1 UNITED STATES DISTRICT COURT

2 NORTHERN DISTRICT OF WEST VIRGINIA

3 United States of America,
Plaintiff,
4 vs. CRIMINAL ACTION NO.

5 5:18-cr-16-01

6 Krishan Kumar Aggarwal, VOLUME VI
Defendant.
7 - - -

8 United States of America,
Plaintiff,
9 vs. CRIMINAL ACTION NO.

10 Cherian John, 5:18-cr-16-02
Defendant.
11 - - -

12 Transcript of proceedings had in the jury trial of
the above-styled actions on June 10, 2019, before Honorable
13 Frederick P. Stamp, Jr., District Judge, at Wheeling, West
Virginia.
14 - - -

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16 The Defendants were present in person.

17 Proceedings recorded utilizing realtime translation.
Transcript produced by computer-aided transcription.
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1 Monday Morning Session,
2 June 10, 2019, 8:00 a.m.
3 - - -
4 (In open court, without the jury.)
5 THE COURT: All right. Good morning. I have
6 received the email that was sent yesterday concerning the DEA
7 form 6 report of investigation as it relates to Dr. Thomas and
8 the statement by the investigator.
9 Let's just -- Mr. Chapman, if you want to just be
10 brief. I think you've set up the motion. What I'd really like
11 to do, given the limited time we have, because I want to start
12 at 8:30 for the jury's sake, is to get a response from the
13 government. But if you just very briefly want to comment.
14 MR. CHAPMAN: Yes, Your Honor. I'm going to try to
15 be brief, but there is first a lot to explain. I'll note
16 that Dr. Aggarwal should be in here shortly. I neglected to
17 have him come in early, but if it's okay, we want to waive his
18 presence.
19 THE COURT: It's all right with me, if it's all right
20 with Dr. Aggarwal. I think, as a matter of law, we can move
21 forward without the party being present.
22 MR. CHAPMAN: First I will lead with exactly what we
23 are requesting. We are requesting to put Dr. Thomas on the
24 stand outside the presence of the jury in order to voir dire
25 him based on this new development related to his experience and

1 ultimately move for disqualification of the expert based on a
2 number of false statements he has made to this Court and to
3 this jury related to his qualifications and experience.
4 As the Court may recall, we moved to exclude this
5 expert on the basis of his lack of experience in this field.
6 We just received a report yesterday indicating that it is true
7 that Dr. Thomas has not treated a suboxone patient under his
8 DATA waiver ever. At least this statement was made in 2012, so
9 2012 prior.
10 In fact, he does prescribe suboxone, but solely
11 intended to treat pain. Now, the Court may be aware that
12 there's on-label and off-label uses of suboxone. Dr. Thomas
13 apparently only uses it off-label to treat patients for pain,
14 which is completely separate and distinct from the practices
15 that are at issue here.
16 He specifically said to the DEA in August -- on
17 August 2nd, 2012, that he has not engaged in the practice of
18 treating drug-addicted patients. His trial testimony, as the
19 Court may recall, the transcript, page 5, lines 15 through 25,
20 the majority of the patients that I treated with suboxone I
21 treated for a pain condition, particularly those patients who
22 are on full agonists, that is, the normal opiates, who want to
23 get off them because of suboxone. I also prescribe suboxone to
24 patients who, while they didn't meet the full definition of
25 having an opiate use disorder but began having loss of control

1 at the beginning of problematic use of opiates, I also
2 prescribed suboxone to patients who had opiate use disorder and
3 full loss of control.
4 He's saying to this Court and to this jury that he
5 uses his DATA waiver to prescribe for suboxone patients.
6 THE COURT: Let's take the record as it is. I think
7 all of us, hopefully, understand where we are at this point.
8 So you're asking that you be able to voir dire
9 Dr. Thomas. When do you want to do that?
10 MR. CHAPMAN: This morning, before he resumes the
11 witness stand. I think it's important to move to disqualify
12 this witness before he utters a single other word to the jury.
13 The problem here, Your Honor, is when we filed our
14 Daubert motion, the response by the government and ultimately
15 the order by this Court, presumed that Dr. Thomas used his DATA
16 waiver to prescribe suboxone.
17 THE COURT: I realize that you don't have the DEA 6
18 statement until yesterday. So I have ruled by the motion to
19 dismiss on the qualifications of Dr. Thomas as to his
20 qualifications up to that point. Then at the pretrial
21 conference, counsel for one party, Dr. John, indicated there
22 wouldn't be any need for a Daubert hearing. There was no
23 statement by Dr. Aggarwal's counsel, nor -- and the government
24 indicated there would be no need for a Daubert hearing, so just
25 so I can sort of refine the issue for you, I think -- unless

1 there's something that we don't know about, I think the issue
2 has to be limited to Dr. Thomas' qualifications as they might
3 be affected in any way by the statement made by the
4 investigator as to Dr. Thomas' statement, which is to say
5 Dr. Thomas stated that although he is a DATA-waived approved
6 practitioner, he does not engage in suboxone treatment for
7 drug-addicted persons.
8 So if -- not to cut you off, but maybe to refine the
9 issues -- and Dr. Aggarwal is present now. Just to refine the
10 issues, let's see what the positions are of the parties with
11 respect to voir diring this. I think the voir dire, if it's
12 allowed, has to be limited to the report of investigation of
13 8-03-2012, and I think that really I don't need to get -- we
14 don't need to go any further. And whether or not that document
15 comes in, I think is something for discussion.
16 Mr. Stallings, do you join in Mr. Chapman's request,
17 or do you have anything briefly to augment that?
18 MR. STALLINGS: Your Honor, I do, and I would suggest
19 that the scope of the voir dire should include Dr. Thomas' --
20 what he actually did in terms of prescribing suboxone for
21 addiction, because that's what the report goes to, which is
22 that it says he didn't. He has said he did. I think that
23 should be -- it's a slightly broader, I think, scope than you
24 just outlined, but it's whether or not and in what
25 circumstances he actually has, since that DEA 6 seems to

1 contradict --
2 THE COURT: We'll see how far that goes, but I really
3 think in fairness to the case that any voir dire, if allowed,
4 has got to be limited to that report, because the rest of the
5 qualifications have been covered pretty fulsomely by counsel.
6 May I hear from you, Ms. Wagner, before we go
7 forward.
8 Thank you, Mr. Chapman.
9 MR. CHAPMAN: Thank you, Your Honor.
10 MS. WAGNER: Thank you, Judge.
11 First, I just wanted to explain to the Court that we
12 were under a misunderstanding about the nature of Dr. Thomas'
13 treatment of his patients. We understood that he -- I'll say
14 what we didn't understand. We didn't understand that the
15 patients that he treated for addiction were also pain patients,
16 so we didn't understand that he did not have patients that he
17 treated exclusively for addiction.
18 Dr. Thomas will explain, if the Court wants to hear
19 from him this morning, that in around 2012, up until 2014,
20 which is when he stopped treating patients altogether, the
21 nature of his clientele changed, in that he was receiving --
22 seeing more patients who were suffering -- who were suffering
23 from chronic pain in his own practice who he saw with markers
24 of addiction or with full-blown opioid use disorder. And in
25 treating those patients whose primary diagnosis was pain, he

1 also treated what was a secondary diagnosis of addiction or
2 markers of addiction, going towards addiction.
3 He also will explain that around that same time he
4 began receiving referrals from other physicians who had chronic
5 pain patients who were showing markers of addiction. And he
6 received those. He'll explain that he conducted inductions in
7 his office for patients who he was putting on suboxone, and he
8 will -- he can explain what he did with those patients.
9 I think that what the defendants' complaint with
10 Dr. Thomas is that he has not treated addiction patients to the
11 scope that they believe he should to be able to qualify as an
12 expert, and our position is he qualifies as an expert. He's
13 had the training. He's had the experience. And if they want
14 to cross-examine him on how much experience he has or whatnot,
15 they are certainly free to do that and defense counsel has
16 shown they're perfectly capable of effective cross-examination.
17 And we believe that's where the issue is remedied, is on
18 cross-examination.
19 THE COURT: Thank you. I'm going to -- in order
20 to -- I'm going to allow some limited voir dire of Dr. Thomas
21 on the report of investigation 6 of 8-3-2012, and if we could
22 specifically make sure that we cover his statement. I know you
23 will, but I think that, in my opinion, is the key issue here.
24 So if we could -- if counsel could address that issue, I think
25 the other matters have been fulsomely addressed and decided

1 through the motion to dismiss and the comments of counsel at
2 the pretrial, and the comments at the beginning of the session
3 as to the qualifications up to yesterday's disclosure of the
4 report, didn't require voir dire.
5 MR. STALLINGS: Very briefly, Judge. We understand
6 the Court's order on that, and I just want to make clear that
7 we will retain our rights to cross-examine him in front of the
8 jury regarding this DEA 6 as well, and nothing about this voir
9 dire process is a waiver of that right.
10 THE COURT: No. There is not at all. But that
11 assumes that that report comes in by one party or another and
12 how it comes in. We can certainly address that. I won't quote
13 him exactly, I know, but I think Chief Justice Rehnquist said
14 in his concurring opinion in Daubert, robust cross-examinations
15 can often be very important, and it may be here, so I really
16 would like to get this matter fulsomely covered as possible.
17 Let's -- Ms. Wagner, is Dr. Thomas -- yes, here he is. Would
18 you --
19 (Dr. Thomas resumes stand.)
20 THE COURT: Good morning, Dr. Thomas, and you have
21 been previously sworn.
22 THE WITNESS: Yes.
23 THE COURT: And the jury is not here, as you can see,
24 and we are going to allow counsel to ask you a few questions on
25 the topic involving qualifications.

1 THE WITNESS: Certainly.

2 **STEPHEN M. THOMAS,**

3 RESUMING THE STAND FOR FURTHER EXAMINATION, HAVING BEEN

4 PREVIOUSLY SWORN

5 VOIR DIRE EXAMINATION

6 BY MR. CHAPMAN:

7 Q Good morning, Doctor. My name is Ron Chapman. I

8 represent Dr. Aggarwal.

9 A Good morning.

10 Q Doctor, prior to -- first, are you aware of the difference

11 between on-label and off-label use of suboxone?

12 A Yes.

13 Q All right. And you understand that on-label use of

14 suboxone would be use solely for patients who are affected by

15 opioid use disorder?

16 A That is correct.

17 Q And off-label use would be the use of suboxone to treat a

18 pain condition or some other condition that is not on-label,

19 correct?

20 A That is correct.

21 Q And you have used buprenorphine for its off-label

22 purposes, correct?

23 A And for its on-label purposes.

24 Q Prior to 2007 and you taking the DATA waiver course, did

25 you use suboxone on-label to treat solely opioid use disorder?

1 A No.
2 Q Okay. After 2007, to the present, have you used suboxone
3 to treat patients suffering from opioid use disorder for solely
4 its on-label purpose?
5 A Not for solely its on-label purpose because of the nature
6 of my practice, but I have used it for its on-label purpose in
7 addition for the treatment of chronic pain in the same patient.
8 Q In addition to its off-label purpose, correct?
9 A Yes, that's correct.
10 Q Now, is it true that you have never worked in a practice
11 that treated patients solely for opioid use disorder?
12 A That is correct.
13 Q Your treatment of the patients that you just referenced
14 was solely for the purposes of treating pain and also to manage
15 potential addiction?
16 A Yes.
17 Q When did you last renew your X number?
18 A Let's see. I can't tell you. I renewed my DEA and my X
19 number at the same time, within the last five years.
20 Q Was it solely in preparation for this case?
21 A Oh, no.
22 Q And approximately when did you take your most recent exam
23 or course for -- to receive your DATA waiver?
24 A I first took the course in 2004. I took the course a
25 second time in 2007.

1 Q Is it true that you were visited by the DEA on August 2nd,
2 2012?
3 A That is correct.
4 Q And is it true that you indicated to the DEA that you do
5 prescribe suboxone, but solely to treat pain?
6 A At that time.
7 Q And that statement has not changed between 2012 to the
8 present, correct?
9 A That's not exactly accurate. So between 2012 and 2014, I
10 did use my DATA waiver to treat patients who had pain and early
11 signs of addictive use.
12 Q But it was for its off-label purpose, correct?
13 A And for its on-label purpose, which is the treatment of
14 opioid use disorder, which these patients were evaluated for.
15 There were -- as I stated in my initial voir dire, while the
16 majority of the patients have been treated with suboxone for
17 its off-label use in pain, the use in the treatment of patients
18 with early signs of opioid use disorder without what we'll call
19 the full-blown spectrum of opioid use disorder and in some
20 patients who had opioid use disorder and pain.
21 Q Isn't it true that you believe people who are receiving
22 suboxone for on-label purposes require counseling?
23 A Yes.
24 Q Isn't it true that you told the DEA that you're not
25 engaged in the practice of treating drug-addicted patients

1 because they require additional ancillary services and
2 treatment such as psychotherapy?
3 A While I told them that in 2012 --
4 Q My only question was, isn't it true that you told the DEA
5 that?
6 A That is what I told the DEA.
7 THE COURT: Explain your answer, if you want.
8 THE WITNESS: Thank you, Your Honor.
9 A While I told the DEA that during their interview in 2012,
10 the opioid crisis has been an evolving one. In the period
11 between 2012 and 2014 I was referred patients who had more
12 significant issues with loss of control, inappropriate use, and
13 inability to use full-agonist opioids for the treatment of
14 their chronic pain. They thus had chronic pain and what I
15 deemed to be opioid use disorder and I treated them with
16 suboxone.
17 Q Isn't it true that you did not provide counseling services
18 to those patients, as you've said to the DEA they require?
19 A I did not. I referred them to counseling providers in the
20 community.
21 Q Approximately -- well, can you recall when your last
22 prescription of suboxone was issued?
23 A Well, it would have to be before June 30th, 2014.
24 Q And at that time, how many patients were you actively
25 treating using suboxone?

1 A For opioid use disorder, or all indications?
2 Q For all indications.
3 A I couldn't tell you. It was not a large number, probably
4 less than 20.
5 Q And approximately what percentage of your practice was
6 using suboxone to treat patients suffering from opiate use
7 disorder?
8 A That would probably be certainly less than 5 percent of my
9 practice.
10 Q Between the date you mentioned in 2013 and when you
11 stopped practicing, have you had any course or certification
12 for the use of suboxone to treat opiate use disorder?
13 A I've taken no additional course. I have relied upon
14 continuing medical education and reading to remain current.
15 Q And how many CEs do you have related solely -- since 2013,
16 related solely to prescriptions for buprenorphine or suboxone?
17 A I couldn't tell you.
18 Q And it's true that you're not board certified in addiction
19 medicine?
20 A I am not and have never claimed to be.
21 MR. CHAPMAN: Your Honor, at this time I have no
22 further questions.
23 THE COURT: Mr. Stallings.
24 VOIR DIRE EXAMINATION
25

1 BY MR. STALLINGS:
2 Q Good morning, Dr. Thomas.
3 A Good morning, sir.
4 Q I just have a few questions. I want to understand the
5 time line.
6 The DEA diversionary investigator visited you in August of
7 2012?
8 A Yes.
9 Q And you stopped practicing altogether on June 30th of
10 2014?
11 A Yes.
12 Q Prior to the DEA visit in August of 2012, had you treated
13 any suboxone patients on-label?
14 A Not strictly, no.
15 Q After June 30th of 2014, you've treated no suboxone
16 patients at all, correct?
17 A That's correct.
18 Q Between August of 2012 and June 30th of 2014, can you tell
19 us approximately how many patients you treated with suboxone
20 on-label.
21 A Of the 20 or so suboxone patients I had, I would say
22 strictly on-label use, five or six.
23 Q So in your entire career, am I accurate that you've
24 treated five or six suboxone patients on-label?
25 A Strictly on-label, yes.

1 MR. STALLINGS: Thank you, Judge. That's all I have.
2 THE COURT: Ms. Wagner, Mr. Cogar?
3 MS. WAGNER: We don't have any questions, Your Honor.
4 THE COURT: Very well.
5 Well, I am going to -- having had the benefit of the
6 questions on the voir dire -- let me just move back. Is the
7 government proposing to use the report of investigation as an
8 exhibit or --
9 MS. WAGNER: No, we're not, Your Honor.
10 THE COURT: -- counsel going to move for that report
11 to be an exhibit?
12 MR. CHAPMAN: Yes, Your Honor. Before the Court
13 rules, I would like to address one additional issue.
14 THE COURT: All right.
15 MR. CHAPMAN: If possible.
16 THE COURT: If you could do that briefly.
17 MR. CHAPMAN: Yes, Your Honor.
18 One, my concerns here is the prejudice. As the Court
19 is aware, Brady v. Maryland and Kyles v. Whitley require the
20 government to seek out -- affirmatively seek out evidence that
21 is in their possession or constructive possession. I don't
22 think anybody would argue that a DEA 6 related to the
23 government's own expert is outside of the possession of the
24 government in this case.
25 Our concern here is the late disclosure of this,

1 after an expert gets off the stand on the weekend, causes
2 significant prejudice in our ability to now challenge this
3 person and his new statements related to his treatment of five
4 or six suboxone patients between August 2nd, 2012, and June
5 30th, 2013. We would certainly have called the DIs in this
6 case, we certainly would have done an investigation of
7 Dr. Thomas to determine whether or not his statements are true,
8 that he actually has treated these patients with opioid use
9 disorder.
10 Our inability to challenge those issues and now bring
11 them to the attention of the jury after they have heard that
12 Dr. Thomas apparently treats some suboxone patients prevents us
13 from having a fair trial in this case, Your Honor. And for the
14 reasons of the late disclosure and for the reasons of this
15 witness' misstatements on the record about his experience and
16 qualifications, and for the reasons for the misstatements by
17 the government in their prior motions practice related to
18 Dr. Thomas' experience and qualifications, Dr. Aggarwal, and I
19 presume Dr. John as well, are seriously prejudiced by this
20 conduct.
21 This is the third time in this case, Your Honor, we
22 have received late disclosure from the government of
23 exculpatory information. Three time's a charm, Your Honor. At
24 this point in time the government should receive some sort of
25 sanction as a result of its conduct, and the only appropriate

1 sanction is an instruction to the jury to disregard this
2 witness' testimony and ultimately a ruling on Rule 29 in this
3 case, Your Honor. Thank you.
4 MS. WAGNER: Your Honor, with respect to the
5 prejudice, there is no prejudice because all of the things that
6 Mr. Chapman has complained that he will not be able to do he
7 either cannot do under the rules of evidence or will have the
8 fair opportunity to do so on cross-examination.
9 He mentioned bringing the diversion investigators in.
10 The diversion investigators can't impeach Dr. Thomas, number
11 one. Number two, there's nothing to impeach him on. He has
12 not made misstatements on the record. He has not made
13 misstatements in that ROI. He explained just now on voir dire
14 that those were true statements at the time that they were made
15 and he's not made misstatements about his treatment of patients
16 in this trial.
17 He explained -- I don't have the transcript, but I
18 wrote down what Mr. Chapman said, that he treated patients
19 primarily for pain and opiate use disorder and some of them --
20 primarily for pain and some of them for opiate use disorder, so
21 there isn't a false statement by Dr. Thomas on the record or
22 anywhere that -- anywhere. So these are things that can be
23 brought out on cross-examination. There's no prejudice to the
24 defendants.
25 And with respect to the late disclosure, we learned

1 about it on Friday and we disclosed it when we received it on
2 Sunday morning. We received it on Sunday morning. We emailed
3 it yesterday. And so it's unfortunate but the prosecution team
4 didn't have it. It's separate matter. It's a regulatory issue
5 that did not appear to us to be within the criminal case, and
6 so it wasn't something that we went looking for.
7 THE COURT: Given the steps the Court has taken by
8 permitting voir dire of this witness on the DEA 6 report, and I
9 think permitting counsel to properly go a little bit beyond
10 that report on other treatment and other actions by Dr. Thomas
11 with respect to treatment for suboxone, I don't believe that
12 under the circumstances in this case, and given the nature of
13 the proceedings, that the defendants have been unfairly
14 prejudiced warranting the kind of sanctions that are requested
15 at this time.
16 When and if there's a request for the admission of
17 the report of investigation, I can act on that and, as I say, I
18 think the additional voir dire was very well done and I think
19 it zeroed in on the report and focused on the statements that
20 were made by Dr. Thomas on the voir dire. In all other
21 respects, I think Dr. Thomas' qualifications are still intact.
22 Any scrutiny of his qualifications would need to go
23 to the DEA report of 8-3-2012, and through cross-examination,
24 and the presentation of other experts and to the extent that
25 it's evidence, closing arguments by counsel.

1 So I'll deny the motion by counsel for the defendant
2 and will permit the examination of Dr. Thomas to proceed.
3 May we bring the jury in, please, Jim.
4 (Jury panel returned to the courtroom at 8:27 a.m.)
5 THE COURT: Members of the jury, good morning.
6 Dr. Thomas is on the stand, and you'll recall he testified last
7 Friday. Wait till you have your notebooks.
8 Dr. Thomas has been previously sworn.
9 Ms. Wagner.
10 MS. WAGNER: Thank you, Your Honor.
11 **STEPHEN M. THOMAS, GOVERNMENT'S WITNESS, PREVIOUSLY SWORN**
12 DIRECT EXAMINATION (Continued)
13 BY MS. WAGNER:
14 Q Good morning, Dr. Thomas. Before we broke on Friday we
15 were getting ready to talk about the last count, patient DC.
16 Before we do that, could we pull up Exhibit 19, page 721.
17 We'll come back to that.
18 Let's talk about patient DC, which relates to Count 16 of
19 the indictment. Do you recall that DC was a patient at
20 Redirections from about October 2013 till the end of 2017?
21 A Yes.
22 Q And while this is pulling up, I would draw your attention
23 to pages 1035 and -- through 1037 of Exhibit 25. I think
24 you'll find them toward the end of the exhibit. And I want to
25 ask you if you found anything remarkable about the initial

1 intake and diagnosis of patient DC.
2 A Yes.
3 Q And what was remarkable about her intake?
4 A This patient's paperwork was essentially blank. While
5 there were a couple of marks on the intake history form, there
6 was no documentation of any -- by the patient of any prior use
7 of any drugs whatsoever in the chart that was included. The
8 patient did not fill out any of the screening questionnaires.
9 Therefore, there was virtually no information available about
10 this patient regarding their past history of use, abuse, or
11 aberrant behavior with drugs, and therefore there was no basis
12 for making the diagnosis of opioid use disorder.
13 Q And if we could pull up Exhibit 25, page 1033. And is
14 this -- when you say there was no indication of her substance
15 use history, is this what you're referring to?
16 A Yes.
17 Q And could we scroll down one page. I think you indicated
18 there was nothing filled in in her social or family history?
19 A That's correct.
20 Q And scrolling down one more page, was the CAGE
21 questionnaire filled out?
22 A It was not.
23 Q And the next page, the drug abuse screening test?
24 A There were no entries.
25 Q And the same with the alcohol screening test on the next

1 page?
2 A That's correct.
3 Q You recall that Dr. John did meet with this patient or
4 there's a reflection that he met with the patient on October
5 3rd, 2013?
6 A Yes.
7 Q After the first visit and intake, did you find anything
8 remarkable about the doctor-patient relationship as it was
9 reflected in DC's medical chart?
10 A There was no evidence of an ongoing doctor-patient
11 relationship or any further interactions. The patient
12 persistently reported no or no levels of symptoms that would be
13 associated with the -- with opioid withdrawal or any other, and
14 the prescriptions continued without change.
15 Q Was there any reflection in DC's medical chart that
16 Dr. John had an individualized treatment plan for her or
17 treatment goals laid out for her?
18 A As the only note was the -- a very brief and inadequate
19 note from the initial evaluation, there was no evidence of a
20 treatment plan associated with the use of the drug.
21 Q All right. And if I could point your attention to the
22 drug screen logs at 9-28 through 9-31 for this patient, did the
23 medical chart reflect that this patient was being appropriately
24 monitored for the use of her medication?
25 A The medical chart reflected none of the results from the

1 wide variety of drug screening logs, which included multiple
2 positives throughout her course for opioids, for oxycodone, for
3 benzodiazepines, and for THC, on occasion. On no occasion in
4 any of the medical records entries by Dr. John or the staff was
5 there significant discussion, interaction, or documentation of
6 these problems.
7 Q And can you tell us with particular respect to the
8 benzodiazepines, what is -- is there a problem with combining
9 suboxone and benzodiazepine?
10 A There is. The basic information regarding suboxone is
11 that by itself it's a relatively safe drug. One of the
12 concerns is that when combined with benzodiazepines or other
13 central nervous system depressants like alcohol, it becomes
14 significantly more toxic, and it is only in those instances
15 that suboxone has been associated with overdose death.
16 Q And if a patient tells a provider that they have a valid
17 prescription for benzodiazepine, what is the doctor's
18 obligation with respect to confirming that or confirming that
19 it's not true?
20 A The doctor -- if the patient tells one that, without
21 medical documentation, it's simply a statement. So it is the
22 doctor's responsibility to obtain medical documentation of that
23 and to monitor the patient appropriately for that drug as well,
24 given the interaction between the two.
25 Q And that's something that the doctor can delegate to

1 someone on his staff?
2 A Yes. The obtaining of a consent form and obtaining the
3 information. However, review of the information, that is, so
4 that the doctor understands the dose, the quantity, the
5 rationale for its use, is not a delegable activity.
6 Q Are there other ways, short of obtaining those records,
7 that a physician could do a quick check to determine whether a
8 patient has a valid prescription for a benzodiazepine or other
9 drug?
10 A West Virginia has a prescription drug monitoring program,
11 and you've actually had it longer than we have in Pennsylvania,
12 and that is a tool where the doctor can check with the state
13 board of pharmacy about what prescriptions have been written
14 for the patient and determine whether or not the patient is
15 legitimately receiving a prescription from the physician, what
16 physician has written it, what pharmacy it's being filled at,
17 and what the doses are of that drug.
18 Q The jury has heard testimony last week that the dose and
19 quantity of medication for Dr. John's patients were filled in
20 by Redirections staff and that those were decisions made not by
21 Dr. John himself, but by others, Ms. Hess, Mr. Handa, and other
22 staff members, at their direction.
23 If that is what happened, is that in the usual course of
24 professional medical practice?
25 A It is not.

1 Q And why is that?
2 A The decision -- the medical part of medication-assisted
3 treatment is the decisions about dose, quantity, frequency, and
4 the manner in which the patient uses any drug, it is not a
5 delegable decision for any controlled substance, including
6 buprenorphine.
7 Q If we could pull up Exhibit 25, page 951, which relates to
8 Count 16 of the indictment, which is a prescription that was
9 issued on July 27th, 2017, and you recall from last week that
10 the parties have stipulated that Dr. John was not present at
11 the clinic on that date.
12 Do you have an opinion with respect to whether this
13 prescription issued to patient DC on July 27th, 2017, was
14 outside the bounds of professional medical practice?
15 A I believe it was.
16 Q And is your opinion to a reasonable degree of medical
17 certainty?
18 A Yes, it is.
19 Q And why is that your opinion?
20 A Because there's no evidence that the doctor was engaged in
21 the professional practice of medicine for the prescription of a
22 medically legitimate controlled substance at the time that this
23 prescription was written.
24 Q All right. And I want to just go back to Count 13 very
25 briefly, because I believe that I had called up the wrong

1 prescription -- or progress note for that date.
2 Could we pull up Exhibit 19, page 721. And I think you
3 gave an opinion last week about the prescription that was
4 issued on January 19th, 2017. Can you just confirm what your
5 opinion is with respect to that prescription.
6 A That prescription was not issued for a medically
7 legitimate purpose in the usual course of professional practice
8 within the accepted bounds of medical practice.
9 Q Dr. Thomas, the jury has heard testimony that on at least
10 some of the dates that the physicians were not present in the
11 clinic the progress note was signed by someone other than the
12 physicians themselves. Assuming that that is true, that it was
13 not the doctors who signed those progress notes, does that
14 change any of the opinions that you have offered with respect
15 to whether those prescriptions were outside the bounds of
16 professional medical practice?
17 A Not at all.
18 Q And why not?
19 A Because the physician is responsible for his DEA number.
20 He is responsible for those things that are done in his name.
21 So in my practice in the use of controlled substances, if I saw
22 that one of my staff, when I had the chart, had been signing my
23 name, that is, forging in the official medical record, there
24 would have been holy hell to pay, because that is not something
25 that we allow other people to do in the use of controlled

1 substances.

2 Additionally, the patients who receive controlled

3 substances are the responsibility of the physician who is

4 treating them, and therefore the physician is responsible for

5 knowing what's going on in their treatment in any area where he

6 would be responsible.

7 So if one is prescribing controlled substances, then one

8 of the things, because of the dependency that the patients

9 experience, the physician is responsible for knowing how the

10 patient is going to get the controlled substance when they are

11 not there, as well as when they are there. And that duty is

12 not one that they can transfer to anyone else, and therefore

13 they're responsible for everything that's done in their name.

14 Q Is reviewing individual progress notes one at a time and

15 never looking at your patient -- a patient's full medical chart

16 an appropriate way to manage your patients?

17 A In any medical practice, but particularly one involving

18 controlled substances, that would be impossible, because that

19 would mean that you'd have to hold all of the information for

20 all of your patients in your head. No physician can actually

21 do that. So the medical record allows us to refresh our

22 recollections of our interactions with the patient and to know

23 what everyone else around us is doing with the patient and

24 what's going on with that patient.

25 So having the medical record, having access to urine drug

1 screens, having access to making sure that the patient has
2 controlled substance treatment agreements and the other
3 information from prior visits is essential. There's no way to
4 simply look at a single progress note and know anything about
5 that patient except what's on that note. And that's never
6 enough.
7 Q And on Friday we talked a little bit about payment, how
8 physicians are paid. I think you indicated generally by salary
9 or based on the complexity of treatment, correct?
10 A Yes.
11 Q And you understand in this case that the doctors were paid
12 a percentage of the patients' fee?
13 A Yes.
14 Q And how would you describe that? Is there a term you
15 would use to describe that sort of payment arrangement?
16 A It's piecework.
17 Q And tell us what piecework is and if it's an acceptable
18 way for doctors to be paid for their work.
19 A Piecework means that you are paid by the piece. So if we
20 were making widgets, and I got paid by the number of nails that
21 I was able to produce over a certain period of time, that would
22 be an example of piecework.
23 For my review of these records, it appears that the
24 doctors were paid piecework, whether or not they had any
25 contact with the patient. The only contribution in terms of

1 the value proposition, that is, what did the doctor add to that
2 interaction, the only contribution of the doctors that is
3 apparent in their noninteraction with the patient is a signed
4 prescription.
5 It is not within the bounds of professional practice,
6 profession meaning services, service for a fee. Rendering a
7 prescription for a fee is the sale of a prescription and not
8 allowed.
9 MS. WAGNER: Those are the questions I have on
10 direct.
11 THE COURT: Mr. Chapman.
12 MR. CHAPMAN: Thank you, Your Honor.
13 CROSS-EXAMINATION
14 BY MR. CHAPMAN:
15 Q Good morning, Doctor. My name is Ron Chapman. I'm going
16 to ask you a few questions. Okay?
17 A Certainly, sir.
18 Q Doctor, prior to August 2nd -- I'm sorry. Prior to 2007,
19 had you treated any patients solely for drug addiction using
20 suboxone?
21 A I'm a pain medicine physician. None of the patients that
22 I have treated with suboxone have ever been solely for the
23 treatment of opioid addiction.
24 Q After you received your DATA waiver in 2007, before August
25 2012, had you ever treated a patient using suboxone solely for

1 addiction?
2 A No.
3 Q And you're aware of the difference between on-label and
4 off-label use of a controlled substance, correct?
5 A Yes.
6 Q And on-label use of a controlled substance like suboxone
7 means treating a patient solely for addiction using suboxone;
8 is that right?
9 A Yes. Because the FDA-approved indication for suboxone is
10 the treatment of opioid use disorder.
11 Q It is permissible to treat patients off-label using
12 suboxone for pain, correct?
13 A Yes. It is permissible for physicians to use any drug
14 off-label as long as it is used for a medically legitimate
15 purpose in the usual course of professional practice.
16 Q And that's how you prescribe suboxone, off-label, isn't
17 that right?
18 A Primarily.
19 Q And you haven't prescribed it solely for an on-label
20 purpose like Dr. Aggarwal and Dr. John, correct?
21 A Not solely, no.
22 Q It's true that you really only started treating patients
23 using suboxone for any form of addiction between August 2nd,
24 2012, and June 30th, 2013; isn't that correct?
25 A For patients who had fully documented opioid use disorder,

1 yes.
2 Q And during that time period you only treated a total of
3 five to six patients using suboxone, correct?
4 A For patients who had fully documented opioid use disorder,
5 yes.
6 Q And the total amount of your prescribing of suboxone
7 between August 2nd, 2012, and June 30th, 2013, approximately
8 eleven months, was five to six patients alone?
9 A Solely for the use of -- for opioid use disorder in the
10 presence of pain, yes.
11 Q And you would agree that that number is less than the
12 number of patients that you actually reviewed records for in
13 this case?
14 A Certainly.
15 Q Doctor, you don't currently practice medicine; is that
16 correct?
17 A No, I do not. I do not have an active clinical practice.
18 Q In fact, you haven't practiced medicine since
19 approximately June 30th, 2013, correct?
20 A That is correct.
21 Q You haven't seen a patient for a medical purpose since
22 June 30th, 2013, correct?
23 MS. WAGNER: Your Honor, if I could just object, I
24 think we have the wrong dates, and I can clean it up on
25 redirect, but it seems to be a date we're referencing.

1 THE COURT: I'll overrule the objection and you can
2 address it on redirect, if you wish.
3 BY MR. CHAPMAN:
4 Q Please tell the jury the exact date you decided to stop
5 practicing medicine and seeing patients.
6 A I closed my active clinical practice on June 30 of 2014.
7 Q 2014. Okay.
8 And that practice was a pain practice, not an addiction
9 medicine practice, correct?
10 A That is correct. I am a pain medicine physician. I have
11 never practiced addiction medicine solely.
12 Q Primarily your work since June 30th, 2014, has been
13 offering testimony in various cases in state and federal court;
14 is that correct?
15 A That's been part of what I've done. I also continue to
16 see claimants for independent medical examinations in personal
17 injury and workers' compensation cases. I do record reviews.
18 I have given a number of lectures, and I've done some teaching.
19 Q You would call all of that work forensic work, right,
20 evaluating patients for disability cases and also testifying in
21 state and federal courts?
22 A You would call it forensic work. I would call it work.
23 Q And nearly 100 percent of your compensation currently is
24 for forensic work like testifying here today?
25 A Yes.

1 Q It is 100 percent; is that correct?
2 A Yes, that's correct.
3 Q One hundred percent of the income you receive is in order
4 for you to either write a report or sit in a witness stand and
5 testify about the treatment of patients?
6 A Currently.
7 Q You don't actually treat patients?
8 A I have not treated patients for the last five years,
9 that's correct.
10 Q You used to testify prior to June 30th, 2014, in medical
11 malpractice cases; is that correct?
12 A I still do on occasion.
13 Q And you do a lot less than you did when you were
14 practicing medicine, correct?
15 A I wouldn't say less. It was always sporadic.
16 Q You've provided a CV to the government in this case; is
17 that right?
18 A Yes, I have.
19 Q Do you have a copy of that with you today?
20 A I don't know. Is it in one of these exhibits? No. But I
21 wrote it. I pretty much know what's on it.
22 Q Isn't it true that since at least June 2016, every time
23 you have testified in a case it has been in a criminal case in
24 a federal district court?
25 A No. There have also been some board actions.

1 Q Licensing board action?
2 A State licensing board, yes.
3 Q None of those were medical malpractice cases, correct?
4 A No.
5 Q You would understand the difference between a medical
6 malpractice case and a case like this, because in medical
7 malpractice you're testifying with respect to the standard of
8 care, right?
9 A That is correct.
10 Q And you would agree that in order for the government to
11 prove its case here, it is required to prove that physicians
12 not only departed from the standard of care, but prescribed for
13 no legitimate medical purpose outside the course of
14 professional practice?
15 A That is correct.
16 Q And you've primarily stopped testifying in medical
17 malpractice cases because you're aware of certain state
18 statutes that prevent you from testifying in those cases unless
19 you've devoted a certain percentage of your practice to the
20 practice of medicine, correct?
21 A Let me correct you, because I just remembered. I
22 testified in a medical malpractice case in Philadelphia that
23 may not be on this version of my CV, a month or two ago.
24 Q Are you aware the state of West Virginia has such a
25 statute that requires physicians testifying to the standard of

1 care to devote 60 percent of their practice to the practice of
2 medicine?
3 A I was not aware of that. I have not testified in the
4 state of West Virginia, even when I was actively practicing.
5 Q Are you aware that the state of West Virginia, in a
6 medical malpractice case, would prevent you from sitting in
7 that witness stand and testifying?
8 A I have just become aware of it.
9 Q Just become aware.
10 Have you ever testified in a medical malpractice case in
11 the state of West Virginia?
12 A As I said, no, I have not.
13 Q How many times have you testified on behalf of the
14 government in a criminal case?
15 A State and federal?
16 Q Yes.
17 A I believe 20.
18 Q And how many times have you testified for the defense in a
19 state or federal criminal case?
20 A I've been retained by the defense but never called to
21 testify.
22 Q How many times have you been retained by the defense?
23 A Twice.
24 Q And how many times have you authored a report favorable to
25 the defense?

1 A Of those two times, there was one time in which I believed
2 that the defendant was not guilty of a controlled substances
3 violation and I authored a report that stated so.
4 Q So 20 times for the government, and then one time for the
5 defense; is that right?
6 A Because that's who has called me and asked my opinion, but
7 in multiple instances when the government has sent me
8 records -- and I can't tell you how many -- I have also found
9 that there was no indication for proceeding with further
10 inquiry or prosecution.
11 Q It's true, sir, that you're board certified in pain
12 medicine?
13 A Yes, I am.
14 Q And you understand that a board certification is a process
15 that a physician goes through to ensure that they have the
16 requisite training and, in some cases, experience to practice
17 in a certain field, correct?
18 A Yes.
19 Q And your board certification in pain medicine allows you
20 to practice in that field, correct?
21 A Yes, it does.
22 Q Now, there's also a board certification available for
23 addiction medicine; is that correct?
24 A Yes.
25 Q And addiction medicine is the type of medicine that was

1 practiced at RTA, correct?
2 A No.
3 Q You're only saying that because you believe that there was
4 no medicine practiced at RTA, correct?
5 A That's correct.
6 Q Okay. Now, it is true, like you said, that there is a
7 board certification process physicians can go through for
8 addiction medicine, right?
9 A Yes, there is.
10 Q And during that board certification process, physicians
11 can receive education in addiction medicine and they can also
12 take a test to prove to the board certification entity that
13 they have that training and experience, correct?
14 A That is correct.
15 Q And it is true that during your entire 30-year career you
16 have not sought to become board certified in addiction
17 medicine, correct?
18 A I have not.
19 Q It is true that you have not sought to take the board
20 certification addiction medicine test to prove your experience
21 and qualifications in the field of addiction medicine, correct?
22 A That is correct.
23 Q That's primarily because you do not practice addiction
24 medicine, do you, sir?
25 A I do not.

1 Q Okay. You're currently employed by a company called SSEA,
2 LLC?
3 A That is a company that I own. It is currently not
4 functioning.
5 Q You're the CEO of that nonfunctioning company?
6 A Yes. It was closed recently.
7 Q And that company was a consulting company?
8 A It did some business consulting and it also developed the
9 software for controlled substances management, the analgesic
10 effectiveness quality improvement program for helping
11 physicians to manage controlled substances in accordance with
12 state and federal regulations in the medical literature.
13 Q As a result of that product not getting off the ground,
14 the company is nonfunctioning and you don't earn any income
15 from that company?
16 A That's correct.
17 Q You're also employed by a company called Pain and
18 Disability Management Consultants, PC, correct?
19 A That is correct.
20 Q And what's the address for that company, sir?
21 A 7240 McKnight Road, Pittsburgh, PA 15237.
22 Q That location on McKnight Road is not a physician's
23 practice, is it?
24 A When I'm there it is.
25 Q You don't practice medicine in that location, do you, sir?

1 A I do independent medical examinations and perform my
2 forensic duties, yes.
3 Q But that's forensic work, not the practice of medicine,
4 correct?
5 A That's correct.
6 Q You would agree that those are two separate things?
7 Evaluating cases and treating patients are two separate things?
8 A They're somewhat separate, but both require a license and
9 malpractice insurance.
10 Q You've been employed by this company since 2000 to the
11 present?
12 A That's correct.
13 Q What percentage of your time is devoted to practicing at
14 Pain and Disability Management Consultants?
15 A At this point, all of it. However, Pain and Disability
16 Management Consultants as it currently exists was an extension
17 of my medical practice that I opened in 2000 and through which
18 I saw patients as well as performed independent medical
19 examinations and record reviews.
20 Q How often are you there at that office on McKnight Road,
21 sir?
22 A More or less daily.
23 Q And that's attached to an attorney's office, isn't that
24 right?
25 A Yes. Attorneys with whom I do no work.

1 Q What's the name of that attorney's office?
2 A The Lazzaro Law Center.
3 Q What does the sign out in front of that building on
4 McKnight Road say?
5 A I rent space at a place that says Lazzaro Law Center,
6 1-800 I Got Hit.
7 Q Primarily the nature of your business at that practice on
8 McKnight Road is to evaluate people who come into your office
9 from that personal injury attorney to determine whether or not
10 they're disabled; isn't that right?
11 A Lazzaro rents me space. I do no business with the Lazaro
12 Law Center.
13 Q You don't see any patients that are also being presented
14 by the Lazzaro law firm?
15 A Lazzaro rents me space. I do no other business with the
16 Lazzaro Law Center.
17 Q I didn't ask you whether you do business with them. I
18 asked you whether you see patients that are also represented by
19 that law firm.
20 A I'm sorry. My business would be seeing independent
21 medical examinations. No, I see no patients represented by
22 that law firm.
23 Q And the patients you see are represented by other PI
24 attorneys?
25 A In the personal injury realm, I have seen both patients

1 for the defense, as well as for plaintiffs. In the workers'
2 compensation realm, I see claimants that are represented by
3 both sides of the bar. I say what I see. I tell the truth.
4 So that way I don't have to remember what it was I said.
5 Q And then between 2013 to the present -- I'm sorry.
6 Between 2014 and 2018, the other employment that you list on
7 your CV is Pain Relief Center, Inc., in Cleveland, Ohio; is
8 that right?
9 A I acted as a business consultant for Pain Relief Center,
10 yes.
11 Q Did you ever live in Cleveland, Ohio?
12 A I went to Case Western Reserve University.
13 Q During the time that you've practiced with this company,
14 did you live there?
15 A No. I -- the doctor who employed me was a friend of mine
16 from college, and he asked me to look at the business of his --
17 of his company, and they also were one of our beta clients for
18 our software.
19 Q And for four years you looked at the business of his
20 company and that was your sole role in this position?
21 A Yes. I was a business consultant.
22 Q You have an MBA as well, right?
23 A I do.
24 Q During that time you were using your knowledge and
25 experience in the business world to evaluate that clinic's

1 business practices?
2 A Their business practices and their prescribing practices.
3 Q But it certainly wasn't the practice of medicine, right?
4 A No. I did not practice medicine there.
5 Q Okay. And between 2014 to 2017, the next experience you
6 list on your CV is Vital Health Partners in Cleveland, Ohio; is
7 that right?
8 A Yes.
9 Q And you were a consultant for Vital Health Partners as
10 well?
11 A A business consultant, yes.
12 Q What nature -- what type of business does Vital Health
13 Partners do?
14 A It was an integrative medicine company.
15 Q What does integrative medicine mean?
16 A Integrative is complementary medicine, acupuncture, herbs
17 and spices, things that are not allopathic or osteopathic.
18 Q Certainly not pain and addiction medicine, right?
19 A I was a business consultant on their business practices.
20 Q Now, under appointments and positions you list an
21 appointment from 2012 to the present with the U.S. Department
22 of Justice on your CV, don't you?
23 A Yes. I act as a consultant for the U.S. Department of
24 Justice.
25 Q Who appointed you to a position in 2012 with the U.S.

1 Department of Justice?
2 A I wasn't appointed to a position. I view the work that I
3 do as consulting. I -- they ask me questions and I answer
4 them.
5 Q You put it down on your CV as an appointment or a
6 position; isn't that right?
7 A It's a position.
8 Q It's not, as you say now, consulting from time to time on
9 various cases. You list this as work experience.
10 A It is work.
11 Q Okay. 2012 to present you list an appointment or position
12 with the Pennsylvania Office of Attorney General Medicaid Fraud
13 Control Unit; is that right?
14 A Yes.
15 Q And you also do regular work for them evaluating cases and
16 testifying, correct?
17 A From time to time. I act as a consultant.
18 Q Is it true that also on your CV you list appointments with
19 the DEA and the FBI, as consultants for them as well?
20 A Yes, I do.
21 Q What percentage of your income currently is devoted to
22 speaking on behalf of the federal government or state
23 governments in cases such as this?
24 A Speaking, you mean testimony?
25 Q Yes. Well, let me rephrase.

1 What percentage of your income is devoted to evaluations
2 of cases for those entities, state and federal?
3 A For all state and federal entities in all jurisdictions
4 across the country, I would say probably 60 to 70 percent of my
5 income. I haven't sat down and counted it.
6 Q 60 to 70 percent of your income on behalf of governmental
7 entities?
8 A Yes.
9 Q Okay.
10 What percentage of your income is devoted to evaluating
11 cases for defendants?
12 A A much smaller amount. As I said, I've only been retained
13 on two occasions in the past, and therefore much less.
14 Q Much less, probably less than 1 percent?
15 A Yes.
16 Q And you're being paid to testify today?
17 A I'm being paid for my time, yes.
18 Q And how much are you being paid for your time?
19 A $5,000 a day.
20 Q How much have you been paid over the course of your case
21 for this time to review?
22 A For this part of the case, I think probably, not including
23 the testimony, about $4,000.
24 Q What's your hourly rate?
25 A $500 per hour, a market rate.

1 Q You spent approximately eight hours reviewing all the
2 documents in this case?
3 A Oh, actually, it's $4,750. I just remembered the invoice.
4 Q So approximately nine hours reviewing documents in this
5 case?
6 A Yes.
7 Q And approximately how many documents did you review during
8 those nine hours?
9 A All of the clinical records, all of the investigative
10 reports. The clinical records were very thin because there was
11 very little in them. And -- so these notebooks, primarily.
12 Q You reviewed all of the discovery in this case, Doctor?
13 A I don't know. I reviewed those things that were listed in
14 my report and those things that I was provided. I'm not sure
15 if I reviewed all of it. I did spend some time listening to
16 the undercover recordings and the transcripts thereof.
17 Q You would agree that it's important for physicians to
18 further the practice of medicine through writing scholarly
19 articles and speaking?
20 A For some, yes.
21 Q For some. And in fact, you've engaged in that practice by
22 writing some articles and lecturing occasionally, correct?
23 A That's correct.
24 Q And the importance of peer-reviewed articles is that
25 physicians can do research and write important topics to help

1 the medical community advance the practice of medicine,
2 correct?
3 A Yes.
4 Q And in fact, you have listed two publications on your CV
5 as publications that you've been involved in authoring,
6 correct?
7 A Yes. That's been a minor part of my practice.
8 Q And the first article is The Short Happy Life of Medical
9 Specialty Pain Medicine, written in 1985?
10 A That's the second. Yes. It's a prospective editorial
11 published in the Allegheny County Medical Society Bulletin.
12 Q And then the other article is Epidural Fentanyl,
13 Complications in Patients Undergoing Pelvic Surgery?
14 A Yes. That was published when I was a fellow.
15 Q And that was written in 1988?
16 A Yes.
17 Q You would agree that none of the articles that you've
18 written or publications that you've written have anything to do
19 with the field of addiction medicine, correct?
20 A No, they do not.
21 Q None of them certainly have anything to do with
22 prescribing suboxone or buprenorphine for patients suffering
23 from addiction, correct?
24 A No, they do not.
25 Q And you've also lectured quite extensively, correct?

1 A Yes.
2 Q About 35 times, according to your CV?
3 A Yes, for various physician and community groups.
4 Q None of those lectures have anything to do with the
5 practice of addiction medicine, correct?
6 A Actually, there is one on addiction. Actually, there are
7 a couple that are about addiction, and some of the others
8 include aspects of addiction and prescribing.
9 Q None of those lectures are related to prescribing
10 buprenorphine to drug-addicted patients, correct?
11 A Yes. The lecture on addiction -- the lectures on
12 addiction talk about it, and the -- one of the lectures I have
13 given to a number of different groups, both medical and lay,
14 has been the control of controlled substances, which is about
15 the manner in which the Controlled Substances Act came about,
16 the categorization of controlled substances, and the ways in
17 which physicians and others should interact with controlled
18 substances in order to provide safe and effective treatment for
19 patients. All of those included a section on buprenorphine and
20 other Schedule III controlled substances.
21 Q So you speak to physicians' groups about prescribing
22 buprenorphine despite the fact that you don't do that anymore
23 and you haven't done it solely for addiction purposes, correct?
24 A I speak to physicians' groups about prescribing controlled
25 substances, of which buprenorphine is one, and about which the

1 medical legitimacy and usually professional practice of its
2 prescription is subsumed into the control of controlled
3 substances.
4 Q How many separate areas of medical practice have you
5 sought expert qualifications in on the witness stand?
6 A I have read my CV and others have determined what my
7 qualifications would be called. I have been certified as an
8 expert in the field of addiction, not addiction medicine, and
9 in the field of pain medicine, and controlled substances
10 management.
11 Q What about in your forensic work, doing evaluations for
12 patients? Have you sought expert qualifications in other areas
13 not related to pain management, addiction medicine?
14 A The business of medicine has come up, but pain medicine,
15 addiction medicine, controlled substances management, and the
16 business of medicine.
17 Q It's your testimony that those are the only areas in which
18 you have sought to testify as an expert witness in?
19 A To my knowledge, yes.
20 Q To your knowledge. Okay.
21 Now, Doctor, you reviewed various medical records in
22 preparation for your testimony in this case, as you've stated?
23 A Yes.
24 Q You reviewed the medical records created by Dr. Aggarwal
25 in this case?

1 A Yes. The medical records of the patient allegedly created
2 by Dr. Aggarwal as denoted by them -- having his name at the
3 top and a scrawl at the bottom.
4 Q You also indicated previously that you reviewed DEA
5 statements; is that correct?
6 A Yes.
7 Q All right. Now, those DEA statements were obviously
8 authored by federal agents during the course of an
9 investigation, right?
10 A Yes.
11 Q Did you rely on those statements for their truthfulness?
12 A They gave me a general view of the investigation. They
13 did not enter directly into my assessment of the medical
14 records or the medical legitimacy of the prescribing.
15 Q So you only used them for background information; is that
16 right?
17 A Essentially, yes.
18 Q You would agree with me that it's important, when
19 evaluating whether or not a patient needs a particular
20 medication or has a medical condition, it would be important to
21 sit across from the patient and speak with them; is that right?
22 A Repeatedly.
23 Q And you've actually testified in this case that you
24 thought it was necessary for Dr. Aggarwal to sit across from
25 these patients every single visit in order to determine whether

1 they needed their next prescription for suboxone, correct?
2 A He would need to repeatedly evaluate them in order to
3 determine whether or not they needed to continue on the dose of
4 suboxone they were given.
5 Q Now, you would agree with me that it's clear, based on the
6 medical records in this case, that these patients had a medical
7 reason for the prescriptions that they received for suboxone,
8 correct?
9 A No.
10 Q You disagree with that?
11 A I disagree with that.
12 Q So you formed an opinion based on the legitimacy of the
13 medication without speaking to these patients; is that true?
14 A No. I formed -- yes. Without speaking to the patients.
15 Q You didn't speak to the patients, did you?
16 A No, but I read the record.
17 Q Did you have the ability to call them up and talk to them
18 about the care they received and whether or not they needed the
19 medication?
20 A My commentary was based upon the record.
21 Q Did you have an opportunity to observe them in court here
22 while testifying about their opioid use disorder and whether or
23 not the medication helped them?
24 A My commentary was based upon the record.
25 Q Sir, my question was did you have an opportunity to sit in

1 the back of the courtroom and observe these patients while they
2 were on the witness stand testifying about the medications they
3 received.
4 A As we know, no, I did not.
5 Q But you would have had the ability to travel here and do
6 that?
7 A There was nothing that stopped me from doing it. However,
8 my opinions were based upon the information contained in the
9 medical record.
10 Q So you don't really care whether or not the patients had
11 said, I saw Dr. Aggarwal every visit?
12 A That was not consistent with any part of the medical
13 record or with the background information.
14 Q Had you learned that a patient took the witness stand and
15 informed this jury that they saw Dr. Aggarwal in the vast
16 majority of group sessions, would that have been important
17 information for you to know prior to saying that these patients
18 didn't need the medication?
19 A Saw and saw are two different things. It depends upon
20 what the meaning of "saw" is. If "saw" is saw the doctor, who
21 evaluated their condition, who evaluated the response to the
22 medication, who evaluated their past medical record, who
23 evaluated their urine drug screens, who evaluated their
24 response to treatment, then yes, that would be important.
25 If by "saw" you mean saw him in the room and had no

1 interaction with him, then no, that would be consistent with
2 the medical record.
3 Q Wouldn't it have been important to sit in the back of the
4 courtroom and observe some of these patients talk about how
5 addiction had taken over their lives and RTA had given them an
6 opportunity to go to work and succeed in life?
7 A No.
8 Q Isn't it true that you just stayed aloof to only what was
9 in the records and you ignored exactly what was going on with
10 these patients in your review?
11 A No. There was no way -- the record is -- and part of the
12 requirements for the use of controlled substances is to
13 document in the record the clinical response to the controlled
14 substance, the issues of any aberrancy in the use of a
15 controlled substance, the issues associated with the dosing
16 decisions made by the physician of the controlled substance,
17 and that was nowhere to be found.
18 Q So your issue isn't that this wasn't going on. Your issue
19 is that it wasn't documented, correct?
20 A As a precept of medicine, if it wasn't documented, it
21 didn't happen. And the rest of the information on background
22 about the nature of the evaluations performed by the physicians
23 and their absolute absence of documentation and the manner in
24 which they handled the patients was consistent with there not
25 being a medically legitimate purpose for the dosing decisions

1 and the prescriptions that were given.
2 Q Dr. Thomas, what federal statute says if it wasn't
3 documented, it didn't happen?
4 A I did not say it was a federal statute. I said it was a
5 precept of medicine.
6 Q Isn't that the reason we have trials, to determine what
7 really happened?
8 A I don't know. We have trials for these people to make a
9 decision about what they believe the truth is.
10 Q It's important for them to understand what the patients
11 actually perceived their treatment was like, isn't it?
12 A I would think that that would be part of their
13 decision-making process. That was not part of my decision --
14 that was not part --
15 MS. WAGNER: Mr. Chapman, please allow --
16 THE COURT: Let's let the witness --
17 A That was not part of my decision-making process, but as an
18 expert in evaluating a medical record, I was looking at whether
19 or not the basic standards for the use of controlled substances
20 were applied by the physicians and undertaken in the treatment
21 that they rendered.
22 Q Did you at least seek to look at DEA statements from
23 interviews with these patients?
24 A I read some. I do not know that I read all of the
25 statements, but I read quite a few.

1 Q Did you incorporate anything that you read related to
2 these patients into your ultimate opinion?
3 A It was part of the background information, yes.
4 Q Which statements particularly did you read about and
5 incorporate into your decision?
6 A I would have to look at my report to tell you that.
7 Q You think that your report incorporates statements from
8 DEA 6s and DEA reports related to those statements?
9 A It does not quote the patients' statements, but it does
10 incorporate that information as I read it prior to reading the
11 medical record and making my judgments.
12 Q Let's talk about the standard you applied in this case.
13 I believe you said that it's your opinion, based on only
14 your review of the records and information provided by the
15 federal government, that Dr. Aggarwal prescribed for a -- not a
16 medically legitimate purpose in the course of professional
17 practice. Were those your words?
18 A Not a medically legitimate purpose in the usual course of
19 medical practice.
20 Q Isn't it true that the statute requires you to determine
21 whether or not the physician prescribed for other than a
22 legitimate medical purpose in the course of professional
23 practice?
24 MS. WAGNER: Objection, Your Honor. Could we
25 approach, please.

1 (The following proceedings were had at the bench, out
2 of the hearing of the jury.)
3 MS. WAGNER: Your Honor, I just wanted to point out
4 that we've already have a motion in limine that this Court has
5 ruled on about the suboxone standard, and that it's an
6 either/or. And I just hope that Mr. Chapman's questions aren't
7 trying to shift the jury's understanding of that to a different
8 standard, and to the extent they are, I think it's something
9 that's appropriately addressed in jury instructions and not
10 with the witness.
11 MR. CHAPMAN: I'm only inquiring, Your Honor, as to
12 the framework he used. I'm not giving the jury any other sort
13 of framework. I think those were his words on the stand, that
14 that's how he evaluated this case.
15 THE COURT: I think my ruling on the motion in limine
16 was a finding based upon the state of the case law in the
17 Fourth Circuit, that of an alternative standard. I don't know
18 whether you are seeking to one side of it or not. I'm sure
19 you're not. But I want counsel to remember that position given
20 the ruling.
21 MR. CHAPMAN: I do intend to discuss whether or not
22 they believed there was a legitimate medical purpose, because
23 that could be incorporated into the requirement, but I'm not
24 going to suggest to the jury an improper standard.
25 THE COURT: Understood.

1 (Bench conference concluded.)
2 BY MR. CHAPMAN:
3 Q So I believe the question that was pending was, isn't it
4 true that the standard in this case is whether or not the
5 physicians prescribed for other than a legitimate medical
6 purpose in the course of professional practice or beyond the
7 bounds of medical practice?
8 A You just said "or." And I have always read that as and,
9 and, and. That is, it's conjunctive as opposed to separate.
10 They all go together. So it must be for a medically legitimate
11 purpose and in the usual course of professional practice and
12 within the usual bounds of professional practice, and that was
13 the way I interpreted it, because being outside of any of those
14 would place the prescribing outside of medically legitimate
15 purpose, usual course of professional practice, and within the
16 bounds of usual professional practice.
17 Q And in this context, in determining that standard, it's
18 important to look at the purpose for the prescription, correct?
19 A It's important to look at the physician's behavior.
20 Q And the purpose for a suboxone prescription would be to
21 treat a patient who's suffering from opiate use disorder?
22 A Yes. The medical diagnosis of opioid use disorder.
23 Q And so once a medical diagnosis is made of a patient that
24 they suffer from opiate use disorder, it would be appropriate
25 then to prescribe buprenorphine in order to treat that opiate

1 use disorder?
2 A Yes. And first the medical diagnosis must be made by the
3 physician.
4 Q And as you testified on Friday, in some cases you yourself
5 have prescribed to patients would didn't even qualify for
6 opiate use disorder but you thought they might be heading in
7 that direction?
8 A But I made a medical diagnosis for which the use of the
9 drug was appropriate and made medical evaluation of all of
10 their behaviors associated with the drug, as well as their
11 responses to the drug.
12 Q But that medical diagnosis was not opiate use disorder.
13 It was some other diagnosis?
14 A Yes. However, opioid use disorder is not like pregnancy.
15 It's not you are or you aren't. It is a continuum of behaviors
16 and responses to the drug that may call for its indication.
17 Q Sir, wasn't your testimony on Friday that you have also
18 prescribed to patients who do not yet suffer from opiate use
19 disorder? Was that your testimony?
20 A From full-blown opioid use disorder, primarily patients
21 that have some aberrant medication behavior; that is, they're
22 starting to go off the rails, being that the majority of
23 patients that have opioid use disorder in the United States
24 started with the legitimate treatment of their pain with an
25 opioid, that there's a point before they have the full

1 diagnosis at which something should be done.
2 Q Dr. Thomas, you're answering more than my question. This
3 experience will be a lot smoother if you answer my question and
4 my question only, okay?
5 A Yes, sir.
6 Q My question was, was that your testimony, that you've
7 prescribed to patients who didn't yet have a diagnosis for
8 opiate use disorder, yes or no?
9 A Yes, it was an off-label prescription for a medically
10 legitimate purpose.
11 Q Under the DSM, DSM-5, there are three types of opiate use
12 disorder, correct?
13 A Yes.
14 Q Mild, right?
15 A Yes.
16 Q Moderate?
17 A Yes.
18 Q And severe?
19 A That is correct.
20 Q And the patients you prescribed to didn't have either
21 mild, moderate, or severe opiate use disorder, according to
22 your testimony?
23 A Not alone.
24 Q They didn't have it.
25 A They did not have all of the criteria of opioid use

1 disorder, that's correct.
2 Q Despite your testimony that you need a diagnosis, you are
3 ready and willing to prescribe to patients who don't have
4 opiate use disorder?
5 A A diagnosis. That is, all of these patients had a
6 legitimate pain diagnosis as denoted by history, physical
7 examination, laboratory data, often a urine screen, and my
8 evaluation of the urine drug screen would be the first
9 indication that they weren't using their full agonist opioid
10 appropriately. So what I said previously, diagnosis, the
11 medical naming of the patient's problem, requires the physician
12 to go through the process of taking a history, doing a physical
13 examination, and evaluating laboratory DATA.
14 THE COURT: I'm going to let him finish his answer.
15 You may inquire.
16 MR. CHAPMAN: Your Honor, the answer is nonresponsive
17 to the question and I move to strike that portion of his
18 answer.
19 THE COURT: Motion to strike denied.
20 BY MR. CHAPMAN:
21 Q Dr. Thomas, you testified that after the decision is made
22 to prescribe to a patient who suffers from opiate use disorder,
23 or according to your testimony, may not yet suffer from it, you
24 believe that they should follow something called the standard
25 medical model; is that right?

1 A Yes.
2 Q And you believe that the standard medical model is
3 something that requires a patient to take a history, perform a
4 physical examination, provide a diagnosis to the patient, and
5 essentially repeat that cycle as the treatment progresses?
6 A Yes.
7 Q In addition to a treatment plan; is that right?
8 A Well, the treatment plan is part of the standard medical
9 model.
10 Q And you're aware that suboxone, unlike other areas of
11 medicine, is a federally regulated area, right?
12 A Federally regulated, but medically determined.
13 Q The practice of addiction medicine and the use of drugs to
14 treat opiate use disorder is laid out in many manuals issued by
15 SAMHSA, correct?
16 A Yes.
17 Q And those manuals seek to guide physicians on how to
18 better improve their practices in order to prescribe suboxone
19 effectively, right?
20 A By SAMHSA and other institutions, because medicine is not
21 static in that way, except for its principles.
22 Q And one of those manuals would be a manual called TIP 63,
23 which has been admitted as Government Exhibit 45; is that
24 correct?
25 A Yes.

1 Q In fact, TIP 63 is titled Medications For Opiate Use
2 Disorder, right?
3 A Yes. I've read it.
4 Q It's a pretty thick manual. It's about 300 and some
5 pages, correct?
6 A Yes.
7 Q And in some manuals it tells physicians everything they're
8 supposed to know before they sit across from a patient who's
9 being treated for opiate use disorder using drugs like
10 buprenorphine?
11 A Not everything, but much of the mechanics of performing
12 the job.
13 Q And in fact, this manual says in the beginning here that
14 it's the best practices put forward by the government. The
15 best practices so the physicians can understand what the
16 up-to-date knowledge is.
17 A Yes.
18 Q And this manual was created by an expert panel of
19 physicians who are board certified in addiction medicine,
20 unlike yourself, right?
21 A Yes.
22 Q And this expert panel seeks to inform doctors on how they
23 can prescribe appropriately?
24 A Yes.
25 Q And if a doctor follows everything in this manual, not

1 only are they prescribing for a legitimate medical purpose in
2 the course of professional practice, but they're exceeding the
3 best practices outlined by the federal government and SAMHSA,
4 correct?
5 A If they follow everything? Yes.
6 Q Okay. Now, where in this manual does it talk about your
7 standard medical model?
8 A It does not label it in that way, but it discusses it.
9 Q Does it say those words at all?
10 A It doesn't -- no, it doesn't say those words. Those are
11 my words.
12 Q Where in this manual does it say a physician like
13 Dr. Aggarwal must sit down with his patients at every single
14 visit and see them prior to continuing suboxone treatment?
15 A That is not what I said.
16 Q You don't believe they have to sit down with the patients
17 at every visit?
18 A I believe that they must render medical services to the
19 patients at those times that they are collecting money from the
20 patients for medical services.
21 Q Okay. So in some cases, Dr. Aggarwal doesn't need to sit
22 across from his patient. He can simply review the medical
23 record and a prescription can be issued. That's appropriate
24 sometimes?
25 A Not if he charges for that.

1 Q So Dr. Aggarwal and the clinic are not allowed to charge
2 for a patient coming in, receiving a urine drug screen, sitting
3 down in a group counseling session, receiving good group
4 counseling, and then receiving a prescription for buprenorphine
5 that resolves some of their issues with addiction. Can't
6 charge for that?
7 A The clinic could charge for the services that they
8 provide. In my opinion, no, a physician who delivers no
9 medical service but only a prescription cannot charge for that,
10 because that's the sale of a prescription.
11 Q So your issue is not that these physicians unlawfully
12 prescribed, but your issue is that they actually charged for
13 the prescriptions that they issued?
14 A No. That is part of my opinion about the unlawful
15 prescribing. However, the absence of history, physical
16 examination, and patient reevaluation for response to the drug
17 means that there was no medical service being provided.
18 Q But you just testified that you thought that a
19 prescription could be issued in absence of a physician in a
20 buprenorphine clinic, correct?
21 A A prescription could be issued for a patient in order to
22 maintain ongoing therapy, if the patient had stabilized on
23 buprenorphine or any other controlled substance in the absence
24 of a physician contact. The physician charging for that is the
25 sale of a prescription.

1 THE COURT: Let's let the doctor finish his answer.
2 And Doctor, if you'd wait until the question is asked.
3 THE WITNESS: Yes, sir.
4 THE COURT: Overlapping.
5 THE WITNESS: I was trying not to.
6 BY MR. CHAPMAN:
7 Q Let's assume for a moment that Dr. Aggarwal has to go on
8 vacation or he has to receive some continuing medical education
9 in addiction medicine in order to further his skills and he
10 leaves. It is okay for a stable patient to come into their
11 clinic, receive their counseling, and receive a prescription
12 issued under Dr. Aggarwal's DEA registration, correct?
13 A For a stable patient for what period of time between
14 visits?
15 Q Let's just say they were seen a month prior.
16 A Generally, when physicians are not available, there is a
17 coverage determination.
18 Q My question was, it's appropriate for that to happen,
19 correct?
20 A The patient could receive a prescription in the absence of
21 a physician visit if all things were stable and there were no
22 dosage changes or other things that would require medical
23 decision-making to occur.
24 Q Now, again, where in this manual -- I'm imagining it
25 doesn't say it in here -- does it say how often a physician

1 should sit across from their patient in an individual
2 physical-patient appointment to evaluate the medication and the
3 necessity?
4 A What the manual says is that the patient should be seen
5 more frequently prior to stabilization and they can be seen
6 less frequently afterwards, but that that care must be
7 individualized to the patient circumstance.
8 Q In fact, there's a portion of this manual that discusses
9 medication management visits; is that right?
10 A Yes.
11 Q And in fact, this manual tells physicians, counselors, and
12 other people working in suboxone clinics what the goals should
13 be for a medication management visit, right?
14 A Yes.
15 Q And medication management visits are these type of
16 follow-up visits that we see at RTA, where patients come back
17 after their induction on suboxone, correct?
18 A Generally. The practice at RTA did not involve the
19 physician seeing the patient at any time after the initial
20 visit without patient request. In my opinion, that should be
21 driven by physician decision-making to see the patient.
22 Q You wouldn't know whether or not these patients saw the
23 physician on follow-up appointments, because you didn't speak
24 to the patients, did you?
25 A I did not speak to the patients. That was part of the

1 background material.
2 Q You just assumed they didn't see them because it didn't
3 indicate it in the medical record; is that right?
4 A No. In some of the instances, I knew that they did not
5 see them on the date that was specified, because the date on
6 which the physician signed the record was not the date on which
7 the patient was present.
8 Q Okay. And that only happened in a few instances; is that
9 right?
10 A I would hardly say that, no. I disagree with that
11 characterization.
12 Q Let's talk about these medication management visits.
13 We're looking at Exhibit 45, page 3-85, and then government
14 Bates 1747. SAMHSA in this manual is telling physicians and
15 those working or providing treatment in a suboxone environment
16 what the goals should be for patients coming back?
17 A Yes.
18 Q Is that right?
19 A Yes, that's correct.
20 Q And the goals in this case, as we look at them, are almost
21 purely psychosocial; isn't that right?
22 A That's not the physician's primary role, because at the
23 top of the list when one is prescribing a drug is the efficacy
24 of the drug in the treatment of the symptoms that the patient
25 would be experiencing. The other --

1 THE COURT: Hold on just a second, please. Let the
2 witness finish his answer, and then commensurate with that,
3 I'll ask the witness to not overlap with the questions.
4 THE WITNESS: I'm trying not to, Your Honor.
5 MR. CHAPMAN: Your Honor, my concern is Dr. Thomas
6 seems to not want to answer the question that is asked but
7 speak about what he wants to speak about, and I know he'll have
8 an opportunity to speak to the government on redirect, and I'd
9 like him to answer my questions directly and not simply talk
10 about the narratives he wants to talk about today.
11 THE COURT: That's argument on your part. The jury
12 will disregard the last statement by counsel.
13 Mr. Chapman, if you'll just ask the questions and
14 I'll make sure that the doctor answers them.
15 And if you'll listen, Dr. Thomas, to the question,
16 and just answer the question. If you need to clarify your
17 answer, indicate that you want to clarify your answer. Okay?
18 BY MR. CHAPMAN:
19 Q Dr. Thomas, as we're looking at the goals of the weekly
20 visits, where does it say in this document that -- let me give
21 you the whole document here, so we're being fair.
22 Where does it say in this document that a physician must
23 sit across from a patient and perform a physical examination?
24 A It does not say that.
25 Q And, in fact, that's not required for a follow-up visit,

1 correct?
2 A Unless there would be something in the history that
3 suggested that it was necessary. One aspect -- so I want to
4 just answer the question. One aspect of monitoring patients
5 who abuse drugs is to assess whether or not they are
6 intoxicated. That is not on this page, but it is in this
7 document.
8 Q That would be determined based on looking at the results
9 of a urine drug screen, would it not?
10 A No. It would be determined by looking at the patient. To
11 tell if someone is intoxicated, you have to look at them.
12 Q You believe it's an absolute requirement for physicians
13 when seeing patients on follow-up visits to sit across from
14 them and look for signs of intoxication?
15 A If one is treating basically unstable patients who have
16 positive union drug screens who may or may not be adherent,
17 this adherence is on this page.
18 Q TIP 63 is the manual. That's the guideline, is it not?
19 A Yes. So it says this is also a time to ensure adherence
20 to pharmacotherapy. I don't know of a way of ensuring
21 adherence to pharmacotherapy other than talking to the patient
22 and evaluating the patient directly. It says, assessing
23 medication effectiveness and side effects. I don't know of a
24 way to assess medication effectiveness and side effects other
25 than looking at the patient, talking to the patient, and asking

1 them about those circles that they've put on that square.
2 Q And can't that be done by assessing for signs of
3 withdrawal or craving?
4 A Most appropriately done by the physician who is
5 prescribing the medication given that even when patients were
6 not stable, that was not part of what was documented in the
7 medical record.
8 Q You don't believe that those areas can be delegated to
9 other staff members; is that your testimony?
10 A Yes. I do not believe that -- only trained individuals
11 would be able to do so, because assessing those things is a
12 medical activity.
13 Q Now, you're aware of various DEA regulations related to
14 prescribing refills of controlled substances. Do you have
15 knowledge of those regulations?
16 A I do.
17 Q And you're aware that Schedule II drugs you can't issue a
18 refill for, correct?
19 A You cannot.
20 Q You're aware that Schedule III through V drugs, which
21 suboxone is within that range, you can issue refills for those
22 controlled substances, correct?
23 A One can.
24 Q One can. And according to DEA regulations, a physician
25 can write a certain number of refills on a suboxone

1 prescription, correct?
2 A According to the strict regulations, yes.
3 Q In your review of the files did you ever see an indication
4 that Dr. Aggarwal issued -- instead of having a patient come
5 back in for a counseling session and a urine drug screen,
6 issued a refill so they could just go to the pharmacy and skip
7 RTA altogether?
8 A No, that wasn't their business model.
9 Q Okay. Doctor, are you familiar with somebody named
10 Dr. Carl Sullivan?
11 A Not off the top of my head, no.
12 Q Are you familiar with West Virginia University?
13 A Yes, I am.
14 Q Are you familiar with the suboxone clinic at West Virginia
15 University?
16 A I know something about their model, yes.
17 Q And you're familiar with the West Virginia model for
18 suboxone clinics?
19 A It's a multidisciplinary model, yes.
20 Q Are you familiar with an article that has been issued by
21 Dr. Sullivan and Dr. Marshalek related to that model
22 buprenorphine clinics in integrated and multidisciplinary
23 approach to treating opiate dependence?
24 A Yes, I am.
25 Q You're aware that that model that has been used at West

1 Virginia University includes the use of medical assistance,
2 case managers, physicians, and therapists functioning as a
3 team. Is that not right?
4 A The multidisciplinary model is used in many circumstances
5 including pain, addiction, psychiatry.
6 Q And in this model physicians can delegate certain tasks to
7 these members of the team in order to increase access to
8 suboxone treatment to a greater number of individuals, correct?
9 A Yes. And there are certain aspects that are not delegable
10 under any circumstance.
11 Q Is it true this model has also been used to allow
12 telemedicine to be used in order to increase access to suboxone
13 treatment to people who are in remote areas?
14 A With trained and licensed providers at both ends.
15 Q And this clinic and this model will in some cases have a
16 physician speaking to patients in a group through a video
17 monitor?
18 A Yes.
19 Q To give them treatment?
20 A I'm sorry. I stepped on you.
21 Q That's okay.
22 A Yes. But they have trained and licensed providers at the
23 other end of the video monitor as well.
24 Q But the physician that's actually doing the prescribing is
25 sitting in West Virginia University while a patient is in a

1 remote area, correct?
2 A Yes.
3 Q You believe that model would be appropriate, right?
4 A The multi-disciplinary model can be useful particularly
5 for people in remote areas. However, the important part of
6 that is trained and licensed professionals at both ends.
7 Q You would agree with me that the model that RTA used had
8 physicians employed at the practice with X numbers, right?
9 A Yes.
10 Q You would agree with me that the model had therapists who
11 were working there as well, correct?
12 A It's my understanding that there was one.
13 Q And also other people involved in therapy with experience
14 in therapy, correct?
15 A But none who were fully trained and licensed.
16 Q Do you believe that SAMHSA requires therapists to be fully
17 trained and licensed in order to provide therapy in this case?
18 MS. WAGNER: Objection, Your Honor. I thought we
19 were talking about the West Virginia model, but it's not clear
20 to me what --
21 THE COURT: Overruled.
22 Q Do you not know?
23 A I don't know -- I was stopping to review the contents of
24 my head. I do not know if there is a specific regulation.
25 However, I do know that dosing decisions and medication

1 decisions are strictly the purview of the physician.
2 Q I appreciate your answering that question, but my question
3 was do you know whether or not SAMHSA regulations require
4 counselors to be licensed?
5 A I do not know.
6 Q Let's take a look. Government Exhibit 45, page 4-1.
7 Bates 1789 is what I'm showing you. And this is from TIP 63.
8 It's true that TIP 63, sir, uses the term "counselor" to refer
9 to a range of professionals, including recovery coaches and
10 other peer recovery support service specialists who may
11 counsel, coach, or mentor people who take OUD medication.
12 Did I read that correctly?
13 A Yes.
14 Q You would agree with me that there is no regulation under
15 SAMHSA guidelines that requires counselors to be licensed?
16 A Yes.
17 Q You would agree with me that recovery coaches are not
18 licensed counselors, right?
19 A No. The majority of recovery counseling is provided by
20 peers. NA, AA, et cetera.
21 Q Peers who have previously suffered from addiction and want
22 to help other people?
23 A Yes.
24 Q And those people don't even have in some cases a high
25 school diploma, right?

1 A Yes. At that level the most important thing is the
2 support of the patient and the recovery process.
3 Q And despite that lack of formal education, they can still
4 provide a valuable resource to addiction patients?
5 A A resource to the patient, but much less to the physician.
6 Q Going back to talking about the West Virginia model and
7 RTA together, your previous answer was when I asked you whether
8 or not there were counselors at the practice, you said there
9 was one. Would you like to revise your answer based on looking
10 at TIP 63 and the regulations that don't require counselors to
11 be licensed?
12 MS. WAGNER: Your Honor, I'm going to object just to
13 the characterization of the testimony. I believe Dr. Thomas
14 was asked whether there were therapists and he said there was
15 one licensed therapist.
16 THE COURT: Overruled.
17 A Because -- no, I would not, because of the way in which
18 that impacts upon my decision-making.
19 Q I'm not sure I understand the answer. I'm going to have
20 to ask again.
21 Would you like to revise your testimony that RTA only had
22 one counselor working at the practice based on a review of TIP
23 63?
24 A Okay. I will revise it to there was only one therapist
25 working at RTA. However, may I continue?

1 Q Sure.
2 A The way in which that impacts my decision-making about the
3 medical decision-making does not change. Because the decisions
4 about dosing, timing, and the delivery of prescriptions is a
5 medical decision that must be made by the physician and if he
6 is -- and that cannot be delegated unless he has reliable
7 information from people who are able to make those judgments.
8 Q So it is permissible for a physician to incorporate
9 knowledge from other individuals in the multidisciplinary team
10 to help them make decisions?
11 A Oh, absolutely.
12 Q And that includes counselors?
13 A That would include counselors and that would include
14 staffing, where you sit around and talk about what's going on
15 with the patient and that would include discussions of
16 observations that those people have made about the patients and
17 that would most necessarily include feedback to the physician
18 about all of that information.
19 Q And in fact, in the West Virginia model it says that
20 medical assistance can help administer screening tools in the
21 assessment of patients, right?
22 A Administer. What it says in that article is they can
23 administer urine drug screens. It does not say they can
24 interpret urine drug screens, which is a medical activity.
25 THE COURT: Let's let the witness finish his answer.

1 Q My question was not about interpretation.
2 A And my answer was about administration, collecting the
3 sample, and interpretation, the nondelegable physician duty.
4 Q And you did read that article that we've been talking
5 about?
6 A Yes.
7 Q Where in that article does it discuss the model that
8 you've testified in this case about, the standard medical
9 model?
10 A I had a copy of it.
11 Q I'd be happy to share it with you.
12 A Please do. That's okay. I have a copy. It got caught in
13 the other papers.
14 Q Please tell us where in this article it discusses the
15 standard medical model that you've testified to.
16 A It does not use those particular words, which represent my
17 way of talking about it. It does use other words that
18 incorporate the ideas.
19 Q Where in this article does it say that physicians should
20 visit with patients with a particular frequency?
21 A It says -- where is that? It does not state a particular
22 frequency. It does, however, state -- one moment, please.
23 That's okay. This article does not state -- oh, there it is.
24 I knew it was here somewhere. It says with respect to
25 frequency of visits patient should initially be seen weekly by

1 the team until they stabilize in their recovery.
2 Q Isn't that what RTA did, saw patients weekly until they
3 were testing consistently for buprenorphine?
4 A No.
5 Q You didn't recall seeing any reference to poly group?
6 A I saw a reference to poly group, but no physician response
7 to aberrant medication-taking behavior. It -- this does not
8 say a physician should respond to aberrant medication-taking
9 behavior. It does say the patient should be stabilized, which
10 means that they are taking buprenorphine and not taking other
11 drugs.
12 Q Let's back up for a second. You believe this article was
13 published in a medical journal?
14 A It was published in a medical journal.
15 Q The West Virginia Medical Journal?
16 A Yes.
17 Q Okay. And you believe that articles published in medical
18 journals are subject to something called peer review?
19 A Yes. But they are not necessarily inclusive of all
20 aspects of the issue which they discuss.
21 Q I understand. But peer review is a process where other
22 physicians review the article to ensure that it comports with
23 the medical standards in the field, right?
24 A To the extent that it contains no false information.
25 Q It's reasonable for physicians in medical practice to rely

1 on peer-reviewed articles to determine best practices in the
2 field, right?
3 A This article is much too thin to be used to determine best
4 practices. For that we would look to the -- for example, the
5 TIP 63 and the TIP 40.
6 Q Not the entire best practices, but just on the topic
7 presented.
8 A Yes.
9 MR. CHAPMAN: Okay. Your Honor, at this time I'd
10 like to admit Defendant's Exhibit 17, which is the referenced
11 article Buprenorphine Clinics and Integrated Multidisciplinary
12 Approach. I've shown a copy to counsel.
13 MS. WAGNER: No objection.
14 THE COURT: Well, I'm not sure that's what Rule
15 803.17 says. It says the statements can come, but not the
16 exhibit. If I'm mistaken, you can correct me. If admitted the
17 statement may be read into evidence but not received as an
18 exhibit. Also it's 803(18).
19 MR. CHAPMAN: Your Honor, the government doesn't have
20 any objection. I think it might be helpful for us to see the
21 article.
22 THE COURT: If the government's not going to object,
23 I'll admit it.
24 Are you objecting, Mr. Stallings, to that?
25 MR. STALLINGS: No, Your Honor.

1 THE COURT: No objection, it's admitted.
2 (Defendant's Exhibit 17 was admitted.)
3 MR. CHAPMAN: Thank you.
4 BY MR. CHAPMAN:
5 Q I'm going to show you the second page of that article. I
6 want to see if you believe this statement in this article is
7 accurate. The physician is responsible for starting, stopping,
8 adjusting the medication, and managing side effects. They
9 should rely heavily upon input from other members of the
10 treatment team as decisions on when to start, stop, and taper
11 buprenorphine can be complicated.
12 Do you agree with that?
13 A Yes. In a true multidisciplinary model, input from other
14 members of the treatment team would be important.
15 Q And those members can include therapists who only need to
16 have some background in addiction medicine, correct?
17 A Counselors.
18 Q And those other members can be case managers who help the
19 clinic run smoothly by screening potential referrals,
20 addressing issues that arise with patients, and managing
21 patient flow?
22 A Yes. That's what it says.
23 Q And those members can also be medical assistants who help
24 administer screening tools in the assessment of patients?
25 A Once again, administering is handing them the form or

1 handing them the cup. It is not the other end of that process
2 which is not mentioned there, which is interpretation.
3 Q You agree with the proposition that 8 to 16 milligrams a
4 day is a pretty standard dose of buprenorphine for a patient?
5 A It is an average dose. Some people require more. Some
6 people require less. And the only way to tell is for the
7 physician to ask.
8 Q Now, you testified previously during direct examination
9 that you believe that in-office induction is the method by
10 which patients should be started on suboxone?
11 A No. I said in-office induction is the method by which I
12 started patients on suboxone. It has become -- because of the
13 logistical difficulties with that, it has become part of many
14 practices not to do in-office induction, in which you've
15 assured that the patient is in withdrawal at the time that they
16 get their first doses.
17 Q You would agree with me that it's permissible for a
18 physician when first treating a patient on suboxone to not
19 start at a lower dose and titrate but to describe a dose they
20 believe is appropriate at that time, correct?
21 A That they believe that is appropriate based upon the
22 history, the physical examination, the degree of withdrawal,
23 the degree of dependence, and other aspects of the information
24 available from the patient.
25 Q Yes. But that method is permissible?

1 A One could start at a higher dose if there were enough in
2 the history and the physical examination and other information
3 that would suggest that that would be appropriate. However,
4 starting at a higher dose without that information would not be
5 medically legitimate.
6 Q There's been testimony in this case that RTA used the same
7 pharmacy, Anile Pharmacy, a couple blocks away. Are you aware
8 that the same pharmacy was used?
9 A Yes.
10 Q You would agree that using the same pharmacy for purposes
11 of preventing against potential diversion is an effective tool,
12 correct?
13 A It prevents any of their scripts going to multiple
14 pharmacies.
15 Q There's nothing that makes a prescription for suboxone
16 illegitimate because it is being sent to the same pharmacy down
17 the street, right?
18 A By itself, no. That would not be something that would
19 make it illegitimate.
20 Q In fact, the manner in which a prescription is
21 communicated to the pharmacy really has nothing to do with
22 whether or not the prescription was issued for a legitimate
23 medical purpose in the course of professional practice, right?
24 A It does have to do with whether or not it meets the
25 federal regulations for prescriptions, but --

1 Q Sure.
2 A By itself, that would not be an issue for the medically
3 legitimate purpose.
4 Q Okay. So just to clarify, if a prescription was delivered
5 to a pharmacy in a way that may have violated federal
6 regulation, you don't believe that has anything to do with the
7 purpose of the prescription being for a legitimate medical
8 purpose and in the course of professional practice, right?
9 A No. That happens at the physician-patient interface.
10 Q So that -- to the extent any impropriety occurred that
11 would happen at the time the physician decides to prescribe the
12 medication?
13 A And the process by which he does so.
14 Q You would agree with me that it is permissible under DEA
15 regulations to have an agent fill in the body of a
16 prescription, right?
17 A Yes.
18 Q And you would agree with me that it's permissible for a
19 pharmacy -- I'm sorry, a practice to phone in a prescription to
20 a pharmacy for a Schedule III through V controlled substance?
21 A Yes, at the direction of the physician.
22 Q Without sending anything in writing to the pharmacy, it's
23 okay to call up and say, I want to give John Smith a dose of
24 Schedule III through V?
25 A Yes, at the direction of the physician.

1 Q That call can be made by somebody other than a physician,
2 as you say, as long as it's at the direction of the physician?
3 A Yes, it can.
4 Q The progress notes you see in this case can be evidence of
5 physician direction, right?
6 A On those instances where the physician had contact and was
7 available to give direction, then yes, they could be evidence.
8 Q And you would agree with me that when a decision is made
9 to communicate an oral prescription to a pharmacy, it's the
10 pharmacy's responsibility to document that prescription on an
11 actual prescription form and keep it for their records?
12 A That is correct.
13 Q So in this case, to extent that fax lists were used of
14 prescriptions and sent to the pharmacy, that would be over and
15 above the communication requirements for an oral prescription,
16 correct?
17 A They would in part meet the requirements, although it
18 wouldn't fulfill all of the regulatory requirements for the
19 prescription.
20 Q Are you saying that the fax list may not independently
21 meet the regulatory requirements but they would be over and
22 above?
23 A No. I'm saying they may not independently meet the
24 regulatory requirements, but they could substitute for an
25 oral -- in part for the oral prescription. That is, because

1 the regulatory requirements require the physician's information
2 and the patient's information as part of that -- and those --
3 and that was not on all of the fax prescriptions and some of
4 the faxed prescription lists were not signed by the physician.
5 Q But that information can be communicated orally; isn't
6 that right?
7 A Yes. But when communicated in writing, one would expect
8 that it be complete.
9 Q You testified that you believed that the physical
10 examinations in this case done by Dr. Aggarwal, you thought
11 were cursory?
12 A Oh, yes.
13 Q It's true that you were not in the room during the
14 physical examination being conducted?
15 A I was not in the room. I read the record.
16 Q It's true that you only heard one recording of a physical
17 examination and this was an audio recording, correct?
18 A Yes.
19 Q And it's true that you had absolutely no video or any
20 ability to know what was transpiring between Dr. Aggarwal and
21 that patient during that visit?
22 A That's correct.
23 Q And it's true that you didn't call that patient up and ask
24 what they experienced during that visit?
25 A No, I did not.

1 Q And it's true that you did not sit in the courtroom and
2 listen to that patient when they testified or that officer when
3 they testified about what they experienced?
4 A No, I did not. I believe I read his report.
5 Q And it's true that you didn't talk to Dr. Aggarwal about
6 how he conducts a physical examination?
7 A No, I did not.
8 Q Were you aware, sir, that a patient testified in this case
9 that Dr. Aggarwal spent 20 minutes with him during that
10 physical examination?
11 A No.
12 Q You would agree with me that 20 minutes is a sufficient
13 amount of time to screen for co-morbidities that may be
14 inconsistent with prescribing buprenorphine?
15 A Yes, it could. It would depend upon what happened in that
16 20 minutes.
17 Q You would agree with me that that is the purpose of a
18 physical examination, is to determine whether or not suboxone
19 is appropriate, right?
20 A It's to determine the patient's physical condition, and
21 that will yield information as to whether or not prescribing
22 the drug is appropriate or inappropriate.
23 Q And in this clinic context these providers were not
24 primary care physicians screening for a host of other
25 complications, right?

1 A Well, actually they were primary care physicians screening
2 for complications associated with the diagnosis of addiction
3 that would impact upon the decision to prescribe or not.
4 Q And SAMHSA only tells us that when we're evaluating
5 patients for suboxone we really only need to do the physical
6 exam for the purposes of determining whether suboxone is
7 appropriate, is that right?
8 A I believe that -- the language is a targeted physical
9 examination, to look for the stigmata, that is, the signs, of
10 opioid use disorder and its sequela, or the things that follow
11 after it.
12 Q Isn't it true, sir, that the reason you take issue with
13 Dr. Aggarwal's physical examinations is only because you don't
14 believe there's sufficient documentation showing what happened
15 during the examination?
16 A Well, it says general and nothing, heart and lungs,
17 regular rate and rhythm, and abdomen benign, yes, that's not
18 enough.
19 Q Okay. But your issue is that the documentation was not
20 enough. You do not know what happened during these physical
21 examinations, correct?
22 A I reviewed the record and so therefore my opinions are
23 based upon the documentation, repeatedly.
24 Q You have employees -- well, when you practiced medicine
25 back in 2014, did you have employees?

1 A I still have employees.
2 Q Did you have medical assistants?
3 A I had medical assistants.
4 Q Did you ever authorize a medical assistant to sign your
5 name to any document?
6 A No.
7 Q How can you be sure?
8 A Okay. I have to take that back. I authorized medical
9 assistants to stamp letters that I dictated.
10 Q Also lab requisition forms. Is that something you might
11 delegate?
12 A No.
13 Q You wouldn't do that?
14 A No. Every lab requisition that I ordered would be
15 reviewed by me because that's my job.
16 Q You would agree with me that counseling is an important
17 part of suboxone treatment. Isn't that right?
18 A Yes.
19 Q And going back to your time treating suboxone patients
20 between August 2012 and June 2014, you didn't feel qualified to
21 render suboxone treatment to patients suffering solely from
22 addiction because you didn't have the ability to prescribe
23 that, right? Or the ability to offer that?
24 A Because I didn't have it directly connected to my
25 practice, was one of the reasons I did not, as a matter of

1 quality control. When I decided to offer it, I referred to
2 qualified addiction counselors.
3 Q It's true that back in 2012 you told the DEA you do not
4 engage in suboxone treatment for drug-addicted persons, right?
5 A For solely drug-addicted persons. I'm not sure exactly
6 what my language was at the time, but the thing that I told
7 them was I did not treat drug addiction directly.
8 Q Okay. You believe that you added the word "solely" in
9 there?
10 A At least. We had a conversation. I don't remember all of
11 the words in the conversation. I know what I communicated to
12 them.
13 Q Isn't it true that you told the DEA during an
14 administrative inspection on August 12th, 2012, that you do not
15 engage in suboxone treatment for drug-addicted persons?
16 A That I didn't use suboxone on-label for the treatment of
17 drug addiction alone.
18 MR. CHAPMAN: Your Honor, at this time we move for
19 admission of Defendant's Exhibit 16, which is the DEA 6 report
20 of August 2nd, 2012.
21 THE COURT: Any objection?
22 MS. WAGNER: Yes, Your Honor. We object to the
23 extent it's hearsay.
24 THE COURT: Could counsel approach, please.
25 (The following proceedings were had at the bench, out

1 of the hearing of the jury.)
2 MR. CHAPMAN: At this time I believe it's valid
3 impeachment because he continues to say he used the word
4 "solely," which is a very vital word in the sentence that he
5 gave to the DEA to prevent them from inspecting his practice.
6 MS. WAGNER: Your Honor, it's not a transcript of his
7 words. It's a report by a diversion investigator and you can't
8 introduce documents such as this one for impeachment.
9 THE COURT: Well, I think there have been cases where
10 a person who makes a statement in a report may be a, quote,
11 qualified -- I'm sorry. Let me finish. May be a qualified
12 witness. But I assume he's not the custodian, but he may be a
13 qualified witness. This would be a regularly conducted
14 activity.
15 MR. CHAPMAN: Yes, Your Honor. It was an
16 administrative inspection as opposed to a law enforcement
17 function offered by the DEA similar to the other reports and we
18 would offer it as a business record, not hearsay.
19 MS. WAGNER: It's irrelevant to any defense. They're
20 using it for the purpose of impeachment only.
21 THE COURT: Well, I'm sorry. I don't know any case
22 law that says you can't admit something as a business record.
23 Even though it may be used primarily for impeachment.
24 Would you show the document to him and just lay some
25 foundation questions about it.

1 MR. CHAPMAN: I can certainly do that, Your Honor.
2 THE COURT: Yeah. Thank you.
3 (Bench conference concludes.)
4 BY MR. CHAPMAN:
5 Q Doctor, you're aware as a physician who is DATA-waived
6 that the DEA can regularly inspect suboxone providers at their
7 will, correct?
8 A Yes.
9 Q And one such inspection did occur of your practice in
10 August 2nd, 2012, correct?
11 A That is correct.
12 Q And that inspection was done by a diversion investigator
13 from the DEA?
14 A There were two.
15 Q And the names of those diversion investigators were Jeff
16 Sussa and John Conlon; is that right?
17 A I would have to take your word for it.
18 Q They showed you DEA credentials and they asked you whether
19 or not you prescribed suboxone to patients?
20 A Yes, they did. We had a conversation about it.
21 Q You were aware that the reason for them asking those
22 questions is to determine whether or not you should be subject
23 to a regulatory inspection of your practice, correct?
24 A That is correct.
25 Q And you've had an opportunity to review the report that is

1 related to that inspection, correct?
2 A Yes, I have.
3 Q And you believe that the statements made by the two
4 diversion investigators in that case are accurate, right?
5 A They reflect the conversation that we had.
6 Q They reflect the conversation accurately, right?
7 A Essentially. I'm not sure about specifically.
8 Q You wouldn't accuse the diversion investigators of lying
9 or making false statements in the report?
10 A No.
11 Q Okay.
12 A But I can tell you what I told them because of the
13 situation that existed at the time.
14 Q Sure. But there's not any one independent statement in
15 this report that you believe is inaccurate, false, or
16 misleading, right?
17 A No.
18 MR. CHAPMAN: Your Honor, I believe at this time a
19 sufficient foundation is made for admissibility of Exhibit 16
20 as a business record.
21 MS. WAGNER: We continue to object, Your Honor.
22 THE COURT: All right. I will admit it and I will
23 hold that the witness is a qualified witness under Rule 803(6).
24 And otherwise it is relevant. Not prejudicial.
25 (Defendant's Exhibit 16 was admitted.)

1 MR. CHAPMAN: I said 15. I meant 16.
2 BY MR. CHAPMAN:
3 Q So you're aware that the diversion investigators on August
4 2nd are attempting to determine whether or not you prescribed
5 suboxone utilizing a DATA waiver like Dr. John and
6 Dr. Aggarwal, right?
7 A That's correct.
8 Q And you understand that your answers were very important
9 for the DEA in furthering their purpose of inspecting providers
10 who use their suboxone waiver?
11 A Yes. I gave them the information that I thought was
12 appropriate at the time.
13 Q Okay. And you wouldn't give them the impression that you
14 do not use your DATA waiver falsely, would you?
15 A No. However, I used my DATA waiver for off-label
16 prescription of suboxone as well as on-label.
17 Q Isn't it true that the DEA here says in the report
18 although he is a DATA-waived approved practitioner, he, meaning
19 you, does not engage in suboxone treatment for drug-addicted
20 persons. Did you say that?
21 A Yes.
22 Q You told them?
23 THE COURT: Mr. Chapman, if we might, let's go ahead
24 and take the midmorning break. Members of the jury, if you'll
25 leave your notebooks by the chairs and please don't discuss the

1 case while you're on the break.
2 Dr. Thomas, you can step down also and we'll return
3 in about 20 minutes. Thank you.
4 (Jury panel exited courtroom at 10:14 a.m.)
5 (Recess taken.)
6 THE COURT: May we bring the jury in, please.
7 (Jury panel returned to the jury box at 10:35 a.m.)
8 THE COURT: Mr. Chapman.
9 MR. CHAPMAN: Thank you, Your Honor.
10 BY MR. CHAPMAN:
11 Q Doctor, on August 2nd, 2012, you knew the DEA was at your
12 practice to determine whether or not you treat patients
13 suffering from drug addiction using buprenorphine, right?
14 A Yes, that's correct.
15 Q And you did, in fact, at that time, prescribe to some
16 patients, as you've testified here to the jury, for the
17 treatment of addiction and pain, right?
18 A At the times the DEA visited me, I prescribed for some
19 patients who primarily had pain diagnoses, and most of those
20 had some indication of an increase in abnormal drug behavior,
21 and therefore I decided on suboxone. They did not have the
22 full-blown diagnosis of opioid use disorder.
23 Q And you prescribed to those patients -- you issued to
24 those patients a prescription using your X number and not your
25 normal DEA number, correct?

1 A Both numbers were on the prescription.
2 Q But what was the prescription issued under, your X number
3 or your DEA registration?
4 A Because generally the pharmacist in our area would not
5 issue buprenorphine without the X number, the X number was
6 included on all of them. I don't know which one the pharmacist
7 used.
8 Q Isn't it true you informed the DEA at that time that you
9 do not engage in suboxone treatment for drug-addicted patients
10 as we are seeing here on this DEA 6?
11 A Yes.
12 Q Moving to page 3 of that document. Isn't it true that you
13 informed the DEA that you do prescribe suboxone, but solely
14 intended to treat pain?
15 A That's what's written, yes.
16 Q Isn't it true that you said that?
17 A I'm not sure I said "solely." But the primary indication
18 for all of my patients was the treatment of pain, yes.
19 Q Isn't it true that you informed the diversion
20 investigators that while you did have a DATA waiver from 2008,
21 that you did not engage in the practice of treating drug
22 addiction patients because you feel that drug-addicted patients
23 require services that you do not provide?
24 A At that time, that was what I told them. However, I was
25 incorrect on the date of my initial DATA waiver. It was

1 actually 2004 and I had retaken the exam in 2007, or the
2 training in 2007. And that is what they recorded, yes.
3 Q Isn't it true that you further told the DEA that you do
4 not engage in any form of treatment for DATA-waived patients,
5 suboxone patients, any form of treatment, Dr. Thomas?
6 A That is what they recorded. I'm not exactly sure that
7 that's exactly what I said. I have no reason to say that it's
8 not true, but the circumstances under which I use buprenorphine
9 is what I've described to you today.
10 Q And it's true that you told them that you do occasionally
11 prescribe suboxone, but solely for the treatment of pain?
12 A That is what it says.
13 Q Isn't it true that in order to get the DEA to go away and
14 not investigate your practice, sir, that you informed them that
15 you do not treat drug-addicted patients at all?
16 A My purpose was not to get the DEA to go away, but that is
17 what the form says, and I prescribe suboxone under the
18 circumstances that I have described to you today.
19 Q You knew that they were looking to determine whether or
20 not you treated patients with addiction, and you told them no;
21 isn't that right?
22 A Yes.
23 MR. CHAPMAN: I have no further questions for this
24 witness, Your Honor. Thank you.
25 THE COURT: Mr. Stallings.

1 MR. STALLINGS: Thank you, Your Honor.
2 CROSS-EXAMINATION
3 BY MR. STALLINGS:
4 Q Good morning, Dr. Thomas.
5 A Good morning.
6 Q Throughout your testimony you discussed whether Dr. John
7 prescribed suboxone to his patients for a legitimate medical
8 purpose or whether something else is happening. Do you recall
9 that testimony?
10 A Yes.
11 Q In your experience, what are the illegitimate purposes for
12 a person to seek treatment at a suboxone clinic like RTA?
13 A Well, the concerns with all controlled substances,
14 including buprenorphine, are those of abuse and diversion.
15 Q In fact, the only real-world illegitimate reason somebody
16 would walk into RTA, go to group counseling sessions, submit to
17 the urine screens, the only illegitimate purpose would be to
18 divert, correct?
19 A Or abuse.
20 Q And I think your testimony would be that that diversion or
21 abuse, that something else happening would be something other
22 than the legitimate practice of medicine, correct?
23 A Yes.
24 Q And just to clarify, is there any other purpose you can
25 think of for a person to go to a clinic like RTA other than

1 diversion and abuse, or legitimately seeking medical treatment?
2 Is there a third option?
3 A Both.
4 Q In all of the evidence that you've reviewed, all the DEA
5 reports, all the DEA memoranda, all the patient charts that you
6 reviewed, did you see any evidence that any of the five
7 patients identified in this indictment of Dr. John, any of
8 those five patients, diverted a single strip of suboxone or a
9 single tab of suboxone?
10 A There's no direct evidence in any of the information that
11 I reviewed that that occurred.
12 Q Not only is there no direct evidence, but wouldn't you
13 agree with me that the evidence shows that those five patients
14 identified in the indictment actually used the suboxone that
15 was prescribed to them?
16 A They took at least some portion of the suboxone, yes.
17 Q From the government's exhibit regarding patient PE, this
18 is his drug screening log, correct?
19 A That is correct.
20 Q That plus in the buprenorphine column means he took his
21 suboxone, correct?
22 A It means he took at least some of the prescription, yes.
23 Q As did SH, correct?
24 A Yes.
25 Q As did AM, correct?

1 A Yes.
2 Q As did JB, correct?
3 A Yes.
4 Q And as did DC, who we heard from in this trial, correct?
5 A Yes. At least one of those had problems with validity, so
6 we're not sure what the test actually said.
7 Q You're not sure that DC took the suboxone she was
8 prescribed?
9 A On tests that have questionable validity, one must
10 question the overall response to the test. However, for the
11 rest of those, yes, the chart would suggest, without actually
12 having the actual urine drug screens available, that the
13 patient took at least some part of the suboxone prescription.
14 Q Dr. Thomas, wouldn't you agree with me that if the DEA
15 diversion investigators had a shred of evidence that any of
16 those five patients diverted a single strip of suboxone, they
17 would have provided that to you before you rendered your
18 opinion?
19 A I don't know. I suspect they would. But I don't know.
20 Q I suspect if they had that evidence, then the prosecutor,
21 when she was asking you questions, would have said, now, the
22 jury heard testimony that -- but you didn't hear any of that,
23 about any diversion for any of these five patients, correct?
24 A No.
25 Q The truth is that all five of these patients actually

1 received suboxone from Dr. John and actually took it, correct?
2 A They took at least some portion of the prescription.
3 Q Now, I want to go back and talk a little bit about some of
4 your qualifications. Dr. Aggarwal's lawyer covered most of
5 that. But generally you would agree that when somebody is
6 evaluating the opinion of a physician, it's important to
7 understand that physician's qualifications?
8 A Certainly.
9 Q And oftentimes people will seek a second opinion from
10 physicians?
11 A Under circumstances of diagnostic insecurity, yes.
12 Q And when you're comparing the -- sometimes those second
13 opinions differ. Two doctors will often disagree, correct?
14 A Two doctors could disagree, yes.
15 Q They could both be expert doctors and they could both have
16 different opinions about a medical issue, correct?
17 A I'm sure they'll hire someone who has a different opinion
18 than mine.
19 Q In your opinion, would it be important to weigh the
20 varying qualifications and experience of those two differing
21 physicians in determining those which opinion you give more
22 weight to?
23 A More important than the qualifications or opinions are the
24 facts, although qualifications and opinions are part of the
25 information that the jury will have to weigh.

1 Q You're aware that the jury's going to hear from at least
2 two other experts in this case, expert physicians in addiction
3 management. You're aware of that, correct?
4 A Yes.
5 Q And you do know there's a phrase in medicine called board
6 certified or board certification. You're familiar with that
7 phrase?
8 A Yes. I have one.
9 Q It has a special meaning in medicine, correct?
10 A Special but not unique.
11 Q You've heard the phrase that it's the gold standard of a
12 physician's qualifications?
13 A That could be said, sure.
14 Q You are board certified in anesthesiology, correct?
15 A I am.
16 Q You are board certified in pain management, correct?
17 A I am.
18 Q You are not board certified in addiction, correct?
19 A That's correct.
20 Q Are you aware of whether the other experts are, in fact,
21 board-certified addiction physicians?
22 A Yes. I've read their qualifications and I believe they
23 are.
24 Q Am I correct that over your entire career you have treated
25 five or six patients with suboxone for addiction?

1 A For the purpose of addiction, diagnosed as opioid use
2 disorder, yes, that's correct.
3 Q And that you haven't practiced medicine actively at all
4 since June of 2014, correct?
5 A That is correct.
6 Q Do you know or have you learned how many suboxone patients
7 the two experts in the courtroom here have treated with
8 suboxone, how many patients they've actually treated with
9 addiction?
10 A That would be none of my business.
11 Q Did you hear the evidence in this case that Dr. John, in
12 2016, had a patient count of approximately 71 to 74 active
13 addicts, substance abuse addicts, who were being treated for
14 suboxone in 2016?
15 A I knew that that was close to the number.
16 Q And that he treated a number between 30 and upwards of the
17 70s suboxone addiction patients from 2013 all the way through
18 2017?
19 A Yes.
20 Q And during that period of time, 2013 to 2017, at most you
21 saw a total of five or six addiction patients and treated them
22 with suboxone, five or six, correct?
23 A Yes. But I treated other patients with suboxone. The
24 process is exactly the same.
25 Q When you were hired by the government to testify -- which

1 is, frankly, the majority of what you do day in, day out, is
2 testify and consult for the government, correct?
3 A Currently, yes.
4 Q You've been hired in a number of federal cases around the
5 country, correct?
6 A I have.
7 Q But they didn't all relate to suboxone; am I right?
8 A They did not.
9 Q In the Lee case out of Middle District of Pennsylvania,
10 that's the area around Scranton, Wilkes-Barre, correct?
11 A That is correct.
12 Q You testified in that case. It was U.S. versus Lee. Do
13 you recall that?
14 A Yes, I do.
15 Q That was a case related to oxy and other related drugs,
16 correct?
17 A Yes. He was a purported pain medicine physician.
18 Q And you testified in the Diaz case out of Mississippi,
19 correct?
20 A Yes.
21 Q And in a case involving ketamine; am I right?
22 A Yes.
23 Q And in the Booker case out of Pittsburgh, Hughes Booker
24 case, do you recall that consultation?
25 A I have consulted. I have not testified.

1 Q Right, and by the way, that case, the Booker Hughes case,
2 was not listed on the list of cases that you work on the
3 government on behalf of, correct?
4 A Because I have written the report, but I have not
5 testified, and on my CV I put on cases in which I have given
6 testimony and not all of those for which I have read or written
7 a report.
8 Q Exactly. So you've listed on your CV and your list of
9 cases a large number of cases in which you've appeared in
10 court, but beyond that there's an even larger number of cases
11 where you've consulted for the government and written reports
12 for the government, correct?
13 A Yes. And in some of those I have found that there have
14 been violations and in others I have not.
15 Q We heard that. And in the Booker Hughes case that we're
16 talking about, that was a case, am I correct, that involved a
17 psychiatric family practice out of Kentucky, where the issue
18 involves the appropriateness of oral screening of pediatric and
19 family patients, correct?
20 A And a doctor who was receiving kickbacks for performing
21 them, yes.
22 Q In those three cases I just pulled by way of example, none
23 of those three cases were you testifying about the propriety of
24 prescribing suboxone to substance-addicted patients, correct?
25 A No. I was testifying about the propriety of the medical

1 practice involved.
2 Q In each of those cases, your opinion was paid for by the
3 Department of Justice, correct?
4 A My time was paid for by the Department of Justice. My
5 opinion belongs to me.
6 Q Your opinion favored the Department of Justice in each of
7 those cases?
8 A In that instance they agree with me, yes.
9 Q Let's talk about your opinions in this case. I believe in
10 direct on Friday I heard you testify approximately ten times
11 that each of your opinions were quote to a reasonable degree of
12 medical certainty. Do you recall that?
13 A Yes.
14 Q Are you familiar with the National Commission on Forensic
15 Sciences?
16 A I have not read anything -- I have no recollection of
17 that, no.
18 Q Are you aware that the United States Department of Justice
19 established the National Commission on Forensic Science as a
20 part of its partnership with the National Institute of
21 Standards and Technology? Is that refreshing your
22 recollection?
23 A No. Go on.
24 Q The purpose of that commission was to improve the
25 reliability of forensic testimony in proceedings like this,

1 correct?

2 MS. WAGNER: Objection, Your Honor. May we approach.

3 THE COURT: Sure.

4 (The following proceedings were had at the bench, out

5 of the hearing of the jury.)

6 MS. WAGNER: Your Honor, I believe that the policy

7 that Mr. Stallings is inquiring of Dr. Thomas relates to

8 fingerprints and technology and not to medical opinions.

9 MR. STALLINGS: It does not. It relates exactly to

10 that phrase and the use of that phrase by an expert witness in

11 court proceedings involving the Department of Justice.

12 THE COURT: What's it say?

13 MR. STALLINGS: His opinion, Judge --

14 THE COURT: What's the National Commission --

15 MR. STALLINGS: It says that standard should never be

16 used by an expert because it's misleading and not based on

17 scientific evidence, certainly grounds for cross-examination.

18 THE COURT: The law in the federal courts -- federal

19 court's still accepting a reasonable degree of medical

20 certainty.

21 MR. STALLINGS: Not that phrase. No. First of all,

22 that's not the standard -- first of all, that's not the

23 standard in this case. But more importantly, that phrase is

24 specifically noted in this policy as being unbased in any

25 scientific evidence and not appropriate for use by an expert

1 witness testifying on behalf of a defendant or a government
2 lawyer. And he used that phrase repeatedly in his standard.
3 MS. WAGNER: I'd like to see the policy, Your Honor,
4 because it is our position that it does not apply -- it applies
5 to forensic fingerprints and forensic technology. That's what
6 it applies to. Perhaps Mr. Stallings could share with us the
7 policy so that we can look at it.
8 MR. STALLINGS: I'm happy to. I thought they would
9 have been familiar with it, but --
10 MS. WAGNER: We are familiar with it. It doesn't
11 apply to this situation.
12 THE COURT: I'm not familiar with it. I've not heard
13 of it and I'm holding in my head some circuit court opinions.
14 MR. STALLINGS: I can produce it, if you give me a
15 moment.
16 THE COURT: That follow the reasonable degree of
17 medical certainty? I'm sorry.
18 MR. COGAR: I am familiar with it, Judge.
19 Mr. Stallings overstates the import of the policy. In fact, it
20 is just a policy with DOJ, for DOJ employees, it's my
21 understanding. My understanding also is it doesn't relate to
22 all expert testimony, even medical testimony, necessarily, but
23 in all events, it's not the law, Judge. It doesn't cover
24 Fourth Circuit law with respect to expert testimony and the
25 manner in which they characterize their testimony. It is just

1 an internal DOJ policy and it's inappropriate for Mr. Stallings
2 to use that for cross-examination for a witness who doesn't
3 even know the policy.
4 MR. STALLINGS: This was brought up by Ms. Wagner on
5 direct repeatedly. She used that language specifically. Is it
6 your opinion to a reasonable degree of medical certainty. I'm
7 allowed to probe him on what that means and the fact that there
8 is no scientific basis for it. Ms. Wagner's poor choice, not
9 mine.
10 MR. COGAR: That's different than saying a DOJ policy
11 says -- it's certainly appropriate for him to inquire about
12 what reasonable degree of medical certainty is.
13 THE COURT: Seems to me the issue is whether or not
14 the term of an opinion reasonable degree of medical certainty
15 is accepted by federal courts in this country, and most
16 importantly the Fourth Circuit Court of Appeals.
17 MR. STALLINGS: No, because it's not a legal issue,
18 Your Honor. With all due respect, it's not a legal issue.
19 It's about how he framed his opinion, what his standard was in
20 response to Ms. Wagner's questions. I'm not going to the legal
21 point. I know he's wrong on the law on that.
22 THE COURT: At the end of the day, the standard by
23 which an opinion should be stated is based on --
24 MR. STALLINGS: But Your Honor, but that's not the
25 issue with this line of questioning. Ms. Wagner elicited that

1 standard repeatedly in her direct examination. And his
2 opinion, his medical opinion, was based on that standard. I'm
3 allowed to probe that, what the basis for that is, and the fact
4 that particular standard instructs witnesses and attorneys not
5 to use it.
6 THE COURT: Absolutely. What I'm interested in is
7 that what is offered is a relevant and admissible standard and
8 you disagree, your client disagrees, and I have not -- I'm not
9 aware of the study and I'm not aware of the import of the
10 study. So I'm going to let you cross-examine him, but I want
11 you to know I'm going to take a look at that study, what my
12 ruling will be, a legal matter, particularly the Fourth Circuit
13 Court of Appeals is that opinions are based on a reasonable
14 degree of medical certainty, are appropriate. And then I may
15 have to instruct the jury to the contrary. You're just going
16 to have to indulge me, but I am absolutely not familiar with
17 that study.
18 MR. STALLINGS: I'll provide it to the Court and to
19 counsel so they can read it.
20 THE COURT: I would want that.
21 MR. STALLINGS: It strongly tells DOJ attorneys not
22 to use that standard.
23 THE COURT: I'm not sure it's important what they
24 tell the DOJ attorneys. What's important is what the jury is
25 told about the proper standard of proof under Fourth Circuit

1 law and the law of other circuits.

2 MR. NOGAY: It's my understanding that the testimony

3 to a reasonable degree of medical certainty is usually only

4 used for future damages in civil cases as opposed to

5 admissibility of opinions, which is to a reasonable degree of

6 medical probability. As opposed to future damages, which must

7 be stated with certainty.

8 THE COURT: Well, but what Mr. Stallings would say

9 is, I think, is that that language would not be acceptable

10 either because the Justice Department -- they're recommending

11 the Justice Department use something else or not use any.

12 Would you say reasonable degree of medical probability would be

13 acceptable?

14 MR. STALLINGS: No. What they say is the expert's

15 opinion, when elicited, should be based on whatever standard is

16 appropriate to that expert's area of testimony. In this case,

17 for a legitimate medical purpose and not outside the bounds of

18 professional practice. When you add that phrase "to a

19 reasonable degree of medical certainty," there is no scientific

20 basis for that phrase, and no legal basis for that phrase, so

21 it improperly adds an aura of authority to the opinion which is

22 not based in science. That's what the opinion says.

23 THE COURT: I would like to read the report and also

24 see if there's any case law that have interpreted that as a

25 standard to be followed. By testimony of expert witnesses.

1 Preferably in the Fourth Circuit.
2 MR. STALLINGS: We'll do that, Your Honor.
3 THE COURT: Thank you very much.
4 (Bench conference concluded.)
5 THE COURT: I will let you inquire.
6 MR. STALLINGS: Thank you, Your Honor.
7 THE COURT: Objection is overruled at this time.
8 BY MR. STALLINGS:
9 Q Dr. Thomas, as we were discussing, the Department of
10 Justice's National Commission on Forensic Science has actually
11 spoke out about the use of the phrase quote, to a reasonable
12 degree of medical certainty, closed quote, correct?
13 A I have not read that document. I have to take your word
14 for it.
15 Q I'll ask you, that phrase that you used repeatedly in
16 direct examination is not defined in the standard medical or
17 scientific reference materials that you rely on, correct?
18 A No. It's a phrase that I have discussed with multiple
19 attorneys over time. It's a phrase that has come into every --
20 actually, every civil or criminal proceeding in which I've been
21 involved, and it is a phrase that has been appended to my
22 opinions repeatedly.
23 Q But you are not aware that the Department of Justice's own
24 commission warned, quote, as such terms have no scientific
25 meaning and may mislead jurors or judges when deciding whether

1 guilt has been proved beyond a reasonable doubt, closed quote,
2 they should not be used. You were not aware of that guidance
3 from the Department of Justice?
4 A I was not aware of that guidance but I also believe that
5 my use of the term, which I can define for you, if you wish, is
6 in order to tell the jury what I meant by what I said.
7 Q You are not licensed to practice medicine in West
8 Virginia, correct?
9 A I am not.
10 Q And I believe you were shown in direct examination
11 Government Exhibit 43. I apologize. Do you recall being asked
12 some questions on direct examination about this exhibit? This
13 is Government Exhibit 43, the West Virginia CSR provisions
14 related to the West Virginia Board of Medicine. Do you recall
15 that?
16 A Yes. It was something that I read previously.
17 Q Now, to be clear, every state has regulations like this
18 statute, correct? That regulate the ability of the state's
19 board to discipline or suspend physicians, correct?
20 A Yes. It's part of the administrative code for physicians.
21 Q And you were asked questions about this specific provision
22 that related to things like physician-patient interaction and
23 the like. Do you recall those lines of questions on Friday?
24 A Yes, I do.
25 Q What this regulation does is it permits the West Virginia

1 Board of Medicine to take certain kinds of disciplinary actions
2 against physicians, including suspending their license to
3 practice if they violate those kind of provisions, correct?
4 A I believe that's one purpose of the administrative code.
5 It's also an instruction to physicians.
6 Q But Dr. John, as we sit here today, you're aware is
7 currently actively licensed to practice medicine in the state
8 of West Virginia, correct?
9 A I have no idea.
10 Q Well, but you do know this case has not been secret,
11 right? This isn't a sealed proceeding?
12 A Oh, I'm aware of that, yes.
13 Q The indictment was public?
14 A Yes.
15 Q It was a press release issued by the Department of Justice
16 when they issued the indictment. Do you recall that?
17 A I had no idea about the press release. I know it's not a
18 sealed proceeding.
19 Q Jeff Sessions proudly announcing his war on opioids
20 continues. Do you recall?
21 A I remember General Sessions making some comments. I
22 didn't know it was about this case.
23 Q And yet so that happened back in May of 2018, correct?
24 A I don't -- as I sit here, I don't know when it happened.
25 I take it that it happened.

1 Q So despite the publicity of this case and the allegations
2 in this case, the West Virginia board of medicine has not taken
3 this Exhibit 43 document and used it to discipline Dr. John to
4 your knowledge, correct?
5 A No, to my knowledge they have not.
6 Q Now, let's look at another document that you testified
7 about. I think it was Exhibit 45. This is a SAMHSA guidance
8 document that sometimes is referred to as TIP 63, correct?
9 A That's what it says on the front.
10 Q You're familiar with this. I think you testified this was
11 one of the things you relied on in reaching your opinion,
12 correct?
13 A I've read it, yes.
14 Q Do you have a copy of that in front of you still?
15 A I do.
16 Q If we could turn to page GX001587. By the way, this
17 document is not a statute, correct? It's not a criminal
18 statute. Am I right?
19 A It is not.
20 Q And it is not a regulation even, correct?
21 A It is not.
22 Q It's guidance, correct? You would agree with me that
23 there are many issues where guidance is provided and a
24 physician could follow it or not follow it but yet still be
25 practicing medicine, correct?

1 A It is not necessary to follow the guidance as if it were a
2 manual. But the guidance does give physicians some direction,
3 particularly in an area of practice where most of us don't
4 normally practice, as to what we should or should not be doing
5 in the appropriate treatment of these patients.
6 Q But this guidance, this SAMHSA document, does state
7 clearly that our nation faces a crisis of overdose deaths from
8 opioids, including heroin, fentanyl and opioids, correct?
9 MS. WAGNER: Your Honor, I would object on the same
10 basis that I've been objecting to this issue, if you would like
11 we can --
12 THE COURT: Overruled.
13 Q Do you agree, sir?
14 A Yes, that is what it says and that is the case.
15 Q And you agree that, according to the SAMHSA guidance,
16 health care professionals such as yourself, treatment
17 providers, and policy-makers have a responsibility to expand
18 access to evidence-based effective care for people with opioid
19 use disorder, correct?
20 A Oh, yes, I definitely agree with that.
21 Q In fact, it says that expanding access to OUD medications
22 is an important public health strategy, right?
23 MS. WAGNER: Your Honor, may we approach, please.
24 THE COURT: Sure.
25 (The following proceedings were had at the bench, out

1 of the hearing of the jury.)
2 MS. WAGNER: I believe that Mr. Stallings' questions
3 again are aimed at the jury nullification argument about
4 expanding treatment and prosecuting physicians who are
5 violating criminal law is taking treatment away from patients.
6 And I believe the judge -- this Court has already ruled on this
7 issue and yet these questions keep coming up, which we believe
8 are aimed at jury nullification argument.
9 THE COURT: Well, I thought the document being
10 referred to has been allowed as guidelines. It's not a
11 regulation. It's not a statute.
12 MS. WAGNER: I agree with that, Your Honor, but what
13 they are emphasizing are parts that are talking about a lack of
14 treatment for patients and that the only purpose of this line
15 of questioning is to make an argument on jury nullification.
16 THE COURT: Well, I'm not sure. I'm not sure it is.
17 Shouldn't be any argument on jury nullification. I think we
18 all agree on that. Nor should it be allowed. What's the
19 purpose of asking these questions?
20 MR. STALLINGS: A few points, Judge. Number one,
21 this is the Government Exhibit, number one. It's entered into
22 evidence. In its entirety. Number two, this witness testified
23 that he relied upon this document in reaching his opinion. So
24 just starting there, this document's fair game to discuss with
25 him on cross-examination. Second, this is the third or fourth

1 time that counsel has accused us of this jury nullification.
2 Their theory of the case is these doctors did not practice
3 medicine and the way they did things at RTA. We're allowed to
4 explore what are the different ways in which physicians can
5 treat patients with opioid addictions, what are the modeling,
6 what are the ways to do it, is this witness really an expert in
7 telling us which model is appropriate and this goes directly to
8 that issue. This is our theory of the case and it promotes
9 their theory of the case. That's not jury nullification.
10 That's defense.
11 THE COURT: I'm not ruling on whether or not it's
12 jury nullification. It's in the guidelines. This Court and
13 maybe another court in other cases held that they are
14 guidelines that can be of assistance or an aid to the jury. So
15 I'm going to allow the question.
16 MR. STALLINGS: Thank you, Judge.
17 (Bench conference concluded.)
18 THE COURT: Objection is overruled.
19 BY MR. STALLINGS:
20 Q SAMHSA's guidelines said that the gap between the number
21 of people with opioid addiction and the capacity to treat them
22 with OUD medication is substantial, correct?
23 A Yes, it does.
24 Q And you would agree with me that one of the overriding
25 purposes of these guidelines and in fact the entire DATA waiver

1 program was to expand the availability of suboxone to the
2 addiction patients around this country who needed it?
3 A To safely expand the use of suboxone to addiction patients
4 who needed it, under medical supervision.
5 Q And while Dr. John and Dr. Aggarwal were out there in the
6 trenches in the war on opioids actually expanding access to
7 such treatment, you in your practice chose not to use your DATA
8 waiver to treat addiction patients with the exception of the
9 handful, correct?
10 A I did make that choice. Because the medically supervised
11 treatment at the time had limitations within my practice,
12 because of all the things that would be expected to be done
13 that were not done in this case.
14 Q Now, I believe you testified that some patients -- and I
15 don't want to mischaracterize your testimony, so if I say this
16 wrong, please correct me, but that some of the patients of
17 Dr. John should have been considered for a higher level of care
18 than the suboxone clinic at RTA and its model provided. Did
19 you testify to that effect on Friday?
20 A I testified particularly about a particular patient, whose
21 initials I can't remember, who had a 40-year history of opioid
22 and cocaine addiction.
23 Q But in general, higher level of care in this context, what
24 it means is a number of other possibilities, which would
25 include inpatient commitment at a hospital, correct?

1 A Well, not commitment. Inpatient treatment, yes.
2 Q Residential rehabilitation, correct?
3 A Yes.
4 Q Now --
5 A And treatment by board certified addiction specialist in a
6 wider multidisciplinary program or in fact for some patients
7 treatment with abstinence followed by naltrexone are all of
8 the -- or an outpatient treatment program with methadone, all
9 of which would be considered for patients who have more severe
10 disease.
11 Q Right. And in reaching your opinion that criticizes the
12 way Dr. John approached these patients and Dr. Aggarwal
13 approached these patients, did you factor in whether or not
14 these patients identified in the indictment, many of which
15 we've heard from in this courtroom, could have afforded 90 days
16 out of their work lives and family lives to attend a
17 residential rehabilitation program?
18 A Then while -- okay.
19 Q I didn't ask you to explain, Doctor. I asked you whether
20 you considered that.
21 A I did not consider that, because I was not considering the
22 patients' behavior. I was considering the doctors' behavior.
23 Q Exactly. You didn't look at how this treatment impacted
24 the patients positively, did you?
25 A I looked at the doctors' behavior because I was asked to

1 judge the doctors' behavior.
2 Q Do you know how much a typical standard 90-day residential
3 rehabilitation program costs?
4 A It's tens of thousands of dollars.
5 Q Now, isn't it also true that denying access to suboxone
6 can be more dangerous than giving access to suboxone?
7 A It can be. In no circumstance did I say they should deny
8 suboxone treatment to any patient.
9 Q In fact, you can analogize addicts who need suboxone to
10 diabetics and diabetes patients who need their medication,
11 correct?
12 A It would be a poor analogy, but one could.
13 Q SAMHSA thought it was a good analogy. They said some
14 people achieve remission without OUD medication, just as some
15 people can manage Type II diabetes with exercise and diet
16 alone. But just as it is inadvisable to deny people with
17 diabetes the medication they need to help manage their illness,
18 it is also not sound medical practice to deny people with OUD
19 access to FDA-approved medications for their illness, correct?
20 A When you said diabetes, I was thinking Type I, which is a
21 different disorder in which there is a deficiency in insulin,
22 as opposed to Type II. However, yes, in that analogy it could
23 work.
24 Q Just like with diabetes, there's different models for the
25 best way to manage patients who have diabetes, just like

1 there's different models for the best way to manage patients
2 who have substance abuse addiction and can benefit from
3 suboxone?
4 A Yes. And all involve the practice of medicine.
5 Q You had a little bit of testimony about this document on
6 direct examination. This is from Government's Exhibit 33,
7 counsel.
8 And I think you were asked the question rather
9 specifically about this document and you testified that this
10 document, quote, did not comply with the requirements of the
11 regulations, closed quote, for being a prescription, right?
12 A Yes.
13 Q Now, I'm going to show you an excerpt. This one is from
14 Dr. John's Exhibit 77. But there are many of them in the
15 record, these telephone prescriptions.
16 As I understand your testimony, both Friday and this
17 morning, when Mr. Chapman was questioning you, if a staffer at
18 RTA with the approval of Dr. John telephoned in a prescription
19 to Anile Pharmacy, and followed up that call or prefaced that
20 call with a facsimile containing information related to that
21 prescription, then Anile Pharmacy could fill that prescription
22 and document it by filling in a telephone prescription form,
23 meeting the requirements of the reg at the pharmacy. Did I
24 hear you correct?
25 A Yes.

1 Q Did you interview anyone from Anile Pharmacy in reaching
2 your opinions?
3 A I did not. Because my opinions on the medical legitimacy
4 of the prescriptions was not based upon the pharmacy record.
5 Q Did you ask the DEA to provide you with the telephone
6 call-in prescriptions for each of the prescriptions at issue in
7 this case?
8 A I had these prescriptions available.
9 Q Did you ask the DEA to provide you with the telephone
10 call-in prescriptions for each of the prescriptions at issue in
11 this case? Did you ask them to give you those?
12 A I had -- if you mean by telephone call-in, the document
13 you just showed me, I had those available.
14 Q On direct exam on Friday, when you were shown that one
15 excerpt from 33, you didn't tell the jury, yes, this document
16 doesn't comply with the regs, but there are documents that do
17 that I'm not looking at right now. You didn't say that on
18 Friday when you were asked that question on direct examination,
19 did you?
20 A No, I did not. I wasn't asked that question.
21 Q You testified, and again, please tell me if I'm misstating
22 what your testimony was, but as I understand what you said on
23 Friday, you said it's important to remember that the urine drug
24 screen is a medical test. It is limited to being ordered by
25 physicians, closed quote. That was your testimony on Friday,

1 correct?
2 A Yes.
3 Q You'd agree with me that's not accurate?
4 A No. Urine drug screens are limited to being ordered by
5 physicians.
6 Q You can't walk into a Walmart or go on to Amazon and order
7 a urine screen?
8 A Not the medical test with gas chromatography, not at a
9 liquid laboratory.
10 Q Is there any regulation that you can point this jury to
11 that prohibits a suboxone clinic staff from ordering a urine
12 screen with connection to a clinical approach to deal with
13 suboxone?
14 A That test cannot be -- it can be ordered under a standing
15 order from the physician. It cannot be interpreted by a
16 nonmedical person.
17 Q I didn't ask what your opinion was on it, sir. With all
18 due respect, I asked if you could direct this jury to a
19 regulation that supports that opinion that you just stated.
20 A I believe that the CMS CLIA guidelines would support the
21 statement that I'm saying. The center for Medicare and
22 Medicaid services.
23 Q You're sticking by your testimony that a doctor has to
24 order a urine screen?
25 A Yes.

1 Q Now, you also testified in that regard that your opinion
2 was based on the assertion that the prosecutor in her
3 questioning to you that Dr. John did not look at urine screen
4 logs. Do you recall that?
5 A Yes.
6 Q And you went on to testify that basically, quote, there
7 was never a medical drug screen. Do you recall that?
8 A Yes.
9 Q In reaching that opinion, did you consider the fact that,
10 contrary to the prosecutor's statement built into her question
11 to you, that Dr. John did in fact review drug screen logs, did
12 you factor that in?
13 A Because in the medical record there never appeared any
14 notation that urine drug screen logs were considered in the
15 treatment offered by Dr. John, it was consistent with the
16 medical record that I reviewed. So no, I did not consider it.
17 Because of the consistency of the medical records and the
18 information that I had received.
19 Q Because the truth is, your opinion was based upon a naked
20 review of the charts plus what the DEA and the prosecutors fed
21 you to base your opinion on; isn't that correct?
22 A I reviewed the information I had available. I did not
23 review information I did not have available.
24 Q So for example, as we already heard, you didn't interview
25 any of the patients, correct?

1 A That is correct.
2 Q You didn't interview Dr. John or Dr. Aggarwal, correct?
3 A I did not.
4 Q You didn't sit and listen to the testimony of any of the
5 patients correct?
6 A I did not.
7 Q And you haven't yet heard testimony from any of the
8 doctors involved, correct?
9 A I have not.
10 Q Now, you -- I think part of your opinion involves a sort
11 of business issues, if I heard correct on Friday; isn't that
12 right?
13 A Yes.
14 Q You have a business degree you said, correct?
15 A I do.
16 Q You've run a business, correct?
17 A I have.
18 Q It did not work out, but that happens, right?
19 A Well, one didn't, one did. I was on the board of
20 directors of Pittsburgh Anesthesia Associates, and that was a
21 successful business. So that --
22 Q Software business didn't work out, but the testifying for
23 the government business is working out well?
24 A The medical practice ran quite well for the 15 years I did
25 it.

1 Q I'm not trying to be snarky here, but you testified about
2 physician compensation on Friday. In fact, I think you said
3 physician compensation is, quote, usually determined either on
4 an hourly basis, how much time does it take you, or based upon
5 the complexity of services rendered, correct?
6 A Yes.
7 Q Isn't it true that in the health care field physician
8 compensation is actually a rather complicated endeavor most of
9 the time? Are you familiar with the Stark Law?
10 A I am familiar with Stark.
11 Q And there's other various regulations that relate to how
12 much and in what manner providers, clinics, hospitals, are
13 allowed even allowed to pay doctors, correct?
14 A Well, particularly when doctors are referring to the
15 business entity involved, because the Stark Law is an
16 antikickback statute and so yes, there are considerations in
17 that. However, this was not about that.
18 Q Well, those considerations imbue the entire health care
19 compensation -- physician compensation arena, and it is often
20 very important for anyone paying a physician to try to pay them
21 what their fair market value is. You would agree with that?
22 A Yes. They need to pay fair market value. That is part of
23 the Stark Law.
24 Q As part of your business analysis of how Dr. John and
25 Dr. Aggarwal were compensated, did you look at all at what

1 Dr. John's fair value is, in other words, what he's making at
2 Weirton Medical Center on an approximate hourly basis and then
3 compare it to what the clinic was reimbursing him for his time?
4 A No. I compared the manner in which he was working with
5 the manner in which he was being paid, and it did not comport
6 with the usual course of professional practice. Because he was
7 not paid services for fee. He was paid by prescription.
8 Q Did you factor into reaching that opinion the fact that he
9 was paid for his work at RTA for situations specifically where
10 no prescription was ever issued for a patient? Were you aware
11 of that?
12 A I was not because the --
13 Q DEA didn't give you that. Right.
14 A The general manner in which I understood him to be paid
15 was per patient contact, even when he was not there. And so
16 the number of patients being in the range of 70 to 80, and
17 being compensated for being at the clinic approximately three
18 hours every two weeks, it was not so much the amount but the
19 manner given that in those times that he was not there he was
20 paid for patient contact that he did not have.
21 Q That's one way you could say it, I suppose, but another
22 way you can say it is Dr. John was compensated for managing a
23 group of patients in their maintenance therapy, correct?
24 A There was no professional service rendered.
25 Q That's your opinion.

1 A No. That's a fact.
2 Q No. That's your opinion, correct? That's not your
3 opinion?
4 A It is my opinion that --
5 Q I didn't ask you to explain the opinion.
6 THE COURT: Hold it. Let's let the doctor finish his
7 answer and you can ask the next question.
8 MR. STALLINGS: Your Honor, I would suggest that
9 answer was nonresponsive and ask the witness to answer the
10 questions asked.
11 THE COURT: You may complete your answer.
12 A It was my opinion that the facts as they were presented in
13 the medical records was consistent with the analysis that I've
14 given you.
15 Q That was your opinion. Now as part of your review of
16 government's files did you also look at examples of some cost
17 ledgers maintained by RTA's owner Jennifer Hess? Do you
18 remember looking at some of those?
19 Let me ask you a different way. Did the DEA show you cost
20 ledgers maintained by Jennifer Hess about how she was paying
21 for costs associated, overhead associated with running RTA, did
22 you review those as part of reaching an opinion on the business
23 aspects of how payment was rendered?
24 A At this moment, I remember seeing some ledgers of the way
25 in which moneys were calculated for the doctors. They were

1 consistent with payment for prescriptions.
2 Q You would agree it costs money to operate a clinic like
3 RTA?
4 A Certainly.
5 Q You have various items of overhead, including staff,
6 lights, et cetera. You have to run the clinic, correct?
7 A Yes.
8 Q Did you do any analysis of whether Ms. Hess was running at
9 a profit, a loss, or somewhere in the middle, say in late 2017?
10 Did you do any analysis of that?
11 A I did not.
12 Q Did you do any review of the text messages and emails that
13 are in the government's possession that show that Jennifer Hess
14 and Chris Handa were having concerns at the end of 2017 about
15 their ability to match their expenses with revenues. Did you
16 review any of that?
17 A Because that did not concern the figures directly, I did
18 not.
19 Q As part of your business opinion did you do anything to
20 determine whether or not RTA could continue operating and
21 helping these suboxone patients if it employed the various
22 issues that you say were necessary in your direct examination?
23 Did you decide whether or not RTA could afford any of the
24 different kinds of degrees of patient interaction that you
25 suggested were appropriate? Factor out whether that was

1 possible at all?
2 MS. WAGNER: Let Dr. Thomas please be allowed to
3 answer.
4 THE COURT: I'm going to ask again, lawyer examining
5 wait till the witness has finished his answer, and if you would
6 listen to the question.
7 Q I'll make it a simpler question, Dr. Thomas.
8 You did not factor in whether or not Jennifer Hess and RTA
9 could afford to operate at this much higher level of
10 interaction that you've suggested is appropriate in rendering
11 your opinion, did you?
12 A The level of interaction that I deemed appropriate was not
13 based upon strictly business interests. It was based upon
14 medical necessity for the rendering of medically legitimate
15 prescriptions in the usual course of professional practice.
16 Q The fact is, you've never worked in a suboxone clinic of
17 any type, correct?
18 A I have not worked at a suboxone clinic.
19 Q You have not acted as business consultant for a suboxone
20 clinic of any type, correct?
21 A I have not.
22 Q That includes the West Virginia model, a variation of the
23 West Virginia model, the Vermont model, or the one employed at
24 the Mayo Clinic. You haven't worked at any of those models,
25 correct?

1 A That is correct.
2 Q You said some things in direct about the kind of
3 interactions that doctors must have with patients in the
4 context of suboxone. As we sit here today, doctors are allowed
5 to interact with patients via telemedicine, right?
6 A Under certain circumstances, yes.
7 Q Under the circumstances of prescribing suboxone, correct?
8 A If it's appropriately staffed, yes.
9 Q So they can literally Skype in if they want to and
10 prescribe suboxone according to the current guidelines and
11 regs, right?
12 A With appropriate staffing at the other end, they could.
13 Q Dr. John didn't do that though. He actually was present
14 at RTA, to your knowledge, for the vast majority of those group
15 counseling sessions, as far as you have seen from the evidence,
16 correct?
17 A But even in the telemedicine example that you give --
18 MR. STALLINGS: Your Honor, could you instruct the
19 witness to answer the question I asked, please.
20 THE COURT: I think he has responded to the question.
21 A Dr. John did not attend the clinic when he did attend the
22 clinic. He did not attend the clinic when he did not attend
23 the clinic.
24 Q That was about as clear as mud.
25 A He was there when he was and -- I'm sorry.

1 THE COURT: That is argument. The jury will
2 disregard the last statement by Mr. Stallings.
3 Q Let's talk about dosing for a moment. On direct
4 examination, and I believe I'm quoting, but again, correct me
5 if I'm wrong, Dr. Thomas, you described that the way to
6 calculate dose as, quote, it's basically the daily dose
7 multiplied by the number of days that the prescription is
8 expected to last to get to the quantity of medication. Do you
9 recall that?
10 A Yes. And for suboxone it would be a number of strips for
11 a daily dose.
12 Q Thank you. I was about to do that exact question next.
13 So just going old school algebra for a moment, right?
14 Daily dose times the number of days that the person expects to
15 need the dose, correct, equals or should equal the quantity,
16 right?
17 A Yes.
18 Q And that daily dose, as you've mentioned, is the number
19 that you're going to fill in to that part of the equation, is
20 the number of strips, right?
21 A Yes.
22 Q As suboxone was typically prescribed at RTA, it was done
23 with strips of 8 milligrams each that are placed under the
24 tongue, sublingual, correct?
25 A That's correct.

1 Q So a 16 million milligram dose is two strips, right?
2 A That is correct.
3 Q 12 milligram dose is 1.5 strips?
4 A That's correct.
5 Q 8-milligram dose is one strip, right?
6 A That is correct.
7 Q Now, before we look at some specific dosages, when the
8 government was asking questions to you about dosage, she
9 prefaced the questions several times by saying that the jury
10 had heard evidence that staff at RTA had made the dosing
11 decisions. Do you recall that?
12 A Yes.
13 Q You did not, I know you didn't, you didn't listen to the
14 testimony of either Jennifer Hess or the patients that the
15 government brought in, did you?
16 A I did not.
17 Q And so you did not hear testimony that the final authority
18 regarding dosing actually rested with Dr. John, correct?
19 A No, I did not.
20 Q And regardless, you would agree with me that it is for
21 this jury to decide whether or not Dr. John had authority over
22 dosing or whether the government's view of the case is correct.
23 It's for them to decide, not you, correct?
24 A Absolutely.
25 Q So let's look at some records from patient PE. And I'm

1 going to zero in on the dates around the date charged in the
2 indictment. Now, are you aware patient PE is the patient
3 referred to in Count 12 of the indictment, correct?
4 A Yes.
5 Q And that relates to a day, December 29th of 2014?
6 A Yes.
7 Q All right. So looking at PE's physician progress note for
8 12-4-2014, we see that the suboxone film line says 8/2
9 milligrams, the number says 45, and the dosage there, the SIG
10 says 12, correct?
11 A That's correct.
12 Q So if we're going to fill in our equation, so we
13 understand how dosage works out on these charts, for PE the
14 daily dose is 12. You would agree?
15 A Yes.
16 Q And the number of days that he expects this dosage to
17 last, we would look at his next visit, assume with me it's 30
18 days later, you would put 30 there, correct?
19 A The number is 30, yes.
20 Q That's a month. A month's supply, essentially, right?
21 A Yes.
22 Q And if we do that math, we've done it wrong, because it's
23 not 12, right? It's one and a half strips, correct?
24 A Yes.
25 Q So that's how you write the equation, 1.5 times 30 and

1 that equals 45. Am I right?
2 A That is correct.
3 Q And that's what we see on the quantity. This is the daily
4 dose, reducing it 1.5, which is the number of strips,
5 multiplied by the number of days he expects to have it, 30, and
6 you get that quantity, 45, correct?
7 A That is correct.
8 Q And we can do that math for any of these physician
9 progress notes. Am I right?
10 A For most of them, it's pretty close to that.
11 Q Right. So that's PE on the day before he comes in on the
12 indictment day, which is 12-29.
13 This is him on the 12-29-14 day, correct?
14 A Yes.
15 Q And we see 8, 2, 45, 12, the same numbers, correct?
16 A Yes.
17 Q And on the day after the indictment day, a month later, PE
18 comes in and again we see 8, 2, 45, 12, correct?
19 A Yes.
20 Q So you would agree with me that as to Count 12, patient
21 PE, he has the exact same dosage of the session before the
22 indictment date that he does on the indictment date, and the
23 session after the indictment date, correct?
24 A He does.
25 Q So PE's dosage did not change on 12-29-14?

1 A That's correct.
2 Q And there are times, are there not, where the number of
3 days that a patient expects to have to use his suboxone are
4 different from session to session, correct? You've seen that
5 in the records?
6 A Yes.
7 Q Sometimes the patient is coming back for a different
8 frequency. He's coming in weekly or biweekly instead of
9 monthly, correct?
10 A Yes.
11 Q But you can adjust the number of days while maintaining
12 the same dosage, as long as you employ this formula; am I
13 right?
14 A That's correct.
15 Q Okay. And isn't it correct that the dosages, the daily
16 dosages, for all five of the patients named in the indictment,
17 did not change on the days of the indictment; isn't that
18 correct?
19 A I don't know that, but as you're asking me the question, I
20 will assume that's true.
21 Q I want to look at a particular patient, because you
22 brought her up, I believe, this morning. Patient DC, which I
23 believe is Government Exhibit 25 and relates to Count 16. So I
24 thought I heard part of your testimony this morning about DC
25 being that as a patient she hadn't -- didn't appear that the

1 forms in her file had been completed, the forms that she
2 prepared before seeing Dr. John. Was that your testimony?
3 A Yes. The initial history, physical examination, and
4 questionnaires were blank.
5 Q Now, you did not listen to Danielle Coen testify, but did
6 you factor in the fact that she told the jury that she
7 initially met briefly with a separate physician and then saw
8 Dr. John? Did you factor that into to your opinion?
9 A It wasn't in the medical record.
10 Q So you do not know what forms might have been filled out
11 by her in connection with that prior visit or whether those
12 forms simply didn't get placed into her file. You have no way
13 of knowing that, correct?
14 A Yes. And there's no evidence in the record that Dr. John
15 reviewed them.
16 Q I suppose Dr. John can tell us, correct? Whether he had
17 an interview with Danielle Coen and talked about her history,
18 correct?
19 A Yes.
20 Q And in fact, he did fill out notes on his intake meeting
21 with her, correct?
22 A Yes.
23 Q And you didn't listen to her testimony about her
24 interactions with Dr. John?
25 A I did not.

1 Q There is another document that I don't think you were
2 shown in the course of your direct examination about DC's
3 medical file. Do you know what this document is?
4 A I can't quite see the top.
5 Q It says at the top --
6 A Trinity Medical Center.
7 Q Authorization for disclosure of health information.
8 A Yes.
9 Q This is a document by which one health care provider will
10 authorize the disclosure of HIPAA-protected patient information
11 to another health care provider, correct?
12 A Yes, that's correct.
13 Q And in this case, Trinity is authorized to disclose to RTA
14 and Dr. John, correct?
15 A Yes, it is.
16 Q Information about the coordination of care and
17 verification of suboxone prescriptions, correct?
18 A Yes.
19 Q And similarly, Redirections returned the favor and
20 Dr. John returned the favor and disclosed information to
21 Trinity medical center about Danielle Coen's care, correct?
22 A Yes.
23 Q All right. Do you know what Trinity Medical Center is?
24 A I do not.
25 Q Do you know what care Danielle Coen was receiving there?

1 A I do not.
2 Q In fact, did the DEA tell you that the vast majority of
3 these patients Dr. John saw had separate primary care
4 physicians of their own? Did the DEA tell you that?
5 A From some of the intake forms that were filled out, that
6 was disclosed.
7 Q And I think you said this morning that in certain respects
8 these two doctors were acting as GPs, as general practitioners,
9 with regard to these patients. Did I hear that correctly?
10 A Yes, you did.
11 Q You know Dr. John has a separate private medical practice
12 where he acts essentially as an internalist and medical
13 practitioner. You're aware of that?
14 A I am.
15 Q Do you know how many patients he sees at his practice?
16 A I do not.
17 Q But you're also aware that his work at RTA was as a
18 contract physician helping an existing suboxone clinic,
19 correct?
20 A That's correct.
21 Q He did not act as the GP for these suboxone patients, sir,
22 did he?
23 A No. He was to act as the suboxone physician for them.
24 Q And many of these patients, if not most of these patients,
25 had their own separate general practitioner who dealt with

1 their other issues, correct?
2 A They -- many of the patients put that into their history
3 and physical forms. But these -- but I must say that the --
4 the release forms that you showed me were among the only ones
5 I've seen throughout the entirety of the case.
6 Q They're in DC's patient file, correct? They're in
7 Government Exhibit 25. I'm just -- they're in Government
8 Exhibit 25.
9 Sir, I listened very carefully, I tried to, to every word
10 of your testimony so far. And I want you to correct me again
11 if I'm wrong, but I did not hear you say that your opinion was
12 based at all on the positive outcomes that these patients
13 actually experienced by going to RTA; am I correct?
14 A No. Because of the absence of medical documentation of
15 positive outcomes from going to RTA.
16 Q Is it your -- I'm not trying to be argumentative, but is
17 it really your testimony that it doesn't matter whether
18 Dr. John's treatment of these patients actually achieved a
19 positive outcome in you reaching your opinion that he wasn't
20 practicing medicine? You're saying that doesn't matter?
21 A If a positive outcome in recovery is abstinence from all
22 other drugs, and an increase in their ability to love, work,
23 and play, their social work and psychological recovery,
24 stability in their lives unassociated with the use of drugs,
25 that was not documented and so I wouldn't know that there were

1 positive outcomes associated with it.
2 Q Well, we're going to have to get a second opinion on that,
3 Doctor. Thank you. Nothing further, Your Honor.
4 THE COURT: Ms. Wagner.
5 REDIRECT EXAMINATION
6 BY MS. WAGNER:
7 Q Dr. Thomas, do the field of pain medicine and addiction go
8 hand in hand?
9 A Yes.
10 Q And in your -- you have a subspecialty in pain management,
11 correct?
12 A Pain medicine, yes.
13 Q Pain medicine. And can you tell us, please, what part of
14 that subspecialty involves addiction.
15 A In pain medicine, we prescribe controlled substances for a
16 multitude of ailments. Because many of the controlled
17 substances we use are habit-forming, all of our patients must
18 be evaluated for the onset of aberrant medication-taking
19 behavior, those things that are addiction or that look like
20 addiction.
21 So every patient in a pain medicine practice is screened
22 for addictive behavior. Every patient in a pain medicine
23 practice is screened for intoxication and all of the aspects of
24 care, urine drug screening and the like, depend upon the risk
25 of the patient using the controlled substances in a way that's

1 not intended.
2 Three quarters of the patients who become addicted in the
3 current opioid crisis start with a medical prescription for a
4 controlled substance. Therefore, all of my patients undergo
5 the same sort of screening that I have talked about. All of my
6 patients have histories and physical examinations aimed at
7 determining whether or not they're abusing their drugs. All of
8 my patients undergo urine drug screening as a medical test with
9 medical interpretation. All of my patients have all of the
10 things that I have said that I believe are necessary for there
11 to be a legitimate medical practice in the prescription of
12 buprenorphine, whether it's -- and any other controlled
13 substance, whether it's for addiction or for the treatment of
14 other ailments.
15 Q And you were asked, I think by Mr. Chapman, that if a
16 physician goes on vacation or is away from the office for
17 training, whether their patient could still get a prescription.
18 Did you in your review of the medical charts find anywhere in
19 any of the medical charts of Dr. Aggarwal or Dr. John any
20 instruction for those patients as to what the doctor wanted
21 their patient to receive?
22 A In my review of the records there was no evidence of a
23 physician instruction for any subsequent prescription, and
24 there was also no response in terms of evaluation of the
25 patient's response to the medication, the patient's side

1 effects of the medication, the patient's aberrant use of the
2 medication, or the use of other drugs that would indicate they
3 weren't stable patients in recovery who can simply be left to
4 their own devices.
5 Q All right. And you were shown some parts of the TIP 63,
6 which is Government Exhibit 45. And one of those pieces of --
7 one piece of that was related to a physician's obligation to
8 assess the medical -- the medication management of their
9 patient, to oversee the medical management of their patient,
10 correct?
11 A Yes.
12 Q What did you see in the medical charts of Dr. John or
13 Dr. Aggarwal that reflected that either doctor was assessing
14 the medication management of their patients?
15 A Nothing.
16 Q And you were asked about whether certain of those
17 assessments could be delegated to other health care providers,
18 correct?
19 A Yes.
20 Q If a physician delegates that -- one of those tasks to
21 another health care provider, is it correct that the physician
22 needs to somehow get that information from them?
23 MR. CHAPMAN: Objection, leading.
24 THE COURT: Objection is sustained.
25 Q Could you tell us what the -- what a physician's

1 responsibility is with respect to other -- to information that
2 other health care providers collect after they've been
3 delegated with those tasks?
4 A That information must be communicated to the physician in
5 the true multidisciplinary model that would include a staffing
6 meeting where people sat around and talked about the patient so
7 the physician could have that, with documentation of that in
8 the medical record. And that would be in order to make any
9 reasonable decision about the next prescription for that
10 patient.
11 Q And was any of that information or that sort of
12 information reflected in the progress notes in the medical
13 charts that you reviewed?
14 A Never.
15 MS. WAGNER: May I confer with cocounsel?
16 THE COURT: Certainly.
17 MS. WAGNER: Those are all the questions I have.
18 THE COURT: Mr. Chapman.
19 MR. CHAPMAN: Nothing further, Your Honor. Thank
20 you.
21 MR. STALLINGS: No further question, Your Honor.
22 THE COURT: Thank you very much, Dr. Thomas. You may
23 step down.
24 Government may call its next witness.
25 MS. WAGNER: The United States rests.

1 THE COURT: All right. Any motions?
2 MR. CHAPMAN: Yes, Your Honor, it would be an
3 appropriate time for a motion. However, I will suggest that we
4 do intend to call two witnesses, and it would be nice if we
5 were able to get to them before the break hour. May the Court
6 hear the motion after that?
7 MS. WAGNER: We don't object to that, Your Honor.
8 THE COURT: Very well.
9 MR. STALLINGS: I just believe for the record --
10 maybe we could come to side bar.
11 (The following proceedings were had at the bench, out
12 of the hearing of the jury.)
13 MR. CHAPMAN: We just have two patient witnesses
14 we're going to call directly before Dr. Helm, and we just want
15 to move them along. My understanding of Rule 29 is it can be
16 raised at any time. However, what I'd like to do is preserve
17 the Rule 29 as if we've raised it now, but just to get these
18 witnesses out the door.
19 MR. STALLINGS: That's all I wanted to come up to say
20 is we move for judgment under Rule 29 on a number of grounds,
21 which we can elaborate for the Court at a later date, but I
22 felt it was important to put this on the record at this stage
23 of the proceeding.
24 THE COURT: Make them at a later time, but you're not
25 objecting to Mr. Chapman --

1 MR. STALLINGS: I would consider them as witnesses
2 taken out of order, before the Rule 29 argument. That's all.
3 (Bench conference concluded.)
4 THE CLERK: The witness is Susan Chappell, S-U-S-A-N,
5 C-H-A-P-P-E-L-L.
6 **SUSAN CHAPPELL, DEFENDANT AGGARWAL'S WITNESS, SWORN**
7 DIRECT EXAMINATION
8 BY MR. NOGAY:
9 Q Hello.
10 A Hi.
11 Q Could you tell the jury your name, please.
12 A It's Susan Chappell.
13 Q Where do you live?
14 A I live in Weirton.
15 Q And how long have you lived in Weirton?
16 A My whole life.
17 Q Did you graduate from our high school?
18 A Yes.
19 Q What year was that?
20 A '77.
21 Q And where do you work now, Susan?
22 A Right now I'm at Dollar General in Weirton.
23 Q What do you do there?
24 A I'm a cashier.
25 Q Was there a time in your life when you became addicted to

1 opiates?
2 A Yes.
3 Q Would you tell the jury a little bit about that, without
4 prying, how you became addicted.
5 A I was diagnosed with arthritis in my early 30s and was
6 prescribed pain medication.
7 Q At some point did you seek treatment at Redirections
8 treatment center in Weirton?
9 A Yes.
10 Q And how did you come to find out about Redirections?
11 A They were the only clinic that didn't have a waiting
12 period of three months or six months.
13 Q Did you feel you needed help at that time?
14 A Yeah. My doctor got -- I guess, busted, and was run out
15 of town.
16 Q Dr. Hagins was your doctor?
17 A No. Dr. Current in Ohio was, but Hagins was before him.
18 Q But in any event, you had a problem; is that correct?
19 A Yeah.
20 Q And you sought treatment at Redirections and were you
21 assigned Dr. Aggarwal?
22 A Yes.
23 Q And did Dr. Aggarwal do a physical examination of you?
24 A Yes.
25 Q And did he ask you about your addiction problems?

1 A My what?
2 Q Did he ask you about your drug-taking history?
3 A Yes.
4 Q And did you -- were you subsequently put on a dose of
5 suboxone?
6 A Yes.
7 Q Did you stay on that dose of suboxone for a long period of
8 time?
9 A Yes.
10 Q Did it prevent you from going into withdrawal?
11 A Yes.
12 Q Did it allow you to have a job and work?
13 A Yes.
14 Q If you didn't have suboxone, would you be able to hold a
15 job or work?
16 A No. I wouldn't even be here.
17 Q Did you ask at the clinic, at times, to have your suboxone
18 increased?
19 A Yes.
20 Q And what were you told when you asked to have it
21 increased?
22 A That they don't normally increase, and I was doing well,
23 and they wouldn't do it.
24 Q They wouldn't do it?
25 A No.

1 Q They wouldn't increase you?
2 A No.
3 Q Had you reached a place where you were stabilized on
4 suboxone?
5 A Yeah.
6 Q Now, if we could call Exhibit 5, Government Bates stamp
7 GX120.
8 Were you given drug screens when you went in, urine tests?
9 A Yes.
10 Q And were you pretty good about always taking your
11 suboxone?
12 A Yes.
13 Q Did it keep you off other drugs?
14 A Yes.
15 Q One time did you fail a drug test?
16 A I did, yeah.
17 Q And what happened to you when you failed that drug test?
18 What happened?
19 A They make you come in to counseling every week and you're
20 only prescribed one week's worth.
21 Q And was that called poly group?
22 A Yes.
23 Q When you were going into counseling sessions, other than
24 poly group, the regular counseling sessions you had to attend,
25 did you see Dr. Aggarwal in those counseling sessions?

1 A Yes.
2 Q Did you feel he was available to answer any questions you
3 had?
4 A Yes.
5 Q Did you feel he was -- you were in a physician-patient
6 relationship with him?
7 A Yes.
8 Q On some -- when you came in to the clinic, you had to fill
9 out progress notes; is that correct?
10 A Uh-huh.
11 Q How you felt, zero to five, zero, one, two, three, four,
12 five; is that correct?
13 A Yes.
14 Q Sometimes you filled them out very detailed, depending how
15 you were feeling; is that right?
16 A Yes.
17 Q Sometimes you would circle one number all of them?
18 A Right.
19 Q Why would you do that? How were you feeling at that time?
20 Were you stabilized, doing okay?
21 A I was stable, yeah. Yeah.
22 Q We can take that exhibit down now.
23 Did you feel they were very strict at Redirections as far
24 as the urine tests?
25 A Yeah.

1 Q Did you feel they were very strict about attending your
2 counseling sessions?
3 A Yes.
4 MR. NOGAY: I have no further questions, Your Honor.
5 THE COURT: Mr. Stallings, do you have any questions
6 of this --
7 MR. STALLINGS: I do not, Your Honor. Thank you.
8 CROSS-EXAMINATION
9 BY MR. COGAR:
10 Q Good morning, Ms. Chappell. How are you?
11 A Fine.
12 Q Ma'am, before you started using suboxone or getting
13 prescribed suboxone at Redirections, did you have any
14 experience with suboxone?
15 A Yes.
16 Q Did you buy it off the street?
17 A Yes.
18 Q How much did it cost?
19 A $20 for a strip, 8-milligram.
20 Q Okay. When you were -- you talked about some of what the
21 process was when you went in to Redirections. Do you recall
22 when prescriptions -- how you got prescriptions --
23 A Yes.
24 Q -- from Redirections? Was it your understanding the
25 prescriptions were faxed to the pharmacy?

1 A Yes.
2 Q When were the prescriptions faxed, to the best of your
3 recollection?
4 A While we were in group, still in group, before we left.
5 Q So while you were in group?
6 A Yeah.
7 Q Now, you talked about when Dr. Aggarwal was in the group
8 counseling sessions. Do you remember that?
9 A Yes.
10 Q Isn't it true he wasn't always in those sessions with you?
11 A He was always -- well, it's kind of hard to say, because I
12 always sat in the back. But when I would sit in the front, you
13 wouldn't see him 'cause he sat in the back all the time. So I
14 mean, there may have been one time I didn't see him, but most
15 of the time he was there.
16 Q And but you do recall times when he wasn't there; is that
17 fair?
18 A No.
19 Q Now, when he was in counseling sessions, he didn't say
20 much, it's my understanding.
21 A No. He observed mostly.
22 Q Now, you were asked some questions about a time where you
23 wanted to increase your dosage of suboxone. Do you remember
24 that?
25 A Yes.

1 Q In fact, you actually wrote on your progress notes, you
2 said, I'm struggling with something.
3 A Yes.
4 Q And I'd like to be increased. Was it Jen Hess that told
5 you that, no, you couldn't have the increase; is that right?
6 A Well, she didn't -- she didn't actually come out and say
7 no, but -- I was telling her that I'm having a problem with my
8 legs swelling at work and I just needed another half of one,
9 and she said that they don't -- they wouldn't recommend it, so
10 I didn't pursue it.
11 Q I understand. But Dr. Aggarwal wasn't the one that had
12 that conversation with you; is that correct?
13 A No. I didn't go to him.
14 MR. COGAR: That's all I have. Thank you, ma'am.
15 MR. NOGAY: Nothing further, Your Honor.
16 MR. STALLINGS: No questions, Your Honor.
17 THE COURT: Thank you very much, Ms. Chappell, for
18 testifying.
19 Members of the jury, let's go ahead and take the noon
20 lunch break. Please leave your notebooks by your chair.
21 Please don't discuss the case while you're on the break or
22 permit anybody to discuss the case with you. We'll return and
23 resume at 1:30 p.m. Thank you.
24 (Jury panel exited courtroom at 11:58 a.m.)
25 (Lunch recess taken.)

1 Monday Afternoon Session,
2 June 10, 2019, 1:30 p.m.
3 - - -
4 THE COURT: All right, may we bring the jury in,
5 please.
6 MR. CHAPMAN: Your Honor, I think we still have the
7 matter of the Rule 29 motion to address.
8 THE COURT: I'm sorry. What?
9 MR. CHAPMAN: I think we still have the matter of a
10 Rule 29 motion to address.
11 THE COURT: I thought you wanted another two
12 witnesses.
13 MR. CHAPMAN: We just wanted to get those witnesses
14 on, or try to, before lunch and figure we'd take up the Rule 29
15 after lunch.
16 THE COURT: Take the witness and I'll excuse the jury
17 again.
18 MR. CHAPMAN: We'll take that witness and excuse the
19 jury for the Rule 29.
20 THE COURT: Okay.
21 (Jury panel returned to the courtroom at 1:32 p.m.)
22 THE COURT: Members of the jury, good afternoon.
23 Dr. Aggarwal may call his next witness.
24 MR. NOGAY: Dr. Aggarwal will call Shawn Marks.
25 THE CLERK: The witness is Shawn, S-H-A-W-N, middle

1 initial A., Marks, M-A-R-K-S.

2 **SHAWN A. MARKS, DEFENDANT AGGARWAL'S WITNESS, SWORN**

3 DIRECT EXAMINATION

4 BY MR. NOGAY:

5 Q Would you tell us your name, please.

6 A Shawn Marks.

7 Q Mr. Marks, how old are you?

8 A I'll be 70 in September.

9 Q And where do you live?

10 A New Cumberland, West Virginia.

11 Q How long have you lived in New Cumberland, West Virginia?

12 A Since 2001.

13 Q Is that in Hancock County?

14 A Yes.

15 Q At some point in your life did you begin to have a problem

16 with an opiate addiction?

17 A Yes.

18 Q Would you tell us -- I don't mean to pry, but tell us

19 basically how it started and what it meant to your life at that

20 point.

21 A Okay. I hurt my back in the '70s, required a couple of

22 operations back in Illinois, where I'm from. The operations

23 got me a lot of good years, and I was a truck driver, halfway

24 successful. After ten, 15 years, somewhere in the '80s, I

25 began to have problems and went to the doctors and it was

1 either more surgeries or more of the opiates.
2 And they started me on those and I started taking them,
3 and it was just a constant progression of there was never
4 enough, and start out with a few and then it was just more,
5 more, more, all the time, to try and get the same results.
6 Ended in more surgery, more opiates, just a constant
7 battle. And I guess it went way downhill, never to the point
8 of any heroin, but it was a constant trying to find some kind
9 of pill to take.
10 Q Now, at some point were you able to try suboxone that you
11 bought on the street?
12 A Yes.
13 Q And how did that seem to affect you?
14 A It seemed like it opened a whole new door. It was totally
15 different. The pain was subsided. It lasted. It wasn't
16 something that helped for a few minutes and then was gone. It
17 actually lasted and I felt in my own mind that this is what's
18 going to fix me, this is going to help me out.
19 Q So what did you do to try to get lawful suboxone
20 treatment?
21 A Googled it. I googled it and come up with suboxone
22 clinics close to me and made the phone call.
23 Q Did you find one at Weirton known as Redirections?
24 A Yes.
25 Q And did you go to Redirections?

1 A Yes, I did.
2 Q And before you were prescribed anything, were you assigned
3 a doctor?
4 A Yes.
5 Q And is that doctor in the room now?
6 A Yes.
7 Q What's his name; do you remember?
8 A Dr. Aggarwal.
9 Q And did he physically examine you?
10 A Yes.
11 Q And did he ask you questions about your addiction?
12 A Absolutely.
13 Q And did he answer any questions you had?
14 A Yeah, but I didn't have a whole lot of questions for him,
15 but yes, he answered anything I wanted to know.
16 Q And did you tell him you were an opiate addict, you were
17 addicted?
18 A Yes. Yes, yes.
19 Q Did you fill out paperwork and questionnaires and things
20 of that nature?
21 A Yes, I did.
22 Q Did you subsequently get a prescription from Dr. Aggarwal
23 for suboxone?
24 A Yes.
25 Q And how did that begin to change, if any, your life?

1 A It was a total change. I mean, it was -- that was all I
2 needed. I began to function as a -- you know, as a citizen of
3 New Cumberland. I was elected to the city council. I just had
4 a whole new life. It was totally different.
5 Q Do you work anywhere now?
6 A I'm -- yeah, I guess you could say I do. I train
7 thoroughbred racehorses, something that I've been passionate
8 about my entire life and did as much as I could on the side,
9 but now I do it as a full-time occupation, you would say.
10 Q And where do you do that?
11 A Mountaineer Park and Presque Isle in Indiana and Kentucky.
12 I travel around a little bit, run horses at different
13 racetracks.
14 Q Would you have been able to train horses before you began
15 taking suboxone?
16 A No.
17 Q How about your personal life, and I don't mean to pry, but
18 your marriage and your relationship with your wife, financially
19 and basically the consortium you have with your wife, could you
20 tell us a little bit about that how that changed.
21 A My name's back on the checking account.
22 Q That is, you can be trusted with the money now?
23 A I can be trusted, yes.
24 Q When you attended -- did you attend counseling sessions at
25 Redirections?

1 A Yes.
2 Q And did you see Dr. Aggarwal when you attended those
3 counseling sessions?
4 A Yes, I did.
5 Q Did you feel you could approach him and ask him questions?
6 A I did. At various times.
7 Q Did he answer them for you?
8 A Yes.
9 Q Did you feel you were in a physician-patient relationship
10 with him?
11 A Absolutely.
12 Q How do you feel about him right now, looking over at him?
13 A I was sick, that's who I'd go to.
14 MR. NOGAY: I don't have any other questions, Your
15 Honor.
16 THE COURT: Any questions by Dr. John? Okay.
17 Cross-examination.
18 MR. COGAR: Thank you.
19 CROSS-EXAMINATION
20 BY MR. COGAR:
21 Q Good afternoon, sir.
22 A Good afternoon.
23 Q Just a few questions, sir.
24 I understand from your medical chart that you had
25 insurance that covered --

1 A Yes.
2 Q -- your prescriptions. How much out of pocket did you pay
3 for your prescriptions?
4 A For my prescriptions?
5 Q Yes, sir.
6 A I think it was $40.
7 Q Looking at the year 2016, when you were going to
8 Redirections, do you recall a time when you were looking at --
9 or maybe the staff at Redirections was looking at tapering you
10 down in your dosage? Does that ring a bell to you?
11 A You know, they did most people, but they told me that I
12 probably wouldn't be because of the situation that I was in.
13 Q I looked at your -- you remember those questionnaires that
14 you filled out, and progress notes?
15 A Sure, uh-huh.
16 Q For about a two-year period you put all zeros, do you
17 remember that, on those questionnaires?
18 A No, I don't remember what the zeros were for, no, I do
19 not.
20 MR. COGAR: All right. That's all I have. Thank
21 you, sir.
22 THE COURT: Mr. Nogay.
23 MR. NOGAY: Nothing further, Your Honor.
24 THE COURT: Thank you very much, sir, for testifying.
25 Members of the jury, I think there's a matter I need

1 to take up with counsel. I know you haven't been out here very
2 long. If you go back in the jury room, we'll get you out here
3 as soon as we can do it.
4 Please leave your notebooks by your chairs and please
5 don't discuss the case while you're in your jury room.
6 (Jury panel exited courtroom at 1:42 p.m.)
7 THE COURT: Yes, sir, Mr. Chapman.
8 MR. CHAPMAN: Thank you, Your Honor. At this time
9 Dr. Aggarwal moves for a judgment of acquittal under Rule 29 of
10 the Federal Rules of Criminal Procedure. I'd like to address
11 the counts largely in order of the indictment.
12 First, speaking of Count 1, the government has
13 charged Dr. Aggarwal with conspiracy to distribute controlled
14 substances. As this Court is well aware, conspiracy requires
15 two or more individuals to agree to engage in a criminal act.
16 And under 841 there's no overt act requirement, but there
17 certainly must be evidence of an actual agreement and evidence
18 that that agreement was to perform something criminal.
19 It's certainly true that lack of knowledge of the law
20 is not a defense to that, but the intent or what must be in the
21 minds of the parties in forming the agreement must be something
22 that violates the law.
23 I had the opportunity, and the Court did, to observe
24 Jennifer Hess on the witness stand, and Chris Handa. And the
25 interesting thing about both of them is both of them testified

1 that they did not get into this practice to engage in something
2 illegal, that they did not know what they were doing was
3 illegal, and that at least Jennifer Hess only formed the belief
4 that what she was doing might have been wrong after she was
5 indicted in this case and after she spoke to counsel. That
6 does not qualify to meet the elements of a conspiratorial
7 agreement under 841. There must be an agreement to violate the
8 law.
9 The government has not produced any other evidence
10 that would indicate that Dr. Aggarwal willingly got into an
11 agreement or that anybody else agreed with him to do something
12 that specifically violated the law. And to the extent that the
13 government argues that the conduct of the defendants or
14 Dr. Aggarwal is sufficient enough to show that he violated the
15 law, we can look at Dr. Thomas' testimony, who has already
16 testified that the physicians were not required to see the
17 patients at every visit. We can look at Dr. Thomas' testimony
18 when he indicated that there's not an absolute regulation,
19 rule, or requirement that Dr. Aggarwal physically perform a
20 physical examination of each patient.
21 The government's proof in that regard fell short to
22 show that the physicians were prescribing for other than a
23 legitimate purpose, outside the bounds of professional medical
24 practice. Because there's no agreement, because there's no
25 proof that the defendants prescribed in that manner, that count

1 must be dismissed.

2 Now, it appears as if the government's case is made

3 up of violations of regulations, not that which should rise to

4 the threshold of prescribing for other than a legitimate

5 medical purpose. The government has made mention of lack of

6 licensed counselors. The government has made mention of faxed

7 prescriptions to the pharmacy being inadequate, made mention of

8 West Virginia board rules that seem to indicate the existence

9 of a physician-patient relationship is required.

10 While the government may show all of those things as

11 potential evidence that the conduct departed, they still must

12 show there was an intentional action to prescribe for other

13 than a legitimate medical purpose in order to prove

14 substantively that the physicians were drug dealing, as opposed

15 to engaging in the treatment. As a result, we believe Count 1

16 should be dismissed.

17 The remaining counts are 5, 6, 7, 8, 9, 10, and 11.

18 I'd like to group 5, 6, and 7 together, because those are the

19 counts where it appears, even to a layperson, and I believe the

20 government is not contesting this point, that Dr. Aggarwal's

21 signature was forged on the progress notes.

22 This Court heard that the progress notes are the

23 fundamental authorization by the physician for the issuance of

24 a prescription. The signature on that form, based on the model

25 and the practice that RTA used, was the authorization for that

1 dose to be issued. In this case, three counts, 5, 6, and 7,
2 Dr. Aggarwal did not sign that form, did not see the patient,
3 was not there on that day, by stipulation we've agreed, and
4 subsequently did not deliver a controlled substance. Delivery
5 must be done by a prescription.
6 The government has the burden to prove actual
7 delivery of a controlled substance. There's no such thing as
8 constructive delivery. There's no such thing as passive
9 delivery by acquiescing to conduct. They must prove that
10 Dr. Aggarwal intended to issue a prescription on that day to
11 the ultimate end user, the patient, or an actual controlled
12 substance.
13 And the government doesn't appear to be contesting
14 the fact that the signatures on the documents related to 5, 6,
15 and 7 are not Dr. Aggarwal's. We can couple this with the
16 testimony of Jennifer Hess, and Jennifer Hess told us that
17 those were essentially forgeries. And she also told us that
18 there was no express statement by Dr. Aggarwal that this should
19 be allowed, that forgery would be permitted. And I don't
20 believe Chris Handa's testimony rose to that level as well. So
21 for Counts 5, 6, and 7, not only does the conduct of
22 Dr. Aggarwal not rise to the level of inappropriate
23 prescribing, but certainly there was no delivery.
24 8, 9, 10, and 11, those are counts where Dr. Aggarwal
25 was out of town, engaging in continuing medical education and,

1 in some cases, a vacation. For those counts the prescriptions
2 were called in, not because Dr. Aggarwal specifically
3 authorized them, but they were called in based on the pattern
4 and practice at RTA.
5 Those prescriptions, as well as the prescriptions in
6 Counts 5, 6, and 7, were not issued for other than a legitimate
7 medical purpose, outside the course of professional practice or
8 beyond the bounds of medical practice.
9 We can look at the testimony of patients BO, SC, PN,
10 and LD, who all unanimously state they regularly interacted
11 with Dr. Aggarwal, they went to an initial patient visit where
12 they received a physical examination, in some cases amounting
13 to 20 minutes of face time with a physician. They provided
14 information on this witness stand and in documentation about
15 their substance abuse issues, which Dr. Thomas admits that
16 having a substance abuse issue is a threshold for receiving a
17 prescription.
18 They all testified that they received benefit from
19 the medication that was received. They all testified that they
20 regularly attended counseling. They all testified that -- with
21 some varying degree, that counseling was helpful for them, and
22 they all continued to engage in regular treatment at RTA, in
23 some cases interacting directly with Dr. Aggarwal or in some
24 cases merely seeing him when he would observe the group
25 practice.

1 There has been no testimony -- and this is especially
2 important given Dr. Thomas' admission that the West Virginia
3 model is appropriate and appropriate to use. There's been no
4 testimony that this model, the model of having physicians sit
5 in in a group therapy session for the vast majority of group
6 therapy sessions, but having them interact with a patient
7 face-to-face, there's been no testimony that model is in any
8 way insufficient, in any way amounts to drug dealing, or is in
9 any way outside the bounds of professional medical practice.
10 Dr. Thomas' testimony must be discredited in its
11 entirety. He's not a practicing physician. He's not a
12 practicing addiction medicine physician. He has only handled a
13 number of patients, just shy of the number of patients he
14 reviewed in this case. And his conflicting statements
15 regarding his involvement in addiction treatment render his
16 testimony useless for determining whether or not these
17 physicians have prescribed outside the bounds of professional
18 practice.
19 In any event, even if we credit Dr. Thomas'
20 testimony, it is clear that the standard medical model that he
21 subscribes to, his own subjective belief of how medicine should
22 be practiced, is not something that is adopted by federal
23 regulations, by TIP 63, by the West Virginia model which is in
24 evidence now. And there's been no evidence this model is
25 inappropriate whatsoever. And for those reasons Counts 5

1 through 11 should be the subject of a judgment of acquittal.
2 And Your Honor, that concludes my presentation on the
3 issue. Thank you.
4 THE COURT: Thank you.
5 Mr. Stallings, would you argue the Rule 29 motion for
6 your client in its entirety.
7 MR. STALLINGS: Thank you, Your Honor.
8 Dr. John would also move for a judgment of acquittal
9 under Rule 29. We believe there's insufficient evidence
10 adduced at this trial of some of the key elements of Counts 1,
11 12, 13, 14, 15, and 16.
12 As to Count 1, the government must show that there
13 was an agreement to commit a crime, and there was no evidence
14 presented to this jury of an agreement between Dr. John and any
15 alleged co-conspirators.
16 I think the government's theory of the case is that
17 Chris Handa, Jennifer Hess, Dr. Aggarwal, and Dr. John were
18 members of the conspiracy as alleged in this case. Mr. Handa
19 specifically said under oath he never entered into an agreement
20 to commit a crime. Both Mr. Handa and Ms. Hess acknowledged
21 during their testimony that it was their belief at the time of
22 the conduct that's at issue that what they were doing was
23 legitimate and legal. So there has been no evidence adduced by
24 the government of a criminal agreement.
25 Second, there's no evidence adduced by the government

1 that Dr. John knowingly and voluntarily joined any criminal
2 agreement. To the extent that the government was able to
3 establish an agreement between Handa and Hess, there's no
4 evidence of any conversation or act by Dr. John where he
5 knowingly and voluntarily joins the criminal undertaking.
6 I would submit -- and not for purposes of the weight
7 of the evidence, but to put in character our theory of the
8 case, there really hasn't been a crime shown, to speak of here,
9 that Dr. John was involved in, but much less any agreement to
10 commit a crime.
11 As to Counts 12 through 16, we believe the government
12 has not adduced sufficient evidence to go to the jury on the
13 issue of whether Dr. John acted knowingly and willfully; in
14 other words, the intent element of this case. Every time a
15 witness such as Ms. Hess was asked about conversations with
16 Dr. John, for example, about delegation of prescribing
17 authority, she confirmed that she never had any such
18 conversations with Dr. John.
19 And as to this issue of the delegation of the
20 prescribing authority, I believe, generously put, the
21 government's evidence is that on days Dr. John was absent that
22 his DEA number was used to issue a prescription for suboxone,
23 but the government has adduced no evidence for this jury that
24 Dr. John ever authorized anyone to use his DEA number on days
25 he was absent. Even if, standing alone, that was sufficient to

1 show a crime, the government has no proof he ever ordered that
2 or authorized that.
3 We would also submit that the use of his DEA number
4 on days he wasn't there is not, in and of itself, a crime, but
5 regardless, even if that's the government's theory, they've not
6 introduced a shred of evidence that Dr. John authorized the use
7 of his DEA number. And that's a specific example, but we
8 believe, in general, the government has simply not met its
9 burden of proving evidence that Dr. John knowingly and
10 willfully violated 21 U.S.C. 841.
11 So we are moving for Rule 29 based on the sufficiency
12 of the evidence to prove Counts 1, 12, 13, 14, 15, 16, and all
13 the elements thereof, and specifically, the existence of an
14 agreement is knowingly and voluntarily joining the agreement,
15 and the intent. Thank you, Your Honor.
16 THE COURT: Thank you, Mr. Stallings.
17 Counsel for the United States.
18 MS. WAGNER: Thank you, Your Honor. We believe both
19 motions should be denied. If I could speak to Count 1 with
20 respect to both motions, because I believe the defendants have
21 essentially argued the same thing, that we have failed to prove
22 an agreement.
23 We have presented sufficient evidence from which the
24 jury could infer that both defendants were -- agreed, and that
25 their agreement to be involved in this is shown by their

1 acceptance of payments for prescriptions that were made by
2 other individuals. There is overwhelming evidence that the
3 payments were made, undoubtedly, payments that were made even
4 for days when both defendants were absent from the clinic.
5 And the government need not show that the defendants
6 agreed to, quote, do something illegal. What they agreed to
7 was to allow Ms. Hess and Mr. Handa and others, other staff at
8 their direction, to make dosing decisions, make decisions about
9 quantity of prescriptions, and to authorize and send those
10 prescriptions out before the physicians had even been in a room
11 with the patients.
12 And the testimony from many individuals -- and the
13 evidence must be viewed in the light most favorable to the
14 government -- is that the doctors did not interact with
15 patients on an individual basis beyond the first visit. That
16 is what the agreement was. It was an agreement to allow others
17 to prescribe and make dosing decisions, to be in a room but not
18 interact with their patients pursuant to a doctor-patient
19 relationship.
20 And while it is correct that violations of the
21 regulations, including the West Virginia Board of Medicine
22 rules, in and of themselves, do not show a violation of 21
23 U.S.C. 846, what they do show is that by their extent, by the
24 scope of those violations, taken together with the other
25 evidence, those are violations from which the jury can conclude

1 that these prescriptions were outside the bounds.
2 With respect to Counts 5, 6, and 7 against
3 Dr. Aggarwal, which relate to prescriptions which appear to
4 have signatures from someone other than the -- Dr. Aggarwal
5 himself, the jury has been presented with evidence in the form
6 of first accepting money from those prescriptions on those two
7 dates; 5 and 6 were one particular date. Count 7 was another
8 date.
9 Dr. Aggarwal received payments on those dates. He
10 knew that prescriptions were issued on those dates, whether he
11 went back and looked at the medical charts or not. That's
12 evidence that, viewed in the light most favorable to the
13 government, the jury can rely on to find that he did know and
14 he was -- he was allowing staff to use his DEA number.
15 And the fact that he did not himself call in or
16 authorize that prescription does not mean that he didn't aid
17 and abet that distribution through his allowing RTA staff,
18 Ms. Hess, Mr. Handa, to use his DEA number.
19 And Mr. Handa did specifically testify that he had
20 authorization to sign Dr. Aggarwal's name. In any event, that
21 evidence, together with the evidence about him accepting
22 payments and evidence that the staff was permitted to use
23 Dr. Aggarwal's DEA number in this regard, is evidence from
24 which the jury could find that he did, in fact, violate the law
25 with respect to those counts.

1 With respect to the remaining counts against
2 Dr. Aggarwal, 8 through 11, again, the fact that these
3 prescriptions were issued -- the testimony, I believe, was that
4 prescriptions were issued no differently on days that the
5 doctors were in the office than on days they were outside of
6 the office. And so, again, that is evidence from which the
7 jury can reasonably infer that the -- and reasonably conclude
8 that the doctors knew what was happening with their DEA
9 numbers, they were allowing it to happen, and they were
10 accepting money. That's sufficient from which -- sufficient
11 evidence from which the jury could find that Dr. Aggarwal aided
12 and abetted the distribution of those controlled substances.
13 And although there was evidence from some of the
14 patients that they saw Dr. Aggarwal on the initial visit and
15 that they generally would see him in the clinic, I think other
16 than Mr. Nall, who indicated he had seen Dr. Aggarwal -- or had
17 an interaction with Dr. Aggarwal in another occasion, the
18 testimony has generally been from the patients that they did
19 not interact with Dr. Aggarwal on an individual basis.
20 With respect to the testimony of Dr. Thomas, again,
21 as we argued in the hearing this morning, Dr. Thomas'
22 qualifications, his experience -- or excuse me, his experience
23 with treating addiction is something that goes to the weight of
24 his testimony and not to whether it should be excluded
25 altogether.

1 And also with respect to the West Virginia model,
2 although there is no evidence that the West Virginia model is
3 not an appropriate model, there is evidence that Redirections
4 was not operating in the same fashion as the West Virginia
5 model. The West Virginia model employs particular types of
6 medical providers, none of which, other than one licensed
7 therapist, was a member of -- and the physicians, was a member
8 of the treatment team.
9 With respect to Dr. John's motion on Counts 12
10 through 16, again, the fact that Dr. John accepted payment for
11 prescriptions that were issued while he was out of the office
12 is evidence from which the jury can conclude that he knew very
13 well what was happening. He was accepting payment for it. And
14 by doing so, by accepting payment in exchange for allowing his
15 DEA number to be used in the fashion that it was, he was aiding
16 and abetting the distribution of controlled substances with
17 respect to each of those patients in each of those counts.
18 THE COURT: All right. First let me review and
19 confirm the standards that the Court has to use in deciding a
20 Rule 29 motion for judgment of acquittal under the Federal
21 Rules of Criminal Procedure.
22 The standard is, if viewing the evidence in the light
23 most favorable to the government, any rational trier of fact
24 could have found the defendant guilty beyond a reasonable
25 doubt. The Fourth Circuit has enunciated those standards time

1 and again. The burden, therefore, is not a heavy one, at least
2 at this stage of the case, on the part of government, and so
3 the Court must look at the evidence up to this point in light
4 of the standards.
5 The courts have also said that in a Rule 29 motion
6 the circumstantial as well as direct evidence can allow the
7 government benefit of reasonable inferences from the facts
8 proven to those sought to be established.
9 First, with respect to the Count 1 conspiracy count,
10 I think there is enough evidence at this stage of the case to
11 necessitate a denial of the motion for acquittal under Rule 29.
12 Again, just as in a Rule 29 motion, in a drug conspiracy, and
13 of course, Mr. Chapman correctly said it's not necessary to
14 prove an overt act, but in that case -- in this case of a drug
15 conspiracy, I think there is sufficient evidence under a Rule
16 29 standard to justify a denial. In drug conspiracies,
17 circumstantial evidence, as well as direct evidence, may be
18 used.
19 I think that the jury could find that the elements of
20 the conspiracy have been shown. I think that a jury could find
21 that there has been an agreement to violate the federal drug
22 statutes, and that the defendant knew of the conspiracy and
23 knowingly and voluntarily became a member of that conspiracy.
24 There's also, I think, sufficient evidence of the
25 violation of regulations and statutes with respect to the

1 conspiracy count.
2 Now, with regard to the Section 841 drug counts as to
3 Dr. Aggarwal, I'll take up as to Counts 5, 6, and 7, as
4 Mr. Chapman has, I think appropriately, argued that those could
5 be separated because of an allegation that Dr. Aggarwal's
6 signature was forged. The jury could find that they were. The
7 jury could find that they weren't. The jury could also find
8 that someone at the direction of and the auspices of
9 Dr. Aggarwal signed those without authority and in violation of
10 the statute.
11 There's also, I think, sufficient evidence not only
12 as to 5, 6, 7, but also to 8, 9, 10, and 11, counts that there
13 could have been and a jury could find a violation of federal
14 and state statutes and regulations, including possibly the
15 guidelines, including possibly the standards that the
16 defendants argued in this case.
17 With respect to Dr. Aggarwal, I reviewed my motion --
18 my finding of denial under Rule 29 as to 5 through 11 is based
19 upon my review of the medical records with regard to patients
20 BO, SC, JP, DS, JP, PN, and LD. All those defendants were --
21 the evidence against them was supported or could be supported
22 under Rule 29 standards by the medical records.
23 Then, of course, there is the opinion of Dr. Thomas.
24 The defendants in the Aggarwal claim, as well as the defendants
25 in Dr. John's case, argue vehemently that Dr. Thomas is not

1 qualified and that his testimony should be disregarded in toto.
2 Certainly for purposes of Rule 29, I think that
3 Dr. Thomas was qualified as an expert witness under Rule 702,
4 because under that rule a person with sufficient background and
5 training and experience, if that testimony could possibly help
6 the jury in making certain findings, that person can qualify as
7 an expert witness.
8 I've qualified Dr. Thomas as an expert witness, and
9 that included the questions asked of him with regard to the
10 investigation memorandum of the DEA which was admitted into
11 evidence in August of 2012.
12 I will be instructing the jury, of course, on
13 consideration of Dr. Thomas, in fact, any other expert witness
14 who testifies in this case, but at this stage I think the jury
15 could consider that testimony as it would any other expert
16 witness.
17 Now, with regard to Dr. John, of course, the rulings
18 that I've made with regard to the conspiracy also applies to
19 Dr. John, and the standards that have been used, and of course
20 the Rule 29 standards as to Dr. John, the conspiracy count and
21 the Section 841 counts.
22 Again, as to the counts for violation of Section --
23 of 21, United States Code, Section 841, that's the drug counts,
24 I think that there is sufficient evidence that a jury could
25 find Dr. John guilty of those -- in those counts.

1 And just as I had tried to follow all of the evidence
2 with regard to Dr. John, as I tried to do with regard to
3 Dr. Aggarwal, I think there was -- is sufficient evidence that
4 the jury could find Dr. John guilty on the drug counts. That's
5 through the patient charts on patients PE, SH, AM, JB, and DC.
6 I've been able to follow all of the government's exhibits
7 deemed to provide sufficient evidence as to those patients.
8 Further, as I've said, as regard to Dr. Thomas and to
9 Dr. Aggarwal, Dr. Thomas' testimony as regard to Dr. John could
10 be sufficiently believed by a jury to find him guilty based on
11 his testimony as an expert witness who has been qualified.
12 And again, the jury would be instructed in the proper
13 method and way of considering Dr. Thomas and other Rule 702
14 expert witnesses. So as to both defendants, the Rule 29 motion
15 for acquittal is denied.
16 May we bring the jury in, please. Thank you.
17 (Jury panel returned to the courtroom at 2:11 p.m.)
18 THE COURT: Thank you. Dr. Aggarwal may call his
19 next witness.
20 THE CLERK: The witness is Janet E. Nall, N-A-L-L.
21 **JANET E. NALL, DEFENDANT AGGARWAL'S WITNESS, SWORN**
22 DIRECT EXAMINATION
23 BY MR. NOGAY:
24 Q Hello, Mrs. Nall.
25 A Hi.

1 Q Would you tell the jury your name, please.
2 A Janet Elizabeth Nall.
3 Q And what do you do for a living?
4 A I'm a registered nurse.
5 Q Where are you a registered nurse?
6 A Ohio Valley Hospital in McKees Rocks, PA.
7 Q To whom are you married?
8 A I'm sorry?
9 Q To whom are you married?
10 A Paul Nall.
11 Q How long have you been married?
12 A A good 13 years. We've been together 19.
13 Q Do you have any children?
14 A Four.
15 Q Your husband testified earlier in the case; is that
16 correct?
17 A Correct.
18 Q Paul Nall. And are you familiar with -- during your
19 marriage with any addiction problems he's had?
20 A Yes.
21 Q Would you tell the jury, please, what type of addiction
22 problems he's had in the last ten years.
23 A Opiates, a lot of narcotics, heroin, you name it. He's
24 started off slow and progressed all the way to heroin.
25 Q At some point did he -- you together decide to seek

1 treatment somewhere in Weirton?
2 A Yes.
3 Q And where was that?
4 A That was at --
5 Q Redirections?
6 A Absolutely. Redirections. It was on Pennsylvania Avenue
7 in Weirton.
8 Q And did your husband go to -- he's testified he went to
9 Redirections and was seen by Dr. Aggarwal. Is that your
10 understanding also?
11 A Correct. Correct.
12 Q Now, I don't necessarily want to know what he told you. I
13 want to know what you saw in him. After he got his first
14 suboxone prescription, would you tell the jury if there was any
15 change in him.
16 A Almost immediately. It is a long process, but a big
17 difference in him once he got on that medication. Saved his
18 life. It saved our life.
19 Q Was he working at the time he was addicted to heroin, for
20 instance, or trying heroin?
21 A No.
22 Q Is he working now?
23 A He has had a solid job for five years.
24 Q And where does he work now?
25 A Tudor's Biscuit World. He manages the back and does

1 inventory. He's the boss' right-hand man.
2 Q Is that income able to provide for you and your family?
3 A Yes, yes.
4 Q Now, does he have moments when he regresses in his
5 treatment?
6 A Is there moments?
7 Q Yes.
8 A Correct, yes. There's many. You know, he has slipped.
9 But for the most part he's done very well with treatment.
10 Q When he was at Redirections, I looked at his records and
11 it looked like he had many failed drug screens?
12 A Yes.
13 Q As a result of that, did he have to go to additional
14 therapy called poly group?
15 A Yes. They increased his therapy. He was going to poly
16 group when they had narcotics, and if you failed I know he went
17 more frequently and he would -- it was certain groups at
18 certain times that he went to. I'm not real sure of the times,
19 but he definitely had to increase.
20 Q Did they ever give up on him or kick him out of the
21 program?
22 A No. No, not at all.
23 Q Did he have a physician there that you're aware of?
24 A Yes.
25 Q Who was that individual?

1 A Dr. Aggarwal is who he saw.
2 Q Do you have any complaints about the physician-patient
3 relationship with Dr. Aggarwal and your husband?
4 A No.
5 MS. WAGNER: Objection, Your Honor; foundation.
6 MR. NOGAY: I'll add a few more questions.
7 Q Are you aware of the physician-patient relationship with
8 Dr. Aggarwal and your husband?
9 A Yes.
10 MS. WAGNER: Objection, Your Honor. This would be
11 based on hearsay.
12 THE COURT: Overruled.
13 Q And did you observe your husband, after he would leave
14 treatment, after he had seen Dr. Aggarwal at Redirections?
15 A Yes.
16 Q Now, your husband testified that Dr. Aggarwal warned him
17 about the dangers of fentanyl. Were you aware of that?
18 A He had spoke to me that they did speak about that, yes.
19 Q The situation your husband's in now with regard to your
20 family life, could you tell the jury how the treatment with
21 suboxone and through Dr. Aggarwal, if it changed your family
22 life at all, and if so, how.
23 A Yes. It went from arguing every day, fighting, him not
24 being a father to our children, not being a good husband, to
25 he's wonderful now. He's very attentive to our children. He's

1 a great husband. He works steady. He brings in money, half
2 the income. And he just is a totally different person. He
3 went from stealing money from us to he now he's on the bank
4 account even. We just got him a bank card. So like it's a
5 slow process, but it has definitely been worth it.
6 MR. NOGAY: I don't have any other questions, Your
7 Honor.
8 MR. STALLINGS: No questions, Your Honor.
9 THE COURT: Ms. Wagner.
10 CROSS-EXAMINATION
11 BY MS. WAGNER:
12 Q Good afternoon, ma'am.
13 A Hi.
14 Q It's true, isn't it, that you didn't attend your husband's
15 visits at Redirections?
16 A Correct.
17 Q And so you weren't in group meetings?
18 A No, I was not.
19 Q And other than the first meeting, you don't know whether
20 he had any meetings with Dr. Aggarwal?
21 A He would tell me after that, whenever he would come out,
22 that, you know, he was in a meeting, the doctor was there, or
23 whatever happened in that time period after the meetings when I
24 would pick him up.
25 Q You're not aware of any individual interactions with your

1 husband and Dr. Aggarwal, are you?
2 A No.
3 Q And you indicated that you're a nurse, correct?
4 A Correct.
5 Q And you knew, didn't you, that the staff at Redirections
6 was making dosing decisions for --
7 MR. NOGAY: Objection, Your Honor; not covered on
8 direct examination.
9 THE COURT: She's been asked about the care that the
10 witness' husband received. I'm going to allow it up to a
11 point.
12 BY MS. WAGNER:
13 Q Ma'am, you were aware, weren't you, that the decisions
14 about your husband's medication were being made by the staff at
15 Redirections and not by the doctor?
16 A That I'm not sure, because I was not there, so --
17 Q Didn't you tell federal agents who interviewed you that as
18 a nurse, you were aware that the physician had delegated his
19 responsibility to others, to the office staff?
20 A I don't -- could you please repeat that. I'm not sure
21 what you're --
22 Q Yes. Didn't you tell federal investigators that it was
23 known that the patients did not see the doctors, including
24 Dr. Aggarwal, and that as a nurse, you knew that the staff had
25 been delegated with the responsibility for providing treatment

1 for the patients?
2 A Well, I may have gotten it confused, because the treatment
3 that he went to before, that was a lot that the physicians
4 never saw the patients. As far as being there, I never went in
5 with him or he just -- I dropped him off and picked him up and
6 I'm not sure who made the decisions. If I did say that before,
7 I may have been confused. I don't really know who was making
8 the decisions there. I just knew that there was a physician
9 there and who my husband had thought was a nurse, possibly,
10 there.
11 Q And are you aware as you sit here today there were no
12 nurses employed at Redirections?
13 A I still don't know if there was or was not, to be honest
14 with you.
15 MS. WAGNER: Those are all the questions I have.
16 THE COURT: Mr. Nogay.
17 REDIRECT EXAMINATION
18 BY MR. NOGAY:
19 Q Were you and your husband interviewed by the United States
20 Attorney's Office?
21 A We were.
22 Q And --
23 MS. WAGNER: Objection. This is beyond the cross,
24 Your Honor.
25 MR. NOGAY: Talking about statements made to

1 officials, Your Honor.
2 THE COURT: I'll allow it. Overrule the objection.
3 BY MR. NOGAY:
4 Q Did the attorneys for the United States show photographs
5 to you and your husband of two doctors?
6 A Yes.
7 Q And what did the appearance of these doctors look like?
8 Could you tell them apart?
9 A Yes.
10 Q And did your husband identify Dr. Aggarwal?
11 A Yes.
12 Q And what was the reaction of the government at that point?
13 MS. WAGNER: Objection, Your Honor.
14 THE COURT: Objection sustained.
15 MR. NOGAY: No further questions, Your Honor.
16 THE COURT: Mr. Stallings?
17 MR. STALLINGS: No questions. Thank you.
18 THE COURT: Ms. Wagner?
19 MS. WAGNER: Nothing further, Your Honor.
20 THE COURT: Thank you, Ms. Nall, for testifying.
21 Defendant Aggarwal may call his next witness.
22 MR. CHAPMAN: Your Honor, Dr. Aggarwal calls
23 Dr. Standiford Helm to the stand.
24 THE CLERK: The witness is Standiford,
25 S-T-A-N-D-I-F-O-R-D, last name Helm, H-E-L-M.

1 **STANDIFORD HELM, DEFENDANT AGGARWAL'S WITNESS, SWORN**

2 DIRECT EXAMINATION

3 BY MR. CHAPMAN:

4 Q Good afternoon, Dr. Helm.

5 A Good afternoon.

6 Q Can you please tell the jury what your current occupation

7 is.

8 A I practice interventional pain management, the definition

9 of which is diagnosis and treatment of subacute and chronic

10 pain, with interventions coupled with other modalities. Other

11 modalities means things like medication management, including

12 opioids, means psychological treatment, means physical therapy,

13 functional restoration, and as an extension of that, because of

14 the issues we face in using the opioids, it goes into addiction

15 medicine.

16 Q Where do you currently work?

17 A I'm in Orange County, California.

18 Q What's the name of your practice?

19 A The Helm Center for Pain Management.

20 Q Who owns that?

21 A I do.

22 Q Do you actively treat patients currently?

23 A I do.

24 Q I'd like to take you all the way back to college. Where

25 did you go?

1 A Harvard College.
2 Q What did you graduate with?
3 A A Bachelor of Arts degree.
4 Q What year did you graduate?
5 A It was 1978.
6 Q After college, did you attend medical school?
7 A Tufts University School of Medicine.
8 Q How long were you at Tufts University School of Medicine?
9 A Four years.
10 Q Did you receive a medical degree after that?
11 A I did.
12 Q And after your medical degree, did you go to any
13 internship or residency programs?
14 A I went to Boston City Hospital and spent a year doing an
15 internal medicine internship.
16 Q Can you just tell the jury what you do doing an internal
17 medicine internship.
18 A It's the first step towards training to become an internal
19 medicine specialist. And it's rigorous year of internship, get
20 a busy city hospital.
21 Q What is internal medicine, if you could just describe it?
22 A It's the diagnosis and treatment of the diseases. It
23 stands in contraposition with surgery, where you're going to be
24 operating. Internal medicine is more on diagnosis and then
25 medical treatment.

1 Q When did you finish the internship at Boston City
2 Hospital?
3 A I finished that in 1978.
4 Q And in 1978 did you attend a residency in UCLA?
5 A I did. I went there from 1978 to 1980.
6 Q What was your residency in?
7 A Anesthesiology.
8 Q Did you successfully complete that residency?
9 A I did.
10 Q And what did you do during your anesthesiology residency?
11 A There you learn how to provide surgical anesthesia for
12 patients, part of which is regional injections and placement of
13 needles to administer medicines, which is the segue over into
14 pain management.
15 Q At the conclusion of your residency, have you received any
16 other formal education, medical or nonmedical?
17 A I got a Master's of Business Administration.
18 Q And where was that from?
19 A Pepperdine.
20 Q How long have you been engaged in the private practice of
21 medicine, Dr. Helm?
22 A Since 1980.
23 Q Have you actively treated patients since 1980?
24 A Correct.
25 Q Are you currently on the medical staff of any

1 institutions?
2 A I'm on three hospital medical staffs and two surgery
3 centers.
4 Q Do you possess a valid DEA X number?
5 A I do.
6 Q And what did you have to do to get that?
7 A There was a -- I believe eight-hour training course that I
8 had to take and then pass an exam upon completion of the
9 course.
10 Q When did you receive that X number?
11 A That's a good question. I'm going to estimate in the
12 early 2000s. Suboxone was authorized in late 2000, so maybe
13 2004, 2005, somewhere in there.
14 Q Since receiving that X number, have you prescribed
15 buprenorphine and suboxone to patients suffering from opioid
16 use disorder?
17 A I have.
18 Q And have you done that continuously between 2004 and the
19 present?
20 A Correct. Or whenever I got the X number.
21 Q Whenever you got it, yeah.
22 Have you had to reapply for your X number and your DEA
23 registration multiple times since 2004?
24 A Well, I had to renew the DEA registration, and with that
25 came the renewal of the X.

1 Q Do you recall how many times you've had to do that?
2 A No.
3 Q Is your DEA registration currently active today?
4 A It is.
5 Q Can you tell the jury what board certification means.
6 A Sure. A board is a test that is administered by a body.
7 The major group in the United States is something called the
8 American Board of Medical Specialty Examiners, and there are a
9 series of boards that exist underneath that, your pediatricians
10 board, obstetricians board, internal medicine, family practice,
11 surgery, specialty boards, and to sit for a board you have to
12 have achieved a certain level of education and then to take an
13 exam of some sort or another.
14 Q Is it important for a physician to be board certified in
15 their particular area of practice?
16 A What it does is provides certification that standards that
17 are uniform across the country have been met.
18 Q And are you board certified in any areas of medicine?
19 A I'm board certified in anesthesiology, with subspecialty
20 certification in pain medicine. I'm certified by the American
21 Board of Addiction Medicine in addiction medicine. I'm a
22 fellow of Interventional Pain Practice, a diplomate of the
23 American Board of Interventional Pain Physicians, and I'm
24 boarded by the American Board of Pain Medicine.
25 Q Specifically with respect to your board certification for

1 addiction medicine, what did you do to achieve that?
2 A That had previously existed under an organization called
3 the American Board of -- American Society of Addiction
4 Medicine, American Board of Addiction Medicine, which was
5 outside of this American Board of Medical Specialty Examiners
6 that I mentioned. And because of the problems with opioid
7 abuse and the need -- the concerns over the need to treat
8 addiction, the decision was made to bring that board into the
9 overview of the American Board of Medical Specialty Examiners,
10 so that was brought in about two years ago under -- called the
11 American Board of Preventive Medicine. And so at that time
12 I -- when it became ABSME board, I took the exam and again with
13 this case it was a 200-question exam that one takes, upon
14 meeting the requirements to take the board.
15 Q And what does having a board certification in addiction
16 medicine allow you to do?
17 A It basically allows me to say that I'm board certified and
18 it provides, again, a nationwide standard that I, along with
19 everyone else who's boarded, have met.
20 Q Are boards responsible for ensuring that physicians who
21 practice in addiction medicine or other areas have the
22 knowledge and experience to practice in that arena?
23 A It's a confirmation that the physicians who are boarded
24 have that knowledge and experience.
25 Q Is there any check and balance to ensure that physicians

1 who are not board certified have that knowledge and experience
2 to practice in that area?
3 A You can't advertise yourself as being board certified if
4 you're not.
5 Q And so that board certification is the marker that lets
6 people know that this person has the skill and experience to
7 practice in that field?
8 A Correct.
9 Q Doctor, what is the American Academy of Pain Medicine?
10 A The American Academy of Pain Medicine is an association of
11 pain physicians that exists, has meetings, has a journal.
12 Q Okay. And what is your relationship with the American
13 Academy of Pain Medicine?
14 A I'm a member of it, and I'm also a delegate for the
15 California Academy of Pain Medicine to the California Medical
16 Association.
17 Q Did you have to be elected to that position, or appointed?
18 A Yes.
19 Q Okay. And what is the American Board of Interventional
20 Pain Physicians?
21 A That is a board that is run by the American Society of
22 Interventional Pain Physicians, which is another organization
23 that I've been involved with. That provides certification for
24 pain doctors. And what's unique about that one is that there's
25 a -- it's the only one that has a component where you actually

1 have to demonstrate the ability to do procedures, actually go
2 into a lab and do procedures on cadavers. It also has other
3 components, including certification in opioid management and
4 also coding and compliance.
5 Q What's your relationship with the American Board of
6 Interventional Pain Physicians?
7 A I'm a diplomate, and let's see, I'm trying to think if I'm
8 still on the board of that. I think I'm still on the board --
9 on the board of the board.
10 Q Board of directors.
11 Are you also a past president of the American Society of
12 Interventional Pain Physicians?
13 A That's correct.
14 Q And how long did you hold that position?
15 A That was a one-year position.
16 Q Is that a national leadership position?
17 A Yes.
18 Q Were you a member of the board of trustees for the
19 California Medical Association?
20 A I was.
21 Q You on the executive committee for the Council of Pain
22 Physicians Societies?
23 A Yes.
24 Q All right. Have you provided assistance for both Health
25 and Human Services and Medicare on specific advisory boards?

1 A I have. And I'm still on the -- what's called the carrier
2 advisory board committee for Medicare in our area.
3 Q And are you a former president of the Orange County
4 Medical Association?
5 A Correct.
6 Q Doctor, can you tell us what the importance in your
7 profession of medical journals are.
8 A Of medical?
9 Q Medical journals, the importance of that.
10 A It's a way of disseminating information.
11 Q And have you been involved in editorial boards for any
12 medical journals?
13 A Several.
14 Q And what do your responsibilities on those editorial
15 boards -- what is your responsibility on the editorial board?
16 A Someone submits an article to be published. They send it
17 out to editors such as myself. We read the articles, we
18 comment on it, we make suggestions as to how the articles can
19 be improved, and I think that we're actually very functional in
20 improving articles.
21 Q Have you received any awards or nomination as a physician
22 in the field of pain management and addiction medicine?
23 A Most recently I got a lifetime achievement award from the
24 American Society of Interventional Physicians. That was about
25 a month ago. Then prior to that there have been many others.

1 Q Were you recognized by *U.S. News and World Report*?
2 A Yeah. The top doctor position, yeah.
3 Q Doctor, have you authored publications in order to advance
4 the practice of medicine?
5 A I have.
6 Q You recall how many publications you've authored?
7 A I laugh because -- I think it's about 15 pages, which
8 would be many hundred publications, I think.
9 Q And are those, by and large, peer-reviewed publications?
10 A Almost all. I try to remember if any are not peer
11 reviewed. I think they're basically all peer reviewed.
12 Q Have you also lectured in the area of pain management and
13 addiction medicine?
14 A Extensively, yes.
15 MR. CHAPMAN: Your Honor, at this time I'd like to
16 offer Dr. Helm as an expert in the field of pain management and
17 addiction medicine.
18 MS. WAGNER: There's no objection.
19 THE COURT: All right. Without objection, Dr. Helm
20 will be and is qualified to serve as an expert witness in pain
21 management and addiction medicine.
22 And members of the jury, I gave you a rather long
23 description of what an expert witness is able to do, generally
24 give opinions in the subject in which he or she is qualified.
25 So Dr. Helm is qualified to give you an opinion in

1 this case regarding the subjects in pain management and
2 addiction medicine. And again, you should consider his
3 testimony as you would in all other respects like any other
4 witness.
5 BY MR. CHAPMAN:
6 Q Doctor, I'd like to move on and ask you whether or not
7 you're familiar with the concepts of best practices, standard
8 of care, and then beyond the bounds of medical practice.
9 A I am.
10 Q Let's talk about best practices first. Can you describe
11 what best practices are, for the jury.
12 A Sure. Best practices would be what the -- it's what it
13 sounds like, the best practices. You go to the academic
14 center, you get the people who are really the leaders of the
15 field, have the most experience, most knowledge, and that might
16 set the standard as to best practice.
17 Q Was TIP 63 created by experts in the field, as you've
18 mentioned?
19 A Yes, it was.
20 Q And is TIP 63 an example of best practices?
21 A Yes.
22 Q Is it criminal for a physician to depart from the best
23 practices in their field?
24 A Not criminal, as long as they're within the standard of
25 care.

1 Q Okay. Let's talk about standard of care. What is
2 evidence of standard of care?
3 A Well, standard of care is what a reasonably trained
4 physician in the community would do in similar circumstances,
5 so it may not be best practices, but it's what people are
6 doing.
7 Q Is violation of standard of care a civil matter?
8 A Based upon all the medical board work I do, yes.
9 Q Is it true that a physician who violates the standard of
10 care could be subject to administrative or civil remedies, but
11 not necessarily criminal?
12 MS. WAGNER: Your Honor, I would just object to the
13 extent that Mr. Chapman is asking Dr. Helm to articulate the
14 standard that applies in this case with respect to essentially
15 what will be instructed at jury --
16 THE COURT: I'll overrule it. I think you can
17 inquire as to what he knows about the standards and how they
18 might apply in this case or not apply to this case, just
19 briefly.
20 MR. CHAPMAN: Thank you, Your Honor.
21 BY MR. CHAPMAN:
22 Q So if a physician departs from the standard of care, is it
23 that they would be subject to a civil and maybe an
24 administrative remedy?
25 A Correct.

1 Q And administrative remedy, what's an example of that?
2 A Medical board sanctions, which could be anything from a
3 letter attached to his file or her file, to probation or loss
4 of a license.
5 Q Now, that third one, practice outside the bounds of
6 professional practice, is that a lower standard than best
7 practices and standard of care?
8 A I would call it -- that would be another way of saying
9 below the standard of care.
10 Q Okay. Now, what is -- what does the phrase "outside the
11 bounds of professional practice" mean to you?
12 A It means that you're doing something that has no medical
13 reason. You know, for example, if one were running a pill mill
14 and people were just lining up and you're writing scripts for
15 them for no medical reason, that would be outside the bounds of
16 professional medical practice.
17 Q Specifically with regard to prescribing suboxone, what do
18 you look at to see whether or not a prescription is prescribing
19 within the bounds of medical practice?
20 A Well, it's the two things we've talked about, you've heard
21 before, one of which is there's got to be a legitimate medical
22 reason, and it's got to be done within the professional
23 practice of the person doing the prescribing.
24 Q And can you give us an example of what might be a medical
25 reason for prescribing a drug like suboxone?

1 A The most common would be are they on-label. One would be
2 a diagnosis of opioid use disorder.
3 Q And in addition to a diagnosis of opiate use disorder,
4 what else would you want to see in order to determine whether a
5 physician was inside the bounds of professional practice?
6 A Well, the big one is that they've established a -- the
7 diagnosis, and in the process of establishing the diagnosis,
8 one would develop the doctor-patient relationship. And then
9 the other issue would be the transmitting the prescription to
10 start treating it, treating the disorder.
11 Q Now, did you have an opportunity to observe Dr. Thomas
12 testify today?
13 A I did.
14 Q And Dr. Thomas testified that he'd prescribed suboxone to
15 patients who didn't quite have a diagnosed opiate use disorder.
16 Do you agree with that?
17 A Sure. You can prescribe any drug off-label, and I
18 absolutely agree that you can use suboxone for diagnoses other
19 than substance abuse disorder.
20 Q Would that be using off-label for the treatment of pain,
21 as opposed to substance use disorder?
22 A There were a couple of things. I would use it for
23 patients who were just looking like they're just having some
24 trouble complying with their opioid therapy. Another one is I
25 currently think that because you do not want patients to be

1 exposed to sedating -- too many sedating drugs because of the
2 risk of overdose, so one shouldn't simultaneously take
3 benzodiazepines and opioids. However, the exception to that is
4 DEA has offered guidance saying it's okay to keep suboxone
5 being prescribed in patients who are on opioids because the
6 risk of them -- excuse me. I misspoke. Suboxone in patients
7 who are taking benzodiazepines, Xanax, Ativan, Valium, because
8 the risk of getting them off it might interfere with the
9 treatment. And for that reason I've got some patients who
10 simply can't get off the benzodiazepines and the only opioid
11 that I will use with them would be suboxone.
12 Q So are there some occasions where it's permissible for a
13 physician, even in absence of a confirmed diagnosis of opiate
14 use disorder, to prescribe suboxone?
15 A Absolutely.
16 Q I'd like to talk about drug treatment prior to the year
17 2000. Did anything significant happen in 2000 in the addiction
18 medicine field?
19 A Well, that was the DATA 2000, the Drug Treatment -- Drug
20 Addiction Treatment Act of 2000 was passed.
21 Q What is DATA 2000?
22 A It allows the -- it was trying to get drug treatment
23 provided by a larger number of physicians so that more patients
24 could get access to that. Before DATA 2000, you had to go to
25 what's called an opioid treatment program, which is a methadone

1 clinic, to get your medicine. You had to go every day. You
2 still have to go every day to get your methadone. And that was
3 a very limited resource that left many people unable to get
4 access to care, so they allowed physicians with the appropriate
5 X waiver to provide medicines approved by the FDA for the
6 office-based treatment of opioid use disorder.
7 Q Was this intended to expand opiate treatment to be able to
8 be provided by physicians that weren't addiction specialists
9 like yourself?
10 A Not only addiction specialists, but it was before it was
11 limited to opioid treatment program. You actually had to go to
12 an OTP or a methadone clinic, which are very hard to find. And
13 you can imagine there's a lot of resistance to opening them up
14 in communities that might otherwise need them, so there simply
15 weren't enough resources to treat the amount of addiction that
16 was seen, even in 2000.
17 Q Now, prior to 2000, did patients in opiate treatment
18 programs require interaction with a physician during their
19 daily visits to the methadone clinic?
20 A No. They had to show up and get their methadone, but
21 there weren't -- to see a physician would not occur on a
22 regular basis.
23 Q Was DATA 2000 somewhat effective in expanding access to
24 opiate treatment?
25 A After late 2002, when the first drug was approved,

1 buprenorphine, in the form of suboxone or Subutex, to -- for
2 docs to use; prior to that there were no other drugs and there
3 haven't been any other drugs approved since then, so suboxone
4 is what we've got to treat opioid use disorder.
5 Q Despite DATA 2000 being implemented, are there still
6 issues today with respect to access to treatment by patients
7 seeking it?
8 A It's a huge problem. There is waiting lists at some of
9 the programs. There's been a push in certain circles for
10 treatment in residential centers and sober living homes, the
11 difficulty being that those facilities simply aren't as
12 effective as medication-assisted treatment with suboxone and
13 counseling. That's really the most effective way of treating
14 it, but the problem we've got is how do you get more patients
15 access to this therapy.
16 Q What happens to patients who are unable to access therapy
17 because of waiting lists or inability to access treatment?
18 A They continue doing whatever they've been doing before,
19 presumably getting illicit opioids off the street or, in
20 increasingly rare cases, prescription meds, but generally the
21 overprescribing of opioids has been -- is getting wrung out.
22 It's been on a downslope since 2015.
23 Q In your experience, what is the risk of a patient going
24 back on the street as opposed to seeking addiction treatment?
25 A Death is a big one, particularly with the fentanyl that's

1 in there.
2 Q Since DATA 2000 has been implemented, are you aware of
3 various models across the United States designed to increase
4 access to patient care?
5 A Yeah. And that is the focus of them all is increasing
6 access, and there are several that Vermont, Massachusetts, West
7 Virginia has one.
8 Q Let's talk about each individually. Are you familiar with
9 the Vermont model?
10 A That's a hub-and-spoke model, where there's a center that
11 works with primary care offices around the -- usually a medical
12 center, and then they will work with counselors coming out from
13 the center into the different primary care physicians' offices;
14 doesn't need to be primary care, could be my office, for
15 example, and providing a comprehensive treatment.
16 Q Does the Vermont model put an emphasis not on
17 physician-patient interaction but on team interaction with
18 other parts of the treatment team?
19 A Yes.
20 MS. WAGNER: Your Honor, I would just object to
21 relevance. I don't think there's any evidence in this case
22 that what was happening at Redirections was like the
23 hub-and-spoke model.
24 THE COURT: Counsel approach, please.
25 (The following proceedings were had at the bench, out

1 of the hearing of the jury.)
2 THE COURT: Was this concept discussed or alluded to
3 in the other case? I haven't followed it.
4 MR. CHAPMAN: It may have been, Your Honor, but I
5 think our focus is on the facts here.
6 THE COURT: Of course. What's the relevancy of this
7 model?
8 MR. CHAPMAN: The greater point that we're getting at
9 is that throughout the United States various agencies,
10 hospitals, states, have been working on novel ways to increase
11 access, and all of those ways have a focus on limiting
12 physician-patient interaction and increasing the use of other
13 team members, as what happened here.
14 Interestingly, the government offered the testimony
15 in the last trial of Dr. Marshalek, who uses the West Virginia
16 model. The West Virginia model is nearly identical and was a
17 foundation for Jennifer Hess' decision to start this clinic.
18 THE COURT: I think you've hit on it, and I think the
19 West Virginia model, to the extent it's been adopted, is very
20 appropriate to talk about, from what I know about it, at least
21 at this stage. I'm concerned about getting into other states'
22 models and somehow opening the door to argue that those are
23 somehow standards of care. You know more about the model, of
24 course, than I do, but that's my concern.
25 MS. WAGNER: Your Honor, this was the subject of a

1 motion in limine in the Naum case, and Judge Keeley ruled that
2 discussions about models that weren't in place were not
3 appropriate and can lead to confusion to the jury. We have no
4 qualms with them discussing the West Virginia model because, as
5 we understand it, that's what this in some ways was attempting
6 to replicate.
7 MR. CHAPMAN: Your Honor, that ruling by Judge Keeley
8 is the main subject of our appeal in that case, and we have
9 very, very good information to suggest that that ruling may
10 have been in error. And we wouldn't want to make it in this
11 case as well.
12 THE COURT: I don't either, but I think
13 independently, I think we're better off if we stick to the West
14 Virginia model and how it applies. And I think you can -- I
15 think you've already covered there are other models of
16 standards. I'm concerned about a Rule 403 unnecessary
17 presentation of cumulative evidence and perhaps getting into
18 some prejudice.
19 MR. STALLINGS: Judge, may I speak on this issue as
20 well, because it will come up with our expert, I think, too. I
21 think there may be a little confusion on the use of the word
22 "model." The West Virginia model is not some statutory scheme.
23 It's an example of a way to treat suboxone patients.
24 We would argue that Dr. Thomas' testimony invited
25 another model, his view of how suboxone needs to be handled.

1 When we say Vermont or we say West Virginia or we say these
2 other ones, we're not talking about statutory state schemes.
3 We're talking about manners of treating suboxone.
4 And part of the relevance of this is to explain that
5 it's not a one-size-fits-all approach. So when Dr. Thomas says
6 this is the way it has to be done, it's important for the jury
7 to understand that there are different ways to approach it. So
8 we have a slightly different view of the relevance of this, and
9 I think for that purpose we could certainly explain that there
10 are other models and generally what they involve.
11 THE COURT: Which I think you may have already done
12 in talking about -- you talked about Vermont and what other
13 state did you talk about?
14 MR. CHAPMAN: Massachusetts. The difference here,
15 Your Honor, is I want to show the jury there are other areas
16 that are struggling with how to apply these concepts and
17 creating models to be able to do that, and all these are unique
18 and separate, which leads to good faith, really.
19 THE COURT: I think you've described the question or
20 two that I'd like to hear, and I don't want to get into detail
21 on any state's model except maybe the state in which the
22 standard of care might be applicable here, which would be West
23 Virginia.
24 MR. CHAPMAN: Okay. Thank you, Your Honor.
25 (Bench conference concludes.)

1 BY MR. CHAPMAN:
2 Q Doctor, can you tell us why different areas of the United
3 States have developed different models for using suboxone to
4 treat patients?
5 A Well, the common theme is they're trying to figure out how
6 to get more patients access to suboxone. And the different
7 states are doing what the different states do best,
8 experimenting with different ways of doing it based upon their
9 very personal -- when I say personal, I mean each state's own
10 structure, population, and health care delivery system.
11 Q And what are the commonalities between those models that
12 you're aware of with respect to physician interaction with the
13 patient?
14 A That there's only so much time a physician has to give to
15 the patient, so the question is how do you expand that, how do
16 you multiply that so that the physician interaction, once
17 you've cleared a patient medically, there is -- there has to be
18 some interaction with a licensed personnel, whether a physician
19 or a nurse practitioner or PA, but that gets cut way down
20 because of the importance of the other factors in treating
21 opioid use disorder, which is the -- primarily the counseling
22 component.
23 Once you use the buprenorphine to control the need to get
24 drugs, you've then got to give the patient time and support to
25 normalize their life and get back into the mainstream so they

1 can live a productive life and have a good relationship with
2 their family. Doesn't happen overnight. It takes time.
3 Q So typically in these models is it the face time with the
4 physician decreases but the counseling and other ancillary
5 services increase?
6 A Correct. And that's because as -- after you've dealt with
7 the medical issue, it's the counseling issues that become the
8 dominant issue that you need to maintain. You follow with the
9 medical issue and slowly wean down the -- off the suboxone, if
10 appropriate; sometimes you don't. I've got patients I keep on
11 suboxone indefinitely. But so there needs to be some physician
12 involvement, to a certain extent, but the major issues you're
13 dealing with are just lifestyle issues.
14 Q Throughout -- after reviewing all the models that you've
15 seen in the United States, have you ever seen any of them that
16 subscribe to Dr. Thomas' standard medical model?
17 A No. Because it doesn't meet the criterion of multiplying
18 the capability of the physician so that more patients can get
19 access to care.
20 Q And what's the risk if Dr. Thomas' standard medical model
21 is applied to the treatment of suboxone in the United States?
22 A Needless death of people who suffer opioid use disorder.
23 Q And why is that?
24 A Because they don't get access to care.
25 Q And what about increasing or requiring a physician to see

1 patients virtually all visits would decrease access to care?
2 A There's simply not enough patient -- not enough physician
3 time to meet that.
4 Q Approximately how many suboxone or DATA-waived physicians
5 are there in the United States; do you know?
6 A I would be guessing. I'm not sure.
7 Q If I threw a number like 34,000 at you, would that sound
8 close?
9 A I'm glad it's that high.
10 Q Would you still be guessing?
11 A Yeah. I don't know how many.
12 Q Let's see if we can get you something here.
13 MS. WAGNER: Your Honor, may we approach, please.
14 (The following proceedings were had at the bench, out
15 of the hearing of the jury.)
16 MS. WAGNER: Your Honor, I've refrained from
17 objecting to this line of questioning, but it's clear to me
18 that the line of questioning continues to go towards a jury
19 nullification argument. I think this ground has been well
20 plowed, and to continue discussing patient access to treatment
21 and lack of access to treatment is only aimed at getting the
22 jury to nullify on grounds that having nothing to do with --
23 MR. CHAPMAN: It is certainly true -- this is a fact
24 we didn't make up -- that applying Dr. Thomas' model across the
25 United States would certainly lead to patient deaths, but that

1 is evidence of the fact that less physician involvement is the
2 strategy employed by not only West Virginia but other areas in
3 the United States in order to increase access. That is vital
4 to the jury's determination of what is the appropriate standard
5 here.
6 MS. WAGNER: No, it is not.
7 MR. CHAPMAN: Because of the reasons that standard
8 needs to be applied in order to take care of patients in this
9 country.
10 MS. WAGNER: The jury does not have to decide how
11 doctors can -- can treat patients or how many patients can be
12 treated. It is not the law that the jury -- that physicians
13 with DATA waivers can pass out suboxone. That is essentially
14 the argument that's being made.
15 It doesn't matter if they're within the confines of
16 the law that they can simply hand out suboxone because suboxone
17 is a good and helpful thing. That's not the standard being
18 applied here, and it's not consistent with this Court's ruling
19 on the suboxone standards. The prescription of suboxone has to
20 be for -- within the bounds of professional medical practice,
21 and what they are arguing is that as long as patients are
22 getting suboxone, then there's no problem. And that's not what
23 the law is.
24 THE COURT: Well, I think there has been a holding
25 that TIP 63 are not regulations or statutes, but they are

1 guidelines that may be used. I understand the argument, but I
2 don't want us to go afield of the fact that ultimately it has
3 to do with a standard, and the standard is -- the federal
4 standard is beyond the bounds of medical practice. And just
5 because there is a statement in some guidelines that may or may
6 not assist, I'm thinking that I think we're getting afield.
7 What are the points you want to make? You got them
8 in through Dr. Thomas, to a degree.
9 MR. CHAPMAN: I can move on from the question about
10 what's the concern of applying Dr. Thomas' model and just move
11 on to what is -- I do need to use the TIP --
12 THE COURT: Which statements in TIPs do you plan to
13 offer?
14 MR. CHAPMAN: Statements about licensed counselors,
15 which is what we've discussed, the statements about medication
16 management visits and what TIP 63 recommends is required, and
17 the fact there is no requirement for individual physician
18 face-to-face interaction. That's primarily it. There may be
19 some minor --
20 THE COURT: Those two I'll let you ask him.
21 MR. CHAPMAN: Okay. Thank you.
22 (Bench conference concludes.)
23 BY MR. CHAPMAN:
24 Q Doctor, have you had a chance to review TIP 63?
25 A Very briefly, yes.

1 Q And in this -- first of all, what is the manual designed
2 for?
3 A TIP means treatment improvement protocol, so it's a
4 treatment improvement protocol for the use of buprenorphine.
5 Q Are you aware of any statements inside the TIP protocol
6 that relate to a standard medical model as Dr. Thomas has
7 testified?
8 A I am not aware of that.
9 Q Are you aware of any statements in the TIP protocol that
10 require a physician to individually assess and interact with a
11 patient on every visit?
12 A No.
13 Q Are you aware of any requirements in the TIP protocol that
14 mandate that a physician see a patient with any regularity
15 whatsoever?
16 A I don't believe there is any specific time mandate.
17 Q Is one of the models that you're aware of something that
18 we've referred to as the West Virginia model?
19 A Correct.
20 Q And how did you first learn about the West Virginia model?
21 Well, let me ask you, did you read something related to the
22 West Virginia model?
23 A I did. There was a short article about it by Dr. Sullivan
24 from the West Virginia University, professor there, in the *West*
25 *Virginia Medical Journal*.

1 Q And just briefly, what does the West Virginia model say
2 about how generally physicians should approach the treatment of
3 suboxone patients?
4 A It's an interesting model in that it's the first one I've
5 seen that did not rely on midlevel practitioners. It just
6 spoke in terms of physicians, although the definition of a
7 physician would include midlevels, and so instead of having
8 midlevels see them each time, you've got the treatment -- the
9 counseling with -- the physician involvement with the
10 counseling to a greater or lesser extent, and that's the
11 interaction with the physician in that model, that venue.
12 Q Did that model discuss Dr. Thomas' standard medical model
13 at all?
14 A No.
15 Q Did it ever discuss a requirement that physicians see
16 their patients every single visit?
17 A No, not in the form of a one-on-one encounter. The seeing
18 was done in the form of the counseling sessions.
19 Q And according to this model, what would a patient
20 generally experience on a follow-up visit after they've been
21 stabilized on suboxone medication?
22 A They would experience counseling. They would attend a
23 counseling session, a group counseling session.
24 Q What other employees, according to the West Virginia
25 model, would be involved in the treatment of patients?

1 A Well, they define four roles. One is a physician, the
2 other would be the counselor, the third would be the clinic
3 coordinator, and the fourth would be the medical assistant.
4 And to my mind, the clinical coordinator and medical assistant
5 roles could be rolled into one.
6 Q Did you have an opportunity to review records related to
7 Dr. Aggarwal's practice at RTA?
8 A I did.
9 Q And based on your review of those records, did you get a
10 sense of whether or not RTA was subscribing to the West
11 Virginia model?
12 A That was my impression.
13 Q And what is your opinion on that?
14 A It's a very appropriate way of expanding care to opioid
15 use disorder, medication-assisted treatment, to patients with
16 opioid use disorder.
17 Q Did you see evidence of counselors being employed by RTA
18 to perform a counseling function?
19 A Yes.
20 Q Did you see evidence of medical assistants being used to
21 screen or administer screening tools?
22 A Yes. They had the urinalyses and then the reported level
23 of opioid withdrawal scale.
24 Q Did delegation to those different employees by a physician
25 appear appropriate, based on the West Virginia model?

1 A That's very -- it is the West Virginia model.
2 Q Generally in the medical community is it permissible for a
3 physician to delegate administering a urine drug screen or
4 administering a screening tool such as the ORT or the CAGE?
5 A Yes.
6 Q And in fact, does the article describing the West Virginia
7 model say that it was permissible for physicians to rely on
8 input from other team members in the treatment?
9 A They specifically say that the physician should take into
10 consideration the input from the other team members. They
11 highlight that.
12 Q Now, did the West Virginia model that you reviewed comport
13 with what's required in TIP 63, the SAMHSA guidelines?
14 A I believe it does.
15 Q Let's talk about buprenorphine as a drug generally. The
16 jury's heard some testimony about this already, but can you
17 tell us how buprenorphine, when it's taken by a patient, acts
18 to prevent craving or withdrawal symptoms?
19 A Yeah. First of all, there's -- make it easy, I'll call it
20 the opioid receptor that the various opioids, whether it's
21 buprenorphine or morphine or hydrocodone, oxycodone, Dilaudid,
22 Demerol, binds to. And one of the things that happens if you
23 take opioids for a while and then you stop abruptly, you go
24 into withdrawal, which won't kill you, but you surely feel
25 miserable. It's like a bad flu.

1 What the buprenorphine does is it binds to the opioid
2 receptor and it's got a couple of characteristics. One, it
3 binds to it very strongly, more so than, say, the morphine or
4 the hydrocodone, et cetera. Secondly, it stays bound for a
5 long time. It'll stay there for over a day. So you can have
6 one day or even every other day dosing. And thirdly, it's
7 what's called a partial agonist.
8 Now, if you just take morphine, one dose, get so much
9 relief and double that you get more, double that you get more,
10 double, and so forth, all the way up. With a partial agonist
11 you get initially some relief, some more relief, some more
12 relief, which is why you can use it in patients who have pain
13 issues, but at some point it stops and you give more and you
14 don't get any more relief. So that's where the partial agonist
15 part is as compared to a pure agonist that gives more, more,
16 more.
17 Because it's a partial agonist, it effectively binds to
18 the receptor, stops the cravings. It's really a very good drug
19 for the -- for its use, treatment of -- medication-assisted
20 treatment of opioid use disorder.
21 Q Is it true that buprenorphine and a drug called naloxone
22 are combined to create something called suboxone?
23 A Yeah. The reason for that is that if you shoot up
24 buprenorphine, you get a high from it. If you mix
25 buprenorphine with naloxone, as in suboxone, and you shoot it

1 up, you don't get the high. The naloxone blocks it. So the
2 buprenorphine -- the suboxone formulation is specifically
3 designed to prevent IV abuse of the drug.
4 Q We've heard about a phrase called in-office induction. Is
5 it a requirement for physicians to engage in in-office
6 induction when initially seeing a suboxone patient?
7 A No. And I think very few physicians are doing it now.
8 Q And why is that?
9 A It's time-consuming and it's unnecessary. You know, I
10 find that if I'm going to do an induction, rather than simply
11 starting the patient off on a dose, I simply describe to them
12 what I want to do. First of all, wait until you go into early
13 withdrawal. And most patients who are substance abusers
14 understand what that is. They know what early withdrawal is.
15 Then I tell them to take two pills or two films and wait
16 half an hour and is the withdrawal gone. If it is, you're
17 done. If you still have withdrawal, you can take another one
18 in a half an hour, and keep on doing that until you're done.
19 I give them ten two-milligram pills and the next day they
20 call us and say, it took me eight pills, it took me four pills,
21 whatever the answer is, to have the withdrawal go away, and
22 that -- they do that at home and then we say, great, that's
23 your dose, and we call in the script for them.
24 Q Have you seen a pretty typical dose across the board of
25 patients who suffer from addiction?

1 A Yeah. Eight to 16 is a reasonable one standard deviation
2 either way of the mean.
3 Q Does suboxone have abuse potential?
4 A It has value on the street in that if you are an addict
5 getting your drugs off the street and you can't get the drugs,
6 if you get suboxone, that'll control your craving until you can
7 get your heroin or whatever it is.
8 Q Now, what does the term "maintenance medication" mean?
9 A That is simply to maintain a patient with opioid use
10 disorder with a medication, in this case suboxone, to treat the
11 opioid use disorder.
12 Q Are there other examples of maintenance medications that
13 you've seen in medical practice?
14 A Well, one that I like now is Sublocade, because if I --
15 you just inject the buprenorphine into the abdomen and it gets
16 released over time. And then the patient comes back in a month
17 and gets it again.
18 And then there's other -- there's the abstinence theory
19 we've talked about where you're just taking a pure blocker, so
20 we talked about pure agonists, partial agonists, with
21 abstinence therapy use an antagonist which blocks the receptor
22 and prevents anything, so if you take opioids you don't get any
23 effect from it.
24 Q How does the prescribing of a maintenance medication
25 differ from prescribing something for an acute injury, let's

1 say?
2 A Again, earlier we were talking about treating diabetes or
3 hypertension, hyperlipidemia, where you are just maintaining
4 medicine over time versus you've got a -- let's say an acute
5 infection, you get a course of antibiotics to treat the
6 infection.
7 Q Is more or less physician involvement required in treating
8 patients with maintenance medications than acute issues?
9 A You just need to follow the patient by whatever parameters
10 that particular disease state requires.
11 THE COURT: Mr. Chapman, let's go ahead and take the
12 midafternoon break, if you're at a stopping point.
13 Members of the jury, leave your notebooks by your
14 chairs and please don't discuss the case while you're on the
15 break.
16 Dr. Helm, you can step down. We'll get together in
17 20 minutes.
18 (Jury panel exited courtroom at 3:13 p.m.)
19 (Recess taken.)
20 THE COURT: May we bring the jury in, please.
21 (Jury panel returned to the courtroom at 3:36 p.m.)
22 THE COURT: All right. Mr. Chapman.
23 MR. CHAPMAN: Thank you, Your Honor.
24 BY MR. CHAPMAN:
25 Q Dr. Helm, I'm handing you what's been marked for

1 identification as Defendant's Exhibit 7. Can you tell me what
2 that document is.
3 A My curriculum vitae.
4 Q Can you check and see if it's an accurate version of your
5 curriculum vitae.
6 A Yeah, reasonably so. There have been some new additions,
7 none of which are relevant.
8 Q How many pages is it?
9 A This version is 25. It's up to 27 now.
10 Q Does that display your qualifications and your experience
11 in the field of pain medicine and addiction medicine?
12 A It does.
13 MR. CHAPMAN: Your Honor, at this time move for
14 admission of Defendant's Exhibit 7.
15 THE COURT: Any objection?
16 MS. WAGNER: No objection.
17 MR. STALLINGS: No objection.
18 THE COURT: Without objection, it will be admitted.
19 (Defendant's Exhibit 7 was admitted.)
20 BY MR. CHAPMAN:
21 Q Doctor, previously you discussed the term
22 physician-patient relationship. What is required to establish
23 a physician-patient relationship?
24 A In my mind, it's an interaction with the -- between the
25 physician and the patient. What I do is actually meet with a

1 patient. Oftentimes somebody else will take the history. I
2 personally take the history, review whatever relevant
3 information might be out there, lab tests, imaging tests, and
4 then I do a physical and talk to the patient about what I think
5 the condition is and what ideas I have at that time about
6 treating it.
7 Q Based on your review of the records in this case -- first
8 of all, did you review records related to each patient for each
9 count of the indictment?
10 A I did.
11 Q And did you determine whether or not there was a valid
12 physician-patient relationship established, based on your
13 review of the medical record?
14 A I thought there was.
15 Q Did you also have an opportunity to sit back in court and
16 hear testimony of some patients?
17 A I did.
18 Q Did that testimony help you in determining whether or not
19 there was a physician-patient relationship?
20 A It corroborated that one did exist.
21 Q Is it your opinion that a physician-patient relationship
22 existed for each patient, with each patient, for each count of
23 the indictment?
24 A Yes.
25 Q Why do you believe that to be the case?

1 A Because in this instance Dr. Aggarwal met with the
2 patients, performed an exam, and generated a diagnosis.
3 Q Let's assume for a fact that Dr. Aggarwal did not sit
4 one-on-one with these patients for subsequent visits after they
5 were stabilized on suboxone. Is that appropriate?
6 A Yeah. I mean, for example, if I see a patient and then my
7 nurse practitioner sees a patient for three months and then I
8 see the patient again, even though I haven't seen the patient
9 for three months, I still have a relationship with that
10 patient.
11 Q I want you to assume for the purposes of this question
12 that Dr. Aggarwal, as the testimony has shown, regularly sat in
13 on counseling sessions and was involved in counseling sessions.
14 Does that process further the physician-patient relationship?
15 A That would serve to -- it doesn't need to be continued.
16 It serves to help continue. It doesn't need to be continued.
17 Q So is a physician required to reestablish the
18 physician-patient relationship at every visit?
19 A No. If you look at the coding requirements laid down by
20 the American Medical Association, which is what we use in the
21 states, if you see a patient and then you see them within the
22 next three years, it's considered a progress note, a follow-up
23 visit. It's only after three years that it's a new visit. So
24 by that standard, it's got a shelf life of three years,
25 physician-patient relationship.

1 Q What is required for a diagnosis of opioid use disorder?
2 A Well, probably the best way to do it is using the current
3 DSM-5 criteria which has the number of criteria, and then if
4 the patient has two, it's mild; three to six, I believe it is,
5 it's moderate; and then more than that, it's severe.
6 Q And are there roughly 11 criteria to help you determine
7 whether or not a patient has an opiate use disorder?
8 A There are.
9 Q For a typical patient who is seeking drugs illicitly off
10 the street, would that type of patient typically have an opioid
11 use disorder?
12 A To my mind, they would definitionally have that, even if
13 you didn't have the answers to the specific eleven questions.
14 Q What if that's all you knew is that patient John Smith was
15 going on the street and buying a bag of heroin a day to feed a
16 habit. Would that be enough to satisfy the requirements for
17 opioid use disorder?
18 A In my mind. You might want more answers to answer the
19 questions specifically relating to the DSM-5 criteria, but the
20 fact that they're illicitly getting drugs to use illicitly
21 is -- pretty much makes the case.
22 Q After your review of all the patients listed in the
23 indictment, do you believe that all of the patients had
24 documentation of an active opioid use disorder at the time they
25 were treated at RTA?

1 A They did. I was able to, using the information in the
2 charts, confirm that they all met the DSM-5 criteria, not
3 simply they were getting it illicitly, but they actually met
4 sufficient criteria to diagnose at least mild.
5 Q Now, let's assume that Dr. Aggarwal, six times in six
6 years, went on vacation or left town to engage in continuing
7 medical education and patients received a maintenance dose of
8 the medication while he was out of the office. Would those
9 prescriptions automatically be rendered outside the course of
10 professional practice if they were rendered under
11 Dr. Aggarwal's DEA registration number?
12 A No. There are a number of things that one could
13 potentially do if one were going to be out of town. First of
14 all, the overarching thing is you don't want to stop therapy.
15 Okay, I'm going to be out of town on the 3rd, we're not going
16 to issue a script to people who come in on the 3rd. You want
17 to maintain the therapy and the counseling and the monitoring
18 with the urine drug screens.
19 The one thing you could do is give a verbal order, we're
20 not changing anything, just maintain the medication.
21 Theoretically, you could have the previous script written for a
22 refill, although that would run the risk of the patients don't
23 show up and lose the counseling, which is really a very
24 important component of it, so you wouldn't want to do that. I
25 think the scripts would still be legitimate prescriptions.

1 Q Okay. From time to time is it permissible for physicians
2 to cover for each other and see each other's patients?
3 A Yes.
4 Q And when a physician elects to cover for another
5 physician, is it a requirement that he or she reestablish the
6 physician-patient relationship as if that was a whole new
7 patient?
8 A No. In this case they're practicing in the same practice
9 or covering physician, no, you simply can't. If I'm covering
10 for a physician who's out of the area and I get a phone call
11 from that patient, I can't go and physically establish the
12 relationship. All I can do is deal with the questions raised
13 on the phone call.
14 Q Doctor, does the manner in which a prescription is
15 ultimately communicated to a pharmacy have anything to do with
16 whether or not it was written for a legitimate medical purpose
17 in the course of professional practice?
18 A Those are two different things.
19 Q And why is that?
20 A Well, the question of whether it's a legitimate medical
21 practice relies upon whether or not the relationship has been
22 established and whether the diagnosis is there that warrants
23 the use of that medication.
24 How a prescription is written or transmitted to the
25 pharmacy is a mechanical issue. There may be an error in that

1 way, but if there is an error, then the pharmacist has
2 mechanisms to contact the office and rectify the error.
3 Q Did you happen to review the documentation for the
4 patients listed in the indictment and see that in some cases
5 the notes weren't incredibly detailed for follow-up visits?
6 A Correct.
7 Q Does the fact that notes may not have been incredibly
8 detailed render automatically a prescription outside the course
9 of professional practice and for no legitimate medical purpose?
10 A No. You've already got the diagnosis of opioid use
11 disorder. They're coming in voluntarily to the center for
12 treatment of opioid use, so there is a legitimate medical need
13 for the medication. The relationship's already been
14 established. I don't see it would be outside the scope of
15 practice.
16 Q Is poor documentation alone a reason to render a
17 prescription outside the course of professional practice?
18 A No.
19 Q You've heard Dr. Thomas testify previously that if it is
20 not documented, it didn't happen. Is that true for these
21 purposes?
22 A Well, the other aphorism would be absence of evidence is
23 not evidence of absence. So that point gets argued both ways.
24 Q Was hearing some testimony from patients helpful for you
25 in determining how the practice operated?

1 A Yes.
2 Q Did you see evidence in the files of treatment contracts
3 between the patient and the physicians at RTA?
4 A Yeah. And it was nice because not only was it a contract,
5 but there appeared to be or there was documentation in there
6 that recognized that treatment of opioid use disorder is at a
7 higher level than HIPAA, and they did things like specifically
8 gave information as required to provide information to the
9 pharmacist. The patient has to allow them, in this case RTA,
10 to communicate with the pharmacy. They can't -- RTA can't
11 communicate to the pharmacy without permission from the
12 patient.
13 Q And are those types of agreements helpful in understanding
14 whether a physician-patient relationship was established?
15 A Yes. And also whether or not it's done in the usual
16 course of professional practice.
17 Q Now, did you see evidence of a Medicaid insurance opt-out
18 form that was signed?
19 A There was.
20 Q Does the method and terms of payment have anything to do
21 with whether or not a prescription -- let's assume they paid
22 cash -- have anything to do with whether or not a prescription
23 was issued for a legitimate medical purpose in the course of
24 professional practice or outside the bounds of medical
25 practice?

1 A No.
2 Q Why is that?
3 A Because the issue of a prescription, you can do -- provide
4 information for free, without charging anything, assuming that
5 the other criteria were met, that the patient was a patient of
6 yours with whom you'd established a relationship and the
7 prescription was appropriate for the diagnosis you developed.
8 Q Historically, have you heard of suboxone clinics utilizing
9 a self-pay basis for treatment?
10 A It's pretty much the rule.
11 Q Self-pay as opposed to insurance pay?
12 A Correct.
13 Q What are some of the complications when insurance
14 companies get involved in addiction treatment for patients?
15 A Oh, boy. You run into the issue of prior authorization,
16 delay in treatment, limits on the number of sessions you can
17 have. The insurance companies can be very creative in creating
18 unnecessary barriers to treatment.
19 Q And what happens when a patient suffers from or is the
20 recipient of an unnecessary barrier for treatment?
21 A Then they don't get treatment and they run the risks of
22 that.
23 Q Would that risk include potential relapse?
24 A Potential relapse and worse.
25 Q Speaking of relapse, did you see evidence in the files of

1 patients repeatedly returning to illicit controlled substances
2 while they were treated at RTA?
3 A The patients at RTA, like patients with substance use
4 disorder in general, did have occasional relapse. That's just
5 part of the territory.
6 Q When you say part of the territory, is a relapse by a
7 patient who's been treated with suboxone quite common?
8 A Yes. That's when you work with them to maintain them, to
9 get them back on path.
10 Q Did you see evidence that RTA used the poly group
11 requirement as a way to deal with people who had relapsed?
12 A That's correct, they did.
13 Q What are your thoughts about that policy that was in place
14 at RTA?
15 A Sure. We have somebody is relapsing, you implement a
16 higher level of care, which is what the poly group was. It's
17 more frequent monitoring.
18 Q Was the poly group requirement a sufficient response to
19 render prescriptions to a patient who relapsed in the course of
20 professional practice and for a legitimate medical purpose?
21 A Yes. Giving scripts in that setting was appropriate,
22 maintaining treatment.
23 Q Now, from time to time there was evidence in the patient
24 files of patients testing negative for buprenorphine. Did you
25 see that?

1 A Yes.
2 Q All right. Now, what are some explanations for why a
3 patient may be negative for that drug?
4 A There are a -- you know, the most common -- well, it
5 implies they haven't taken the suboxone.
6 Q Could escalating use be an explanation for that?
7 A They could have overconsumed.
8 Q Is a negative urinalysis test for a patient who's being
9 treated with suboxone, is that something that should cause that
10 patient to be kicked out of the program and no longer
11 prescribed that medication?
12 A No. You would treat that the same way as you would
13 somebody having the presence of an illicit drug. You work with
14 them and explain -- try to get them back on path.
15 Q Would that involve additional counseling?
16 A It would.
17 Q Did you see a patient consent form in the file where
18 patients consent to suboxone treatment or advised of the risks?
19 A Yes.
20 Q Did that form appear appropriate for this type of
21 practice?
22 A Absolutely.
23 Q Is that quite commonplace in practices that use suboxone
24 to treat patients?
25 A And also in any practice that prescribes any type of

1 opioid.
2 Q Did you see evidence that RTA used one pharmacy primarily
3 to fill the controlled substance prescriptions?
4 A Yes.
5 Q And is evidence of the fact that a clinic uses one
6 pharmacy evidence of improper conduct?
7 A No.
8 Q Why is that?
9 A Because it allows for, one, administrative ease, had a
10 good working relationship with the pharmacy. The patients all
11 know where to go and what to expect. You're controlling what's
12 happening with the pharmacy.
13 Q Did you also see evidence of screening forms used, such as
14 a CAGE questionnaire or a drug abuse screening test, the DAST
15 test?
16 A Correct.
17 Q Are those screening tools important for diagnosing
18 patients with substance use disorder?
19 A They're useful tools to assess the patient's condition at
20 the time they take the test.
21 Q Does failing to score that test with a number on the
22 bottom but instead looking for answers render a prescription
23 outside the course of professional practice?
24 A In no way. The tests are ancillary. They're not core, to
25 my mind.

1 Q Does it render the prescription outside the bounds of
2 professional practice?
3 A No.
4 Q Doctor, with the patient history forms that were used, was
5 the information on them sufficient for you to determine whether
6 or not the patient suffered from opioid use disorder?
7 A Again, I was able to make that diagnosis on the specific
8 involved patients based upon the form, the data that was in the
9 chart.
10 Q Now, is it true that, by and large, patients who suffer
11 from opiate use disorder, provided that they don't have any
12 issues that might make treatment more complicated, by and large
13 they qualify for suboxone treatment?
14 A Suboxone, on-label use for suboxone, is opioid use
15 disorder.
16 Q Doctor, we've heard some testimony that in 2015 RTA and
17 Dr. Aggarwal specifically were audited by the DEA. Have you
18 ever been the subject of a DEA audit before?
19 A They came in and asked about suboxone prescribing, yes.
20 Q And did the DEA review any records?
21 A What they did specifically in my case is two agents came
22 in. I took them back to my office. They had a list of
23 patients who had been dispensed suboxone under my X, and wanted
24 me to pull up the records on those patients to see if the
25 information in my records conformed with what they had. It

1 did. They thanked me and left.
2 Q Did they give you a clean bill of health, not indicate
3 there were any problems with your prescribing?
4 A As far as I know. If there was a formal written report, I
5 haven't reviewed it, but we -- when they left, we were on
6 amiable terms.
7 Q When they leave after the DEA audits your practice, does
8 it give you a good feeling that what you're doing is without
9 issue, is compliant?
10 A My personal attitudes towards the DEA is we're on the same
11 side, they and me.
12 Q Doctor, I just want to ask you some final questions
13 related to the specific patients, patient BO in Count 5.
14 A Which exhibit is that?
15 Q Well, we're not looking at one specifically right now, but
16 just overall dealing with patient BO. And I have a copy of
17 your report, if you need it to refresh your memory.
18 Do you believe that BO suffers from substance use
19 disorder?
20 A I went through all -- again, I don't have a specific
21 memory as I sit here specifically of BO. I remember BO was a
22 patient. But yes, I diagnosed everyone with substance use
23 disorder.
24 Q Do you believe that the treatment by Dr. Aggarwal of
25 patient BO was for a legitimate medical purpose in the course

1 of professional practice?
2 A Yes. Opioid substance use disorder.
3 Q Do you believe that Dr. Aggarwal was actually practicing
4 medicine when he was treating BO?
5 A Yes.
6 Q Like to talk specifically now about Count 6, patient SC.
7 Did you see patient SC testify today?
8 A Yes.
9 Q And do you believe that patient SC suffered from opiate
10 use disorder?
11 A Yes.
12 Q And do you believe that the prescriptions issued to SC
13 were within the bounds of medical practice?
14 A Very much so.
15 Q And were they for a legitimate medical purpose?
16 A Yes.
17 Q Like to move now to Count 7, patient JP. Did you review
18 the patient file of patient JP?
19 A I did.
20 Q And do you believe that the prescriptions issued to
21 patient JP were for a legitimate medical purpose?
22 A I do.
23 Q Were those in the course of professional practice?
24 A They were.
25 Q Were those in the bounds of practicing medicine?

1 A Yes.
2 Q Moving on to Count 8, patient DS, did you have an
3 opportunity to review that file?
4 A Yes.
5 Q Do you believe that patient DS suffered from opiate use
6 disorder?
7 A Yes.
8 Q Do you believe that prescriptions issued to DS were within
9 the course of professional practice?
10 A Yes.
11 Q Do you believe that Dr. Aggarwal was practicing medicine
12 when he issued prescriptions to DS?
13 A I do.
14 Q Count 9, patient JB, same questions. Did you review the
15 file?
16 A I did.
17 Q Did you believe that JB suffered from opiate use disorder?
18 A Yes.
19 Q And do you believe the prescriptions issued to JB were in
20 the course of professional practice?
21 A Yes.
22 Q For a legitimate medical purpose?
23 A Yes.
24 Q Moving on to Count 10. As soon as I find my tab, I'm
25 pretty sure you can guess my questions.

1 Patient PN, did you see the wife of patient PN testify
2 today?
3 A I did.
4 Q Do you believe patient PN suffers from opioid use
5 disorder?
6 A He did, yes.
7 Q Did you also review patient PN's medical record?
8 A I did.
9 Q Do you believe the prescriptions were issued in the course
10 of professional practice?
11 A They were.
12 Q For a legitimate medical purpose?
13 A Yes.
14 Q Final count, doctor, patient LD. Did you have a chance to
15 review LD's file?
16 A I did.
17 Q Do you believe that Dr. Aggarwal was practicing medicine
18 when he treated LD?
19 A I do.
20 Q Do you believe he suffered from an opiate use disorder?
21 A I do.
22 Q Were the prescriptions issued for a legitimate medical
23 purpose?
24 A Yes.
25 Q In the course of professional practice?

1 A Yes.
2 Q Was there anything that you reviewed out of all the
3 patient charts that you reviewed that gave you an indication
4 that Dr. Aggarwal had ceased practicing medicine and decided to
5 engage in the practice of drug dealing to his patients?
6 A No.
7 MR. CHAPMAN: May I have one moment, Your Honor.
8 THE COURT: Yes, sir.
9 MR. CHAPMAN: No further questions, Your Honor.
10 Thank you.
11 MR. STALLINGS: No questions, Your Honor.
12 THE COURT: Counsel for the government,
13 cross-examination.
14 CROSS-EXAMINATION
15 BY MS. WAGNER:
16 Q Dr. Helm, how are you?
17 A I'm well. How are you doing?
18 Q Your regular practice is in California, correct?
19 A Correct.
20 Q Is it fair to say that in your absence there, your clinic
21 today, that prescriptions under your DEA registration number
22 and your X number are not being issued by your staff for
23 patients?
24 A That's correct.
25 Q And why not?

1 A Well, they're being issued by nurse practitioners, but we
2 both agree that to do so in my absence would be not in
3 conformity with the law.
4 Q And your nurse practitioner that you speak of is, in his
5 or her own right, a DATA-waived practitioner?
6 A Correct.
7 Q So your nurse practitioner can see patients, evaluate
8 them, and then order a prescription based on his or her medical
9 determination about what is appropriate for a patient?
10 A That's correct.
11 Q What other staff do you employ at your clinic?
12 A At this point we've got some MAs, front office scheduling,
13 and then a clinical coordinator for clinical trails.
14 Q All right. When you say MAs, is that medical assistant?
15 A That's correct.
16 Q And is that person or persons, do they have -- what kind
17 of medical background do they have?
18 A They have medical assistant training, which is not
19 licensed.
20 Q All right. So would you consider them nonmedical
21 laypersons?
22 A Yeah. They're trained, but they're trained for what they
23 do, but they're not licensed to make any medical decisions.
24 Q All right. And would you agree that you and your nurse
25 practitioner, who individually sees patients, what you and your

1 nurse practitioner do is different than what your MAs, your
2 medical assistants who are nonmedical laypersons, can do?
3 A Correct.
4 Q And so you and your nurse practitioner can see patients,
5 make decisions about dosage, make decisions about quantity of
6 medication to go home with them?
7 A Correct.
8 Q And make diagnoses, all of those things?
9 A Yes.
10 Q Do you employ a licensed therapist in your practice?
11 A We used to, and we just had to cut it out because
12 financially it wasn't viable. We did it for years and had to
13 stop.
14 Q Is your model set up -- do you have a group counseling
15 model like the West Virginia model, or is your model different?
16 A No. Our model's different and we -- well, what I
17 personally do is to see patients and follow them up and then
18 refer them out for the counseling. I would add that I have in
19 my office a physician whose practice is solely MAT,
20 medication-assisted treatment, and so we've got that in the
21 office, but that's just someone who's not part of my practice,
22 per se. He's simply using the space.
23 Q So he's doing work similar to your work but -- and in your
24 space, but he's not part of your company?
25 A Well, true, but yes, it's not part of my company. That's

1 not a confusing way of phrasing it. But he is doing
2 medication -- I do medication-assisted treatment, but he's more
3 fully involved with the model with counseling and the
4 practitioners. He has more resources that he is bringing to
5 bear at the time of the encounter than I have.
6 Q In contrast, what you're doing is making referrals to
7 specific other providers?
8 A Correct.
9 Q And in your practice do you take insurance?
10 A Yes, I do.
11 Q And you don't have a cash-only payment policy, correct?
12 A Well, we do see patients that are cash, but we're not
13 solely cash practice.
14 Q But you do not require patients to -- who have insurance
15 to forgo the use of their insurance and pay you cash instead?
16 A Correct.
17 Q Now, I just want to clarify something, but I know what
18 your report says, but the way the testimony came out, I just
19 want to clarify.
20 Did you only review the seven patients related to the
21 charges against Dr. Aggarwal, or did you review all of the
22 medical charts charged in the indictment, including what was
23 charged against Dr. John?
24 A No. I limited it to the patients -- I was provided a
25 broader list and -- but didn't review the patients who I was

1 not tasked to review.
2 Q So you reviewed seven patient charts?
3 A I believe that's correct, yeah.
4 Q And is it true that you didn't review reports of witness
5 interviews?
6 A That is correct. I did not.
7 Q And you didn't review grand jury testimony?
8 A That is correct.
9 Q And we understand you were here in the courtroom this
10 morning and you heard some patients' testimony, correct?
11 A Yeah. That's the totality of it, yeah.
12 Q So you didn't interview patients independently?
13 A That is correct. I did not.
14 Q Now, you don't delegate responsibility for providing
15 medical treatment for your patients to your MAs who don't have
16 medical training, correct?
17 A Correct.
18 Q And is it correct that patients who receive a prescription
19 for suboxone under your DEA registration number are regularly
20 seen by you?
21 A Or the nurse practitioner, one of the two of us.
22 Q All right. If the nurse practitioner sees your patients,
23 is she issuing a prescription under your DEA number or under
24 her X number?
25 A Her. When she prescribes it, it should go under hers.

1 Q Is that also true if you have someone cover for you or you
2 cover for someone else?
3 A Well, generally what happens is she covers for me, or if
4 she goes on vacation, I cover for her, so it's -- that's the
5 totality of the universe that would be doing the covering.
6 Q When you cover for her, you are issuing a prescription
7 under your DEA number, and when she covers for you, she's
8 issuing a prescription under her DEA number?
9 A That's correct. We fax in -- we use -- we fax in the
10 scripts and with -- you know, meeting the DEA's requirements
11 for faxing, and they won't have the -- they won't fax in the
12 suboxone unless you enter in your DEA number. So it comes up
13 and it's her DEA number, I change it and put in mine.
14 Q And do you physically do that, or do you have one of your
15 staff do the actual faxing?
16 A No. It's done within the electronic medical record,
17 because it needs dual authentication.
18 Q And you are the one pushing the button?
19 A That's correct.
20 Q And when you push the button, there's an electronic
21 signature belonging to you that is put on that fax?
22 A Correct.
23 Q Would you agree with me that a doctor cannot delegate
24 decisions about doses of suboxone for their patients?
25 A No question. I think everywhere that's discussed it's

1 clear that only the physician can change the dose.
2 Q And that's true of suboxone and any other controlled
3 substance?
4 A Correct.
5 Q And is it also true that only the physician or nurse
6 practitioner with the DATA-waived -- DATA waiver can make a
7 decision to maintain a dose? That's a medical decision, isn't
8 it?
9 A Yeah.
10 Q And would you also agree that it's the physician who
11 must -- or the DATA-waived practitioner who must decide the
12 quantity of medication to go home with the patient?
13 A Yeah. The quantity's just a function of the dose and the
14 duration of the script, but yes.
15 Q And the jury saw that this morning. That's a decision, a
16 medical decision, by the doctor or DATA-waived practitioner?
17 A It's all integrated together.
18 Q And that's something that you don't let other individuals
19 do for your patients?
20 A Correct.
21 Q And you would agree that if someone other than
22 Dr. Aggarwal was making those decisions for Dr. Aggarwal's
23 patients, that would be outside the bounds of professional
24 medical practice?
25 A If someone else were making it, if someone were making a

1 suggestion and he said, I concur with that, that would be
2 acceptable.
3 Q And if somebody made the decision and communicated the
4 prescription to the pharmacy before the doctor saw his patient
5 or said, yes, I agree with your suggestion, that would be
6 outside the bounds of professional medical practice, wouldn't
7 it?
8 A Only if the physician knew about it. Because the
9 physician, you know, if I were working with -- you know, let's
10 say the West Virginia model, and the patients go to the
11 counseling sessions and the forms get filled out and at the end
12 of the counseling session I sign the reports, I would assume
13 that the -- or if I decide, gee, we've got to lower the dose on
14 this patient from ten to eight, I would assume that would all
15 be transmitted after I had made that delegation or that
16 assessment.
17 Q And if you knew that that prescription was being
18 communicated to the pharmacy while you were still in the group,
19 still signing off on progress notes, you would agree that that
20 would be outside the bounds?
21 A Well, if I signed off on the note, it would be fine.
22 Q Is it your testimony that that prescription can go to the
23 pharmacy before the doctor authorized it?
24 A I thought you said while I was signing off on the notes,
25 implying that the ones were going off that had already been

1 signed off. No. The physician should be approving the script
2 before it goes.
3 Q Now, you've reviewed seven medical charts in this case.
4 Lots of progress notes contained in those medical charts,
5 correct?
6 A Correct.
7 Q And would you agree that there was nothing in the progress
8 notes, not talking about the initial intake, but the progress
9 notes, that indicated why patients were either being maintained
10 on a particular dose or increased -- excuse me, decreased -- we
11 didn't see a lot of increases -- or their quantity was
12 changing? Would you agree that there was no written
13 explanation in the progress notes for why those changes were
14 made or why the decision to maintain was made?
15 A The quantity, the quantity change would be driven just by
16 the duration of the script, as we described earlier. The
17 dosing changes, there were dosing changes that were made or
18 decisions to maintain the dose that were not -- without
19 documentation as to why that decision was made.
20 Q Now, there are some tasks that a physician can delegate to
21 other individuals, correct?
22 A Correct.
23 Q And would one of those be -- well, let me back up.
24 Is it true that a physician should monitor his patients'
25 medication use in the context of a suboxone clinic, or any

1 other controlled substance?
2 A Sure.
3 Q And some of the ways to do that are checking the
4 prescription monitoring program?
5 A Prescription monitoring program, urine drug screens,
6 patient self-report.
7 Q All right. And film counts can be used?
8 A Yeah. The problem with film counts is that if somebody
9 wants to game it, it's easy to borrow film, so I put less
10 weight on that.
11 Q But it's out there. It's a way to monitor.
12 A You're correct.
13 Q And some of those things, like the checking the
14 prescription monitoring program, doing film counts, if they're
15 going to be done, those can be delegated to other individuals?
16 A I'd say sort of, in that -- I don't want to get too
17 confused here, but in California there are limits as to who can
18 check the prescription drug monitoring program. But let me
19 just say generally, yes, I agree with you, aside from technical
20 issues like that.
21 Q So you yourself, you check your own -- your patients'
22 prescription monitoring information yourself?
23 A I'm very fortunate. My nurse practitioner does it. I
24 just look at what she's already pulled up.
25 Q She pulls it up and you look at it?

1 A Correct.
2 Q Do those always get printed and put in the medical charts?
3 A They do get put in the medical charts.
4 Q At a minimum, you would make a reflection, a notation, in
5 the chart that it had been checked?
6 A We used to just make a notation, and then we decided it
7 would be better to document that it was in there.
8 Q And so is it fair to say that, at a minimum, the
9 information -- if you're not yourself checking it, the
10 information is being communicated to you by someone who's been
11 delegated with that task?
12 A Correct.
13 Q Now, urine drug screens, do you use those in your
14 practice?
15 A Very important.
16 Q And who orders the urine drug screen?
17 A Well, if the staff sees -- we do it about every six
18 months, not necessarily on clockwork, but more or less, and if
19 they see it's been about six months, they will get the urine
20 drug screen before the patient comes in or before I see the
21 patient.
22 Q So they're collecting -- they're sort of administering the
23 test?
24 A Unless I see the patient and say, gee, I want to get a
25 urine drug screen.

1 Q And what kind of test do you use? Do you use like the
2 dipstick? Do you send them to the lab?
3 A Both. I mean, my personal belief is that a lot of money's
4 been spent on urine drug screens. If the cup, the
5 point-of-care test, the amino assay, is appropriate, I'm happy
6 with that, we're done. If there are questions, then you send
7 it out to the lab for confirmation.
8 Q And in either instance, it's you who is looking at the
9 results?
10 A I or -- well, I don't see the results until later.
11 Q But you see them.
12 A I will ultimately see -- I'm sorry. I don't mean to talk
13 over you. Or my nurse practitioner.
14 Q You or the person in your office who has authority to
15 prescribe suboxone?
16 A Correct.
17 Q And are you aware that there's been testimony in this case
18 that Dr. Aggarwal did not interpret the test results that came
19 from the lab?
20 A I was confused by that, because I saw that test results
21 being recorded. At least it looked to me like there were
22 probably point-of-care amino assay testing that was recorded
23 and it seemed interpretable to me, so I'm not sure where the
24 statement came that he wasn't reviewing them.
25 Q Well, if I told you that the urine drug screens were sent

1 to a lab for quantitative tests and that those results are
2 what's recorded in the urine drug screen log and that they were
3 recorded by somebody else, would that cause you concern?
4 A No. It's just a clerical entering of data, because it was
5 put onto a sheet that had the urine drug screens over time.
6 And I think one was displayed earlier this morning. And that
7 looked to me like results of a urine drug screen. I'm not sure
8 what more information one would want or need.
9 Q Well, let me ask you this: Is it your testimony that a
10 person who is trained simply to collect urine can also
11 interpret the results from a quantitative drug screen result?
12 MR. CHAPMAN: Objection; asked and answered.
13 THE COURT: Overruled.
14 A No. I don't think that's what happened in this case. I
15 think the -- it was collected and then results from wherever
16 the results were from were entered into the chart, which would
17 have been seen by the physicians.
18 Q Well, what I'm asking is the actual results that came from
19 the lab, in this case it was IntegraLab. The testimony is
20 those weren't interpreted by the doctors, that they were
21 interpreted by the person who collected the urine, sometimes by
22 the therapist, and sometimes by other nonmedical laypersons.
23 If that were true, and that's for the jury to decide, but if
24 that were true, is that appropriate?
25 A I guess where I'm getting confused -- and I don't want to

1 be argumentative -- is what's the definition of interpreted.
2 What I saw were those charts that had the grid and on the top
3 was buprenorphine and then a variety of other illicit drugs,
4 and then on the Y axis the dates, and plus and minuses entered
5 as to what the results were.
6 Q Is it sufficient for a physician to rely on a log like
7 that instead of looking at the actual results that came from
8 the lab, the actual piece of paper that's returned?
9 A Yeah, I think the log is fine. It's binary, is the result
10 positive or not. Unless there's some definition of positive
11 that I'm not appreciating here, are there some cases where it
12 was felt to be ambiguous or the data entered in the log was
13 inaccurate in some way.
14 Q And if the testimony -- well, the testimony in this case
15 has also been that the doctors reviewed progress notes one at a
16 time and that they did not review those urine drug screen
17 results. If that were the case, is that an appropriate level
18 of assessment by a physician of their patients' compliance with
19 their medication?
20 A Well, the results of the urine drug screen need to enter
21 into the care at some point; at the latest at the next visit.
22 Q So they should have been looking, at a minimum, at the
23 urine drug screen log?
24 A Well, I don't know if they weren't. I mean, they're in
25 the chart, so presumably my position generally is if

1 something's in the chart, then it's in the chart and it's hard
2 to say it's not in the chart.
3 Q Well, okay.
4 And to the extent that a physician delegates another
5 task -- a task to another person, is it fair that the doctor
6 has an obligation to elicit the information or confirmation
7 those tasks have been done?
8 A Well, that's an interesting question. You would hope that
9 if you're asking people to do something that it gets done.
10 Unrelated to this case, I volunteer in my practice that's an
11 ongoing problem. I guess the answer would be, an ideal world,
12 sure, you want to know what is happening. The question is how
13 do you know that it's not happening, would be the problem.
14 Q So you're going to go and ask the person, was this done.
15 They don't come to you with the results. You're going to go
16 ask them for the results or confirmation that it was done?
17 A Sometimes I might. The reality is that I freely admit I
18 get pulled many ways and I might well forget. I don't know
19 what the specific is in this case, but I'm saying that in my
20 personal experience the risk is always there, just because
21 you're relying on people to do things and they don't always do
22 it.
23 Q If it's information that you need to make a medical
24 determination about what prescription your patient should get,
25 what dose, what quantity, you're going to get that information?

1 A It should be in the chart.
2 Q Now, are you aware that the testimony in this case is that
3 Dr. Aggarwal was not interacting with his patients on an
4 individual basis during the group counseling sessions?
5 A Correct.
6 Q And would you agree with me that if Dr. Aggarwal was not
7 doing that and prescriptions were going to those patients, that
8 would be outside the bounds of professional medical practice?
9 A No. And I think one of the beauties -- one of the issues
10 that you need to face when you're trying to multiply access to
11 buprenorphine for opioid use disorder is how do you get the
12 interaction with a licensed provider. And in many places
13 they're using the midlevels.
14 What it seems that Dr. Sullivan's come up with in the West
15 Virginia model is you have the physician, however that's
16 defined, it could be a nurse practitioner or PA, be present at
17 the group sessions. And as I understand what Dr. Sullivan's
18 describing, that is sufficient. The doctor is there in the
19 group sessions.
20 Q Well, let's talk about the West Virginia model.
21 You understand that in the West Virginia model the
22 prescribing physician is present in the group every time that a
23 prescription is issued to a patient, and that every time the
24 physician is leading the group, he's asking his patients one by
25 one, how are you doing on your medication, what's going on with

1 your progress, how are you doing in your recovery, what's going
2 on in your life?
3 A That may be. If that is the case, it wasn't described in
4 the *West Virginia Medical Journal* article that Dr. Sullivan
5 wrote.
6 Q And is that the article about telemedicine, or is that a
7 different article?
8 A It's one specifically about the West Virginia model for
9 opioid -- telemedicine is another whole issue that I don't
10 think we want to get into.
11 Q I'm just trying to figure out which article you're
12 referring to.
13 A Yeah, he wrote one in, again, the *West Virginia Medical*
14 *Journal* -- medical society journal just describing the problem
15 of opioid use disorder, what buprenorphine is, and then going
16 on to describe this model with the four roles of physician, the
17 counselor, the clinic coordinator, and then the assistant.
18 Q All right. Are you aware that in Dr. Sullivan's West
19 Virginia model that the prescribing physician, along with the
20 other team members that you just described, meet for 30 minutes
21 before the group counseling session to talk about patients'
22 medication and progress?
23 MR. CHAPMAN: Objection, Your Honor; facts not in
24 evidence.
25 THE COURT: I think we've had questions about the

1 West Virginia model during the afternoon, so I'll permit it.
2 A That was not contained in the article he wrote in the *West*
3 *Virginia Medical Journal*, medical society journal.
4 Q All right. And are you aware that patients -- at least
5 patients in the early recovery are required to attend a
6 60-minute group counseling session every week?
7 A They did -- the weekly -- the weekly visits at the start
8 was included in the article.
9 Q And that basically lasts for the first three months of
10 treatment?
11 A Something on that order.
12 Q And patients are also, in that first three months,
13 required to attend individual counseling outside of the group
14 counseling session, correct?
15 A I didn't get that from the article in the West Virginia
16 Medical Society journal.
17 Q All right. And do you also understand the West Virginia
18 model -- in the West Virginia model, patients, particularly in
19 that early three-month period, are required to attend four peer
20 recovery community groups like AA or NA meetings a week during
21 that -- the initial time frame?
22 A I think that was in there.
23 Q All right. And all of those things are very different
24 than what was going on at Redirections, true?
25 A There was no AA, NA log that I saw. You know, again, the

1 information you provided regarding the pre-sessions was not
2 available to me, and then finally the -- what was the other?
3 Q The one hour?
4 A Yeah, the one hour, the one-on-one, how are you doing,
5 that wasn't present in that article. What was present was just
6 that the decision as to the dosing is a collaborative --
7 ultimately it's the physician's, but the physician is urged to
8 collaborate with the other members of the team in coming to
9 that decision.
10 Q And you understand from your review of this case that the
11 physicians were not always in the group session at
12 Redirections?
13 A My understanding is that they were, I would say -- well,
14 almost always in the sessions. There were some times when I
15 understand that the physicians were in an adjacent room, and
16 then we got the couple of times when you went out for CME or
17 vacation, whatever it is.
18 Q You talked a little bit about induction in your practice
19 and the fact that in-office induction is really not what the
20 consensus requires anymore, true?
21 A That's correct.
22 Q All right. And for you, you give a dose, you send the
23 patient home, or you send them home with a dose and talk to
24 them the next day and the next day?
25 A Yeah. You know, it's a one-day trial. Sometimes I don't

1 even induce. I just simply start on an arbitrary dose.
2 Q But you check on them?
3 A Yeah.
4 Q And they come back in a week?
5 A Correct.
6 Q And are you aware from the materials you reviewed that
7 patients who started at Redirections were given either a two-
8 or three-week dose and then came back after that time frame?
9 A Yeah. I don't have any problem with that.
10 Q You don't do it, though?
11 A Sometimes I'll see them back in four weeks.
12 Q A new patient?
13 A Yeah.
14 Q Now, did you review the undercover audio that took place
15 in this case with respect to Dr. Aggarwal?
16 A No.
17 Q Would you agree with me that during an intake it's
18 important for a physician to find out what drug an individual
19 has been using or is addicted to?
20 A Sure. I thought that was included in the intake forms the
21 clients filled out.
22 Q And would you agree that it's important to find out what
23 amount of drug the person used?
24 A I think that was at least asked on the intake form.
25 Q And when is the last time the patient used?

1 A That's also on the intake form.
2 Q And how are those things important to the process of
3 either inducting a patient or figuring out what dose to put
4 them on?
5 A Well, first of all, trying to find out what drugs they're
6 using so you know what you're dealing with and the extent
7 they're using. And there's also the question, are they
8 currently in withdrawal.
9 Q And you were asked about the doctor-patient relationship
10 and when you have to reestablish that relationship frequently?
11 A Correct.
12 Q Now, when you have a patient who then becomes your nurse
13 practitioner's patient, before you prescribe to that patient
14 again, you renew that doctor-patient relationship, don't you?
15 A Well, I -- you know, in my practice I see the patient.
16 Q Every time you order a prescription for them?
17 A Yeah.
18 Q Now, you were asked about whether -- I think about ways
19 that a prescription to maintain medication can be done in your
20 absence, basically. And you indicated that there could be a
21 verbal order to maintain or you could write for a refill.
22 A Correct.
23 Q And you would agree that in this case there was no writing
24 for refills?
25 A Correct.

1 Q Was there any reflection in any of the medical charts you
2 reviewed, including the ones -- the progress notes for the
3 individual counts that are charged against Dr. Aggarwal, was
4 there any reflection in the medical chart that before he went
5 on vacation or before he went to his training to learn more
6 about addiction medicine that he made a verbal order for his
7 patient to continue on a certain medication or to get a
8 different medication?
9 A No. It's not documented either way.
10 Q Now, you went through some of the -- or Mr. Chapman took
11 you through some of the papers that were in the medical charts,
12 treatment contract, medical insurance forms, those things, and
13 I think you said it was nice, what you saw was nice.
14 A The forms were appropriate.
15 Q Okay. They looked nice, correct?
16 A That too.
17 Q Now, you were also asked about whether the fact that a
18 patient -- excuse me. The fact that patient charts were not --
19 I think the phrase was incredibly detailed, does not render the
20 prescriptions automatically outside the bounds?
21 A Correct.
22 Q Correct? Okay.
23 Would you agree that the fact that the progress notes,
24 time after time after time, were not incredibly detailed or
25 detailed at all would be just more than just poor

1 documentation?
2 A No, I wouldn't, because again, you've got the diagnosis of
3 opioid use disorder. You're maintaining the patient with the
4 buprenorphine, the suboxone. You're getting urine drug
5 screens. The assessment of withdrawal is being made. The
6 patient's attending a group session where the physician is
7 present. So I would say that it is in the course of
8 professional practice.
9 Q You were asked about whether the method and terms of
10 payment and the fact that Redirections didn't accept insurance
11 had anything to do with prescriptions being outside the bounds.
12 Do you remember that?
13 A Correct.
14 Q I think what you answered about it was because they could
15 provide it for free.
16 A Well, even if it were provided for free, it still wouldn't
17 be outside the bounds. The payment manner doesn't matter. The
18 payment method doesn't matter. It's still -- you know, do you
19 have a relationship with the patient and is there medical
20 indication for the prescription.
21 Q And you'd agree with me that Redirections wasn't providing
22 free medical treatment for their patients?
23 A That wasn't my implication.
24 Q And are you aware that Dr. Aggarwal was getting paid $72
25 for every patient who came to Redirections and received a

1 prescription?
2 A Correct.
3 Q And I think you -- just to stay on the insurance piece for
4 a minute, I think, unless I misheard you, you said that
5 self-pay was sort of the rule in suboxone clinics.
6 A Correct. It is not -- in my experience, most
7 medication-assisted treatment is self-pay, except for the
8 suboxone clinics. If you're talking about the residential
9 detox facilities.
10 Q Inpatient?
11 A Inpatient would be one. Another would be residential
12 detox facilities, followed by sober living homes. Those are
13 all driven by insurance. Medication-assisted treatment is
14 primarily cash.
15 Q All right. You don't charge -- you don't have a cash-only
16 policy?
17 A If patients have insurance for the suboxone for opioid use
18 disorder, I charge that. If not, we do it under cash.
19 Q And are you aware of what Dr. Sullivan's program, the West
20 Virginia model, does?
21 A Not financially, no. He didn't go over that in that
22 article.
23 Q Would you be surprised to learn that they accepted
24 insurance?
25 A No. Sounds like he's doing what I would do.

1 Q Now, you were asked about relapses being quite common.
2 You would agree that you've got really a vulnerable population
3 of individuals who are seeking help for addiction, true?
4 A Correct.
5 Q And I think the question was posed that when someone has
6 relapse, they're taking other opioids, or if they show up with
7 a negative buprenorphine screen, that you do not just discharge
8 them. The doctor works with them, correct?
9 A That's correct. And that's true with addiction treatment
10 across the board.
11 Q Now, you were asked a bit about Dr. Thomas' testimony this
12 morning with respect to the standard medical model. A lot of
13 what he was talking about are things that you incorporate in
14 your medical practice, correct? You have an ongoing
15 relationship with your patients, you talk to them, you ask them
16 what's going on in their -- with their medication, with their
17 treatment, true?
18 A Correct. I would say that standard medical model is a new
19 phrase for me.
20 Q All right. But the principles that are embodied by that
21 standard medical model are, in fact, principles that you, as a
22 physician treating patients either with suboxone or with other
23 controlled substances, utilize every day?
24 A Yeah. Assuming that's what he means by it, but what
25 you're describing is what I do.

1 Q Would you agree with me -- you were asked early on in your
2 testimony, would you agree that DATA 2000 is not a standard of
3 care?
4 A Well, yeah, it's a guideline and guidelines -- most
5 guidelines -- wait, DATA 2000.
6 Q Yes.
7 A DATA 2000 is a law.
8 Q Right.
9 A I'm sorry. I was thanking of the TIP.
10 Q Not the TIPs, DATA 2000. Is that a standard of care or
11 something else?
12 A It's a law.
13 Q What does it authorize?
14 A It allows the office-based treatment of opioid use
15 disorder.
16 Q And I think, based on what you testified about standard of
17 care, you would agree with me that it is below the standard of
18 care to delegate to a nonDATA-waived practitioner the medical
19 decision-making about dose and quantity of medication?
20 A Yeah. As we said earlier, dosing clearly is the
21 responsibility of the physician and only the physician.
22 Q And would you agree with me that not providing any medical
23 treatment to patients who are receiving prescriptions is below
24 the standard of care?
25 A I'm not sure what you mean when you say not providing any

1 medical treatment.
2 Q Well, sitting in a room and not interacting with your
3 patients at all, what medical care is being provided there?
4 A Oh, no. I think -- what happens with medication-assisted
5 treatment is that you first control the withdrawal and the
6 craving and create a situation in which the patient can undergo
7 the counseling. And the major components on the baseline
8 are -- foundation of the suboxone treatment are the long-term
9 counseling that allows the patient to hopefully recover and
10 become a functional member of society.
11 So I think that in that setting the necessary amount of
12 medical care is being provided. You're not providing -- you're
13 not serving as the patient's primary care physician or dealing
14 with issues other than the opioid use disorder. So you do have
15 a chance to observe the patient and make sure that they're not
16 obviously impaired in some way.
17 Q Now, I think you indicated in your report with respect to
18 all seven of Dr. Aggarwal's patient charts that they reflected
19 an assessment of progress towards treatment goals. Do you
20 recall writing that?
21 A Yes.
22 Q Okay. Would you agree with me that in the medical -- in
23 the progress notes there was nothing written to indicate the
24 patients' progress towards treatment goals?
25 A The notes were very limited. You're correct.

1 Q Would you agree with me that there was really no
2 articulation of the patients' treatment goals beyond the
3 initial intake in the medical charts?
4 A There was -- indirect proxies, I would say, in terms of
5 the information was there in terms of the withdrawal ratings
6 and the UDS, but there was no explicit statement of achievement
7 toward any specific delineated goal.
8 Q And I think we've already established that there was
9 nothing in the progress notes that suggested to anyone what
10 Dr. Aggarwal wanted his patients to receive as far as
11 treatment, dose, or quantity of prescription?
12 A Other than the occasional changes in prescription -- in
13 dosing, when that occurred.
14 Q And is it your belief that those changes in dose were made
15 by the doctor?
16 A They had to have been.
17 Q If the testimony was that when patients checked in, the
18 dose of medication was filled in by nonmedical laypersons, or a
19 licensed therapist who herself was not and could not have been
20 a DATA-waived practitioner, would that change your view?
21 A Well, I would imagine that what they were putting in was
22 the dose the patient was on when they came in, not a change in
23 the dose. You know, they are competent to record current
24 medications, MAs do that routinely, but they can't record --
25 they can't make the determination to change the dose.

1 Q And so if that was done, that would have been outside the
2 bounds of professional medical practice?
3 A That being changing the dose?
4 Q Yes.
5 A The dose change can only be done by the physician.
6 Q And that includes quantity changes, too, correct?
7 A Well, if there's a decision, for example, to put somebody
8 into a higher level care, the poly dose, and you're going to
9 see them back in two weeks instead of four weeks, then the dose
10 is unchanged. It's just a shorter duration. So that to me
11 seems like just a mechanical process.
12 Q Isn't it the practitioner's decision to decide how
13 frequently the patient has to come back and get a new
14 prescription?
15 A If the patient meets -- well, if the patient meets the
16 criteria for going into the poly group and being seen more
17 frequently, that would strike me as being -- that's pretty
18 mechanical. Either you meet the criteria or you don't. That's
19 implementation of a protocol which is presumably laid down by
20 the physicians.
21 Q Are you aware that the SAMHSA guidelines explicitly state
22 that physicians must decide dosage, quantity of medication to
23 take home, and those things can't be delegated?
24 A Correct.
25 Q Now, you were asked about benzodiazepines and suboxone.

1 And you, in your practice, sometimes prescribe a patient both
2 suboxone and benzodiazepine when you can't get someone off of
3 the benzo?
4 A I won't prescribe the benzo, but if somebody else is
5 getting a benzo and they can't get off it, suboxone would be
6 the opioid of choice.
7 Q You get the records for the patient who's getting the
8 benzodiazepine from the other physician, correct?
9 A Well, I get it from our prescription drug monitoring
10 program.
11 Q Now, even though you will still prescribe a patient using
12 a benzodiazepine with suboxone, you monitor that patient very
13 closely, don't you?
14 MR. CHAPMAN: Your Honor, objection to relevance.
15 There's no patients in the counts of the indictment for
16 Dr. Aggarwal that were prescribed benzodiazepines with
17 suboxone.
18 MS. WAGNER: Mr. Chapman asked Dr. Helm very specific
19 questions about --
20 THE COURT: Mixing the two. Overruled.
21 BY MS. WAGNER:
22 Q You agree that you monitor those patients closely?
23 A Yes, I monitor all patients closely, but --
24 Q And there's a danger with mixing suboxone and benzos,
25 because both can repress respiratory function and other

1 functions of the body?
2 A There's less danger with suboxone and benzos than there is
3 with the pure mu agonists. There were deaths associated with
4 benzodiazepines when the first studies were done in France on
5 suboxone. But those deaths occurred in patients who were
6 injecting high doses of benzodiazepines IV, which is not the --
7 presumably not the case in the patients we are seeing.
8 And as I mentioned earlier, the DEA specifically said that
9 you didn't need to wean patients on opioid treatment therapy
10 off of the benzodiazepines because of the barriers to response
11 to therapy are greater than -- or the risks from their not
12 getting therapy are greater than the risk of concomitant use of
13 the two drugs.
14 Q Still, there's a risk?
15 A There's always a risk. I see patients who overdose, if
16 they're taking medicines regularly, they take too many
17 antihistamines and that's what tips them over.
18 Q And you testified that sometimes patients need a higher
19 level of care than a suboxone clinic can offer?
20 A That can be. It's problematic in that that higher level
21 of care may not exist or be accessible.
22 Q But it's fair to say that suboxone's not a
23 one-size-fits-all drug and that you have to have individualized
24 treatment programs -- or treatment plans for patients?
25 A Sure.

1 Q Would you agree with me that the medical charts of the
2 seven patients that you reviewed reflected -- the charts
3 themselves -- only one interaction or -- other than one patient
4 who had two interactions, but only one or two interactions
5 between the patient and the doctor?
6 A Well, no. I mean, Dr. Aggarwal was signing the follow-up
7 forms, the biweekly or whatever the time period was visits.
8 Q Did those progress notes reflect an individual interaction
9 with Dr. Aggarwal and his patients?
10 A No. We've already established that the documentation was
11 scanty.
12 MS. WAGNER: May I have a moment, Your Honor.
13 Those are all the questions I have for the witness.
14 THE COURT: Thank you.
15 Mr. Chapman.
16 MR. CHAPMAN: Thank you, Your Honor.
17 REDIRECT EXAMINATION
18 BY MR. CHAPMAN:
19 Q Doctor, in your review of charts did you determine that
20 Dr. Aggarwal was practicing medicine for all patients listed in
21 the indictment?
22 A I thought he was.
23 Q Did the fact that there may be some differences between
24 RTA and the West Virginia model ever lead you to the conclusion
25 that RTA was not practicing medicine?

1 A No.
2 Q Does the fact that RTA accepted cash ever lead you to the
3 conclusion that RTA was not practicing medicine?
4 A No, not in the slightest.
5 Q Did the fact that documentation in some cases may have
6 been not very complete lead you to the conclusion that
7 Dr. Aggarwal wasn't practicing medicine at RTA?
8 A No. That's a documentation issue, which is totally
9 different.
10 Q Does the fact that ancillary staff or auxillary personnel
11 reviewed the actual urine screen report ever lead you to the
12 conclusion that Dr. Aggarwal wasn't practicing medicine at RTA?
13 A Yeah. I don't understand the criticisms about the urine
14 drug screen.
15 Q Is it true that those issues discussed by Ms. Wagner are
16 just minor deviations from some of the practices that other
17 models have used?
18 A That was my interpretation.
19 Q Okay. Do any of those issues have anything to do with
20 whether or not a prescription is issued for a legitimate
21 medical purpose in the course of professional practice?
22 A No, I don't believe they do.
23 Q Does the fact that Dr. Aggarwal may have occasionally not
24 been there when prescriptions were issued render those
25 prescriptions issued outside the course of professional

1 practice for other than a legitimate medical purpose?
2 A No. Again, I don't know that he didn't offer a verbal,
3 continue -- I'm going to be gone next week, continue the meds,
4 which would have been sufficient to meet that criterion.
5 Q Did you see any evidence in the file -- in all the patient
6 files that you reviewed that suggested that Dr. Aggarwal
7 delegated the ability to change dosages to other members of the
8 staff at RTA?
9 A No.
10 MR. CHAPMAN: Thank you, Your Honor. No further
11 questions. Thank you, Doctor.
12 THE COURT: Thank you.
13 MR. STALLINGS: No questions, Your Honor. Thank you.
14 MS. WAGNER: Nothing further, Your Honor.
15 THE COURT: Thank you very much, Doctor, for
16 testifying today here. You may step down.
17 All right. Who is the next witness to be?
18 MR. NOGAY: Your Honor, it's our handwriting expert,
19 Vickie Willard. She's going to take a while.
20 THE COURT: Let's go ahead then, members of the jury,
21 and stop for the day, given that information.
22 Please leave your notebooks by your chairs. Please
23 don't discuss the case among yourselves or with anybody or to
24 permit anybody to discuss the case with you, and we'll see you
25 tomorrow morning at 8:30 a.m. Thank you very much for your

1 attention today.
2 And I'll meet with counsel immediately after the jury
3 is excused.
4 (Jury panel exited courtroom at 4:52 p.m.)
5 THE COURT: All right. Thank you. Who will be
6 testifying tomorrow?
7 MR. NOGAY: Your Honor, tomorrow Dr. Aggarwal will
8 call Vickie Willard, our handwriting expert; Justin Reed, who
9 is a former patient. Phil Carroll was subpoenaed for today.
10 He did not appear. He might appear tomorrow. He's a former
11 patient, will be very brief. Then we have Diana Sikora Anile,
12 who is the pharmacist, and we have relayed -- related to Your
13 Honor the issues that might arise in her testimony. And then
14 Clyde Woody Miller would be testifying briefly about how he
15 drafted medical charts that have already been stipulated to.
16 And then we expect to call Dr. Aggarwal as our final witness.
17 THE COURT: With respect to Mr. Miller, is he just
18 going to be introducing a summary exhibit under Rule 1006?
19 MR. NOGAY: Yes, Your Honor. He compiled it and it
20 has some red and blue lines on it. He's just going to explain
21 how he did that. And as I said, they've already been
22 stipulated to for authenticity and admissibility, because
23 Dr. Aggarwal will be using them in his testimony.
24 THE COURT: Oh, all right.
25 And will that be the final witness -- will those be

1 the witnesses for the defendant Aggarwal's case?

2 MR. NOGAY: Yes, Your Honor. We've released from

3 subpoena -- I sent an email yesterday to the government about

4 this. We released Dr. John Capito and Mandy Dietrich from

5 their subpoenas.

6 THE COURT: And if we were to complete those

7 witnesses, Dr. John prepared to start up tomorrow?

8 MR. STALLINGS: Yes, Your Honor. Our first witness

9 would be Lori Bernardi. Our second witness would likely be

10 Lori Baltich.

11 I want to follow up on something Mr. Nogay mentioned.

12 We would also and have under subpoena John Boyd from Anile

13 Pharmacy, and as the Court knows, his lawyer has asserted he

14 will assert the Fifth Amendment rather than testify. We've

15 communicated to his lawyer that we're requesting that he appear

16 at 8:15 tomorrow morning, so that if the Court is inclined, the

17 Court could hear the basis for that witness' invocation of the

18 Fifth outside of the presence of the jury and make a

19 determination, as we've suggested, that he is unavailable to

20 testify. And if that's the case, we wouldn't call John Boyd.

21 We would call our investigator, Keri Bozich, to testify about

22 John Boyd's prior statements. I think that would probably take

23 us through the conclusion of the day tomorrow.

24 THE COURT: All right. Can you give me the names of

25 those witnesses again because -- Lori Bernardi.

1 MR. STALLINGS: Yes, Your Honor.
2 THE COURT: And then?
3 MR. STALLINGS: Lori Baltich, then John Boyd,
4 potentially.
5 THE COURT: And John Boyd.
6 MR. STALLINGS: And if unavailable, the investigator,
7 Keri Bozich. And Your Honor, I don't expect us to get to
8 witnesses beyond that, but if we did, Dr. John would
9 potentially testify, and Dr. Murphy, the expert, would
10 potentially testify.
11 MR. COGAR: I'm sorry. What was the last thing you
12 said?
13 MR. NOGAY: Dr. Murphy.
14 MR. STALLINGS: Like I said, I don't expect us to get
15 to them, but if so, we would have them available to bring in,
16 if necessary.
17 MR. COGAR: Thank you.
18 THE COURT: Is Dr. Chavez designated as an expert for
19 Dr. John?
20 MR. STALLINGS: He is, Your Honor, and to be frank,
21 we haven't made the decision about whether to call him to rebut
22 or not.
23 THE COURT: I just wanted to refresh my memory as to
24 who he was listed by. Very well. If the witness is permitted
25 to assert the Fifth Amendment, does the government have a

1 position on using another witness by declaring him unavailable?
2 MR. COGAR: Obviously, I want to wait to see what the
3 basis for it is and also the statement -- I don't think I'm
4 aware of the specific statement that has been mentioned about
5 admitting in the event that Mr. Boyd or Dr. Boyd is declared
6 unavailable. So I'd like to assess that first, before we take
7 a position, Your Honor.
8 THE COURT: As a general proposition, is that
9 permissible?
10 MR. COGAR: I think in some circumstances, yes.
11 THE COURT: What would those be?
12 MR. NOGAY: 804.
13 THE COURT: Assert Fifth Amendment appropriately,
14 would that be a circumstance?
15 MR. COGAR: Yes, Judge. There's a -- there's a
16 condition in 804(A)(2) -- or (A)(1), excuse me, which is an
17 exemption, unavailability due to the application of privilege.
18 And so but the other exceptions relate to the type of statement
19 that can come in, so again, I'd like to just evaluate that
20 before we take a position.
21 THE COURT: I just want to be able to think about it
22 this evening.
23 MR. NOGAY: Your Honor, would you prefer that both of
24 the pharmacists come in first that might assert the Fifth?
25 Ms. Potter, Shari Potter, is representing Diane Sikora now, and

1 she asked if we could do that first because she had a speaking
2 engagement in the afternoon.
3 THE COURT: I have no problem with your bringing both
4 of them in, if you want to accommodate.
5 MR. NOGAY: We'll do that first thing in the morning.
6 THE COURT: And accommodate counsel for the witness.
7 MR. NOGAY: That's fine. Thank you, Your Honor.
8 Appreciate it.
9 THE COURT: Okay. Thank you.
10 (Proceedings adjourned at 5:00 p.m.)
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1 CERTIFICATE

2 I, Cindy L. Knecht, Registered Professional Reporter
3 and Official Reporter of the United States District Court for
4 the Northern District of West Virginia, do hereby certify that
5 the foregoing is a true and correct transcript of the
6 proceedings had in the above-styled action on June 10, 2019, as
7 reported by me in stenotypy.
8 I certify that the transcript fees and format comply
9 with those prescribed by the Court and the Judicial Conference
10 of the United States.
11 Given under my hand this 26th day of July 2019.
12 /s/Cindy L. Knecht

13 Cindy L. Knecht, RMR/CRR
14 Official reporter, United States
District Court for the Northern
District of West Virginia
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