IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
v.	)	**No. 1:19-cr-10043-STA**
	)	
JAY SHIRES, M.D.	)	
LORAN KARLOSKY, M.D.	)	

MEMORANDUM IN SUPPORT OF MOTION TO COMPEL THE GOVERNMENT TO SUPPLEMENT ITS EXPERT DISCLOSURE NOTICE

-AND-

MEMORANDUM IN SUPPORT OF INITIAL MOTION TO EXCLUDE OPINION TESTIMONY AND FOR AN EVIDENTIARY HEARING

The defendant, LORAN KARLOSKY, M.D., through counsel, has respectfully moved this Court to exclude the opinion testimony indicated in the government's notice from August 2020, to hold an evidentiary hearing, and to compel the government to provide sufficient notice.

Given that this case concerns prescribing, medical judgment, physician supervision, and related healthcare issues, the government's failure to file compliant expert disclosures significantly impairs Dr. Karlosky's ability to effectively investigate and determine potential defense experts, to engage in necessary pretrial and trial preparation, and to raise all the critical issues before the Court concerning the admissibility of the government's proposed opinion testimony under *Daubert* and *Kumho*.

I. The government's notice is insufficient.

Pursuant to Rule 16(a)(1)(G) of the Federal Rules of Criminal Procedure, when the government intends to introduce opinion testimony, it must provide a "written summary of any testimony that the government intends to use under 702, 703, or 705 of the Federal Rules of

Evidence in its case-in-chief at trial." The summary must "describe the witness's opinions, the bases and reasons for those opinions, and the witness's qualifications." *Id.* The government's notice in this case is insufficient.

The Advisory Committee Notes for Rule 16 explain why section (a)(1)(G) was added to Rule 16.

> The amendment is intended to minimize surprise that often results from unexpected expert testimony, reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert's testimony through focused cross-examination.
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> With increased use of both scientific and nonscientific expert testimony, one of counsel's most basic discovery needs is to learn that an expert is expected to testify. . . . This is particularly important if the expert is expected to testify on matters which touch on new or controversial techniques or opinions. The amendment is intended to meet this need by *first*, requiring notice of the expert's qualifications which in turn will permit the requesting party to determine whether in fact the witness is an expert within the definition of Federal Rule of Evidence 702.
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> *Second*, the requesting party is entitled to a summary of the expected testimony. This provision is intended to permit more complete pretrial preparation by the requesting party. For example, this should inform the requesting party whether the expert will be providing only background information on a particular issue or whether the witness will actually offer an opinion. In some instances, a generic description of the likely witness and that witness's qualifications may be sufficient, e.g.
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> *Third*, and perhaps most important, the requesting party is to be provided with a summary of the bases of the expert's opinion. [T]he amendment requires a summary of the bases relied upon by the expert. That should cover not only written and oral reports, tests, reports, and investigations, but any information that might be recognized as a legitimate basis for an opinion under Federal Rule of Evidence 703, including opinions of other experts.

Fed. R. Crim. P. 16, Advisory Committee Notes (1993 Amendment) (emphasis added).

If a party fails to comply with Rule 16, the district court has the discretion to prohibit the introduction of the evidence. *See* Fed. R. Crim. P. 16(d)(2).

The defense must also be "able to analyze the steps that led the government's [experts] to their conclusions." *United States v. Davis*, 514 F.3d 596, 611–13 (6th Cir. 2008) (finding government "clearly violated" Rule 16(a)(1)(G)). A vague avowal of a witness's experience is not enough. *See United States v. White*, 492 F.3d 380 (6th Cir. 2007) (concluding government's summary that listed "general subject matters to be covered, but did not identify what opinion the expert would offer on those subjects" insufficient).

The notice in this case provides three categories of witnesses: (1) Dr. Stephen D. Loyd,[2] (2) David Roose of the Drug Enforcement Administration "or an agent with similar training and expertise," which "would offer a foundation and context for his analysis of Practice Fusion records in connection with this case," and (3) Doug Pate of the Tennessee Bureau of Investigation "or a law enforcement witness with similar training/experience/expertise" who "may testify" about the Controlled Substances Act, "red flags" for law enforcement in controlled substance prescribing, the Tennessee CSMD and how it can be used to spot "red flags," and "red flags" in the prescribing patterns at Downtown Medical Clinic." *See United States v. Shires et al*., Case No. 1:19-cr-10043-STA, Expert Notice (Aug. 17, 2020) (hereafter *Expert Notice*).

By not providing the identity of each expert, the government wholly deprives the defense of the ability to challenge their qualifications. *See White*, 492 F.3d at 406–07. Other than vague generalities, nothing specific is provided in the notice that provides a basis for the "red flags" opinion testimony. *See United States v. Jones*, 81 Fed. App'x 45, 49 (6th Cir. 2003) (where law enforcement officer testified about a single use dose of crack cocaine such that quantity at issue consistent with distribution).

[2] Dr. Loyd's qualifications were also the subject of a motion filed by Dr. Shires, which Dr. Karlosky moved to join.

The notice states that Mr. Roose's and Mr. Pate's testimony "would be factual" and that these witnesses would "recount their experiences, observations, and use of current legal forensic standards in their job duties," such that the notice is provided "out of an abundance of caution." *Id.* at p.2. The notice attaches Dr. Loyd's CV, Mr. Roose's CV, and a half-page summary of Mr. Pate's education, experience, and training. *Id.*

A. The notice regarding Dr. Loyd's testimony is insufficient.

The notice indicates that Dr. Loyd conducted a "file review" for the patients listed in Counts 2–8 "as well as other patients seen at the Downtown Medical Clinic." *Id.* at p.2. The notice does not indicate how many patients' files Dr. Loyd reviewed or what constituted each "file" he saw, nor does it indicate how the patient files were selected among Downtown Medical Clinic's patients. The government indicates that Dr. Loyd will testify about the "usual course of professional practice for medical providers, including nurse practitioners."[3] *Id.* at p. 2. The "usual course of professional practice" is an element of the government's case and concerns the defendants' mental state. The government does not indicate Dr. Loyd's qualifications to opinion on standards applicable to nurse practitioners, as opposed to standards for physicians. The government's notice provides that Dr. Loyd will testify regarding "troubling findings" that formed the basis for his opinions, including poor recordkeeping, improper assessment of patients, failure to offer "safer" treatment modalities, ignoring "red flags," and failing to inform patients of increased risks. The government does not identify all of Dr. Loyd's opinions or the basis for his expertise regarding "red flags." Finally, the government's notice indicates that Dr. Loyd "is compiling a supplement to his report, assessing the precepting practices used to review Mary

[3] *See also* Expert Notice, at p. 2) (identifying Dr. Loyd's opinion that prescribing practices "were outside the scope of professional medical practice and without a legitimate medical purpose").

Bond's work." *Id.* at p. 2. Critical issues with respect to Drs. Shires and Karlosky concern precepting.

B. The notice regarding Mr. Roose and Mr. Pate (or other unidentified witnesses with similar experience) is insufficient.

The government's notice fails to identify particular witnesses but submits that it may call Mr. Roose and Mr. Pate. In addition, the notice fails to provide the basis for Mr. Roose and Mr. Pate's respective opinions, and the information provided regarding Mr. Pate's background, training, and experience is particularly deficient. There is no report and the half-page summary does not provide any information on how his education in accounting and business administration or his receipt of a Master of Arts qualifies him to opine on, for example, the "red flags" law enforcement looks for in controlled substance prescribing, the "red flags" that can be used by law enforcement and medical boards when reviewing prescribing and dispensing patterns, or the "red flags" in Downtown Medical Clinic's prescribing patterns.

Indeed, contrary to the conclusions asserted in the notice, alternate explanations may exist for many so-called "red flags." Confirmation and anchoring biases may explain why the law enforcement agents and reviewing physician here assumed certain patient behavior was a "red flag," whereas another medical professional may view it as a neutral or positive datapoint:

> One of the most well described biases is confirmation bias, a "tendency to look for, notice, and remember information that fits with our preexisting expectations … information that contradicts those expectations may be … dismissed as unimportant."… Anchoring bias is related; it occurs when an incorrect initial impression is made and then all subsequent work focuses on that incorrect impression. …
>
> The negative impact of the operation of these biases may account for the predominant notion that providers can tell upon first impression whether a patient is actually in pain or "on the level." Perhaps a patient appears comfortable and happy when the provider sees him or her sitting in the exam room; when he or she reports severe, even crippling pain after walking to the exam room, the provider may decide he or she is not "on the level" and ignore other information. In reality, this is a typical presentation with lumbar stenosis.

> Confirmation and anchoring bias may combine to explain the unfortunate effects of provider, institutional, and regulatory reliance on red flags for diversion. *One such red flag is when a patient asks for a particular opioid drug by name. Suppose a patient said, "Vicodin makes me itch, but Percocet worked well for me when I hurt my back a few years ago." If the provider has decided the patient is not diverting based on an initial impression, they may interpret the patient's statement as an indicator she is a good historian. Otherwise, she would quickly be suspected of diverting and denied a prescription that would otherwise relieve the acute pain.*
>
> Confirmation and anchoring biases in this arena are not limited to providers. … Payment in cash, one red flag, is grounds for denying patients their prescription, regardless of the reasons. Another red flag is multiple pharmacy customers with the same diagnoses and prescriptions from one provider. Other specialty physicians, such as pulmonologists who have multiple patients with asthma all prescribed bronchodilators, are not subject to the same suspicion as similarly situated pain physicians.

Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 Law & Psychol. Rev. 1, 38–41 (2015–16).

C. The notice does not reference Dr. Karlosky or include the government's witnesses' opinions about the precepting/supervision of Ms. Bond's prescribing practices.

The indictment in this case acknowledges that Ms. Bond provided patient care at Downtown Medical Clinic and that Dr. Shires and Dr. Karlosky supervised her work. (Doc. 4). In Tennessee, supervision may be remote and requires periodic after-the-fact review of prescriptions that have already been written and, presumably, filled by the time supervision occurs. That perhaps explains why the expert disclosure in this case does not reference Dr. Karlosky. Indeed, Dr. Loyd's opinions about the patient care at Downtown Medical Clinic does not appear to reference Dr. Karlosky a single time. The sole report provided in this case relates solely to the conduct of Ms. Bond, not Dr. Karlosky.

II. The government has not established that its witnesses are qualified by knowledge, skill, training, or experience.

To offer an expert opinion, a witness must be qualified based on his "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Fed. R. Evid. 702 advisory committee notes citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). *Accord Thomas v. City of Chattanooga*, 398 F.3d 426, 432 (6th Cir. 2005). Whether each of three witnesses identified in the government's notice and their experience is sufficient depends, in some part, on "the nature and extent of that experience." *United States v. Cunningham*, 679 F.3d 355, 379 (6th Cir. 2012).

With respect to Mr. Roose and Mr. Pate, the government has not provided expert reports. Instead, Dr. Karlosky was provided with varying degrees of information about their respective backgrounds. The government did not provide information about Mr. Roose's testimony but did provide a relatively lengthy *curriculum vitae* for Mr. Roose. By comparison, the government provided some information about Mr. Pate's proposed testimony but almost nothing about his background and training. As a result, the government has not established that Mr. Pate is qualified to testify about the Controlled Substances Act or the reasons each drug is scheduled. Based upon his resume, Mr. Pate does not have a background in chemistry or pharmacology. Mr. Pate is not qualified to testify about "red flags" in prescribing or dispensing practices, appropriate/inappropriate MME levels in patients, dangerous drug combinations, or the number of

prescriptions and/or amounts of pills prescribed by an individual provider. Finally, Mr. Pate is not qualified to testify about "red flags" in the prescribing practices of the defendants in this case or Downtown Medical Practice. Accordingly, the government has not carried its burden to establish that Mr. Pate is qualified to testify as an expert. In short, Dr. Karlosky submits that Mr. Pate is not qualified to testify regarding a clinical context for investigations into medical providers including (1) the Controlled Substances Act or how and why drugs are scheduled; (2) what proper professional medical treatment looks like in a pain clinic setting; (3) what constitutes a "red flag;" and (4) whether certain patient files included "red flags" that were allegedly inconsistent with legitimate medical treatment. Mr. Pate does not have sufficient expertise to qualify as an expert witness in this case.

At this time, a similar analysis cannot be performed for Mr. Roose because the government has not provided information about his analysis and testimony beyond a general description of the subject area.

III. Opinion testimony that expresses a legal conclusion must be excluded; opinion testimony that uses the wrong standard must be excluded.

Opinion testimony that expresses a legal conclusion must be excluded. *See Berry v. City of Detroit*, 25 F.3d 1342 (6th Cir. 1994) ("'This circuit is in accord with other circuits in requiring exclusion of expert testimony that expresses a legal conclusion.'") (quoting *Hygh v. Jacobs*, 961 F.2d 359 (2d Cir. 1992)). *Compare* Fed. R. Evid. 704 (providing that an opinion "is not objectionable just because it embraces an ultimate issue" with an exception in criminal cases where "an expert witness must not state an opinion about whether the defendant did or did not have a mental state or condition that constitutes an element of the crime charged or of a defense").

In *Berry v. City of Detroit*, the Sixth Circuit concluded that the district court improperly permitted an expert to testify to a legal conclusion by testifying that a police department's conduct

amounted to deliberate indifference. The Sixth Circuit explained that "[a]lthough an expert's opinion may 'embrace an ultimate issue to be decided by the trier of fact,' Fed. R. Evid. 704(a), the issue embraced must be a factual one." *Id.* at 1353. According to the court, if a proper foundation had been laid, the expert could have testified that the department's discipline was lax and to the consequences of lax discipline. The expert crossed the line, however, by testifying that lax disciplinary policies indicated deliberate indifference. *Id. See also Woods v. Lecureux*, 110 F.3d 1215, 1220 (6th Cir. 1997) ("[T]estimony offering nothing more than a legal conclusion-i.e, testimony that does little more than tell the jury what result to reach-is properly excludable under the Rules. It is also appropriate to exclude 'ultimate issue' testimony on the ground that it would not be helpful to the trier of fact when 'the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.'"). In this case, Dr. Loyd is expected to testify that "the specific prescriptions listed in Counts 2 through 8 as well as the general prescribing practices at issue during the timeframe of the indictment, were outside the scope of professional medical practice and without a legitimate medical purpose." *Expert Notice*, at p. 2. Such testimony improperly draws a legal conclusion as to an element of the offense and should be excluded.

Furthermore, the government may not attempt to use opinion testimony as a "conduit" for the admission of inadmissible hearsay. *See United States v. Tipton*, 269 Fed. Appx. 551, 560 (6th Cir. 2008) (affirming exclusion of opinion testimony concerning tax liability based solely on related hearsay of defendants concerning their assets). The proposed testimony of Dr. Loyd is merely an improper "conduit" for the government to admit hearsay statements included in the reviewed files.

Whether the prescribing patterns at Downtown Medical Clinic were "outside the scope of professional medical practice and without a legitimate medical purpose" is an element of the case that the government must prove beyond a reasonable doubt. In addition, the government's reliance on a selection of patient files—which cannot have been complete given the additional information produced in reciprocal discovery after Dr. Loyd prepared his report, *see* Reciprocal Discovery Production of May 14, 2021 (Doc. 171), and the second EMR extraction from Practice Fusion, which ostensibly corrected an issue with being able to review the physician co-signatures in the charts and potentially other information[4]—along with its reliance on the concept of "red flags" is problematic. For example, the report does not identify any of the reference materials Dr. Loyd consulted to reach his conclusions and generally provides very little information that would minimize surprise and provide defense counsel with a "fair opportunity to test the merit of the expert's testimony."

In addition to impermissibly usurping the jury's function, Dr. Loyd's conclusion that the legal standard was violated is not supported by his report, which evaluates Ms. Bond's prescriptions closer to negligence or malpractice than anything approaching a drug trafficking enterprise. *E.g.*, *Expert Report* at DOJ_0121971 ("The medical record did not meet the standard set forth by the chronic pain guidelines of the State of Tennessee for the prescribing of opioid medicine."). Because of the way the Supreme Court interpreted the concept of practicing medicine outside the scope of professional medical practice and without a legitimate medical purpose in *United States v. Moore*, 423 U.S. 122 (1975), any testimony that relies on best practices or policy guidelines—but does not detail when a medical professional acts as a conventional drug dealer—

[4] *See* E-Mail correspondence from government counsel to prior defense counsel dated October 3 and October 7, 2020 (attached hereto as **Exhibit 1**).

should be deemed inadmissible and excluded. *See also Gonzales v. Oregon*, 546 U.S. 243 (2006). According to the DEA, "Federal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice,' in a way that will provide definitive guidelines that address all the varied situations physicians might encounter." 71 Fed. Reg. 52716, 52717 (Sept. 6, 2006). This is because physicians require latitude in determining what course of action should be taken in the care of their patients, and the DEA "has neither the legal authority nor the expertise to…issue guidelines that constitute advice on the general practice of medicine." *Id.* at 52719.

Dr. Loyd, the government's medical expert, does not reference any source relevant to the question of whether Ms. Bond (and, by extension, her supervising physicians) acted as drug dealers, as distinct from the question of whether they acted below a standard of care, were negligent, committed malpractice, or were just bad doctors/medical professionals. Any opinion premised on the disclosed sources therefore lacks the necessary "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 592. Any proffered opinions from government experts based on these sources should be found inadmissible.

IV. The proposed opinion testimony does not satisfy the requirements of the Supreme Court's decisions in *Daubert* and *Kumho Tire*.

The proposed opinion testimony fails the test for opinion testimony enunciated in *Daubert v. Merrell Down Pharmaceuticals*, 509 U.S. 579 (1993), and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence. *Daubert*, 509 U.S. at 587. The rule provides.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and

> methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The committee notes to Rule 702 further elaborate on the standards for such testimony:

> *Daubert* set forth a non-exclusive checklist of trial courts to use in assessing the reliability of scientific expert testimony. The specific factors explicated by the *Daubert* Court are (1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally applied in the scientific community. The Court in *Kumho* held that these factors might also be applicable in assessing the reliability of nonscientific expert testimony, depending upon "the particular circumstances of the particular case at issue." …. *Daubert* itself emphasized that the factors were neither exclusive nor dispositive. [Identifying examples of other factors.]

Rule 702 requires this Court to be a gatekeeper, ensuring that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589, 597. The trial court's objective "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. The proponent of the evidence must establish admissibility by a preponderance of the evidence. *See Nelson v. Tenn. Gas Pipeline, Co.*, 243 F.3d 244, 256 (6th Cir. 2001).

An application of the *Daubert* or *Kumho* factors to the opinion testimony concerning the standard of practice of nursing and/or physician supervision reveals that the proposed testimony is inadequate, even if portions of it are arguably relevant:[5] (1) the opinion cannot be tested because

[5] Dr. Karlosky would agree that the government must prove beyond a reasonable doubt that the medications at issue were controlled substances under the CSA. However, purported "red

it is entirely subjective and cannot be reasonably assessed for reliability,[6] (2) the "analysis" provided by Dr. Loyd and Mr. Pate, in particular, are effectively determinative legal conclusions, not subject to peer review or publication in the sense of a traditional science or experimental method, (3) there is no known potential error rate, and the danger of error in opinion is exacerbated by the imprimatur of its being given by the government's doctor or law enforcement in a criminal trial, (4) there are no standards or controls, and (5) there is no indication of general acceptance.

Additionally, applying some of the other applicable factors listed above that further interpret the *Daubert* and *Kumho* standards also show that the proposed testimony falls short of acceptable standards: (1) the basis for the opinions at issue was prepared for and comes directly from the context of litigation, (2) there is an extrapolation from a chain of inferences to arrive at a conclusion (*i.e.*, the available patient file and its documentation deficiencies; the selection of a handful of patient files from among the larger patient population), and (3) there is no accounting for alternative explanations. Accordingly, the opinions offered for Dr. Loyd, Mr. Roose, and Mr. Pate (or their equivalents) are improper and should be excluded. *Cf. United States v. Dukes*, 779 Fed. App'x 332 (6th Cir. 2019) ("Testimony on an ultimate issue in a case…is not automatically inadmissible. But an expert cannot provide the jury with a legal conclusion.") (citations omitted)

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flags" do not rise to the same level of relevance an elements of the government's required proof; Dr. Karlosky separately challenges the reliability and appropriateness of such testimony. *Cf. United States v. Russell*, 142 F.3d 438 (6th Cir. 1998) (citing with approval expert testimony about red flags in pharmacy's practices but not the meaning of the term); *see also United States v. Tran*, 609 F. App'x 295, 297 (6th Cir. 2015) (noting "trial counsel conceded that 'any opinion [expert] gives…indicating that there should be red flags raised [by defendant's prescriptions] is perfectly appropriate").

[6] In fact, advances in forensic evidence have made it all too clear that law enforcement impressions and opinions about ultimate guilt are just as subject to error as any law impression about guilt or innocence. DNA exonerations are not a panacea. Many cases, this one included, have determinative facts that do not turn on objective science. Accordingly, the opinion testimony at issue does not assist the trier of fact.

(finding government expert's testimony "came close to being impermissible" but that the Court need not decided if testimony resulted in error because any error would have been harmless) *United States v. Lopez-Medina*, 461 F.3d 724, 744–45 (6th Cir. 2006) (reversing conviction and finding plain error when law enforcement eyewitness was allowed to opine during his testimony about circumstances observed being consistent with production and distribution of cocaine).

As also explained above in the section regarding the insufficiency of the government's notice, the government's notice that two of its expert witnesses will offer opinions about the "red flags" present at Downtown Medical Clinic also fails to meet the standards of *Daubert* and *Kumho*.

Ultimately, Dr. Loyd's opinion—and so, too, potentially Mr. Pate's opinion—relies upon an unrepresentative and non-random sample of patient files hand-picked by the government. Based on this sampling, these witnesses came to the conclusion about Ms. Bond's general prescribing practices and patient care. It appears that the government, not Dr. Loyd, chose the patient files subject to expert review. The government has not established what method or scheme was used in picking these files for Dr. Loyd's review. In this case, Dr. Loyd reviewed approximately six patient files (or, a portion of their files that the government had after the clinic closed, prior to reciprocal discovery of additional clinic records and the second Practice Fusion extraction). However, upon information and belief, approximately 1,700 patient charts were at least partially encapsulated in the data produced in discovery. The principle of reliability requires that an expert base his testimony on sufficient facts or data, support his testimony with reliable principles and methods, and reliably apply his methodology to the facts of a given case. This opinion testimony does not meet that test.

Courts have approved statistical sampling and extrapolation, but only when "statistical sampling with an appropriate level of representativeness has been utilized and approved." *Little*

Hocking Water Ass'n v. E.I. du Pont de Nemours & Co., 90 F.Supp. 3d 746 (S.D. Oh. 2015) (quoting *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1020 (5th Cir. 1997)). The Sixth Circuit has recently put this point more directly when it quoted a Fourth Circuit case: "[C]herry-picking data is just as bad as omitting it or making it up altogether." *United States v. Lang*, 717 Fed. App'x 523, 536 (6th Cir. 2017) (where defendant did not reference lack of EMRs necessary to a full record until "long after the time for a *Daubert* hearing had passed," where expert limited testimony to the paper files of each patient on which he offered an opinion, and where issue was whether record as a whole contradicted expert's factual basis, finding no error). *See also United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co*., 839 F.3d 242 (3d Cir. 2016) (setting forth "Fundamentals of Statistical Sampling"); *Gonzales v. Corning*, 885 F.3d 186, 199 (3d Cir. 2018) (ruling testimony of expert inadmissible where supposedly random sample "tainted by selection bias and statistically insignificant in light of the millions of Oakridge shingles installed during the class period" such that it was "the antithesis of a random sample of Oakridge shingles.")

With respect to Mr. Roose's testimony, the government's notice provided a single paragraph of information, informing that his testimony "would offer a foundation and context for his analysis of Practice Fusion records in this case." *Expert Notice*, at p.3. The government's notice therefore offers no methodology either with respect to the "foundation and context" of his testimony or the resulting "analysis." It is not possible to discern Mr. Roose's opinion. It is not possible to determine whether his analysis meets *Daubert* and the Rules of Evidence. An evidentiary hearing and a supplemental disclosure are required before this Court should let the government's evidence be presented to the jury. Given the reliability issues raised in Dr. Karlosky's other motions concerning Practice Fusion (*e.g.*, the way in which the government obtained the data, the challenges faced in accessing or understanding the data, and Practice

Fusion's history of deception), it will be particularly important to ensure that any testimony by Mr. Roose or "an agent with similar training" about Practice Fusion be tested and deemed trustworthy before it is presented to a jury.

In his motion to dismiss the indictment because its use of the Controlled Substances Act to prosecution a supervising physician based on after-the-fact review of a nurse practitioner's prescriptions for controlled substances violates vagueness and federalism principles, Dr. Karlosky showed that, despite the practice's acceptance, it is unconstitutional to premise liability on an ambiguous regulation governing the practice of medicine. In cases brought based on similar theories, the government has used expert testimony to hold medical practitioners criminally liable for their subjective prescribing decisions. The fact that expert testimony has been allowed on the question of whether a prescription was issued within the scope of professional practice and for a legitimate medical purpose in similar cases does not mean it should be in this case. *See, e.g., United States v. Wells*, 211 F.3d 988 (6th Cir. 2000) (expert reviewed prescribing records and patient file to determine that prescriptions were outside the scope of the professional practice and not issued for a legitimate medical purpose)

V. The proffered expert testimony does not meet Fed. R. Evid. 403's balancing test.

Even assuming the testimony by Dr. Loyd, Mr. Roose, and Mr. Pate are both relevant and met the other requirements of Rule 702, the Court should still find these witnesses' testimony inadmissible. "Like all evidence, the admissibility of expert testimony is also subject to ... balancing of probative value against likely prejudice under Rule 403." The need for a thorough and careful Rule 403 analysis of opinion testimony is particularly important in this case. The Supreme Court recognized that "expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible

prejudice against probative force under Rule 403 ... exercises more control over experts than lay witnesses." *Daubert*, 509 U.S. at 595 (citations omitted). "Unless the expertise adds something, the expert at best is offering a gratuitous opinion, and at worst is exerting undue influence on the jury that would be subject to control under Rule 403." *United States v. Hall*, 93 F.3d 1337, 1343 (7th Cir. 1996).

In *United States v. Stapleton*, the court reviewed a detective's proposed testimony that the defendants' clinic exhibited the characteristics of a typical pill mill. 2013 U.S. Dist. LEXIS 1060422, 2013 WL 5966122, at *7 (E.D. Ky. 2013). During the course of the challenge to the detective testimony, the government "made key concessions" including that the detective would not rely on hearsay. *Id.* at *4. However, despite admitting that he lacked the necessary expertise to reach medical conclusions, the expert planned to "testify about what makes particular features of a pain clinic suspicious, including why certain physician behavior is a red flag because it is inconsistent with legitimate pain management." *Id.* In addition to limiting the testimony based on lack of expertise, the court reasoned that it would be unduly prejudicial to allow testimony comparing the defendants' clinic to a typical pill mill. *Id.* at * 18. "When a law enforcement expert offers a 'point by point examination of profile characteristics with specific reference' to the defendant, there is a particularly acute risk the jury will convict simply because the defendant fits the profile." *Id.* at *7 (quoting *United States v. Quigley*, 890 F.2d 1019, 2023 (8th Cir.), cert. denied, 493 U.S. 1091(1989)).

Here, the probative value of any testimony or proof that extrapolates from Dr. Loyd's review of nine patient files to general prescribing practices of Ms. Bond and her supervising physicians and/or the general standard of care provided at Downtown Medical Clinic is substantially outweighed by the danger of unfair prejudice, confusing the issues, and misleading

the jury. Because Dr. Loyd's testimony only addresses Ms. Bond's conduct in this case, there is an inherent danger that the jury will be adversely influenced by their bad acts and impute them to Dr. Karlosky. Likewise, Dr. Loyd's testimony will likely confuse the jury because it does not address whether Dr. Karlosky knew or should have known of Ms. Bond's conduct as it relates to the entire patient population at Downtown Medical Clinic. For this same reason, Mr. Pate's testimony will likely mislead the jury because his opinions about, for example, "the 'red flags' law enforcement look[s] for in controlled substances prescribing patterns" and the 'red flags' in the prescribing patterns at Downtown Medical Clinic during the timeframe of the indictment" is drawing an inference for the jury rather than presenting information to the jury from which it may be drawn. Next, regarding reliability, the issues with Practice Fusion mean that, if the jury hears law enforcement testimony about Practice Fusion rather than a representative of Practice Fusion, there will be powerful and potentially misleading testimony about the reliability of the underlying records and any subsequent analysis. After all, law enforcement testimony is cloaked with the authority of the government. Finally, the government's proposed medical expert testimony will be confusing because there is no defined standard of care.

The government cannot lump Dr. Karlosky in with Ms. Bond's prescribing patterns for purposes of charging him with a conspiracy and then fail to provide any specific information regarding his conduct. To offer testimony about Ms. Bond's conduct in such circumstances would be unfairly prejudicial.

VI. The proffered testimony violates Dr. Karlosky's Sixth Amendment right to confront the witnesses against him.

The Confrontation Clause of the Sixth Amendment and the Supreme Court's decision in *Crawford v. Washington*, 541 U.S. 36 (2004), require the exclusion of any testimonial hearsay Dr. Loyd and the government's other tendered law enforcement "experts" might offer. The

Confrontation Clause gives a criminal defendant the right "to be confronted with the witnesses against him." U.S. Cont. Art. VI. The central concern of the Confrontation Clause is "to ensure the reliability of the evidence against a criminal defendant by subjecting it to rigorous testing in the context of an adversary proceeding before the trier of fact." *Maryland v. Craig*, 497 U.S. 836, 845 (1990). Pursuant to the Confrontation Clause, a defendant is "guaranteed an opportunity for effective cross-examination." *Delaware v. Van Arsdall*, 475 U.S. 673, 678–79 (1986).

In *Crawford v. Washington*, 541 U.S. 36 (2004), the Court expressed the opinion that "the Framers would not have allowed admission of testimonial statements of a witness who did not appear at trial unless he was unavailable to testify, and the defendant had had a prior opportunity for cross-examination." *Id.* at 53–54. "Where testimonial statements are at issue," the majority concluded "the only indicium of reliability sufficient to satisfy constitutional demands is the one the Constitution actually prescribes: confrontation." *Id.* at 69.

In this case, Dr. Loyd will be called to offer opinion testimony to establish that the patients who received treatment at Downtown Medical Clinic from Mary Ann Bond were "red flags" when they shared their medical and family histories such that the treatment they received as not legitimate and outside the course of professional conduct. Allowing the government to hide testimonial hearsay under the veil of opinion violates the right to confrontation. *See United States v. Crockett*, 586 F.Supp.2d 877, 887–89 (E.D. Mich. 2008).

> Of course, under Federal Rule of Evidence 703, an expert may rely on information "perceived by or made known to the expert at or before the hearing," and "the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted." Fed. R. Evid. 703. However, the rules of evidence must succumb to the defendant's Sixth Amendment rights, including the right to confront witnesses, when there is a conflict. *Crawford*, 541 U.S. at 61, 124 S.Ct. 1354 (holding that the Sixth Amendment is not subject to the "vagaries of the rules of evidence").
> ...
> In other words, the government must offer evidence that establishes a foundation for the test results that satisfies the Court making the admissibility decision under

> Rules 104 and 901, but there also must be evidence from which a rational juror could conclude that Williams tested the substance later removed from the property room by the defendant. *See Douglass v. Eaton Corp.*, 956 F.2d 1339, 1348 (6th Cir.1992) (Ryan, J., concurring), abrogated on other grounds by *Weisgram v. Marley Co.,* 528 U.S. 440, 120 S.Ct. 1011, 145 L.Ed.2d 958 (2000). Williams's report cannot furnish that link without violating the hearsay rule and the Confrontation Clause. Rule 703 states: "Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect." But even this balancing test, heavily weighted in favor of exclusion, is not available to the government. The *Crawford* decision represents "a fundamental re-conception of the Confrontation Clause," *United States v. Cromer*, 389 F.3d 662, 671 (6th Cir. 2004), and disavows the idea that judicial balancing tests can substitute for cross-examination. By allowing the court the option of admitting otherwise inadmissible evidence, for example, Rule 703 could be understood to contemplate the very judicial balancing that *Crawford* eschews.

Id. at 887–88 (concluding lab reports could not be used to authenticate the instrument printouts).

VII. Conclusion.

WHEREFORE, for the reasons summarized above, Dr. Karlosky respectfully asks this Court to exclude the testimony of the government's experts identified in the August 2020 notice, to hold an evidentiary hearing on this motion, and to compel the government to supplement its notice.

Respectfully submitted this 1st day of September 2021, by:

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CERTIFICATE OF SERVICE

I certify that on September 1, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's electronic filing system.

/s/Stephen Ross Johnson
STEPHEN ROSS JOHNSON

From: Mortezavi, Saba (CRM)
To: Jen Free; Henry Leventis; LaRonda R Martin
Cc: Petro, Emily (CRM); Pennebaker, Andrew (CRM)
Subject: RE: Downtown Medical Practice Fusion
Date: Wednesday, October 7, 2020 1:22:00 PM
Attachments: Description of Practice Fusion Items Produced.pdf

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Counsel,

The Practice Fusion production noted below is available for download via USAfx. Attached is a brief description of the items produced to us by Practice Fusion. Please note the production has not been bates stamped. We may produce a "discovery" version of this production with bates numbers in the near future. The password to unzip the files is 6i7t7xmEiP8ExQ87s9vU.

Best,

Saba Mortezavi
Senior Paralegal Specialist
U.S. Department of Justice
Criminal Division, Fraud Section
Contractor - CACI
Cell: (202) 255-4925

-----Original Message-----
From: Pennebaker, Andrew (CRM) <Andrew.Pennebaker@CRM.USDOJ.GOV>
Sent: Saturday, October 3, 2020 4:12 PM
To: Jen Free <jfree@byrdslaw.com>; Henry Leventis <hleventis@bonelaw.com>; LaRonda R Martin <Laronda_Martin@fd.org>; Petro, Emily (CRM) <Emily.Petro@CRM.USDOJ.GOV>; Mortezavi, Saba (CRM) <Saba.Mortezavi@CRM.USDOJ.GOV>
Cc: Jim Harwood <jharwood@practicefusion.com>
Subject: Re: Downtown Medical Practice Fusion

All:

The government has requested by trial subpoena and received, today, a download link for, a complete reproduction of Downtown Medical's EMR records from Practice Fusion.

The primary reason for this is to ensure that all of the records have matching identifiers, since we recently realized that the re-export of the audit log had identifiers that did not match the initial (2017) documents. In other words, we asked for it out of an abundance of caution.

We will send you all a download link for the production shortly.

Thanks,
Drew

Sent from my iPhone