UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
FRANKFORT

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Criminal No. 3:15-cr-14-GFVT-REW
	)	
V.	)	
	)	**MEMORANDUM OPINION**
ROBERT L. BERTRAM, M.D., *et al.*,	)	**&**
	)	**ORDER**
Defendants.	)	

*** *** *** ***

"No one will deny that the law should in some way effectively use expert knowledge wherever it will aid in settling disputes. The only question is as to how it can do so best." Learned Hand, *Historical & Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 40 (May 1901). As the above-styled criminal jury trial approaches, both parties seek to exclude certain expert witnesses noticed by the opposite side, alleging the proposed experts are unreliable, irrelevant, or will not assist the trier of fact. Specifically, the five Defendants seek to exclude three Government experts, Ms. Lee Guice, Dr. Earl Berman, and Dr. Andrea Barthwell, and the Government asks to exclude two defense experts, Dr. Erik Sandefer and Dr. Scott A. R. Haas. After a thorough *Daubert* hearing and for the reasons that follow, the Court finds all five experts should be allowed to testify, subject to one limitation, and DENIES both of the pending motions to exclude.

I

Defendants Robert L. Bertram, Jr., M.D.; James W. Bottom; Robin G. Peavler, M.D.; Brian C. Walters; and Bryan S. Wood, M.D., have been jointly charged with one count of

conspiracy to defraud a healthcare benefit program in violation of 18 U.S.C. § 1349 and ninety-nine counts of healthcare fraud in violation of 18 U.S.C. § 1347. [*See* R. 1.] The factual predicate behind the indictment is set forth in greater detail in previous orders of the Court [*see, e.g.*, R. 82], but, in short, Defendants are accused of submitting claims to Medicare, Medicaid, and other private payors for payment for urine drug tests that were not medically necessary. Trial by jury is currently set to begin on January 31, 2017. [R. 134.]

Several months ago the parties exchanged expert reports, prompting admissibility challenges from both sides. Defendants move to exclude the testimony of Ms. Lee Guice; Earl Berman, M.D.; and Andrea Barthwell, M.D.[1] [R. 93.] The Government also filed a *Daubert* motion, wherein it asks to exclude the testimony of Erik Sandefer, Ph.D., in its entirety and the testimony of Scott A. R. Haas, M.D., in part. [R. 94.] The Court held oral argument on October 5, 2016, with the parties and all five proposed experts. [*See* R. 129.] With that hearing in mind, the Court now addresses the parties' requests.

II

A

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which states:

> 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.

[1] Defendant Brian C. Walters initially moved for the exclusion of the three Government witnesses. [*See* R. 93.] Subsequently, all other Defendants joined in his request. [R. 99; R. 100; R. 101; R. 102.]

Fed. R. Evid. 702. From Rule 702 comes a two part test for admitting expert testimony. First, is the expert qualified and the testimony reliable? And, second, is the evidence relevant and helpful to the trier of fact? *See, e.g., United States v. Jones*, 107 F.3d 1147, 1156 (6th Cir. 1997).

The seminal case applying the first prong of the test is *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). In that decision, the Supreme Court explained that a district court's gatekeeping responsibility is implicit in Rule 702, "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. Further, the Supreme Court listed several specific factors to help determine the reliability of expert testimony based on scientific knowledge. *See id.* at 590, n. 8. These factors include whether a theory or technique can be or has been tested; whether the theory has been subjected to peer review and publication; whether there is a high known or potential error rate; whether there are certain operation standards that should have been or were followed; and whether the theory or technique is generally accepted within the scientific community. *Id.* at 592-94. Later, in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the Supreme Court determined that the gatekeeping obligation and subsequent factors established in *Daubert* apply with equal force to non-scientific experts. However, those factors are not definitive and district courts "must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho*, 526 U.S. at 152.

As for the second prong of the test, district courts "must ensure that the proposed expert testimony is relevant to the task at hand and will serve to aid the trier of fact." *United States v. Smithers*, 212 F.3d 306, 313 (6th Cir. 2000). The Supreme Court in *Daubert* referred to this prong as the "fit" requirement. *See id.*; *Daubert*, 509 U.S. at 591-93. Because "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes,"

courts must consider whether a particular expert's testimony will truly assist the trier of fact to understand the evidence in the case at hand. *Daubert*, 509 U.S. at 591.

Notably, the Court's gatekeeping role under the case law "is not intended to supplant the adversary system or the role of the jury." *Allison v. McGhan Medical Corp*., 184 F.3d 1300, 1311 (11th Cir. 1999). Instead, "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. Whether or not to admit expert testimony is a matter over which the district court ultimately enjoys broad discretion. *See, e.g., Tamraz v. Lincoln Elec. Co*., 620 F.3d 665, 672 (6th Cir. 2010).

B

1

Defendants challenge the relevance of three experts noticed by the Government: Ms. Lee Guice, Dr. Earl Berman, and Dr. Andrea Barthwell. For the reasons explained below, all three of these experts will be allowed to testify, as the Court finds the experts' testimony will, indeed, assist the trier of fact.

a

The Government seeks to elicit testimony from Lee Guice and Earl Berman about the rules and regulations governing Medicare and Medicaid coverage for urine drug testing. [*See* R. 106 at 1.] Ms. Guice, the Director of Policy and Operations at Kentucky's Department of Medicaid Services, would testify as to Medicaid procedures. And Dr. Berman, the Medical Director of CGS Administrators,[2] would testify about appropriate Medicare urine drug testing

[2] CGS Administrators, LLC, is a contractor that administers Part B Medicare services in Kentucky and Ohio, as well as home health and hospice care for approximately twenty states. As the director, or chief

protocol.

Defendants lodge two chief complaints about Ms. Guice and Dr. Berman's proposed testimony. First, they argue the two witnesses will merely summarize certain administrative regulations and will offer only a summary of various statutes and rules that is untethered from the facts and unhelpful to the jury. But allowing this type of expert testimony in similar federal prosecutions is common practice. As the Sixth Circuit has stated, "[t]he Medicare program operates within a complex and intricate regulatory scheme and we cannot say that the average lay person, including any Medicare beneficiary, commands a working knowledge of Medicare reimbursement procedures." *United States v. White*, 492 F.3d 380, 403 (6th Cir. 2007). The same ostensibly holds true for the Department of Medicaid Services. The case law makes clear that Medicare and Medicaid experts are permitted to testify about how their respective agencies apply rules, "as long as the testimony does not incorrectly state the law or opine on certain ultimate legal issues in the case." *United States v. Davis*, 471 F.3d 783, 788-89 (7th Cir. 2006). Admitting testimony from Medicare and Medicaid employees with specialized knowledge of the programs' procedures is appropriate in the instant prosecution, where the jury will be called upon to determine whether Defendants acted to defraud either of the programs. *See, e.g.*, *id.*; *White*, 492 F.3d 380; *United States v. Strange*, 23 F. App'x 715 (9th Cir. 2001).

Apart from that initial argument, Defendants maintain Ms. Guice and Dr. Berman are representatives of their respective employers and, thus, "victims" of Defendants' alleged fraud. As victims, Defendants contend Guice and Berman cannot offer objective testimony. This case is inapposite, however, to the ones relied upon by the defense. *See United States v. Hill*, 749

medical officer, for CGS Administrators, Dr. Berman serves as the medical director for Kentucky and Ohio's Part B Medicare—or physician and/or provider—services. [*See* Transcript ("Tr.") at 14-15.]

F.3d 1250 (10th Cir. 2014) (discussing scenarios where, for example, a pediatrician expert's testimony buttressed the credibility of a sexual assault victim); *United States v. Rivera*, 43 F.3d 1291, 1295 (9th Cir. 1995) (noting potential impropriety, but ultimately allowing, attending physician's expert testimony that a victim "did not fake the rape"). Defendants' concerns about buttressing the victim's credibility or admitting severely biased expert testimony into evidence might give the Court more pause if either Ms. Guice or Dr. Berman was a personal victim who lost money or otherwise suffered at the hands of Defendants. Instead, Ms. Guice and Dr. Berman are tangential victims at best and are more aptly described as mere employees of their respective departments. While the Court is not privy to the specifics of the two individuals' work lives, it stands to reason that neither individual personally saw a change in salary or suffered other repercussions as a result of Defendants' alleged criminal activity. Thus, any potential policy reasons for excluding or limiting an actual victim's testimony are largely irrelevant in the present case.

Further, as stated above, expert testimony from Medicare and Medicaid employees in healthcare fraud trials is commonplace. In *United States v. Davis*, for example, an Indiana Medicaid employee was allowed to testify as an expert in a prosecution in which the defendant was accused of defrauding Indiana Medicaid. *See* 471 F.3d 783, 788-89. Surely in *Davis* this Indiana Medicaid employee represented a "victim" of the defendant's alleged fraud under Defendants' logic. *Id.* But the court allowed this employee to testify under Federal Rule of Evidence 702 and 704, and the Court follows suit for Ms. Guice and Dr. Berman.[3] Defendants,

[3] To the extent Defendant Walters specifically argues that page three of Dr. Berman's report should be excluded even if Dr. Berman is otherwise allowed to testify, the Court directs the parties to its analysis below regarding the propriety of Dr. Barthwell's SelfRefind testimony. Defendant Walters argues that the local coverage determinations discussed by Dr. Berman pertain chiefly to when and how drug tests

of course, remain free to point out any concerns about the experts' potential lack of objectivity through thorough cross-examination. *See* Fed. R. Evid. 611(b) (explaining that matters of a witness's credibility may be addressed through cross-examination); *Stevens v. Bordenkircher*, 746 F.2d 342, 346 (6th Cir. 1984).

b

The Government also seeks to introduce the testimony of Dr. Andrea Barthwell, an addiction treatment specialist who boasts special knowledge related to urine drug testing protocol in addiction medicine. She plans to testify to four opinions, as set forth in her report, which all concern the reasonableness and/or medical necessity of SelfRefind's drug testing practices. [*See* R. 106-3.] At the *Daubert* hearing, defense counsel conceded Dr. Barthwell was qualified to testify as to whether the urine drug tests at issue in the case were medically necessary when they were ordered. [*See* Tr. at 152-53.] And Dr. Barthwell's education and professional experiences undoubtedly also qualify her to testify about the medical necessity of SelfRefind's general practices—indeed, Dr. Barthwell manages a number of substance abuse treatment clinics akin to the SelfRefind chain of clinics. [*See* Tr. at 92 (explaining Dr. Barthwell's experiences both designing and managing a residential treatment program on the Outer Banks of North Carolina, and practicing addiction medicine at her own clinic in Chicago).] But Defendants' real qualm with Dr. Barthwell's testimony is not that she is unqualified to testify about SelfRefind or that

should be ordered by addiction treatment physicians, not to how laboratories like PremierTox should process claims. [*See* Tr. at 48-50.] As set forth in greater detail below, testimony about Medicare guidelines on when and how entities like SelfRefind should order urine drug testing is relevant to the charges against Defendants as managers of PremierTox, because the indictment includes a conspiracy charge. [*See* discussion, *infra*, at 7-9.] Mr. Walters may wish to challenge the admissibility of such testimony against him personally for reasons outside the scope of Rule 702 and *Daubert*, but the Court considers that matter by subsequent opinion.

she used improper methodology in formulating her conclusions. Instead, Defendants contend Dr. Barthwell's testimony is irrelevant and therefore inadmissible. [*See* R. 93 at 10-12.]

Specifically, Defendants maintain Dr. Barthwell's testimony is not germane in this case because it relates only to the actions of SelfRefind, not PremierTox. SelfRefind is not formally charged in the indictment, and Defendants would have the Court find that information regarding the propriety of the SelfRefind clinics' practices will not assist the trier of fact. Defendants, however, are charged not only with actually defrauding healthcare benefit programs in connection with the submission of PremierTox urine drug screens, but also with *conspiring* to commit such acts. [*See* R. 1 at 6-7.] Because of this, Defendants' argument fails.

The indictment alleges the following factual relationship between SelfRefind, PremierTox, and the five Defendants. SelfRefind refers to Addixxion Recovery of Kentucky, LLC, a chain of substance abuse treatment clinics headquartered in Danville, Kentucky, and owned by two of the Defendants, Dr. Robin Peavler and Dr. Bryan Wood. [*Id.* at 1.] PremierTox, Inc., refers to a clinical laboratory located in Russell Springs, Kentucky. [*Id.*] PremierTox was formed in September 2010 and owned at that time by another two of the Defendants, Mr. James Bottom and Mr. Brian Walters. [*Id.*] On December 27, 2010, Dr. Peavler, Dr. Wood, Mr. Bottom, Mr. Walters, and Dr. Robert Bertram, Jr., entered into an agreement whereby they would operate, own, and maintain PremierTox and equally share in the laboratory's profits and losses. [*Id.* at 1-2.] Notably, before that agreement arose, Drs. Peavler and Wood began referring all urine samples from SelfRefind patients to PremierTox for a quantitative confirmation test. This referral began around October 2010. [*Id.* at 5.]

Around December 2010 when the five Defendants entered into the agreement to mutually operate PremierTox, Defendants agreed to collect the SelfRefind urine samples even though the

PremierTox equipment necessary to perform testing on those samples was not yet functioning. [*Id.*] Thousands of SelfRefind urine samples were stored in freezers, and these samples were not tested until the time period between April and October of 2011. [*Id.* at 6.] According to the indictment, over a thousand frozen urine samples were tested months after they had initially been collected. Notably, the older, frozen samples were tested despite the fact that more recent samples had been collected and tested in the intervening time. [*Id.*] The tests on the frozen samples were submitted for payment to Medicare, Medicaid, and other healthcare entities, and the Government now charges the five Defendants with healthcare fraud based on the medical unnecessity of those tests, as well as conspiracy to commit that fraud. [*Id.* at 6-12.]

In light of this factual framework and the conspiracy charge, Dr. Barthwell's testimony regarding SelfRefind's practices is surely pertinent evidence. A conspiracy agreement may be proven indirectly, by facts and circumstances that lead to a conclusion that an agreement existed. *See, e.g.*, Sixth Circuit Pattern Jury Instruction § 3.02, *available at* http://www.ca6.uscourts.gov/sites/ca6/files/documents/pattern_jury/pdf/09_Chapter_3_0.pdf. Here, Dr. Barthwell's experiences and credentials are all but directly on point with the facts of the case. The jury will ultimately determine whether and how Dr. Barthwell's testimony leads to a conclusion about the legality or illegality of PremierTox's urine drug testing claim submissions.

2

The United States has also filed a motion seeking exclusion of two defense experts, Dr. Erik Sandefer and Dr. Scott A. R. Haas. At the *Daubert* hearing held on October 5, 2016, the Government conceded that, after hearing the testimony of Dr. Haas, its concerns about his testimony were cured. [*See* Tr. at 256-57.] Dr. Haas is a forensic psychiatric physician, board certified by the American Board of Psychiatry and Neurology in general psychiatry. [R. 94-2 at

2.] He plans to testify to three opinions, as set forth in his report, regarding whether SelfRefind properly ordered urine drug tests in the first instance, whether PremierTox conducted tests pursuant to a valid physician order, and whether the delays in testing the frozen urine drug samples obviated the usefulness of the tests in identifying, diagnosing, or treating the patients' medical conditions. [*See id.* at 4-5.] The *Daubert* hearing provided Dr. Haas with an opportunity to discuss certain qualifications and experiences beyond what is reflected in his curriculum vitae and report. [Tr. at 256.] The Government now believes Dr. Haas is qualified to testify about the three opinions set forth in his report, and the Court agrees. [*Id.*]

The Government's sole challenge, then, is to the admissibility of defense expert Dr. Erik Sandefer's testimony. Sandefer holds a Ph.D. in pharmaceutical sciences from the University of Kentucky College of Pharmacy, and since 1992 he has owned a pharmaceutical clinical contract research company, Scintipharma, Inc. [Tr. at 162-63.] By way of contractual agreements with various pharmaceutical companies, Scintipharma participates in the companies' drug development processes and performs research testing on human volunteers. [*Id.*] It is clear from Dr. Sandefer's *Daubert* hearing testimony that he regularly sends urine drug samples from his clinical studies to laboratories. [*See, e.g.*, Tr. at 168-69.] However, Dr. Sandefer is not a medical doctor. He has never participated in the treatment of a patient suffering from a substance abuse disorder, and he has never ordered urine drug tests for the purpose of actually treating a patient suffering from substance abuse, addiction, or any other disease. [*See* Tr. at 173.]

Unlike with Dr. Haas, the *Daubert* hearing did not assuage the Government's concerns about the relevance of Dr. Sandefer's testimony. As the Court noted at the outset, Rule 702 requires that expert testimony "fit" a particular case—that is, the Court must determine whether a

proposed expert's testimony is sufficiently tied to the facts of the case such that it will actually assist the trier of fact. *See Smithers*, 212 F.3d at 313-14. There is no doubt Dr. Sandefer has obtained special knowledge through his training and over the course of his career about how his laboratory of choice typically processes samples. [*See, e.g.*, Tr. 178.] The question here, though, is whether Dr. Sandefer's special knowledge of laboratory sample processing in the pharmaceutical research context is appropriate. Defendants are on trial for healthcare fraud, and the jury must decide whether Defendants defrauded various payors by submitting claims for urine drug tests that were no longer medically necessary.

Dr. Sandefer readily admitted throughout the *Daubert* hearing that he could only testify to the "research side" and not the "clinical side" of the Government's questions. [*See, e.g.*, Tr. at 179-80.] Further, he admitted to having no firsthand knowledge of the information a clinical laboratory performing urine drug testing receives from a referring medical provider. [Tr. at 183-84.] He nonetheless maintains a laboratory's procedures for testing samples submitted for research purposes and samples submitted for medical or clinical purposes would be the same:

> Q. [Mr. McCaffrey:] Do you know what information - - do you have any firsthand knowledge of what information a clinical lab that's performing medical urine drug testing receives from the referring provider?
>
> A. [Dr. Sandefer:] No.
>
> Q. And in your experience, where you are - - you're not submitting these tests to a lab for any medical reason; it's for a research reason?
>
> A. That's correct. But procedurally, once received into the lab, should be the same. Once received into the lab - - again, they don't know what it's being brought to them for.
>
> Q. And that's - - that's an assumption that you're making, since you don't have any experience with a medical lab that's performing medical urine drug testing?
>
> A. When - - when I submit a urine sample for drug screening at a LabCorp,

> specifically for LabCorp, they have no idea why I'm submitting it. They don't know if it's for research. They don't know if I suspect my son's doing something. They don't know if it's a CDL license. They have no idea why I'm submitting the sample.
>
> Q. Your opinion, I gather, is that an analytical lab does not have the ability or the authority to determine medical necessity?
>
> A. Yes.
>
> Q. And what experience do you draw upon; what in your background do you draw upon to reach that conclusion about medical necessity testing?
>
> A. Well, my - - my experience, again, working with LabCorp. They have - - they have no idea why we are submitting the sample for this analysis. They don't know if it's for a diagnosis. They don't know if it's, again, for a Commercial Driver's License. They don't know if it's - - if it's me submitting it because I had an exposure and I'm wondering if I'm testing positive for a Lortab that I took. They - - they don't know. And this is, you know, an independent lab separate from what - - from my own business. They have no clue what I'm submitting.

[Tr. 183-85.]

The Sixth Circuit has upheld a district court's decision to exclude the expert testimony of a pharmacist who endeavored to testify as a defense witness in a healthcare fraud trial because of that witness's "fit" problem. *See United States v. Silber*, 456 F. App'x 559, 561-62 (6th Cir. 2012). The pharmacist's expertise clearly may have been useful in another context, but he was only able to testify generally to the appropriateness of certain medications and not specifically to whether relevant prescriptions were medically appropriate in the defendant's case. *Id.* The Sixth Circuit noted that, despite the exclusion of the witness, the defendant could still establish a particular point through cross-examination of the prosecution's expert, and it ultimately agreed with the district court judge that the pharmacist's testimony was reliable but not relevant to the facts of the case. *Id.*

The *Silber* case is in some ways akin to the present situation, but at the end of the day the

matter remains one soundly committed to the Court's discretion. *See Tamraz*, 620 F.3d at 672. *Silber* does not mandate finding the expert inadmissible in this case; it only upholds a particular district judge's decision to exclude. Despite recognizing Dr. Sandefer presents a close call, the Court will allow him to testify as an expert for the defense subject to certain limitations.

Under Rule 702, *Daubert*, and subsequent case law, "rejection of expert testimony is the exception, rather than the rule." Fed. R. Evid. 702, advisory committee's note, 2000 amend.; *see also In re Scrap Metal Antitrust Litigation*, 527 F.3d 517, 530 (6th Cir. 2008). Moreover, "[a]n expert's lack of experience in a particular subject matter does not render him unqualified so long as his general knowledge in the field can assist the trier of fact." *Dilts v. United Group Servs., LLC*, 500 F. App'x 440, 445 (6th Cir. 2012) (citing *Surles ex rel. Johnson v. Greyhound Lines, Inc*., 474 F.3d 288, 293-94 (6th Cir. 2007)). Nevertheless, the Court shares the Government's concerns regarding Dr. Sandefer's experiences as they relate to a laboratory testing urine samples for medical purposes.

In light of his employment history, education, and other qualifications, Dr. Sandefer may testify about his personal experiences sending *research* samples to laboratories, and he may describe what those laboratories knew and currently know about the samples which he sends in for testing. However, he may not project his experiences, which flow primarily from a career in pharmaceutical research, onto PremierTox or any other laboratory which he has no personal knowledge. Testimony about those laboratories' procedures for purposes of the practice of clinical medicine are beyond the scope of this expert. Moreover, Dr. Sandefer may not speculate as to what PremierTox knew about the samples it received from SelfRefind or other clinics. And, of course, the defense must refrain from eliciting any testimony from Dr. Sandefer that opines about the PremierTox owners' mental state, which constitutes an essential element of the

crime. *See* Fed. R. Evid. 704(b).

Subject to these limitations, Dr. Sandefer is free to testify, and in return, the Government may raise any concerns about Dr. Sandefer's lack of experience in addiction medicine. The jury will then be free to weigh Dr. Sandefer's testimony against that of Government witnesses such as Dr. Barthwell to determine the ultimate criminal liability of PremierTox and the five Defendants. *See Daubert*, 509 U.S. at 596 (noting vigorous cross-examination and the presentation of contrary evidence as the primary means of combating "shaky but admissible evidence").

III

Accordingly, and the Court being otherwise sufficiently advised, it is hereby **ORDERED** that the Defendant's Motion to Exclude [R. 93] and the Government's Motion to Exclude [R. 94] are both **DENIED**.

This the 9th day of November, 2016.

Gregory F. Van Tatenhove
United States District Judge