (R318, TT-Day 21, pp. 2-40; R319, TT-Day 22, pp. 13-28); and Dr. Hal Blatman (R311, TT-Day 20, p. 48), and their medical need admitted. Gov't Br., #006111600501 (2/22/2013), pp. 38, 49-67.

None of the witnesses, lay and expert, of the prosecution were able to contradict the fact that each and every one of the patients, Dr. Volkman had prescribed pain medication for, suffered from pain related illnesses warranting pain medication. Any and all differences in expert opinion is in the amount of pain medi-

cation prescribed for treatment of pain, and specifically that of four patients: Kristi Ross (Count 10), Steve Hieneman (Count 11), Brain Brigner (Count 18), and Ernest Ratcliff (Count 20), in connection with the enhanced punishment under 21 U.S.C. § 841(b)-(1)(C), with other serious health and risk factors as being "contributed" or "contributing" in all four patients, according to the government's lay and expert witnesses, and admitted and described by the government. Gov't Br., #006111600501 (2/22/2013), pp. 38, 49-67, citing testimony of: Dr. Harry Bonnell, pp. 54, 55, 62, 63; Dr. Bryan Castro, pp. 60-64; Dr. Douglas Kennedy, pp.51-54, 56, 61; Dr. George Pettit, p. 50; Dr. Michael Policastro, pp. 51-53, 56, 62, 66-67; Dr. Christin Rolf, pp. 55-56; Dr. Forrest Tennant, p. 54; and Dr. Wayne Wheeler, p. 60.

The trial Court also found that there is no proof of drugs for money, to-wit: "And I would add there's no testimony per se in this case about personal profit." (R458, TT-Day 24, #7250-7252)

SUMMARY OF ARGUMENT

Under Supreme Court and Sixth Circuit controlling precedent, the standard of review is de novo requiring a general remand limited only by the scope of the outstanding jurisdictional issues of fact and law arising from 21 U.S.C. §§ 802(21), 812(b), 823(f)-(4), 830(b)(3)(A)(ii), 841(a)(1),(b)(1)(C), 846, and the Fifth Amendment barriers of "due process of law" upon the vagueness of the Controlled Substances Act, 21 U.S.C. § 801, et seq., notice requirements of Due Process, and the arbitrary expansion of the elements of 21 U.S.C. §§ 841(a)(1), (b)(1)(C), and 846, by and through incorporation of elements of 21 C.F.R. § 1306.04(a) from

the Attorney General, without authority, below.

The Supreme Court in Burrage v. United States, 134 S. Ct. 881 (2014), concluded that a general jury instruction, "where use of the drug distributed by the defendant is not an independently sufficient cause of the victim's death or serious bodily injury," is not legally sufficient to satisfy the Due Process requirement, in the context of enhanced punishment under 21 U.S.C. § 841(b)(1)-(C), and vacated and remanded the instant matter for further proceedings, accordingly. Because the Sixth Circuit, trial court, and government relied upon a "contributing-cause" theory rejected in Burrage, the jurisdictional reach of 21 U.S.C. §§ 841(a)(1), (b)(1)(C), and 846, and the other offenses predicated thereupon and charged in the indictment, is now in question, and foreclosed against the trial Court's arbitrary jury instruction and expansion of subject-matter-jurisdiction upon the pretext of 21 C.F.R. § 1306.04(a) and against its reliance on the arbitrary opinion in United States v. Kirk, 584 F.2d 773, 784 (6th Cir. 1978), overruled in effect by United States v. Graham, 275 F.3d 490, 543 (6th Cir. 2001)("We know there is no federal common law crime.").

The trial Court's arbitrary jury instruction and expansion of the subject-matter-jurisdiction under the Controlled Substances Act and other acts of Congress is as a whole "particularly vexing" under Burrage, 187 L.Ed.2d 715, 727-728 (2014), and the Fifth Amendment guarantee to "due process of law" requires a general remand for an adjudication of the jurisdictional facts and law de novo as to each and every count of the indictment and its dismissal for vagueness and lack of jurisdiction. United States v.

Salisbury, 983 F.2d 1369, 1377-1378 (6th Cir. 1992)(collecting cases), citing, e.g., North American Van Lines, Inc. v. United States, 243 F.2d 693, 697 (6th Cir. 1957)(Rev. and Rem. with directions to dismiss indictment for vagueness of criminal statute and lack of jurisdiction).

ARGUMENT

A GENERAL REMAND DE NOVO TO THE DISTRICT COURT IS REQUIRED UNDER THE FIFTH AMENDMENT GUARANTEE TO "due process of law" FOR ADJUDICATION OF THE JURISDICTIONAL QUESTIONS AND GROUNDS CLARIFIED IN UNITED STATES v. BURRAGE, 134 S. Ct. 881 (2014), AND UNADJUDICATED IN THE INSTANT MATTER.

I. Scope of Review and Remand

The Sixth Circuit standard of review for criminal statutes is de novo as to "each element of the crime." United States v. Lutz, 154 F.3d 581, 586 (6th Cir. 1998); accord Davis v. Lafler, 609 F.3d 870, 876 (6th Cir. 2010)(quoting Jackson v. Virginia, 443 U.S. 307, 324, n. 16 (1970)); United States v. Yeager, 303 F.3d 661, 664 (6th Cir. 2002)(dismissing appeal for lack of jurisdiction, quoting Steel Co. v. Citizens for a Better Env., 523 U.S. 83, 94 (1998)(quoting Mansfield, C. & L. M. Ry. Co. v. Swan, 111 U.S. 379, 382 (1884)), in relevant parts:

> "An appellate federal court must satisfy itself not only of its own jurisdiction, but also of that of the lower courts in a cause under review."
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> "The requirement that jurisdiction be established as a threshold matter 'springs from the nature and limits of the judicial power of the United States' and is 'inflexible and without exception.'"

See also, United States v. Lucido, 612 F.3d 871, 877-78 (6th Cir. 2010), in relevant part:

> "Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause."

See also, North American Van Lines, Inc. v. United States, 243 F.2d 693, 696-99 (6th Cir. 1957)(Rev. and Rem. with directions to dismiss indictment for vagueness of criminal statute and lack

of jurisdiction); United States v. Wiltberger, 18 U.S. (5 Wheat.) 76, 95 (1820)("It is the legislature, not the Court, which is to define a crime, and ordain its punishment." The "intent" of the legislature controls the jurisdictional question.), quoted by the Solicitor General, Donald B. Verrilli, Jr., Brief of the United States, Persaud v. United States, No. 13-6435, p. 20, filed Dec. 20, 2013, in the United States Supreme Court.

To the extent that the instant remand under Burrage involves a question of subject-matter-jurisdiction under 21 U.S.C. § 841-(a)(1) and (b)(1)(C), any remand to the District Court below on this subject-matter requires review by this Court, and an adjudication below--as to "each element of the crime"--must be rendered de novo, Lutz, 154 F.3d at 586, including the question of "whether a remand order is limited or general," United States v. McFalls, 675 F.3d 599, 604 (6th Cir. 2012), citing United States v. Gibbs, 626 F.3d 344, 360 (6th Cir. 2010), with the presumption being the remand is "general," also citing United States v. Helton, 349 F.3d 295, 299 (6th Cir. 2003); see also United States v. Moore, 131 F.3d 595, 598 (6th Cir. 1997)(same); United States v. Shafter, 23 Fed. Appx. 380, 382 (6th Cir. 2001)(A remand is presumed to be general unless it "convey[s] clearly the intent to limit the scope of the district court's review by outlining the chain of intended events, and leaving no doubt as to the scope of the remand."); followed United States v. Combs, 2012 U.S.Dist. LEXIS 128923, No. 7-01-17-DCR (E.D. Ky. 9/11/2012).

Even if this Court exercises discretion under 28 U.S.C. § 2106 to limit the scope of remand, United States v. Ambrose, 564 Fed. Appx. 184, 188-189 (6th Cir. 2014), that statutory authority

is clearly limited by the overarching duty of this Court, and, upon remand, that of the district court to first adjudicate by law the jurisdictional issues, respectfully, in connection with 21 U.S.C. § 841(a)(1) and (b)(1)(C), de novo, Lutz, 154 F.3d at 586, and thus generally, and limited only upon resentencing, if any, that must be "convey[ed] clearly" by this Court. Shafer, 23 Fed. Appx. at 382; see also MacKay, 715 F.3d at 846-847.

II. Effect of Burrage on this Case

In rejecting the Eighth Circuit's "contributing-cause" standard for enhanced punishment under 21 U.S.C. § 841(b)(1)(C) in the context of an unlawful distribution of heroin by Marcus Burrage, who was not a physician licensed to prescribe the heroin under the Controlled Substances Act, ("CSA"), to Joshua Banka, who died after injecting some of the heroin and other drugs, the Supreme Court explained when holding, in relevant parts:

> "Presumably the lower courts would be left to guess. That task would be particularly vexing since the evidence in § 841(b)(1) cases is often expressed in terms of probabilities and percentages. One of the experts in this case, for example, testified that Banka's death would have been "[v]ery less likely" had he not used the heroin that Burrage provided. App. 171. Is it sufficient that use of a drug made the victim's death 50 percent more likely? Fifteen percent? Five? Who knows. Uncertainty of that kind cannot be squared with the beyond-a-reasonable-doubt standard in criminal trials or with the need to express criminal laws in terms ordinary persons can comprehend. See United States v. L. Cohen Grocery Co., 255 U.S. 81, 89-90, 41 S. Ct. 298, 65 L.Ed. 516 (1921).
>
> But in the last analysis, these always-fascinating policy discussions are beside the point. The role of this Court is to apply the statute as it is written-even if we think some other approach might "accord[d] with good policy." Commissioner v. Lundy, 516 U.S, 235, 252, 116 S. Ct. 647, 133 L.Ed. 2d 611 (1996)(quoting Badaracco v. Commissioner, 464 U.S. 386, 398, 104 S. Ct. 756, 78 L.Ed.2d 549 (1984)). As we have discussed, it is written to require but-for cause.
>
> We hold that, at least where use of the drug distributed by the defendant is not an independently sufficient cause of the victim's death or serious bodily injury, a defendant

> cannot be liable under the penalty enhancement provision of 21 U.S.C. § 841 (b)(1)(C) unless such use is a but-for cause of the death or injury. The Eighth Circuit affirmed Burrage's conviction based on a markedly different understanding of the statute, see 687 F.3d, at 1020-1024, and the Government concedes that there is no "evidence that Banka would have lived but for his heroin use," Brief for United States 33. Burrage's Conviction with respect to count 2 of the superseding indictment is therefore reversed, and the case remanded for further proceedings consistent with this opinion."

Burrage v. United States, 571 U.S. ___, 134 S. Ct. 881, 187 L.Ed.2d 715, 727-728 (2014); see also applied on remand from United States v. MacKay, 715 F.3d 807, 846-847 (10th Cir. 2013), at 20 F.Supp. 2d 1287 (10th Dist. 5/7/2014), explaining, in relevant parts:

> "Having found Burrage to be a sufficient change in controlling legal authority and that justice requires that Burrage is applicable here, the Court must now decide what effect, if any, Burrage has on MacKay's resentencing. At the close of Mackay's trial, the Court instructed the jury that it must decide on Counts 1 and 2 whether Mr. Wirick's death "resulted from" the use of the drugs prescribed by MacKay. The jury was not given any further direction as to what "result from" meant.
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> "... Neither this Court nor the Tenth Circuit had the benefit of Burrage, which has made a contrary decision of the law applicable. In making such a finding, the Court need only look to the evidence regarding Counts 1 and 2 presented at trial. Dr. Frikke's autopsy report stated that each of the drugs present was below the concentration range reported to cause death when it is the only drug present. Drs. Grey and Hall opined that Mr. Wirick's death resulted from a combination of drug toxicities, and Dr. Baden blamed pneumonia as the sole cause of Mr. Wirick's death. Not one of the four medical experts testified that either the oxycodone or hydrocodone, acting alone, was a but-for cause of Mr. Wirick's death. Had this Court had the advantage of knowing Burrage at the close of MacKay's trial, it certainly would have instructed the jury differently, and just as clearly would have granted MacKay's Motion for Judgment of Acquital on Counts 1 and 2 inasmuch as not only was the instruction insufficient, but so too was the evidence."

Unlike Dr. MacKay, who was licensed to prescribe drugs for legitimate medical need under state law and the CSA generally, and specifically contemplated by 21 U.S.C. § 802(21)("in the

course of professional practice") for each and every patient exhibiting symptoms of pain, a "currently accepted medical use," § 812(b), and "medical purpose" for prescribing or dispensing "controlled substances," § 823(f)(4), via "valid prescription" "issued for a legitimate medical purpose," § 830(b)(3)(A)(ii), in "[c]ompliance with applicable State, Federal, or local law relating to controlled substances," § 823(f)(4), all with due deference to congressional intent to leave regulation of medical practice to state government, pursuant to § 903, as found and clarified in Gonzales v. Oregon, 546 U.S. 243, 258-264, and 267-271 (2006), Marcus Burrage was not a "'practitioner' eligible to prescribe" the controlled substances under § 802(21) and otherwise prohibited by the Controlled Substances Act, § 801, et seq. in the matter of Burrage v. United States, 134 S. Ct. 881 (2014), under the principles of strict construction and "intent" of Congress required for the limited jurisdiction of the United States, Wiltberger, 18 U.S. at 95; Lutz, 154 F.3d at 586; and Lucido, 612 F.3d at 877-878, and clarified in Gonzales v. Oregon, 546 U.S. at 267-271.

Two medical experts, Dr. Eugene Schwilke, a forensic toxicologist, and Dr. Jerri McLemore, a Iowa state medical examiner, testified at Burrage's trial, and came to similar conclusions that "heroin 'was a contributing factor' in Banka's death, since it interacted with the other drugs to cause 'respiratory and/or central nervous system depression,'" while Dr. McLemore described the cause of Banka's death as "'mixed drug intoxication' with heroin, oxycodone, alprazolam, and clonazepam all playing a 'contributing' role." "Dr. McLemore could not say whether Banka would have lived

had he not taken the heroin, but observed that Banka's death would have been 'very less likely.'" Burrage, 187 L.Ed.2d at 720-721.

As distinguishable from the appellant's pain-management medical practice, there was overwhelming evidence that Dr. MacKay had acted "outside the usual course of medical practice or without a legitimate medical purpose" as defined and regulated by 21 C.F. R. § 1306.04(a) and 21 U.S.C. §§ 802(21), 812(b), and 841(a)(1), and the Tenth Circuit examined the trial record and set forth in detail the evidence introduced at Dr. MacKay's trial proving, beyond any reasonable doubt as to 40 of the original 129 counts charged in the indictment, that he had unlawfully prescribed controlled substances for patients outside the usual course of medical practice. United States v. MacKay, 715 F.3d, at 813-814.

Dr. Mackay also defended his action successfully as to the remaining 89 counts by challenging the sufficiency of the indictment and evidence, while challenging the lack of sufficient notice and vagueness of the Controlled Substances act and asserted a violation of his "due process rights." Id., at 814-816.

Despite the Government's contention that Dr. Mackay had "waived his sufficiency challenge," id., at 816-817, the Tenth Circuit examined the facts of each of the 7 patients Dr. Mackay had prescribed Controlled Substances for, the testimony of all 7 of the patients, who had received the prescriptions, and the testimony of Dr. Bradford Hare, a pain management doctor, about his review of Dr. MacKay's medical charts. Id., at 816-821.

The Tenth Circuit rejected Dr. MacKay's assertions, in relevant part:

> "Hare testified that no medical justification existed for the prescriptions Defendant wrote Russell and that Defendant prescribed the Lortab outside of a legitimate medical purpose. Trial Tr., 105, July 27, 2011. Hare testified Blanscett was receiving narcotics from other doctors and that Defendant was providing early refills without any indication the medications were helping Blanscett. Id. at 112. As to Crower, Hare believed Defendant never had adequate information or a diagnosis to allow Defendant to initiate the prescribing of controlled substances. Id. at 136-37. Hare stated no information supported prescribing the amount of opioid medications prescribed to Allen Starr. Id. at 148. As to Johnson, Hare found inadequate support to justify prescribing controlled substances and added that a check of the controlled substances database would have shown she was obtaining hydrocodone on a regular basis. Id. at 157-58. Finally, Hare testified that long-term prescribing of increased doses of pain medication to Stubblefield with no further evaluation was unjustified. Id. at 162."

Id., at 822-823.

And finally, Dr. MacKay did not raise a defense that the prescriptions he had written were within congressional intent under 21 U.S.C. § 903 in that:

> "... absent a positive conflict, none of the Act's provisions should be 'construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates ... to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State."

Gonzales, 546 U.S. at 270-271; and compare United States v. MacKay, 715 F.3d at 812-846; and on resentencing 20 F.Supp.3d 1287 (Memorandum Decision and Order), in toto.

Equally important, on resentencing, the MacKay Court did make the predicate inquiry and finding that MacKay had been first duly convicted of violating 21 U.S.C. § 841(a)(1), prior to determining whether the enhancement provisions of § 841(b)(1)-(C) had been met, id., in accordance with Congress' intent under 21 U.S.C. §§ 802(21), 812(b), 823(f)(4), 829(c), 830(b)(3)(A)(ii) and 903, and Gonzales v. Oregon, 546 U.S. at 258-264 & 267-271,

and Burrage v. United States, 187 L.Ed.2d at 727-728, supra.

Here, the Supreme Court has generally vacated the judgment below, and remanded the case to this Court for further consideration in light of Burrage, which reopens the duty of this Court to "satisfy not only ... its own jurisdiction, but also that of the lower court[]," United States v. Yeager, 303 F.3d at 664, supra, prior to proceeding to the issue on remand regarding 21 U.S.C. § 841(b)(1)(C) under Burrage, as further demonstrated in the MacKay case and Gonzales v. Oregon, supra.

a. The Panel's "case-by-case" Approach Violates Due Process

The Panel primarily relied on an express "case-by-case approach," citing United States v. Kirk, 584 F.3d 773, 784 (6th Cir. 1978)(quoting 21 C.F.R. § 1306.04(a)) and 21 U.S.C. § 841(a)-(1), in reaching its conclusion that the appellant had violated the CSA, prior to proceeding to its secondary conclusion that the enhancement provisions of 21 U.S.C. § 841(b)(1)(C) also applied, while applying an abuse of discretion standard of review, citing United States v. Theunick, 651 F.3d 578, 589 (6th Cir. 2011), and United States v. Franklin, 415 F.3d 537, 553 (6th Cir. 2005, and rejecting the appellant's reliance on Gonzales v. Oregon, 546 U.S. at 269-270, to support his argument that the District Court erred in its jury instruction. United States v. Volkman, 736 F.3d 1013, 1019-1022, 1026-1031 (6th Cir. 2013)

The Panel began with its conclusion stating, in relevant part:

> "A violation of the Controlled Substances Act (CSA) occurs when a physician dispenses or distributes a controlled substance in a manner that is not authorized by law--i.e., the prescription is issued by a physician without 'a legitimate

> medical purpose by an individual practitioner acting in the usual course of his professional practice." Kirk, 584 F.2d at 784 (quoting 21 C.F.R. § 1306.04(a)); see also 21 U.S.C. § 841(a)(1)."

Id., at 1026.

Clearly, the Panel relied on the Attorney General's 21 C.F.R. § 1306.04(a), quoted in Kirk, 584 F.2d at 784, and thus administrative law, id., as if controlling precedent, i.e., Federal common law, in an attempt in error to rely on an administrative pretext to define the terms "a medical purpose by an individual practitioner acting in the usual course of his professional practice," id., at 1026, after only a few pages earlier rejecting that the Supreme Court's decision in Gonzalez v. Oregon has any "relevance --or lack thereof--in the setting of a criminal prosecution," because the case "dealt only with the question of the Attorney General's ability to define 'legitimate medical purpose' in light of state medical standards to the contrary." Id., 736 F.3d at 1019-1120. The Panel cannot have it both ways, and is without judicial power and jurisdiction by law to proscribe, ratify and rely on federal common law in the context of criminal statutes. See United States v. Graham, 275 F.3d 490, 543 (6th Cir. 2001)("We know there is no federal common law crime."), citing United States v. Hudson and Goodwin, 11 U.S. 32, 3 L.Ed. 259, 7 Cran. 32 (1812); and compare, United States v. Dempsey, 733 F.2d 392, 395 (6th Cir. (1984)(same); Fisch v. General Motors Corp., 169 F.2d 266, 272-73 (6th Cir. 1948), in relevant part:

> "The district courts are not courts of general jurisdiction. Their jurisdiction is limited and their powers lie dormant until jurisdiction is conferred by Congress under its constitutional authority and jurisdiction cannot be conferred in any other way. Mayor v. Cooper, 73 U.S. 247,

252, 8 L.Ed. 851. In Lockerty v. Phillips, 319 U.S. 182, 187, 63 S. Ct. 1019, 1022, 87 L.Ed. 1339, the court said:

> 'The Congressional power to ordain and establish inferior courts includes the power 'of investing them with jurisdiction either limited, concurrent, or exclusive, and of withholding jurisdiction from them in the exact degrees and character which to Congress may seem proper for the public good.' Cary v. Curtis, 3 How. 236, 245, 11 L.Ed. 576; Lauf v. E.G. Shinner & Co., 303 U.S. 323, 330, 58 S. Ct. 578, 582, 82 L.Ed. 872; Hallowell v. Commons, 239 U.S. 506, 509, 36 S. Ct. 202, 509, 36 s. Ct. 202, 203, 60 L.Ed. 409; Smallwood v. Gallardo, 275 U.S. 56, 48 S. Ct. 23, 72 L.Ed. 152; Toucey v. New York Life Ins. Co., 314 U.S. 118, 129, 62 S. Ct. 139, 141, 86 L.Ed. 100, 137 A.L.R. 967. See also, United States v. Hudson and Goodwin, 7 Cranch 32, 33, 3 L.Ed. 259; Mayor v. Cooper, 6 Wall. 247, 252, 18 L.Ed. 851; Stevenson v. Fain, 195 U.S. 165, 167, 25 S. Ct. 6, 7, 49 L.Ed. 142; Kentucky v. Powers, 201 U.S. 1, 24, 26 S. Ct. 387, 393, 50 L.Ed. 633, 5 Ann. Cas. 692; Chicot County Drainage Dist. v. Baxter Bank, 308 U.S. 371, 376, 60 S. Ct. 317, 319, 84 L.Ed. 329."

See also, McNutt v. Gen. Motors Acceptance Corp. of Ind., 298 U.S. 178, 189 (1936)(The "burden of establishing federal jurisdiction" is on the requesting party, and the lack thereof may be raised "at any time when the lack of jurisdiction appears"); reaffirmed Siding & Insulation Co. v. Acuity Mut. Ins., 754 F.3d 367, 369 (6th Cir. Mar. 20, 2014), explaining, in relevant part:

> "If the district court lacks original jurisdiction, our appellate jurisdiction extends no further than 'correcting the error of the lower court in entertaining the suit.' Steel Co. v. Citizens for a Better Env't., 523 U.S. 83, 95, 118 S. Ct. 1003, 140 L.Ed.2d 210 (1998)."

Indeed, the government admits, Br. #006111600501 (2/22/2013), p. 38, that the trial Court relied on 21 C.F.R. § 1306.04(a), to instruct the jury, R482, TT-Day 25, #9593-9594, and ratify federal common law crime from, Kirk, 584 F.2d at 784, in relevant part:

> "Two of the essential elements of the substantive counts from two to forty eight are: The prescriptions issued by the appellant to various persons must have been 'not in the usual course of professional practice' and 'not for a legitimate medical purpose.'
>
> It has been held that there is no difference in the

meanings of the statutory phrase, "In the usual course of professional practice" and the regulations' phrase, "legitimate medical purpose." U.S. v Plesons, 560 F.2d 890, 897 (8th Cir. 1977); U.S. v Rosenberg, 515 F.2d 190, 197 (9th Cir. 1975), cert. den. 423 U.S. 1031, 96 S. Ct. 562, 46 L.Ed 2d 404.

Sec. 841(a)(1), 21 U.S.C., of which appellant was charged with violating, provides that,

"Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally (1) to *** distribute *** a controlled substance."

Sec. 1306.04(a), 21 C.F.R., provides,

"A prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, ***"

The burden of proof is upon the government to prove these elements. U.S. v. Black, 512 F.2d 864, 867 (9th Cir. 1975); U.S. v. Clifford T. Green, et al., 511 F.2d 1062, 1069,1072 (7th Cir. 1975), cert. den., 423 U.S. 1031, 96 S. Ct. 561, 46 L.Ed.2d 404; U.S. v Carroll, 518 F.2d 187, 189, 207 (6th Cir. 1975).

While physicians are exempt from the provisions of the drug abuse statutes when they dispense or prescribe controlled substances in **good faith** to patients in the regular course of professional practice, they are liable to prosecution under Sec. 841, 21 U.S.C. "xxx when their activities fall outside the usual course of professional practice." U.S. v. Moore, 423 U.S. 122, 124, 96 S. Ct. 335, 337, 46 L. Ed.2d 404 (1976); U.S. v. Ellzey, 527 F.2d 1306 (6th Cir. 1976).

No reported decision sets out specific guidelines of what is required to support a conclusion that an accused acted outside the usual course of professional practice in issuing prescriptions for controlled substances. The decisions reflect a case by case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts." (bold print added for emphasis)

It is clear that the Kirk Court's finding of the lack of "decision" to define "the essential elements," that is "the meanings of the statutory phrase, "In the usual course of professional practice" and the regulations' phrase, "legitimate medical purpose," 21 C.F.R. § 1306.04(a), marks the beginning of the Sixth Circuit's unconstitutional adoption of federal common law upon its

expansive interpretation of United States v. Moore, 423 U.S. 122, 124, (1976), out of the District of Columbia, and other caselaw which "failed to set[] out specific guidelines," much less "the essential elements" necessary to extend the crime proscribed in 21 U.S.C. § 841(a)(1) to the conduct of doctors in prescribing pain medications for patients suffering from pain, Kirk, 584 F.2d at 784, and the lack of jurisdiction below.

Dicta or not, the Supreme Court's decision in Gonzales v. Oregon, 546 U.S. at 258-271, in fact points out that in Moore, 423 U.S. at 135 and 143, the Supreme Court has gone no further than to "address[] a situation in which a doctor 'sold drugs, not for legitimate purposes, but primarily for the profits to be derived therefrom," at 135, and has not "considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician," at 143, quoted in Gonzales, at 269. The Gonzales Court also pointed to the legislative facts and commands under 21 U.S.C. § 823(f) that, as part of its enforcement, "the Attorney General looks not just to violations of federal drug laws; but also he 'shall' also consider '[t]he recommendation of the appropriate State licensing board or professional disciplinary authority' and the registrant's compliance with state and local drugs laws," and:

> "Further cautioning against the conclusion that the CSA effectively displaces the States' general regulation of medical practice is the Act's pre-emptive provision, which indicates that, absent a positive conflict, none of the Act's provisions should be 'construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates ... to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State.' § 903."

Gonzales, at 271.

In light of that fact that "the [CSA] statute manifests no intent to regulate the practice of medicine generally," id., at 270, as further confirmed by the Sixth Circuit in Kirk, 584 F.2d at 784, it must be presumed that there is no "positive conflict" with congressional intent not to "displace[] the States' general regulation of medical practice," Gonzales, at 271, and the Ohio Revised Code ("ORC") 119.032, chapter 4731-21, et seq. (1998-2008), which authorized and regulated the pain medications prescribed by the Appellant for all of his patients in question and treated for symptoms of pain and suffering, according to 21 U.S.C. §§ 823(f) and 903, Gonzales, at 269-271. Nonetheless, the Panel, district court and the prosecution made a calculated decision to disregard the Appellant's lawful reliance on the said ORC at trial and on the initial direct appeal, United States v. Volkman, 736 F.3d at 1019-1022, 1026-1031, supra, under the theory of federal common law derived from Kirk, 584 F.2d at 784, in violation of the Appellant's 5th Amendment right to "due process of law." See, United States v. Graham, 275 F.3d at 543; United States v. Dempsey, 733 F.2d at 395; and Fisch v. General Motors Corp., 169 F.2d at 272-73, supra; and compare North American Van Lines, Inc., v. United States, 243 F.2d at 696-699, reaffirmed and explained United States v. Salisbury, 983 F.2d 1369, 1377-1378 (6th Cir. 1992), in relevant part:

> "The due process of law clauses of the Fifth and Fourteenth Amendments require criminal statutes to provide notice to the accused of the nature and specific elements of the crime charged. Colavutti v. Franklin, 439 U.S. 379, 390, 58 L.Ed. 2d 586, 99 S.Ct. 675 (1979); North American Van Lines v. 243 F.2d 693, 697 (6th Cir. 1957). The 'void for vagueness' doctrine requires that a statutory prohibition be sufficiently defined so that ordinary people, exercising ordinary

> common sense, can understand it and avoid conduct which is prohibited, without encouragement of arbitrary and discriminatory enforcement. Kolender v. Lawson, 461 U.S. 352, 357, 75 L.Ed.2d 903, 103, S. Ct. 1855 (1983); United States v. Avant, 907 F.2d 623, 625 (6th Cir. 1990); Nelson v. United States, 796 F.2d 164, 167 (6th Cir. 1986), citing Arnett v. Kennedy, 416 U.S. 134, 159, 40 L.Ed.2d 15, 94 S. Ct. 1633 (1974), reh'g denied, 417 U.S. 977, 94 S. Ct. 3187, 41 L.Ed. 2d 1148 (1974), quoting, United States Civil Serv. Comm'n v. National Ass'n of Letter Carriers, 413 U.S. 548, 579, 37 L. Ed.2d 796, 93 S. Ct. 2880 (1973); United States v. Thomas, 274 U.S. App. D.C. 385, 864 F.2d 188, 194 (D.C. Cir. 1988). The law must be specific enough to give reasonable and fair notice in order to warn people to avoid conduct with criminal consequences. Kolender v. Lawson, 461 U.S. at 357; Smith v. Goguen, 415 U.S. 566, 574, 39 L.Ed.2d 605, 94 S. Ct. 1242 (1974); Stout v. Dallman, 492 F.2d 992, 994 (6th Cir. 1974); United States v. Thomas, 864 F.2d at 194-195. In addition to notice, a statute must also establish minimal guidelines to govern enforcement. Kolender v. Lawson, 461 U. S. at 358; Smith v. Goguen, 415 U.S. at 574; United States v. Thomas, 864 F.2d at 194.
>
> Due process is violated where a statute provides no definite standard of conduct, thereby giving law enforcement officers, courts and jurors unfettered freedom to act on nothing but their own preferences and beliefs. Smith v. Goguen, 415 U.S. at 775, 578."

In order to satisfy these requirements of "due process of law," "notice ... of the nature and specific elements of the crime" and "minimal guidelines to govern enforcement," id., the questions raised by the Gonzales Court regarding the "intent" of Congress, Wiltberger, 18 U.S. at 95, not to "displace[] the States' general regulation of medical practice," under 21 U.S.C. §§ 823(c)(4) and 903, Gonzales, 546 U.S. at 267-271, clearly trigger the duty of the Sixth Circuit to "satisfy itself not only of its own jurisdiction, but also that of the lower court[]," Yeager, 303 F.3d at 664, quoting Steel Co., 523 U.S. at 94, and Mansfield, 111 U.S. at 382, a duty not foreclosed by the vague administrative interpretations of the Kirk Court, 584 F.2d, at 784, much less by the "good faith" rationale adopted by and from United States v. Moore, 423 U.S. at 124, and Kirk, at 784. See

also, Metro. Hosp. v. United States HHS, 712 F.3d 248, 270-271 (6th Cir. 2013), in relevant part:

> "Adherence to precedent promotes stability, predictability, and respect for judicial authority." [Hilton v. South Carolina Public Railways Comm'n., 502 U.S. 197, 202, 112 S. Ct. 560, 116 L.Ed.2d 560 (1991)] Accordingly, a court may disregard stare decisis and depart from established precedent only upon 'some compelling justification.' Id. These considerations have 'special force in the area of statutory interpretation, ... [where] the legislative power is implicated, and Congress remains free to alter what we have done." Id. (quoting Patterson v. McLean Credit Union, 491 U.S. 164, 172-73, 109 S. Ct. 2363, 105 L.Ed.2d 132 (1989)."

Therefore, in addition to the clear violation of the Appellant's Due Process rights, Salisbury, 983 F.2d at 1377-1378, and the duty of this Court to make the jurisdictional inquiry, Yeager, 303 F.3d at 664, the need to clarify the intent of Congress to not "displace[] the States' general regulation of medical practice," under 21 U.S.C. § 823(f)(4) and § 903, Gonzales v. Oregon, 546 U.S. at 267-271, and clarify for the medical professional and doctors a reliable bright line between them and the pitfall of an erroneous prosecution by "law enforcement officers, courts and jurors [with] unfettered freedom to act on nothing but their own preferences and beliefs," Salisbury, 983 F.2d at 1377-1378, citing Smith v. Goguen, 415 U.S. at 575, 578, warrants this Court's remand of the entire matter to the District Court for a full and fair adjudication of the jurisdictional facts and law brought to light in Gonzales v. Oregon, 546 U.S. at 258-264 & 267-271, even if "technically dicta, its import is clear and therefore binding upon this Court." Hrometz v. Local 550, Int'l of Bridge Constr. & Ornamental Ironworkers, 227 F.3d 597, 602 (6th Cir. 2000) citing United States v. Oakar, 111 F.3d 146, 153 (D.C. Cir. 1997)("Care-

fully considered language of the Supreme Court, even if technically dictum, generally must be treated as authoritative.")

Technically, the Supreme Court's opinion in Moore, 423 U.S. at 124, is dicta in that it arose from a case out of the District of Columbia, and was summarily adopted by the Sixth Circuit in Kirk, 584 F.2d at 784, to engraft a federal-common-law "good faith" element on to the CSA and the administrative law of the Attorney General, 21 C.F.R. § 1306.04(a), id., now overruled by implication of the fact that "there is no federal common law crime," Graham, 275 F.3d at 543, citing Hudson and Goodwin, 11 U. S. 32 (1812), and further by the clarifications announced in Gonzales v. Oregon, 546 U.S. at 258-271, regarding the duty of the federal courts to apply state law in determining the scope of legitimate and professional medical practice of doctors under 21 U.S.C. § 823(f)(4) and 903, absent a showing of "positive conflict" as contemplated by the statutory mandate of Congress. Id. No such showing has been made by the United States below.

b. The Jury Instruction Error Below Requires Remand

The jury instruction below is "particularly vexing," Burrage, 187 L.Ed.2d at 727-728, to direct the jury as to the evidence required to satisfy "the beyond-a-reasonable-doubt standard in criminal trials," under 21 U.S.C. § 841(a)(1), and to establish that the drugs in question were an "independently sufficient cause of the victim's death," id., as to each one of the deceased patients of the appellant under the enhanced punishment provisions of 21 U.S.C. § 841(b)(1)(C), and deprived the appellant of his Fifth Amendment right to "due process of law," in connection with 21 U.S.C. §823(f)(4) and 903, Ohio law, ORC 119.032, ch. 4731-21,

See also, MacKay, 20 F.Supp.2d 1287, supra, and compare Gonzales v. Oregon, 546 U.S. at 258-271; 42 U.S.C. § 290bb-2a.

Cursory review of the erroneous jury instruction reveals that the trial court adopted it in substantial part from the Attorney General's 21 C.F.R. § 1306.04(a), quoted in Kirk, 584 F.2d at 784. The jury instruction states, in relevant part:

> "In addition to alleging that defendant knowingly and intentionally dispensed a mixture and substance containing a detectable amount of oxycodone, a Schedule II controlled substance, not for a legitimate medical purpose in the usual course of professional practice, Counts 4, 5, 6, 8, 9, 10, 11, 17, 18, 20 and 21 of the indictment also allege that the death of the individuals named in those counts resulted from the use of the substances distributed or dispensed by the defendant.
>
> In order to establish that a death resulted from defendant's conduct, the government need not prove that the death was foreseeable to the defendant, but the government must prove beyond a reasonable doubt that the death would not have occurred had the mixture and substance containing a detectable amount of oxycodone, a Schedule II controlled substance dispensed by defendant, not be[en] (SIC) ingested by the individual."

Tr., PAGEID#: 8593,ll. 14-25, & 8594, ll. 1-3 (filed 8/08/2012).

There, the language "a legitimate medical purpose in the usual course of professional practice" is also a verbatim recital taken from the Kirk, 584 F.2d at 784, quoting the Attorney General's 21 C.F.R. § 1306.04(a), supra. Not only is this an administrative rule, the Gonzales Court has rejected that the Attorney General has any authority to define the elements of the crime proscribed under the CSA, 546 U.S. at 260, and, more to the point, nor is there any power or authority delegated to the district court to proscribe any "federal common law crime." Graham, 275 F.3d at 543; Wiltberger, 18 U.S. at 95.

Over the appellant's timely objection below, the trial court declined to correct this error by giving an instruction consistent

with the Gonzales Court's opinion that 21 U.S.C. §§ 823(f) and 903 compel the conclusion that Congress intended that the CSA not "displace[] the States' general regulation of medical practice," 546 U.S. at 270-271.

Further confounding and confusing the jury instruction, the district court's instruction wholly failed to instruct the jury as to whether the death of each deceased patients "resulted from" the controlled substance, oxycodone, as a "contributing-cause," or as "an independently sufficient cause" of death, required under Burrage, 187 L.Ed 2d at 727-728, and the Fifth Amendment guarantee to "due process of law." Yeager, 303 F.3d at 664; citing Steel Co., 523 U.S. at 94; citing Mansfield, 111 U.S. at 382.

CONCLUSION

Therefore, this Court is under a duty to generally remand this case to the district court with directions for an adjudication of each and every jurisdictional element and limitation, in connection with the relevant provisions of the CSA, and specifically 21 U.S.C. §§ 802(21), 812(b), 823(f)(4), 841(a)(1) and (b)-(1)(C), 846, and 903, and otherwise, as law and justice so require.

Wherefore, premises considered, the Appellant prays for this Court to reverse and remand this case to the District Court for a full and fair adjudication of the jurisdictional grounds and issues raised heretofore, and with directions for the District Court to dismiss the indictment where the lack of jurisdiction is shown, as law and justice so require.

Respectfully submitted,

Paul H. Volkman M.D.

Paul H. Volkman, M.D.,
in propria persona

CERTIFICATE OF SERVICE

I, Paul H. Volkman, hereby certify that a copy of the foregoing brief was duly served, by delivery of a copy in an envelop with first class prepaid postage affixed thereto and addressed to: Timothy D. Oakley and Christopher K. Barnes, Assistant United States Attorneys, United States Attorney's Office, 221 East Fourth Street, Suite 400, Cincinnati, Phio 45202;

this 27th day of April, 2015.

Signed,

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Chapter 4731-21 Drug Treatment of Intractable Pain

4731-21-01 Definitions.

As used in Chapter 4731-21 of the Administrative Code:

(A) "Addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life. Physical dependence alone is not evidence of addiction.

(B) "Believes" or "has reason to believe" does not require absolute certainty or complete unquestioning acceptance; but only an opinion based on reasonable information that a patient is suffering from addiction or drug abuse or engaging in diversion of drugs.

(C) "Board" means the state medical board of Ohio.

(D) "Diversion" means the conveyance of a prescription drug to a person other than the person for whom the drug was prescribed or dispensed by a practitioner.

(E) "Drug abuse" means a maladaptive or inappropriate use or overuse of a medication.

(F) "Emergency" means an unforeseen combination of circumstances or the resulting state that calls for immediate action.

(G) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found. "Intractable pain" does not include pain experienced by a patient with a terminal condition. "Intractable pain" does not include the treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(H) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

(I) "Physical dependence" means a physiologic state of adaptation to a specific drug or medication characterized by the development of a withdrawal syndrome following abrupt cessation of a drug or on administration of an antagonist.

(J) "Practitioner" means any of the following:

(1) An individual holding a certificate to practice medicine and surgery or osteopathic medicine and surgery under Chapter 4731. of the Revised Code;

(2) An individual holding a certificate to practice podiatric medicine and surgery under Chapter 4731. of the Revised Code and practicing within his or her scope of practice as defined in section 4731.51 of the Revised Code; or

(3) An individual holding both of the following:

(a) A certificate to practice as a physician assistant under Chapter 4730. of the Revised Code and practicing within his or her scope of practice in compliance with that chapter; and

(b) A certificate to prescribe under Chapter 4730. of the Revised Code and exercising physician delegated prescriptive authority in compliance with that chapter.

Exhibit 1

(K) "Prescription drug" means a drug which under state or federal law may be administered or dispensed only by or upon the order of a practitioner and includes the term "dangerous drug" as defined by section 4729.02 of the Revised Code.

(L) "Protracted basis" means for a period in excess of twelve continuous weeks.

(M) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury, which will likely result in death. A terminal condition is one in which there can be no recovery, although there may be periods of remission.

A terminal condition shall be determined to a reasonable degree of medical certainty in accordance with reasonable medical standards by a patient's attending medical doctor or doctor of osteopathic medicine and one other individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery who has examined the patient.

(N) "Tolerance" means decreasing response to the same dosage of a prescription drug over time as a result of physiologic adaptation to that drug.

(O) "Utilizing prescription drugs" means prescribing, administering, dispensing, supplying, selling or giving a prescription drug.

Effective: 11/30/2008

R.C. 119.032 review dates: 11/06/2007 and 11/30/2013

Promulgated Under: 119.03

Statutory Authority: 4730.07, 4730.39, 4731.05, 4731.052

Rule Amplifies: 4730. 39, 4731.22, 4731.052

Prior Effective Dates 11/11/98

4731-21-02 Utilizing prescription drugs for the treatment of intractable pain.

(A) When utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions, a practitioner shall comply with accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) An initial evaluation of the patient shall be conducted and documented in the patient's record that includes a relevant history, including complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases or conditions; and an appropriate physical examination; Directed to area of complaint!

(2) A medical diagnosis shall be established and documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism;

(3) An individualized treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall specify the medical justification of the treatment of intractable pain by utilizing

Exhibit 2

prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success. The prescription drug therapy shall be tailored to the individual medical needs of each patient. The practitioner shall document the patient's response to treatment and, as necessary, modify the treatment plan;

(4)

(a) The practitioner's diagnosis of intractable pain shall be made after having the patient evaluated by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain. For purposes of this rule, a practitioner "specializes" if the practitioner limits the whole or part of his or her practice, and is qualified by advanced training or experience to so limit his or her practice, to the particular anatomic area, system, or organ of the body perceived as the source of the pain. The evaluation shall include review of all available medical records of prior treatment of the intractable pain or the condition underlying the intractable pain; a thorough history and physical examination; and testing as required by accepted and prevailing standards of care. The practitioner shall maintain a copy of any report made by any practitioner to whom referral for evaluation was made under this paragraph. A practitioner shall not provide an evaluation under this paragraph if that practitioner would be prohibited by sections 4731.65 to 4731.69 of the Revised Code or any other rule adopted by the board from providing a designated health service upon referral by the treating practitioner; and

(b) The practitioner shall not be required to obtain such an evaluation, if the practitioner obtains a copy of medical records or a detailed written summary thereof showing that the patient has been evaluated and treated within a reasonable period of time by one or more other practitioners who specialize in the treatment of the anatomic area, system, or organ of the body perceived as the source of the pain and the treating practitioner is satisfied that he or she can rely on that evaluation for purposes of meeting the further requirements of this chapter of the Administrative Code. The practitioner shall obtain and review all available medical records or detailed written summaries thereof of prior treatment of the intractable pain or the condition underlying the intractable pain. The practitioner shall maintain a copy of any record or report of any practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph; and

(5) The practitioner shall ensure and document in the patient's record that the patient or other individual who has the authority to provide consent to treatment on behalf of that patient gives consent to treatment after being informed of the benefits and risks of receiving prescription drug therapy on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, and after being informed of available treatment alternatives.

(B) Upon completion and satisfaction of the conditions prescribed in paragraph (A) of this rule, and upon a practitioner's judgment that the continued utilization of prescription drugs is medically warranted for the treatment of intractable pain, a practitioner may utilize prescription drugs on a protracted basis or in amounts or combinations that may not be appropriate when treating other medical conditions, provided that the practitioner continues to adhere to accepted and prevailing standards of care which shall include, but not be limited to, the following:

(1) Patients shall be seen by the practitioner at appropriate periodic intervals to assess the efficacy of treatment, assure that prescription drug therapy remains indicated, evaluate the patient's progress toward treatment objectives and note any adverse drug effects. During each visit, attention shall be given to changes in the patient's ability to function or to the patient's quality of life as a result of prescription drug

Exhibit 3

usage, as well as indications of possible addiction, drug abuse or diversion. Compliance with this paragraph of the rule shall be documented in the patient's medical record; No repeat PE required!

(2) Some patients with intractable pain may be at risk of developing increasing prescription drug consumption without improvement in functional status. Subjective reports by the patient should be relevance supported by objective data. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient. Compliance with this paragraph of the rule shall be documented in the patient's medical record;

(3) Based on evidence or behavioral indications of addiction or drug abuse, the practitioner may obtain a drug screen on the patient. It is within the practitioner's discretion to decide the nature of the screen and which type of drug(s) to be screened. If the practitioner obtains a drug screen for the reasons described in this paragraph, the practitioner shall document the results of the drug screen in the patient's medical record. If the patient refuses to consent to a drug screen ordered by the practitioner, the practitioner shall make a referral as provided in paragraph (C) of this rule;

(4) The practitioner shall document in the patient's medical record the medical necessity for utilizing more than one controlled substance in the management of a patient's intractable pain; and

(5) The practitioner shall document in the patient's medical record the name and address of the patient to or for whom the prescription drugs were prescribed, dispensed, or administered, the dates on which prescription drugs were prescribed, dispensed, or administered, and the amounts and dosage forms of the prescription drugs prescribed, dispensed, or administered, including refills.

(C) If the practitioner believes or has reason to believe that the patient is suffering from addiction or drug abuse, the practitioner shall immediately consult with an addiction medicine specialist or other substance abuse professional to obtain formal assessment of addiction or drug abuse.

(1) For purposes of this rule:

(a) Addiction medicine specialist means a physician who is qualified by advanced formal training in addiction medicine or other substance abuse specialty, and includes a medical doctor or doctor of osteopathic medicine who is certified by a specialty examining board to so limit the whole or part of his or her practice.

(b) Substance abuse professional includes a psychologist licensed pursuant to Chapter 4732. of the Revised Code and certified as a clinical health psychologist, an independent chemical dependency counselor, or a chemical dependency counselor III.

(2) The practitioner shall do all of the following:

(a) Document the recommendations of the consultation in the patient's record;

(b) Continue to actively monitor the patient for signs and symptoms of addiction, drug abuse or diversion; and

(c) Maintain a copy of any written report made by the addiction medicine specialist or substance abuse professional to whom referral for evaluation was made under this paragraph.

(3) Prescription drug therapy may be continued consistent with the recommendations of the consultation. If the consulting addiction medicine specialist or other substance abuse professional believes the patient

to be suffering from addiction or drug abuse, prompt referral shall be made to one of the following:

(a) An addiction medicine specialist or substance abuse professional; or

(b) An addiction medicine or substance abuse treatment facility.

Effective: 11/30/2008

R.C. 119.032 review dates: 11/06/2007 and 11/30/2013

Promulgated Under: 119.03

Statutory Authority: 4731.05, 4731.052

Rule Amplifies: 4731.22, 4731.052

Prior Effective Dates: 11/11/98

4731-21-03 Continuing Medical Education.

The board encourages those practitioners who encounter patients with intractable pain in the usual course of their practices to complete continuing medical education related to the treatment of intractable pain, including coursework related to pharmacology, alternative methods of pain management and treatment, and addiction medicine.

R.C. 119.032 review dates: 11/06/2007 and 11/06/2012

Promulgated Under: 119.03

Statutory Authority: 4731.05, 4731.052

Rule Amplifies: 4731.22, 4731.052

Prior Effective Dates: 11/11/03

4731-21-04 Tolerance, Physical Dependence and Addiction.

(A) Physical dependence and tolerance by themselves do not indicate addiction.

(B) Physical dependence and tolerance are normal physiological consequences of extended opioid therapy, and do not, in the absence of other indicators of drug abuse or addiction, require reduction or cessation of opioid therapy.

R.C. 119.032 review dates: 11/06/2007 and 11/06/2012

Promulgated Under: 119.03

Statutory Authority: 4731.05, 4731.052

Rule Amplifies: 4731.22, 4731.052

Prior Effective Dates: 11/11/98

4731-21-05 Violations.

A violation of any provision of any rule in this chapter of the Administrative Code, as determined by the

Exhibit 5

board, shall constitute "failure to use reasonable care discrimination in the administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code; "selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code, if done knowingly or recklessly, as those words are defined in section 2901.22 of the Revised Code; and "a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

R.C. 119.032 review dates: 11/06/2007 and 11/06/2012

Promulgated Under: 119.03

Statutory Authority: 4731.05, 4731.052

Rule Amplifies: 4731.22, 4731.052

Prior Effective Dates: 11/11/98

4731-21-06 Exceptions.

(A) A practitioner who treats pain by utilizing prescription drugs is not subject to disciplinary action pursuant to this chapter of the Administrative Code under the following circumstances:

(1) The treatment of pain for a patient with a terminal condition: "death waiver" Paul Crum

(2) The treatment of pain associated with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition; Aaron Gillispie, metastatic CA

(3) Treatment utilizing only drugs that do not exert their effects at the central nervous system level; and

(4) Treatment utilizing only drugs that are not controlled substances and are classified as antidepressants.

(B) A practitioner who treats intractable pain by utilizing prescription drugs is not subject to disciplinary action by the board under section 4731.22 of the Revised Code solely because the practitioner treated the intractable pain with prescription drugs. The practitioner is subject to disciplinary action only if the prescription drugs are not utilized in accordance with section 4731.052 of the Revised Code and the rules adopted under this chapter of the Administrative Code.

(C) A Medical doctor or doctor of osteopathic medicine who provides comfort care as described in division (E)(1) of section 2133.12 of the Revised Code to a patient with a terminal condition is not subject to disciplinary action by the board under section 4731.22 of the Revised Code if the treatment of pain for a patient with a terminal condition is provided pursuant to the requirements of section 2133.11 of the Revised Code.

R.C. 119.032 review dates: 11/06/2007 and 11/06/2012

Promulgated Under: 119.03

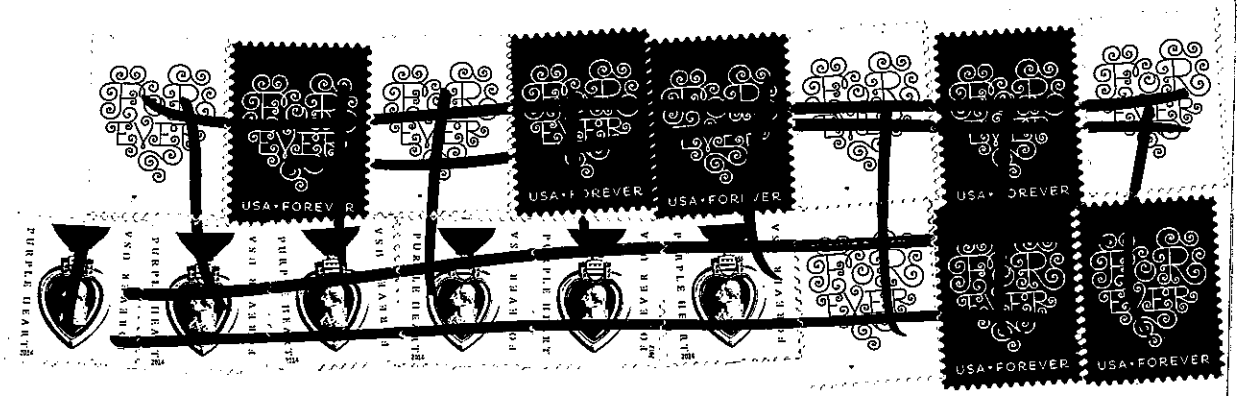
Statutory Authority: 4731.05, 4731.052

Rule Amplifies: 4731.22, 4731.052

Prior Effective Dates: 11/11/98

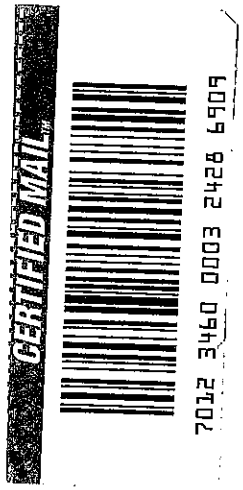
Exhibit 6

Paul H. Volkman
#19519-424
U.S. Penitentiary
P.O. Box 33
Terre Haute, IN 47808



Legal Mail

Clerk,
Sixth Circuit Court of Appeals
100 East Potter Stewart U.S. Courthouse
Cincinnati, OH 45202-3988



INMATE IDENTIFICATION CONFIRMED

8-24

Federal Correctional Complex
Terre Haute, IN 47802
Date:_____

...as processed through special mailing procedures for ... letter has been neither opened nor inspected. ... or problem over which this facility has ... return the (material) for further information ... closes correspondence to be forwarded ... to the above listed address.

APR 27 2015

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT OF THE RETURN ADDRESS, FOLD AT DOTTED LINE