

EXHIBIT 69

SUBMITTED UNDER SEAL

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Volume I
Pages 1 to 222
Exhibits 1 - 18

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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BRIANNA BOE, et al.,
Plaintiffs,
UNITED STATES OF AMERICA,
Intervenor Plaintiff,

vs.

HON. STEVE MARSHALL, in his
official capacity as Attorney
General of the State of
Alabama, et al.
Defendants.

Civil Action No.
2:22-cv-184-LCB

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CONFIDENTIAL DEPOSITION OF JENIFER
LIGHTDALE, M.D., a witness called on behalf of the
Defendants, taken pursuant to the Federal Rules of
Civil Procedure before Carol H. Kusinitz, Registered
Professional Reporter and Notary Public in and for
the Commonwealth of Massachusetts, at the Offices of
Holland & Knight, LLP, 10 St. James Avenue, Boston,
Massachusetts, on Monday, May 6, 2024, commencing at
9:12 a.m.

APPEARANCES ON PAGE 2

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1 PRESENT: 2 GLBTQ Legal Advocates and Defenders 3 (by Jennifer Levi, Esq.) 4 18 Tremont Street, Boston, MA 02108, 5 617.388.5140, jlevi@glad.org - and - 6 Human Rights Campaign (Via Zoom) 7 (by Cynthia Cheng-Wun Weaver, Esq.) 8 1640 Rhode Island Avenue, NW, 9 Washington, DC 20009, 202.527.3669, 10 Cynthia.Weaver@hrc.org - and - 11 King & Spalding LLP (Via Zoom) 12 (by Katherine Vessels, Esq.) 13 1700 Pennsylvania Avenue, NW, Washington, 14 DC 20005, 202.737.0500, kvessels@kslaw.com, 15 for the Plaintiffs. 16 United States Department of Justice (Via Zoom) 17 (by James Fletcher, Esq.) 18 150 M Street, NE, Washington, DC 19 20530, James.Fletcher@usdoj.gov, 20 202.598.0083, for the Intervenor 21 Plaintiff. 22 Alliance Defending Freedom 23 (by Roger G. Brooks, Esq.) 24 15100 N. 90th Street, Scottsdale, AZ 85260, 480.444.0200, rbrooks@adflegal.org, for the Defendants. Also Present: Shannon Minter, Esq. (Via Zoom) *****	1 E X H I B I T S (Continued) 2 NO. DESCRIPTION PAGE 3 Exhibit 5 Pages S1-S4 and S247-S258 from 54 4 article entitled "Standards of 5 Care for the Health of 6 Transgender and Gender Diverse 7 People, Version 8," by E. 8 Coleman, et al., from 9 International Journal of 10 Transgender Health, 2022 11 Exhibit 6 Article entitled "GRADE 67 12 guidelines: 3. Rating the 13 quality of evidence," by Howard 14 Balshem, et al., from Journal 15 of Clinical Epidemiology, 2011 16 Exhibit 7 Article entitled "Guidelines 87 17 for sedation and anesthesia in 18 GI endoscopy," by Dayna S. 19 Early, M.D., et al., from 20 Gastrointestinal Endoscopy, 21 2018 22 Exhibit 8 Article entitled "GRADE 93 23 guidelines: 14. Going from 24 evidence to recommendations: the significance and presentation of recommendations," by Jeff Andrews, et al., from Journal of Clinical Epidemiology, 2013 Exhibit 9 Article entitled "GRADE 101 guidelines: 15. Going from evidence to recommendation -- determinants of a recommendation's direction and strength," by Jeffrey C. Andrews, et al., from Journal of Clinical Epidemiology, 2013
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1 I N D E X 2 3 WITNESS DIRECT CROSS REDIRECT RECROSS 4 JENIFER LIGHTDALE, 5 M.D. 6 BY MR. BROOKS 7 7 ***** 8 E X H I B I T S 9 NO. DESCRIPTION PAGE 10 Exhibit 1 Article entitled "Pediatric 10 11 Endoscopy Quality Improvement 12 Network Quality Standards and 13 Indicators for Pediatric 14 Endoscopic Procedures: A Joint 15 NASPGHAN/ESPGHAN Guideline," by 16 Jenifer R. Lightdale, et al., 17 from Journal of Pediatric 18 Gastroenterology and Nutrition, 19 March 2022 20 Exhibit 2 Document entitled "Appraisal of 13 21 Guidelines for Research & 22 Evaluation II, AGREE II 23 Instrument," updated December 24 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology for the development of soc8" Exhibit 4 Expert Rebuttal Declaration of 51 Jenifer R. Lightdale, M.D., M.P.H.	1 E X H I B I T S (Continued) 2 NO. DESCRIPTION PAGE 3 Exhibit 10 Two-page chain of emails dated 103 4 February 7, 2023, with redac- 5 tions, with attachment entitled 6 "Draft 12-point Strategic Plan 7 to Advance Gender Affirming 8 Care through strengthening the 9 WPATH SOC-8," Bates Pages 10 BOEAL_WPATH_091211-91218 11 Exhibit 11 Article entitled "Clinical 109 12 guidelines for children and 13 adolescents experiencing gender 14 dysphoria or incongruence: a 15 systematic review of guideline 16 quality (part 1)," by Jo 17 Taylor, et al., from Archives 18 of Disease in Childhood, 2024 19 Exhibit 12 Article entitled "Patient 111 20 safety during procedural 21 sedation using capnography 22 monitoring: a systematic review 23 and meta-analysis," by Rhodri 24 Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 Exhibit 14 Article entitled "Effects of 126 Intravenous Secretin on Language and Behavior of Children With Autism and Gastrointestinal Symptoms: A Single-Blinded, Open-Label Pilot Study," by Jenifer R. Lightdale, M.D., et al., from Pediatrics, November 2001

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Page 6 1 EXHIBITS (Continued) 2 NO. DESCRIPTION PAGE 3 Exhibit 15 Excerpts from Institute of 141 4 Medicine book entitled Clinical 5 Practice Guideline We Can 6 Exhibit 16 Article entitled "Evaluating 187 7 Patient-Centered Outcomes in 8 Clinical Trials of Procedural 9 Sedation, Part 2, Safety: 10 Sedation Consortium on 11 Endpoints and Procedures for 12 Treatment, Education, and 13 Research Recommendations," by 14 Denham S. Ward, M.D., et al., 15 from Anesthesia & Analgesia, 16 2018 17 Exhibit 17 Article entitled "Risk Factors, 199 18 Morbidity, and Treatment of 19 Thrombosis in Children and 20 Young Adults With Active 21 Inflammatory Bowel Disease," by 22 Naamah L. Zitomersky, et al., 23 from Journal of Pediatric 24 Gastroenterology and Nutrition, September 2013 Article entitled "The Dutch 214 Protocol for Juvenile Transsexuals: Origins and Evidence," by Michael Biggs, from Journal of Sex & Marital Therapy, 2022 *****	Page 8 1 A. Correct. 2 Q. You're not an expert in neurology or 3 cognition? 4 A. No. 5 Q. Do you have any publications relating to 6 mental health at all? 7 A. Yes. I think somewhere back there there's 8 something about kids with IBD and going to college. 9 That's, like, maybe ten years ago. I worked with a 10 fellow. 11 Q. Do you have any expertise at all relating 12 to gender dysphoria or gender identity? 13 A. No. 14 Q. Have you ever diagnosed any patient with 15 gender dysphoria? 16 A. No. 17 Q. Have you ever treated a patient for 18 anything who, to your knowledge, suffered from 19 gender dysphoria? 20 A. Yes. 21 Q. But your treatment had nothing to do with 22 the gender dysphoria? 23 A. Correct. 24 Q. All right. Do you consider yourself to be
Page 7 1 PROCEEDINGS 2 JENIFER LIGHTDALE, M.D. 3 a witness called for examination by counsel for the 4 Defendants, having been satisfactorily identified by 5 the production of her driver's license and being 6 first duly sworn by the Notary Public, was examined 7 and testified as follows: 8 DIRECT EXAMINATION 9 BY MR. BROOKS: 10 Q. Dr. Lightdale, good morning. 11 Let me start by making sure that I 12 understand the scope of the expertise that you're 13 bringing to the table. 14 You're not a psychiatrist, correct? 15 A. I am not a psychiatrist. 16 Q. Nor a psychologist? 17 A. No. 18 Q. You don't have any degree relating to 19 psychology? 20 A. No. 21 Q. You're not an expert in adolescent 22 developmental psychology? 23 A. No. 24 Q. Or indeed adolescent anything, correct?	Page 9 1 an expert in medical ethics? 2 A. No. 3 Q. You've never taught a course in medical 4 ethics? 5 A. No. 6 Q. And other than a basic medical school 7 course, have you had any special training in medical 8 ethics? 9 A. Yes. As part of conducting research, you 10 have to get trained in responsible conduct of 11 research. So I have done that. 12 Q. You did not have any role at all in the 13 development of the WPATH Standards of Care Version 14 8, did you? 15 A. No. 16 Q. Nor any version of the WPATH Standards of 17 Care? 18 A. No. 19 Q. And you weren't, at any stage, invited to 20 review or comment on a draft? 21 A. No. 22 Q. Do you have any knowledge of who comprises 23 the membership of WPATH? 24 A. No.

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Page 10 1 Q. Do you have any knowledge of the process 2 that was used to develop the WPATH SOC-8 other than 3 the methodology web page you refer to in your expert 4 report? 5 A. No. Just the web page. 6 Q. And you're not a member of the Endocrine 7 Society, correct? 8 A. No. 9 Q. And do you have any knowledge at all as to 10 the policies or procedures followed by any gender 11 clinic in Alabama? 12 A. No. 13 MR. BROOKS: Let me ask the reporter to 14 mark as Exhibit 1 an article from 2022 with such a 15 long title, "Pediatric Endoscopy Quality Improvement 16 Network Quality Standards," and it goes on from 17 there, of which Dr. Lightdale is the first author. 18 (Document marked as Lightdale 19 Exhibit 1 for identification) 20 Q. Dr. Lightdale, is this in fact a paper of 21 which you are the lead author? 22 A. Yes. 23 Q. And can you generally describe for the 24 record what this paper is.	Page 12 1 follow the AGREE II methodology to actually develop 2 our guidelines." 3 Q. So let me break that into two halves. I 4 think what you first said is that AGREE II, what its 5 primary function is is a methodology to evaluate -- 6 maybe "quality" is not the right word, but the 7 quality of a set of clinical practice guidelines; is 8 that right? 9 A. Yeah. I wouldn't say "quality" is the 10 right word. It is a way to look at how guidelines 11 are developed and to really say that they met 12 certain steps. And, you know, you can think of it 13 as a strategy, you can think of it as a framework, 14 and it's a way of assessing the guidelines. 15 Q. Assessing them with -- for what purpose? 16 That is, are you trying to find out their 17 reliability? You said "quality" isn't the right 18 word, but assessment towards what end? 19 A. So basically it is, in the end they want to 20 appraise the guidelines and to say did they meet 21 certain points of developing it. 22 You know -- yeah. 23 Q. But the purpose isn't simply to award a 24 gold star. The purpose is to give clinicians some
Page 11 1 A. Yes. So this is one of five documents that 2 came out of a joint process of a society that I 3 actually currently am the president of, which is the 4 North American Society of Pediatric GI, Hepatology 5 and Nutrition, or NASPGHAN, with the European 6 Society of Pediatric Gastroenterology, Hepatology 7 and Nutrition, which is ESPGHAN. And what we were 8 doing for quite some time was working together to 9 come up with joint standards and also ways to 10 measure high-quality pediatric endoscopy. 11 Q. Now, in the abstract, in Column 1 of the 12 first page of Exhibit 1, about two inches down into 13 the abstract, it states that this project "used the 14 methodological strategy of the Appraisal of 15 Guidelines for Research and Evaluation," and it 16 refers to AGREE II. 17 Can you explain what AGREE II is. 18 A. Yes. So AGREE II, in my words, when I talk 19 about it, is a framework or it's basically a way 20 that you can decide that a guideline has been 21 developed in a methodologically sound way. And so 22 it's basically something you use, frankly, usually 23 after the fact. But in our case, we said, "Let's 24 start using it right away and say we're going to	Page 13 1 comfort that these guidelines are reliable; am I 2 correct? 3 A. You know, you can use AGREE II and make a 4 decision that you're not going to follow certain 5 steps. So it's really just a way of laying out what 6 are all the different things that can go into 7 building a guideline, and then you can look at a 8 guideline and say, Yup, they met X, Y and Z, but 9 they decided not to do A, B and C. 10 Q. Okay. And I think then what you said was, 11 for your project, you decided to create a set of 12 guidelines with an eye already on the criteria set 13 forth by AGREE II, correct? 14 A. Yeah. We work as a group -- again, I'm 15 working with Europeans here and a lot of North 16 Americans, so it's a huge group of people. And I 17 think for keeping us all on the same page, AGREE II 18 gave us a framework to work in. 19 Q. All right. 20 MR. BROOKS: I'm going to ask the reporter 21 to mark as Exhibit 2 a document entitled "AGREE II 22 Instrument" dated December 2017. 23 (Document marked as Lightdale 24 Exhibit 2 for identification)

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Page 14 1 Q. And let me ask you first to take a look at 2 this and identify it for the record, if you can. 3 A. Sure. This looks like a pdf of the AGREE 4 II, what they call the Instrument. 5 Q. And explain to me what the Instrument -- 6 what the AGREE Instrument is. 7 A. So I can't say I'm completely familiar with 8 this exact, you know, document, but an instrument is 9 essentially a tool you can use to apply something. 10 So I presume it's something to apply to AGREE II. 11 Q. And it says that it's put out by The AGREE 12 Next Steps Consortium. Is that a group or a name 13 that means anything to you? 14 A. Not exactly. So I think AGREE is something 15 I was aware of. And then what was more important 16 for me is it was updated, and it's been updated 17 now -- that's why it's now AGREE II -- and this 18 update was actually 2017. 19 And why that's relevant is this thing that 20 we talked about before was actually started in, 21 like, 2018. So everybody was talking about AGREE II 22 as, you know, a way that used a framework. 23 Q. Okay. Let me ask you to turn in this 24 document -- and this is unusual -- turn to Page 0,	Page 16 1 concept of you do it in a good way, yes. 2 Q. And we'll talk more about what that means. 3 A. Okay. 4 Q. In the second paragraph, the last sentence 5 says, "The quality of guidelines can be extremely 6 variable and some often fall short of basic 7 standards." 8 Do you see that language? 9 A. Yes. 10 Q. And is that consistent with your own 11 observation in your professional life? 12 A. Yes. 13 Q. That is, you have seen many documents that 14 claim to be clinical practice guidelines that fall 15 short of basic standards? 16 A. No, I wouldn't say that. I would say I've 17 been in the field of medicine longer than guidelines 18 have been around. And so you've watched an 19 evolution in how guidelines come about, what we 20 actually are ready to consider a clinical practice 21 guideline, if you will. 22 And this -- again, there's been a lot of 23 evolution around this, but there's an effort to try 24 to make sure that we have defined this in some way.
Page 15 1 if you would. 2 A. Okay. Is it 0, like, right there? 3 Q. No, it's not the first page. The first 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 14 Do you see that? 15 A. Yes, I do. 16 Q. And is it consistent with your 17 understanding that the purpose of clinical practice 18 guidelines is to assist practitioner and patient 19 decisions? 20 A. Yes. 21 Q. And that those are to be systematically 22 developed? 23 A. I mean, yes. I think we want good 24 guidelines. So systematically is, you know, the	Page 17 1 So that -- which it wasn't. Like, in 2010 there was 2 really very little definition. Certainly in 2000 3 there was almost no definition. 4 Q. And are you prepared to testify that, as of 5 today, that clinical practice guidelines that are 6 being created recently are uniformly of good 7 quality? 8 A. No. They're still not of uniform good 9 quality. But I think they're being held to a 10 different standard. There is now a sense of one 11 needs to go into a guideline with a methodology 12 behind producing the guideline. And that wasn't the 13 case for many years. So... 14 Q. During those many years, on what basis were 15 guidelines created, if not using a systematic 16 methodology? 17 A. So in -- I mean, I was in medical school 18 from 1991 to 1995, and best practice was expert 19 derived, like somebody said, "Here's the best way to 20 do it," and everyone said "Okay." And we really -- 21 really that's not the way you decide what is 22 evidence, right? So the concept of evidence-based 23 medicine is really 1995-ish. 24 Q. Look at the third paragraph on this Page 0.

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Page 18 1 And the second sentence in that third paragraph 2 reads, quote, "To that end, the AGREE instrument is 3 a tool that assesses the methodological rigour and 4 transparency in which a guideline is developed." 5 Do you understand the distinction being 6 made between methodological rigour and transparency? 7 A. Yes. 8 Q. And do you understand those to be two key 9 aspects of an appropriate method of developing a 10 guideline? 11 A. So there are two components that need to be 12 considered when developing a guideline, is the way I 13 think of it. 14 Q. Those being rigour and transparency? 15 A. Methodology, rigour -- I mean, you could 16 put those two together, but you need a methodology 17 and you need transparency when you develop a 18 guideline. 19 Q. All right. If we look on the second 20 page -- this is a European document. I see the 21 spelling, and they seem to have numbered their pages 22 like they number the floors on an elevator. 23 So if you look at the second page, numbered 24 1, there is table that says, "Comparison of the	Page 20 1 II; am I correct? 2 A. One, two, three, four, five, six, seven, 3 eight, yes. 4 Q. Okay. And one of those is whether 5 systematic methods were used to search for evidence, 6 correct? 7 A. Can I just say, it's a little bit 8 confusing, to be honest, because it's Number 8 to 9 14, so my math tells me it's six. I don't know why 10 that is. 11 Q. It is because of the place that it says 12 "New Item 9" is why. So the numbering is messed up. 13 A. Okay. Okay. 14 Q. I had miscounted myself for exactly the 15 same reason. 16 But now we can put the numbering aside, 17 perhaps, and one of the criteria for Rigour of 18 Development is Line 8, "Systematic methods were used 19 to search for evidence," correct? 20 A. Yes. 21 Q. And one is whether the criteria for 22 selecting the evidence were clearly described, 23 right? 24 A. Yes.
Page 19 1 Original AGREE and AGREE II items." Do you see 2 that? 3 A. Yes. 4 Q. And down a little more than halfway through 5 the table is a section headed "Domain 3. Rigour of 6 Development." Do you see that? 7 A. Uh-huh. 8 Q. And under that are, in the "AGREE II" 9 column, seven categories or items that are 10 indicated. Do you see that? 11 A. You're talking in this column here 12 (indicating)? 13 Q. Yes. 14 A. Okay. 15 Q. Just take a moment and look at it. You'll 16 see that the first column is "Original AGREE Item," 17 and the second is the revised AGREE II set of 18 criteria, right? 19 A. Yes. 20 Q. So back to where we were. "Rigour of 21 Development" under the AGREE II column there are 22 seven specific items under the -- pardon me. I'm 23 turning over the page. There are eight specific 24 items under the "Rigour of Development" for AGREE	Page 21 1 Q. Looking at 11, whether the -- not only the 2 health benefits, but side effects and risks have 3 been considered in formulating the recommendations, 4 right? 5 A. Yes. 6 Q. And whether there -- Item 12, one of the 7 criteria of rigour is whether there is an explicit 8 link between the recommendations and the supporting 9 evidence. Do you see that? 10 A. Yes. 11 Q. And let me pause on that one for a moment. 12 Why is it important that guidelines provide an 13 explicit link between the recommendations and the 14 supporting evidence? 15 A. I mean, the link might be that there is no 16 evidence. 17 So I guess I'm -- for me, these are all, 18 frankly, a bit subjective, but you want to be able 19 to connect what you're saying as recommendations to 20 what we know or don't know. 21 So that is totally reasonable, to say 22 there's an explicit link, and the link is simply 23 that there is no evidence. That's the one issue. I 24 mean, there's lots of issues everybody has with all

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Page 22 1 of these things, by the way. 2 But, yes, you need to be able to say what 3 recommendations you're making and what evidence 4 you're using or lack of evidence you're using to 5 support that recommendation. 6 Q. And in the interests of transparency, you 7 need to not only be able to say that, but you need 8 to say it; am I correct? 9 MS. LEVI: Object as to form. 10 A. Yeah, I mean -- so these are, like -- these 11 are things that they have said, "Gee, it's nice if 12 we can do all of this," and you want to be able to 13 say, in a guideline, did they do something. But I 14 think there's still a lot of -- you need to sort of 15 not be able to make such a stand, like, one dominant 16 statement that there has to be a link between -- 17 well, I guess -- I'm not a lawyer. 18 What I guess what I'm worrying about is 19 that one doesn't need to be able to say there's 20 supporting evidence. So the whole thing about 21 guidelines and where AGREE sort of goes a little bit 22 wrong is that the answer is that part of guidelines 23 is also identifying big gaps and where we need more 24 evidence.	Page 24 1 A. Yes. But we were, in our guideline, 2 definitely dealing with a lot that had no evidence 3 behind it. 4 So for us these are very -- you know, 5 you're sort of doing your best to say, "Okay, here's 6 the framework we're trying to work in and how do we 7 work when there's not much evidence." 8 So what I don't like about Number 12, if 9 you want to focus on that, is this concept of 10 explicit and supporting evidence where, what if 11 there is no explicit link, and what if there's no 12 supporting evidence. 13 You still could meet the AGREE II criteria. 14 You still could explain how you came to your 15 recommendation. 16 Q. If you turn to Page Number 2 in the 17 document, there's, towards the bottom, "Domain 6. 18 Editorial Independence." And the first item there, 19 Number 22, is a little differently phrased between 20 AGREE and AGREE II. 21 The AGREE II statement from 2017 says, 22 quote, "The views of the funding body have not 23 influenced the content of the guideline," close 24 quote.
Page 23 1 And so if part of a guideline is to say we 2 don't have any evidence, then how does one make a 3 link between that and a recommendation? 4 And you may still need a recommendation. 5 So that's the other thing is, you come up with these 6 questions that you need to be able to answer, and so 7 sometimes there is no evidence there. So... 8 Q. You said in your answer, "I'm not a 9 lawyer," and -- 10 A. No, I'm not. 11 Q. -- just to be clear -- 12 A. So none of us loves this stuff that's, 13 like, so specific. But, yes. 14 Q. But just to be clear, this is also not a 15 legal document. 16 A. Right. 17 Q. And I'm asking questions precisely to 18 understand kind of the boundaries of how you as a 19 practitioner understand the document. 20 A. Okay. 21 Q. And it's indeed how you understood it when 22 you were embarked on the project we just looked at, 23 where you attempted to be guided by the AGREE II 24 criteria, correct?	Page 25 1 Do you consider that to be an important 2 criteria for the reliability of a guideline? 3 A. Yeah. 4 Q. Why? 5 A. Well, I think there's -- the way I've 6 always read this, at least, is -- and it was sort of 7 noticeable that you had this change from 22, like 8 from the original one to 2017. But I think what we 9 get into is you have external groups that would like 10 a guideline on something, and they offer to pay. 11 And so what's sort of noticeable is they 12 went from "editorially independent" into the views 13 of it haven't influenced, which is -- I don't know, 14 you were sort of -- and I think there has been some 15 trying to understand. 16 But there is worry that there's groups that 17 are funding guidelines that would like them to take 18 a certain direction. And so it's just important to 19 make sure that whoever is funding the guideline 20 isn't actually influencing it, that they're kept 21 totally out of the loop. 22 Q. Let me ask you to turn to Page Number 20. 23 Actually, let me back up for a moment here. 24 I should show you the context of what we're in. If

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Page 26 1 you back up to Page 6, you'll see a heading that 2 says "User's Manual." And the next page says 3 "User's Manual: Instructions for Using the AGREE 4 II." 5 Now, whether or not in this form, do you 6 believe that you have seen an official set of 7 instructions for how to apply the AGREE II 8 Instrument? 9 A. So -- this probably is the most I've ever 10 really looked at it. 11 Q. But you've seen it before, you think? 12 A. I've followed a methodologist who probably 13 was using it. 14 Q. Okay. You don't consider yourself is 15 methodologist? 16 A. I'm not a methodologist. 17 Q. Can you describe -- when you distinguish 18 yourself from a methodologist, what is the expertise 19 of a methodologist that you relied on in the course 20 of your own projects relating to developing 21 guidelines? 22 A. So the methodologist guides the process, 23 and they're making suggestions about what 24 methodologies to be used.	Page 28 1 A. Oh, the NASPGHAN. 2 Q. NASPGHAN, there we go. 3 How many projects involved with developing 4 clinical practice guidelines have you been 5 personally involved in in your professional career? 6 A. A number. I don't know, actually. 7 Q. And in each one of those, there's been a 8 methodologist involved you relied on? 9 A. No. 10 Q. How did you go about it in a case in which 11 there was not a methodologist involved, since you 12 don't consider yourself to be a methodologist, a 13 methodology expert? 14 A. So I've been involved with guidelines since 15 2005, maybe was the first one that I got involved 16 with, and there were no methodologists at that time. 17 So, you know, it's a new concept, that you would 18 bring somebody in who doesn't know the content but 19 simply is an expert in the methodologies. 20 Q. Okay. 21 At any rate, if you turn to Page 20 now of 22 the document, and indeed flip through whatever pages 23 you like, and I think you will see that kind of item 24 by item from the table we looked at earlier, there
Page 27 1 Q. In that context, is a methodologist 2 somebody who has special expertise in the process 3 for developing guidelines? 4 A. So, for me, a methodologist is someone 5 who's ready to say that they have delved into this 6 and really worked on it. Some people have taken 7 courses. Some people haven't. There's no, like, 8 degree in methodology that I know of. 9 Q. So when you say "delved into this," I think 10 you were gesturing, like, the details of the AGREE 11 Instrument, correct? 12 A. Into, yes, the very specific words. 13 Q. And that's not you. You didn't go and 14 consult the document step by step -- 15 A. No. 16 Q. -- as you went? 17 A. No. 18 Q. You would talk to a methodologist? 19 A. Yes. 20 Q. Okay. Then all I can do is ask for your 21 understanding as a result of having done that on 22 the -- how did you pronounce that bunch of letters? 23 A. PEnQuIN. 24 Q. No, the organization --	Page 29 1 are headings and a ranking table from 1 to 7, and 2 then a discussion of how you would arrive at your 3 ranking. Am I describing it fairly? 4 A. Yes. 5 Q. And are you on numbered Page 20 now? 6 A. Yes. 7 Q. This is under the heading "Rigour of 8 Development," and the Subpoint 7, "Systematic 9 methods were used to search for evidence." 10 And is it consistent with your 11 understanding that, at least in concept, a user who 12 wants to use the AGREE II instrument to evaluate a 13 set of clinical practice guidelines would be -- is 14 essentially asked by the AGREE II instrument to go 15 through each one of these items and assign a rating 16 between 1 and 7? 17 MS. LEVI: I'm going to just let you know, 18 you can take the time that you need to -- 19 THE WITNESS: Look at what's happening 20 here. 21 MR. BROOKS: Absolutely. 22 MS. LEVI: -- look at this before you answer 23 the question. 24 THE WITNESS: Yeah. I was sort of

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Page 30 1 looking -- 2 MS. LEVI: Flip through the document. Take 3 whatever time you need to familiarize yourself. 4 THE WITNESS: I appreciate that. 5 MS. LEVI: Yeah. Of course. 6 A. Okay. So ask the question and let me see 7 if I can understand what I'm looking at to answer 8 it, maybe. 9 Q. You earlier described the kind of primary 10 function of AGREE II as a tool to evaluate a set of 11 guidelines after it's been created? 12 A. Yes. 13 Q. And you mentioned that your team on the 14 NASPGHAN project had said, "Well, let's keep those 15 criteria in view as we do it, rather than only 16 afterwards," right? 17 A. Yeah. And actually, I will say -- it was 18 on Page 0. It says it provides a methodological 19 strategy for the development of guidelines. So 20 that's the way we chose to use AGREE II. 21 Q. Perfect. And my question is, as we look at 22 Page 20, or indeed a number of pages here, is it 23 consistent with your understanding that this is 24 designed for a user who is attempting to evaluate a	Page 32 1 provided including search terms used, sources 2 consulted, and dates of the literature covered." 3 Do you see that? 4 A. Yes. 5 Q. And is that something that your team did 6 when you published your NASPGHAN guidelines? 7 A. Yes. 8 Q. And why did you consider that to be 9 important information to disclose to the user 10 community? 11 MS. LEVI: Object as to form. 12 A. Right. So I think one needs to make sure, 13 when you develop a guideline, that you explain how 14 you searched for evidence. 15 I will tell you, what stood out to me 16 immediately in this sentence is I think there's 17 supposed to be a comma after "provided." So these 18 are just -- I mean, lots of people have lots of 19 different ways of searching for evidence, so there's 20 lots of ways you could explain what you did. 21 And if you're going to do A -- there's a 22 lot of "mays" in the rest of this paragraph, but if 23 you are going to do some sort of electronic 24 searching, then, yes, you're going to use very
Page 31 1 set of guidelines to, on a point-by-point basis, 2 assign a rating, a strength rating between 1 and 7, 3 and there is discussion that tells you how to go 4 about deciding that strength rating? 5 A. What I will say, looking at it, obviously 6 again, and remembering working with it, is one needs 7 to Likert scale -- so you're giving a rating -- and 8 then they're attempting to at least give you how you 9 want to think about that Likert scale; so, you know, 10 what you should look at and how to rate it and, you 11 know, what you're considering. And then honestly, 12 in the end, you're going to use your best gut -- you 13 know, your judgment on where you're going to rank 14 them between 1 and 7. 15 Q. So I think I'm learning a fancy technical 16 term for rating something between 1 and 7. 17 Likert -- 18 A. Likert scale. 19 Q. He gets credit for that, huh? 20 The beginning of the discussion under 21 "User's Manual Description" on Page 20, and we're in 22 Subheading 7, "Systematic methods were used to 23 search for evidence," the text reads, "Details of 24 the strategy used to search for evidence should be	Page 33 1 specific search terms. 2 It's possible you don't have an electronic 3 database of what you're looking for, so you'd still 4 be able to explain that. The important thing is to 5 explain what strategy you used to search for 6 evidence. 7 Q. And have you made any effort to determine 8 whether, in connection with the SOC-8 guidelines, 9 WPATH disclosed search terms or information 10 sufficient to replicate the searches done? 11 A. Have I made efforts? Can you explain what 12 you mean by that. I read the website. 13 Q. Do you know whether WPATH, in connection 14 with SOC-8, disclosed search terms or other 15 information sufficient to replicate the searches 16 they did for evidence? 17 A. So I read the website. I haven't, like -- 18 and then I'm trying to remember it. But I have 19 memory that they explained how they went looking for 20 their evidence, and also they had moments when they 21 knew there wasn't evidence. So they were making 22 decisions along the way of what to do if there was 23 nothing in the literature. 24 Q. Do you know whether WPATH, in connection

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Page 34 1 with SOC-8, disclosed search terms used? 2 A. So I don't know. 3 Q. And do you know whether they disclosed 4 enough information of any type to replicate searches 5 that they did for relevant evidence? 6 A. My memory is that it was a transparent, 7 rigorous process, where they explained how they 8 searched for evidence. I don't remember looking or 9 understanding if they had specified the search terms 10 on the website, is the truth. I don't remember that. 11 But they explained how they did systematic 12 literature reviews, in my memory. 13 Q. The second sentence reads, "Sources may 14 include electronic databases," and then it lists 15 some examples, "databases of systematic reviews," it 16 lists the example of the Cochrane Library and DARE, 17 "handsearching journals," and it proceeds. 18 Then it says, in the final sentence, "The 19 search strategy should be as comprehensive as 20 possible and executed in a manner free from 21 potential biases and sufficiently detailed to be 22 replicated." 23 And, again, I want to ask you whether you 24 know whether, in any context relating to SOC-8,	Page 36 1 Page 21, and this, still under "Rigour of 2 Development," is a new criteria that states, quote, 3 "The criteria for selecting the evidence are clearly 4 described," close quote. 5 And there the first sentence reads, quote, 6 "Criteria for including/excluding evidence 7 identified by the search should be provided. These 8 criteria should be explicitly described and reasons 9 for including and excluding evidence should be 10 clearly stated." 11 Do you have any knowledge as to whether, in 12 connection with any aspect of SOC-8, WPATH disclosed 13 the criteria it used for including or excluding 14 evidence? 15 A. We're not looking at the website, but my 16 only memory is that it seemed like a very reasonable 17 thing that they explained as to how they did their 18 search, including the inclusion/exclusion criteria. 19 Q. Do you have any recollection that they 20 provided any inclusion or exclusion criteria? 21 A. So I know, or my memory -- and, again, this 22 is, for me, common in pediatrics and even common in 23 what I did -- that they felt there weren't many 24 randomized controlled trials. So they were not
Page 35 1 WPATH disclosed how it conducted its searches with 2 sufficient detail to be replicated. 3 A. My memory of the website is they explained 4 that they did detail -- you know, they did a 5 systematic literature search and that they explained 6 how they came up with their evidence. But beyond 7 that, I don't know. I didn't look. 8 Q. You would agree with me, would you not, 9 that telling the world that you did a systematic 10 search is a very different thing from describing 11 with enough detail to be replicated? 12 A. Not per se. I think -- you want to explain 13 how you did your search, and ideally somebody can go 14 and do the search and feel that you found the same 15 evidence, but I think -- you know, what is that? 16 What is sufficiently detailed? 17 To me, again, there's a lot still that's 18 very sort of, you know, subjective. And that is why 19 I think, in the end, this description is giving us 20 how to do this. But you're -- in the end, there's a 21 Likert scaling, and you're going to use your best 22 judgment on whether somebody did something in a 23 sufficiently detailed way. 24 Q. Let me ask you to look at the next page,	Page 37 1 going to be limiting things to just randomized 2 controlled trials. 3 And then I think this concept of excluding 4 articles not written in English, that's pretty 5 common for all of us to sort of struggle with, like, 6 at what point do you want articles written in other 7 languages, or do you just limit it to English- 8 speaking publications. 9 MR. BROOKS: Let me ask the reporter to 10 mark as Exhibit 3 a printout of a web page from the 11 WPATH website that says -- that's entitled 12 "methodology for the development of soc8." 13 (Document marked as Lightdale 14 Exhibit 3 for identification) 15 Q. Obviously I'm showing you paper rather than 16 the screen. 17 A. I appreciate that. 18 Q. Did you, in fact -- well, let me ask first, 19 would you look through this and see whether this 20 appears to be a printout of the WPATH methodology 21 web page that you mentioned a moment ago. 22 A. Yes, in the sense that it looks really 23 different. I think that on the web you see these 24 sort of -- these pictures, like a tic-tac-toe box.

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Page 38 1 Q. You do. But let's focus on the text and 2 see whether -- if you keep going, you'll get to 3 text. 4 A. Okay. Yes. 5 Q. "Yes," this looks like what you recall 6 looking at? 7 A. Yeah. 8 Q. And how long did you spend -- well, did you 9 print this out and study it on paper? 10 A. No. 11 Q. You just looked at it on the screen? 12 A. Yes. 13 Q. And for about how long did you study that 14 on the screen? 15 A. I mean, you had to open up each of those 16 boxes and sort of look at things, but probably an 17 hour maximum. 18 Q. Okay. Would you point me to anything in 19 this WPATH web page methodology that either 20 discloses or talks about disclosing criteria for 21 inclusion or exclusion of evidence. 22 A. Okay. So let me take a minute to see. 23 Q. Take your time. 24 A. (Reviewing document) Yeah, no. So	Page 40 1 associated text, to evaluate any disclosures that 2 may have been made in the guideline itself? 3 A. I didn't look at the SO -- I didn't look at 4 the guideline. 5 Q. Okay. 6 If you turn in the AGREE II document, 7 Exhibit 2, I think that was -- 8 A. Yeah. 9 MS. LEVI: Take your time. 10 Q. -- to Page 22, at the beginning -- now 11 we're under a new heading here, quote, "The 12 strengths and limitations of the body of evidence 13 are clearly described," close quote. 14 And the first sentence there under "User's 15 Manual Description" reads, "Statements highlighting 16 the strengths and limitations of the evidence should 17 be provided." And then it continues, "This ought to 18 include explicit descriptions - using informal or 19 formal tools/methods - to assess and describe the 20 risk of bias for individual studies and/or for 21 specific outcomes and/or explicit commentary of the 22 body of evidence aggregated across all studies." 23 Do you see that? 24 A. Yes.
Page 39 1 basically what they are saying -- it's right here is 2 where they're really talking about their systematic 3 review. 4 Q. You're looking at page numbered, in the 5 lower right-hand corner, 6 out of 10? 6 A. Yes. 7 Q. And 2.4.2? 8 A. 2.4 -- it's 2.4.1 and 2.4.2. 9 Q. All right. And my question is, where in 10 this document does it discuss criteria for inclusion 11 and exclusion of studies? 12 A. Yeah. So it looks like what they did was 13 they went through a prior guideline, and they were 14 identifying what needed to be updated and then what 15 needed new recommendations and where were systematic 16 reviews required. And they basically then move into 17 more of, like, a GRADE process, if you will, where 18 they're specifying the population, et cetera, PICO 19 questions. 20 And I do not see in this piece of text that 21 they talk inclusion/exclusion criteria. They say 22 they conduct their systematic reviews. 23 Q. Did you, yourself, study any portion of the 24 Standard of Care 8 itself, recommendations and	Page 41 1 Q. Can you describe for me what is meant, 2 within medical science, by risk of bias associated 3 with a study? 4 A. So all studies have some bias in them -- 5 that's what you learn in the responsible conduct of 6 research training -- and it is important to consider 7 studies that way. 8 And in this case they're saying -- they're 9 asking -- this particular item on the AGREE II 10 framework says, when you did your process of looking 11 at the evidence, that you have come up with some way 12 of assessing bias in each study that you looked at. 13 Q. I think in that answer, and therefore in 14 the field, you use "bias" in a way that perhaps is a 15 little different from the layman's understanding of 16 "bias." Can I ask you to explain what you meant by 17 "bias" in that answer. 18 A. Well, I mean, "bias" is a big word, and 19 it's not something I personally -- I mean, I just 20 walk around with my own head -- where we all have 21 unconscious ways of thinking about things. And then 22 sometimes, especially in medicine, there can be very 23 explicitly conscious bias where you really hope 24 something works.

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Page 42 1 So you have to be looking at a study to 2 understand whether it was designed in a way to 3 ideally account for the fact that there's bias. 4 And then when you write a guideline, you're 5 going to be thinking about -- or you're trying to 6 assess evidence, assess a study, you're trying to 7 say, "Okay, how would I rate this bias and/or think 8 about this bias?" 9 And, again, for AGREE, bringing it back to 10 this, you would want to have a way that you went 11 through your evidence and you said, every study, 12 "Okay, this is what I found, but what was the risk 13 of bias in the study?" 14 So there are usually worksheets you're 15 working through as you look through every piece of 16 evidence, or something like that, that lets you 17 systematically say what the bias is. 18 Q. And in this context, bias isn't limited to 19 situations in which -- isn't limited to the issue of 20 humans who are involved wanting one result or 21 another; it can also include an experimental design 22 that just skews results, can it not? 23 A. Bias can, yeah, be a lot of different 24 things.	Page 44 1 it? 2 A. (Reviewing document) Well, I mean, what I 3 can tell you is that they presented evidence tables, 4 so I would need to understand what's in the evidence 5 table. But presumably part of the evidence table is 6 how strong was the evidence, and bias takes away 7 from strength. 8 Q. So do you have an understanding of what an 9 evidence table is? 10 A. I mean, in the abstract. Like, tables can 11 look lots of different ways. 12 Q. But explain to me in the abstract what an 13 evidence table is. 14 A. So, evidence tables -- and actually, I 15 think somewhere I just read they've been commenting 16 on this -- they can look lots of different ways. 17 But it's a way of explaining what you looked at that 18 you're saying is your evidence for what you're going 19 to make a statement about. 20 Q. And did your NASPGHAN team publish, make 21 available to the user community, evidence tables 22 relating to those guidelines? 23 A. So we put a lot of appendices on. So we 24 filled out a lot of different worksheets as we read
Page 43 1 Q. It doesn't necessarily imply any conscious 2 intent on the part of the people involved in the 3 experiment? 4 A. Yes. Bias can be both, I mean, conscious 5 and unconscious. It can happen accidentally, 6 systematic bias, built in. 7 Q. You can have an experimental structure 8 which results in false positives, and that would 9 create a risk of bias? 10 A. Or false negatives. 11 Q. Or false negatives. 12 A. Absolutely. 13 Q. Okay. I just wanted to make sure we didn't 14 misunderstand it as a layman might ordinarily 15 understand "bias." 16 A. Okay. 17 Q. Do you know whether, in connection with any 18 of the recommendations in SOC-8, WPATH disclosed or 19 provided any description of risk of bias of studies 20 that it relied on? 21 A. I didn't look at the guideline, so I can't 22 comment on that. 23 Q. And nothing in the methodology web page 24 that you looked at told you about that either, did	Page 45 1 every paper. I mean, everybody was assigned 2 different things to read, and then you had to sort 3 of start to build it up and put it more and more 4 synthesized together. 5 So, yes, along the way there are different 6 tables that give evidence for each recommendation. 7 Q. Things that, to your mind, fall within the 8 general description of evidence tables? 9 A. Again, evidence tables are -- it's kind of 10 a vague concept in the sense that there are so many 11 different ways you can lay out what your evidence 12 is. But, yes. 13 Q. And I'm not asking about a specific format. 14 A. Yeah. 15 Q. I think you've described the flexibility of 16 that. 17 Do you have any knowledge -- why is it 18 important, putting aside format, to publish, to make 19 available to the user community evidence tables 20 presenting the evidence that you -- that underlie 21 your guidelines? 22 A. Well, I mean, I think it is important, when 23 you put out -- again, this may be where we are now 24 in 2024, but when you put out a recommendation on

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Page 46 1 how to practice medicine, you want to be able to say 2 that your recommendation is backed up by 3 different -- you know, ideally different studies or 4 at least different findings that would make up your 5 recommendations. So... 6 Q. Is it also important to do that to enable 7 other members of the medical, scientific community 8 to evaluate whether they agree or disagree with your 9 treatment of the evidence? 10 A. Yeah. I think that's part of the 11 transparency piece of guidelines. 12 Q. And do you have any knowledge at all as to 13 whether, in connection with SOC-8, WPATH published 14 anything that could be described as evidence tables? 15 A. I don't know. I don't know. 16 Q. Turn with me, if you would, to Page 38. 17 And this is under heading "Editorial Independence." 18 This is the language we looked at earlier. There it 19 says, Item 22, "The views of the funding body have 20 not influenced the content of the guideline." 21 And it says, at the end of the first 22 paragraph there, quote, "There should be an explicit 23 statement that the views or interests of the funding 24 body have not influenced the final recommendations,"	Page 48 1 Q. A financial interest? 2 A. Yeah, sure. That's a better word. 3 Q. I think that term gets used in various of 4 the documents. 5 Do you have a view as to whether it is, in 6 fact, important, as it says here in this first 7 paragraph, that, quote, "there should an explicit 8 statement that the views or interests of the funding 9 body have not influence the final recommendations"? 10 And you commented earlier that that language had 11 changed. 12 A. Yeah. 13 Q. So what's going on there? 14 A. It has changed. And I think that -- by the 15 way, this is, again -- these are things you might 16 fill out this and -- you know, every guideline has 17 somebody -- usually, by the way, it's a group of 18 people that are going to use this Likert scale and 19 then come to consensus around the Likert scale. So 20 there's, you know, even consensus building around, 21 okay, where do we feel. 22 But I think that there has been, as 23 guidelines have become more and more important, 24 there has been more pharmaceutical money in the mix,
Page 47 1 close quote. 2 Do you see that? 3 A. Yes. 4 Q. Who funded your NASPGHAN guideline project? 5 A. It was mostly sweat equity, a lot of 6 volunteer effort. But there was a little bit of 7 funding from both societies. 8 Q. And in the case where there is external 9 funding, do you consider it important -- an 10 important aspect of transparency to disclose 11 interests of the funding body? 12 A. So I think it would depend exactly what the 13 external funding is. So -- you know, I'm just 14 looking at this list, and some of these I would want 15 to know are -- you know, are very appropriately 16 disclosed, and some -- I don't know if it's as 17 important. So... "Pharmaceutical companies" is the 18 one that stands out in that list. 19 Q. And why is that? 20 A. I think a pharmaceutical company has a -- 21 I'm going to use a word I shouldn't use -- vested 22 interest, I think that's the right word, but they 23 have money at stake depending on how a guideline 24 goes.	Page 49 1 and it has become important to make a statement, 2 intriguingly not that you don't have a 3 pharmaceutical company funding you -- this implies 4 you could have a pharmaceutical company funding you, 5 but you should explicitly state that that 6 pharmaceutical company did not influence the final 7 recommendations, which has been an odd thing the 8 whole time. Like, looking at it, you're like, "Who 9 would let a pharmaceutical company influence your 10 final recommendations?" But anyway, I guess you 11 need to be able to do that. 12 Q. You think such a thing has never happened? 13 A. They'd like to, but... 14 Q. Do you believe that the language was 15 changed to require an explicit statement -- these 16 aren't requirements -- to call for an explicit 17 statement precisely to force the participants to 18 focus on ensuring that there is no influence from 19 the funding body? 20 A. Intriguingly, no, actually. I think what 21 this was saying, and what AGREE II seems to have 22 done, is allow for pharmaceutical companies to be 23 involved in guideline development, or at least to 24 fund them. As long as you write a statement and

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Page 50 1 disclose that they're involved, it's saying, Okay, 2 you can say that -- you know, that seems to be okay. 3 So it's almost allowing for this, as 4 opposed to before -- or whatever. I think before, 5 none of us would have thought that this could be 6 happening, but... So we've moved into, "Well, just 7 make a disclosure statement about it." 8 Q. Well, it's not just a disclosure -- only a 9 disclosure statement, is it, Dr. Lightdale? It 10 calls for an explicit statement that views and 11 interests of the funding body have not influenced 12 the final recommendation, correct? 13 A. It's calling for that. It's saying you 14 should make that statement. 15 Q. And that goes beyond disclosure of who the 16 funder is? 17 A. I mean, it's saying "the funding body." So 18 this particular statement is the funding body, 19 right, that they're asking for. 20 Q. Let me ask you to turn to Page 41, which is 21 headed "Overall Guideline Assessment." 22 A. Yes. 23 Q. And this simply asks the rater, having 24 completed everything else, to rate the overall	Page 52 1 is a copy of the report you submitted in this case. 2 A. Yeah. 3 Q. If you would turn to Paragraph 26. 4 Let me ask you a quick question. Have you 5 served as an expert witness before this case? 6 A. On a couple of occasions. Not a case like 7 this, but, yes. 8 Q. All right. And did anybody assist you in 9 preparing your actual written report? 10 A. No. 11 Q. Let me take you to Paragraph 26, and there 12 you explain what GRADE is, all caps, G-R-A-D-E. 13 We'll talk about that a certain amount. And you 14 state that GRADE "is currently the most commonly 15 used system for classifying evidence and the 16 strength of recommendations." 17 Do you see that? 18 A. Yes. 19 Q. And what is the basis for your assertion in 20 your expert report that GRADE is the most commonly 21 used system for classifying evidence? 22 A. Just gut instinct, like what you're hearing 23 everyone talking about. 24 Q. Is there any close competition, or is GRADE
Page 51 1 quality of this guideline, again from a scale of 1 2 to 7, which you referred to as a Likert scale. 3 But then it does something else, and it has 4 a three-level statement. It begins, "I would 5 recommend this guideline for use," and then the 6 answers provided are "Yes," "Yes, with 7 modifications," and "No." 8 Do you see that? 9 A. Yes. 10 Q. And do you have an understanding of what a 11 rating of "No" by a rater is supposed to signify? 12 A. I think so. I mean -- 13 Q. What is it? 14 A. -- it would mean that the rater does not 15 think the guideline should be -- it's in their 16 opinion that the guideline shouldn't be recommended 17 for use. It's letting you say that as an assessor. 18 MR. BROOKS: All right. Let me ask the 19 reporter to mark as Exhibit 4 the Expert Rebuttal 20 Declaration of Dr. Jenifer Lightdale. 21 (Document marked as Lightdale 22 Exhibit 4 for identification) 23 Q. And here let me -- Dr. Lightdale, if you 24 would just take a look at this and confirm that this	Page 53 1 really by far the leading methodology used to rate 2 the strength of evidence today? 3 A. I would say it's the main way that people 4 are using -- or at least that people feel like they 5 can say are using the GRADE process. They'll ask if 6 you're following that. 7 Q. Let me ask you to find Exhibit 1 again. 8 That is the NASPGHAN paper. 9 And in this paper we looked at your 10 reference to AGREE there, but in the course of this 11 work -- I don't mean to make a memory test -- if you 12 turn to Page 32, there's a discussion of your team's 13 use of GRADE, as well as the AGREE, towards the 14 bottom of the first column. 15 So am I correct that, in your most recent 16 project to develop clinical practice guidelines, 17 your team used the GRADE system to rate the quality 18 of the evidence you found? 19 A. Yes. That's how we chose to rate evidence. 20 Q. And you, in fact, used the GRADE rating 21 system at two stages; am I correct? That is, first 22 you used it -- I'm looking about an inch and a half 23 from the bottom of the first column on 32 -- first 24 used it "to assess the quality of evidence ('very

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Page 54 1 low,' 'low,' "moderate," or 'high),'" and then a few 2 lines down it says, "The GRADE approach was then 3 used to determine the strength of recommendations as 4 'strong' [or] 'conditional,'" correct? 5 A. Yes. 6 Q. So GRADE provides means of rating both the 7 strength of evidence and the strength of 8 recommendations, right? 9 A. Yes. You can use it that way, yes. 10 Q. And your team did use it that way? 11 A. Right. 12 MR. BROOKS: Okay. Let me ask the reporter 13 to mark as Exhibit 5 excerpts -- an excerpt from the 14 WPATH SOC-8, which is appendices, including Appendix 15 8 titled "Methodology." 16 (Document marked as Lightdale 17 Exhibit 5 for identification) 18 Q. Dr. Lightdale, I've got the cover page -- 19 SOC-8 itself is a very long document, and I have not 20 put the whole thing in front of you. You will see 21 the cover page, the table of contents, and then, 22 beginning at Page S247, "Appendix A, Methodology." 23 A. Okay. 24 Q. And my first question for you is -- let me	Page 56 1 to make one objection, and clear to you, that in 2 answering the questions, you are instructed not to 3 disclose any conversations you've had with counsel. 4 THE WITNESS: Okay. Okay. 5 MS. LEVI: His questions aren't directed 6 towards that. 7 MR. BROOKS: That is correct. I feel 8 strongly on that point. 9 Q. Well, since you didn't know it existed, I 10 was going to ask why did you choose simply to rely 11 on the web page rather than the appendix that is 12 more detailed, but the answer is, you didn't know 13 the appendix existed? 14 A. Well, I don't remember knowing about that. 15 But I will tell you, I mostly stuck with what was 16 described -- I was asked, I got a phone call and was 17 asked, could I look at this and make comments, and I 18 made some comments based on the web page. So... 19 Q. Okay. Let me call your attention to Page 20 250 in the methodology appendix that's Exhibit 5, 21 and there's a short paragraph headed "Grading of the 22 evidence." 23 A. Okay. 24 Q. And that states, quote, "The Evidence
Page 55 1 ask you to flip through that Appendix A, which is 2 perhaps six pages long, and ask whether you think 3 you have ever seen this document before. 4 A. Okay. I'll just flip through it. I have 5 not looked at it before. 6 Q. Okay. 7 A. I will need to look at it if we're going to 8 start talking about it. 9 MS. LEVI: Take the time you need to look 10 at it. 11 THE WITNESS: Okay. Okay. 12 Q. Let me ask you -- 13 A. I don't want to start to speed read. 14 Q. No, that would be ill-advised. 15 But first, let me ask you this: Did you 16 know that SOC-8 had a methodology appendix as part 17 of the published standard of care? 18 A. No. 19 Q. When you were asked to prepare your report, 20 somebody directed you to the methodology web page 21 but not to the methodology appendix? 22 A. I mean, I was in the web page. I'm, like, 23 going through different -- 24 MS. LEVI: And I'm just going to -- I want	Page 57 1 Review Team assigned evidence grades using the GRADE 2 methodology. The strength of the evidence was 3 obtained using predefined critical outcomes for each 4 question and by assessing the limitations to 5 individual study qualities/risk of bias, 6 consistency, directness, precision, and reporting 7 bias." 8 Do you see that? 9 A. Yes. 10 Q. Do you have any knowledge as to whether, in 11 fact, anybody within the SOC-8 team ever assigned 12 evidence grades to any evidence using the GRADE 13 methodology? 14 A. No. All I have is their instructions. 15 Q. If the team told the world, in the 16 published appendix, that they assigned evidence 17 grades using the GRADE methodology, and in fact they 18 did not do so, you, as a person with expertise in 19 developing clinical practice guidelines, would 20 consider that to be quite problematical, would you 21 not? 22 MS. LEVI: Object as to form. 23 A. I'm also feeling like -- can you repeat the 24 question, because I'm trying to focus on what you're

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Page 58 1 asking. 2 Q. If the SOC development team told the world, 3 in their methodology appendix, that they assigned 4 evidence grades using the GRADE methodology and in 5 fact it did not do so, that would cause you serious 6 concern as somebody with experience in developing 7 and using clinical practice guidelines, would it 8 not? 9 A. So as someone who has experience, I can 10 tell you that the GRADE methodology can be applied 11 in different ways. So I would have to understand 12 more why someone is telling me that it wasn't done, 13 because there are so many ways to use it. So... 14 Q. My question is a simple and a hypothetical 15 one. 16 A. Okay. 17 Q. If they told the world, "We assigned 18 evidence grades using the GRADE methodology," and 19 they simply did not do so, that would cause you 20 serious concern, would it not? 21 MS. LEVI: Object as to form. 22 A. I would be mystified why they would do 23 that. 24 Q. You wouldn't go so far as saying it would	Page 60 1 specifically set out in the GRADE system, correct? 2 A. Not per se. There's actually a fair amount 3 of ways that you can make decisions yourself about 4 how you are going to grade evidence. So -- and then 5 the strength of recommendations. 6 And for instance -- and I'm not, frankly, 7 looking at what you've given me. But, you know, how 8 are you going to decide something is of high 9 quality? How many -- how are you going to decide 10 some of this stuff? 11 And so even the process of putting together 12 a guideline is a certain amount of consensus about 13 how you're going to use GRADE methodology. So I 14 don't think it's black and white. It's a process 15 you go through. 16 Q. Is it your testimony, Dr. Lightdale, that 17 the GRADE system does not provide black-and-white 18 definitions, textual definitions of very low, low, 19 medium and high quality evidence? 20 A. It gives you that way of ranking your 21 evidence. But in terms of what does it mean to be 22 high quality, that can also be, like, decided along 23 the way of what we're going to decide is high 24 quality evidence. So that is not a highly -- that's
Page 59 1 concern you? 2 A. Honestly, I'd be more concerned with 3 somebody trying to say that it didn't happen and to 4 say, "Well, why do you think it didn't happen?" 5 Again, there are so many ways to take GRADE and then 6 put it into use in the sense of -- I mean, 7 there's -- whatever. You're using GRADE methodology 8 but it's just a methodology. So now you apply it, 9 and what it looks like can look very different ways. 10 So how we used it in our worksheets, if you 11 will, and how our process worked is, using GRADE 12 methodology -- as we went through our development 13 process, we had to make decisions about how we were 14 going to use GRADE methodology. 15 So for me it would be someone telling me, 16 "Oh, it didn't happen." I'd say, "Well, how do you 17 know that? You know, why are you saying that?" 18 That would be the bigger concern, to be honest. 19 Q. The GRADE system for rating evidence has a 20 specific set of four levels of strength, correct, as 21 described in your NASPGHAN document; that is, very 22 low, low, moderate or high? 23 A. That is how we did it, for sure. 24 Q. And, indeed, definitions of those terms are	Page 61 1 not a firmly defined thing, high quality evidence. 2 Q. As you sit here today, you don't recall the 3 precisely defined meaning of high quality evidence 4 from GRADE? 5 A. I think GRADE talks about what can be high 6 quality evidence, but there are also things that 7 they know also can be high quality evidence. 8 So the classic is randomized controlled 9 trials can be high quality evidence, but so can very 10 well defined -- or, you know, designed observational 11 trials. 12 So you can't just say, just because 13 something is an observational trial, that it's not 14 the same evidence -- or not the same quality. You 15 actually need to be assessing every study, no matter 16 what the design is. 17 So, again, high quality is a process to 18 decide something is of high quality when -- okay. 19 I'll try to stop talking. 20 There's a lot of ambiguity here. 21 Q. Was WPATH's use of the widely accepted 22 GRADE system for classifying the strength of 23 evidence and the strength of recommendations an 24 important part of the basis for your conclusion in

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Page 62 1 your expert report that, and I quote, "WPATH's 2 method for developing SOC-8 is exemplary," close 3 quote? 4 A. I made that statement because I was so 5 impressed by how they had spelled out their entire 6 process on the web page for developing their 7 guideline and had really shown it to be very 8 carefully a priori thought about, it was very 9 rigorous, it seemed to me to be very transparent in 10 what they had done, how they had come up with their 11 groups, how they'd organized themselves. They gave 12 a lot of information there that, honestly, most 13 societies aren't doing at this point. 14 So it was very impressive how they had 15 taken a lot of steps to spell out what they had 16 done. 17 Q. Was their use of the widely accepted GRADE 18 system to rate evidence and the strength of 19 recommendations an important part of the basis for 20 your conclusion that their method for developing 21 SOC-8 was exemplary? 22 A. No. I would say it was more that they said 23 what method that they used. 24 So, you know, I think -- I mean, again,	Page 64 1 developing and presenting summaries of evidence and 2 provides a systematic approach for making clinical 3 practice recommendations," and it cites Guyatt, et 4 al., close quote. 5 Do you see that? 6 A. Yes. 7 Q. Does the name "Guyatt" mean anything to 8 you? 9 A. So for me it is a reference that one often 10 uses when you are explaining that you used GRADE. 11 So, you know, it's a person. 12 Q. Do you know who Professor Guyatt is? 13 A. Not in any meaningful way, no. 14 Q. Do you know anything about his reputation 15 in the field of evidence-based medicine? 16 A. He is the first author on this sort of 17 important text that you use to say you're using 18 GRADE. 19 Q. You've never heard him speak at a 20 conference? 21 A. No. No. 22 Q. Okay. In your report you mention that some 23 criticisms have been made of the GRADE system of 24 evaluating the strength of evidentiary support, but
Page 63 1 GRADE for me is something common and I sort of had a 2 sense of just how much work it is and how rigorous 3 it is. 4 But I think you could -- I was frankly more 5 impressed with the whole shebang. So for me it's 6 more explaining very clearly how you went through 7 the process of developing your guideline, not 8 necessarily that one used GRADE. Like, that wasn't 9 what made me feel so good about it. It was the 10 whole description of a rigorous and transparent 11 process. 12 MS. LEVI: Roger, I'm just checking. We've 13 been a little over an hour. Would now be -- 14 MR. BROOKS: Let me -- I'll wrap up this 15 series of questions shortly. 16 MS. LEVI: Okay. 17 MR. BROOKS: If you're all right, we'll go 18 for a few more minutes. 19 Q. In the second column on Page 250, S250, is 20 a section "Grading criteria for statements." Do you 21 see that? 22 A. Yes. 23 Q. And there, in the second sentence, it says, 24 quote, "This is a transparent framework for	Page 65 1 you, yourself, have recently used GRADE -- 2 A. (Nods head) 3 Q. -- and I think you've -- you have to... 4 A. Oh, yes. Sorry. 5 Q. And I think you've testified that it is 6 much the most widely used system for evaluating the 7 strength of evidence currently. 8 A. (Nods head) 9 Q. And as we've seen, WPATH states that they 10 used GRADE to determine the strength of evidence, 11 correct? 12 A. Yes. 13 Q. What was your point in mentioning that 14 GRADE has been criticized? 15 A. Well, I think, as I've been saying, for me 16 this is still an evolution, and I think you have to 17 approach anything we do around guidelines with an 18 understanding that nothing's perfect, right? 19 So -- and that, by the way, is everything. 20 That's the evidence we're using to make the 21 guidelines or lack of evidence. That's how we 22 create groups that are going to make the guidelines. 23 And then there's actually how you're going to put 24 the guideline together and the methodology you're

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Page 66 1 going to use. 2 And in there is GRADE has emerged as a 3 methodology we're all coalesced around, but you know 4 that it is not perfect. And I'll say to my own, 5 there are many different ways you can use it. And 6 so part of process is even deciding how you're going 7 to use it, and, you know, there are still a lot of 8 judgment calls to it. 9 So in pursuit of perfection continues, and 10 therefore, criticism is welcome to keep making it 11 better. 12 Q. All right. Well, you've made some 13 criticism of GRADE in your expert report. Let me 14 ask you this. 15 A. Yes. 16 Q. Have you ever published -- have you ever, 17 in any publication, criticized GRADE in any way? 18 A. No. 19 MR. BROOKS: All right. Let's take a 20 break. 21 MS. LEVI: Okay. 22 (Recess) 23 MR. BROOKS: Let me ask the reporter to 24 mark as Exhibit 6 an article from 2011 entitled	Page 68 1 So Dr. Guyatt has got some subordinates, 2 but he is the senior person on this project? 3 A. (Nods head) 4 Q. Do you think that you have ever before 5 today seen -- and there are, I think, at least 15 in 6 this numbered sequence. I'm not going to put them 7 all in front of you, I promise. 8 Do you think you have seen any of these 9 numbered papers setting out the GRADE system? 10 A. I don't know that I've ever seen the papers 11 specifically before. 12 Q. Okay. I want to call your attention to 13 Page 404, Table 2, which provides statements of the 14 meaning of the four levels of evidence. And I'll -- 15 there are many places I could have gone to show you 16 these same definitions. This is just one. 17 And there's two columns -- there's three 18 columns. One is "Quality level," "High," 19 "Moderate," "Low," "Very low." The second column 20 says "Current definition." And, again, this paper 21 is as of 2011. And the final column reads "Previous 22 definition." 23 Let me ask you to look at the column that 24 says "Current definition" and tell me whether those
Page 67 1 "GRADE guidelines: 3. Rating the quality of 2 evidence." 3 (Document marked as Lightdale 4 Exhibit 6 for identification) 5 BY MR. BROOKS: 6 Q. And, Dr. Lightdale, let me ask generally, 7 are you familiar with a series -- a numbered series 8 of papers published that detail the GRADE system? 9 A. I'm familiar. 10 Q. And you'll see there's a number of authors, 11 of which Dr. Guyatt is the last. 12 Are you able to tell me, just for the 13 record, generally what the significance of the last 14 named author is on an academic paper? 15 A. Yes. 16 Q. What is that? 17 A. So, generally speaking, the last author is 18 your senior person, who then is usually looking at 19 the first person -- those two people are usually the 20 people who are writing the paper together. 21 Q. Okay. The first person probably did the 22 most work, and the last person is the most senior -- 23 A. Senior, yes. 24 Q. -- responsible person.	Page 69 1 are indeed the definitions of -- or the statements 2 of the meaning of the quality levels within the 3 GRADE system for rating evidence that you are 4 familiar with. 5 A. I would have to compare it, but it looks 6 approximately like what we used. In other words, 7 even this is something that one might reword for 8 your own purposes a little bit. 9 Q. If you look at the definition of "Low," it 10 says, quote, "Our confidence in the effect estimate 11 is limited: The true effect may be substantially 12 different from the estimate of the effect." 13 Do you see that language? 14 A. Yes. 15 Q. And do you have an understanding of what 16 that means, what it means if you assign that rating 17 to the results of a study? 18 A. So, yes. 19 Q. What is that understanding? 20 A. So I think this -- a lot of this is 21 subjective ratings of evidence. And here, when 22 you -- when the group decides something's of low 23 confidence, or frankly if an individual is doing 24 their grading of evidence as part of the process,

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Page 70 1 you would say that your confidence in what's been 2 found, or the effect estimate, is not great, and 3 that the true effect might be different from what is 4 being found, or not found, as the case may be. 5 Q. Just to pause for a moment. Am I correct 6 that it is considered good practice, if you're 7 rating a body of evidence, to have more than one 8 rater independently evaluate each study? 9 A. We have, yeah. 10 Q. And then did you have a process for 11 resolution if they disagreed? 12 A. Yes. 13 Q. Was that documented in any way in what you 14 disclosed to the public in connection with your 15 NASPGHAN guidelines? 16 A. I don't think it shows up in the final 17 paper exactly. It's more -- well, actually, there 18 are a couple of times that we couldn't come to 19 consensus, and we make that clear, that we have 20 certain things that we couldn't come to consensus 21 on. 22 And by the time you get to that point, 23 you've gone through a lot of process here. This is 24 around grading the various pieces of evidence that	Page 72 1 in terms of what we know and what's been found and 2 what's estimated to have been found, because even 3 statistics are just estimates. 4 So I think when you say the true effect is 5 likely to be incredibly different from what is 6 known, it's usually in a situation where we just 7 don't have much of an estimate of effect or even any 8 estimate of effect; and therefore you don't really 9 know, and you actually -- not only don't you know, 10 but you don't have any confidence in what is 11 being -- is out there. 12 Q. So if you assigned a rating of very low to 13 an individual published study in which a certain 14 treatment is administered and a certain outcome is 15 reported, am I correct that what you are saying with 16 that "very low" designation is, "The design of the 17 study is such that I have no confidence that, if it 18 was repeated on a different patient, you would get 19 the same outcome"? 20 MS. LEVI: Object as to form. 21 A. Yeah, well -- I'm actually not -- 22 THE WITNESS: Can I answer? Or is that -- 23 MS. LEVI: Yes. 24 A. I'm actually not sure that it would be
Page 71 1 are going into your recommendation. 2 But, yes, sometimes there was not enough to 3 even achieve consensus. 4 Q. The rating of "very low" states that the 5 articulation of what that means here in this paper 6 from Dr. Guyatt is, quote, "We have very little 7 confidence in the effect estimate: The true effect 8 is likely to be substantially different from the 9 estimate of effect." 10 Do you have an understanding of what is 11 meant by that definition of a very low rating? 12 A. Again, for me, this is all relative, right? 13 So "very low" is even less than "low." You have 14 even less confidence in what's been found, and the 15 true effect is likely to be incredibly different 16 from what we have found so far. 17 Q. What does it mean to say that the true 18 effect is different from the estimate of effect? I 19 think, to a layman, that might be a bit cryptic. 20 What does that mean? 21 A. So what it would mean -- again, and I'm 22 sort of staying away from statistics, which affect 23 estimate to some extent. It could be interpreted 24 statistically, but it also can be just interpreted	Page 73 1 about design of the study. It's just -- the bottom 2 line there is, you have a very low confidence in 3 the -- well, this is about GRADE, but you have very 4 low confidence in the known evidence that's out 5 there, and that if there was a different study or 6 perhaps -- perhaps a different design, but it also 7 could be that -- what I usually wind up in this 8 world in is just a case study or something like 9 that, that we don't actually know, based on an N of 10 1, what is going to happen if you did it across, you 11 know, a thousand people. 12 Q. Okay. Fair enough. 13 Let me take you to the first page of this 14 paper. 15 A. Okay. 16 Q. Exhibit 6. 17 A. Yes. 18 Q. "GRADE guidelines: No. 3." And on the 19 first page in the second column is a Heading Number 20 2, "What we do not mean by quality of evidence," 21 and then Heading 3 that says, "Opinion is not 22 evidence." 23 Now, you testified earlier that -- I forget 24 exactly what year you said, but you may have said

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Page 74 1 about 2005 -- this evidence-based medicine wasn't a 2 thing yet? 3 A. Well, 1995. 4 Q. 1995, thank you. 5 A. When I graduated from medical school, it 6 was just coming around. 7 Q. I see the heading here that says, "Opinion 8 is not evidence." And do you have an understanding 9 of what that means, what's being said in the context 10 of evidence-based medicine? 11 A. Let me take a look at what they wrote here 12 in this paragraph. 13 Q. Please. 14 A. (Reviewing document) 15 MS. LEVI: Take your time to review the 16 whole article if you need to as well. 17 Q. And, look, if the answer is, "I don't have 18 an opinion," that's fine. I just... 19 A. (Reviewing document) 20 Q. Let me ask a better question. 21 A. Yeah, thanks. 22 Q. Let me withdraw that question, because I 23 don't want to just have you sit here and interpret 24 what they wrote.	Page 76 1 have to go on. Is that part of what you're telling 2 me? 3 A. No. I think they wrote a lot of paragraphs 4 here, because it is tricky in medicine to feel like 5 things are black and white. So, you know, they're 6 just not that specific. You just can't be. 7 And so they're taking a lot of time here -- 8 again, I'd have to get into it more -- to think 9 about something I think all of us in guidelines 10 think about, which is, okay, what do we -- how do we 11 take evidence, synthesize it, but also make sure 12 that we feel like we can have opinions on the body 13 of the evidence we're looking at and can make a 14 recommendation. 15 I mean, that is the consensus process 16 around guidelines and the guideline development 17 process in a nutshell. It's we have got evidence, 18 but then we have to go beyond evidence, because 19 evidence itself is not good enough, basically. 20 Q. For purposes of guideline -- as the terms 21 are understood today in guideline development, do 22 you consider expert opinion itself to be scientific 23 evidence? 24 MS. LEVI: Object as to form.
Page 75 1 A. Great. 2 Q. But that's context, and my question for you 3 now is, in your work today, for instance developing 4 the NASPGHAN guidelines, did you consider expert 5 opinion to be scientific evidence? 6 MS. LEVI: Object as to form. 7 A. Yeah, so I think it was incumbent upon us 8 as a group to do our best to be understanding where 9 there was evidence and what that evidence was and 10 what the strength of the evidence was, and then, in 11 the absence, especially, of evidence, then to also 12 understand how strongly we were ready to make 13 recommendations. And that was, like, a constant 14 tension for us throughout the entire process. 15 And I think why they're writing all these 16 paragraphs here that I'm trying to read very quickly 17 is this is very hard in medicine. It's very hard. 18 You know, there is constantly a give-and-take on 19 where is there evidence, what does that evidence 20 mean, how does it apply to whatever you're trying to 21 look at it for, and then where is there more 22 experience of it, experience driving opinion. So... 23 Q. Well, so let me see if I understand what 24 you're saying. Sometimes expert opinion is all you	Page 77 1 A. So expert opinion, again, is -- I'm not 2 sure what you mean by "expert opinion." Like, who 3 makes somebody an expert, and how do they have an 4 opinion? 5 So I think it's just always trying to 6 understand it and to be ready to see it as a 7 relative thing, where you might have high, you know, 8 medium, low, and even very low. It's like -- I 9 mean, there's just basically -- it's constantly 10 relativity to what we're doing in this process of 11 trying to put it together and give people guidance. 12 Q. Well, I'm not trying to be tricky. Let's 13 assume that we're talking about the opinions of -- 14 in your own field, I assume there are some people 15 who everybody would acknowledge are experts, true? 16 A. Experts are people who have emerged as 17 giving statements and leading a field, but every 18 expert does come with their own ways that they do 19 something. 20 And so, yes, you can see somebody as an 21 expert. You also want to understand how they -- how 22 they do it. So you sort of have to look beyond just 23 are they an expert and say, "Well, why are they an 24 expert, and is that what I need at that moment?"

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Page 78 1 Q. We talked earlier about evidence tables and 2 rating the strength of evidence. For purposes of 3 developing clinical practice guidelines, do you 4 consider expert opinion to be scientific evidence? 5 A. No. I think it's important. So expert 6 opinion becomes as important as whatever's been 7 published as evidence. 8 Q. Okay. Let me take you back -- 9 THE WITNESS: I have a bad question. Am I 10 allowed to have a Coca-Cola? 11 MR. BROOKS: Absolutely. 12 THE WITNESS: Get some sugar. 13 MS. LEVI: Just to be clear, at any time if 14 you need a break, it's fair to ask for it. 15 MR. BROOKS: Exactly. 16 THE WITNESS: I left the coffee in the 17 other room, and I think I need some sugar. 18 MS. LEVI: If you want me to get your 19 coffee -- 20 THE WITNESS: No, no, no. It was quite 21 cold. 22 MS. LEVI: Nobody wants you to be 23 uncomfortable. 24	Page 80 1 Am I correct that a conditional 2 recommendation, in some guidelines, the term that's 3 used for that is a "suggestion" or a "weak 4 recommendation"? 5 A. Yeah -- 6 MS. LEVI: Object as to form. 7 A. We had a very specific concept, which is 8 "conditional recommendation" was defined as 9 suggesting that implementation might vary. So it 10 was recommended, but we knew that it might or might 11 not be something people would choose to implement. 12 Q. Did it also, whether it was a conditional 13 or unconditional recommendation, relate to any 14 extent to the strength of the evidence that you had 15 to support that recommendation? 16 A. So they were two different things that we 17 were, you know, grading. So we were grading the 18 quality of the evidence, and then we were also 19 making a recommendation. And very often our 20 conditional recommendations were where there was low 21 quality evidence. 22 Q. And this is an example where you've 23 expressly said up front that there was low quality 24 evidence, right?
Page 79 1 BY MR. BROOKS: 2 Q. If you would find Exhibit 1 again, NASPGHAN 3 guideline -- I love that term. 4 A. Thank you. We've thought about a name 5 change, but it's hopeless at this point. 6 Q. And I'll be clear for the record, I'm using 7 this for exemplary purposes. These are guidelines 8 relating to pediatric endoscopic procedures, a topic 9 utterly unrelated to the subject matter of this 10 case. And maybe that's a good thing. 11 If you -- this paper, in fact, includes 12 recommendations and suggestions -- this paper 13 contains the guidelines that your team developed; am 14 I right? 15 A. Yes. 16 Q. And if you would turn to Page 37, I have 17 just picked an example, Standard 36, to ask you a 18 few questions about. 19 A. Okay. 20 Q. And this is -- Standard 36 is a conditional 21 recommendation that, quote, "Endoscopic biopsies 22 should be obtained as appropriate for the procedural 23 indication, consistent with current evidence-based 24 guidelines, when available."	Page 81 1 A. Yes. This one had low quality evidence. 2 Q. And you also disclosed the vote in your 3 consensus process? 4 A. Yes. 5 Q. Which was a Delphi process? 6 A. We used a Delphi process to come to 7 consensus to vote on recommendations themselves. 8 Q. Is a Delphi process a fairly well defined 9 thing in the art? 10 A. So most of us talk about a modified Delphi, 11 because Delphi itself was probably way prior to 12 where we are now, which is lots of ways you can do 13 things across continents without having to get 14 together. 15 But Delphi is well described, and it's an 16 iterative, good process for coming to consensus. 17 So... 18 Q. Is it a process -- is anonymity in the 19 voting an inherent part of the Delphi process? 20 A. Yes. 21 Q. Why is that? 22 A. I think anonymity is a way of trying to 23 mitigate bias, to come back to that word. So... 24 Q. Why is it important that the voting be

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Page 82 1 anonymous? 2 A. I think that the Delphi process is designed 3 to let each individual stand, you know, in their own 4 convictions and their own -- you know, to basically 5 vote on their own decisions on how they want to do 6 things. 7 And, yeah, it's just important, because it 8 doesn't let necessarily one person sway a process, 9 like what would happen in an open room. So... 10 Q. You might have somebody who is highly 11 respected that more junior participants are 12 reluctant to disagree with? 13 A. Sure. That could happen. 14 Q. You might have peer pressure of some sort, 15 that somebody is reluctant to be the odd man out? 16 A. Yeah. 17 Q. Has every Delphi process that you've ever 18 participated in been anonymous in its voting? 19 A. Yes. 20 Q. Why did you disclose the breakout of the 21 vote? 22 A. We made a decision early on, before we did 23 any of it -- again, working with methodologists and 24 trying to decide how we were proceeding -- with what	Page 84 1 conditional? 2 A. Well, I think there's a debate about 3 frankly what is that. So pediatric endoscopy is a 4 field where we take longer with colonoscopies for 5 lots of different reasons, and I don't think we have 6 tended to be focused on time the way that adult 7 colonoscopists have. 8 And so there's actually a lot of people who 9 are reticent. I'll tell you, I personally voted 10 "strongly agree" there. I agree with you, for me 11 this was a no-brainer. But there are a lot of 12 people who are quite reticent to have there be some 13 sort of regulation or, in this case, a standard, 14 even, to say, you know, that time matters. 15 So that's still a foreign concept in 16 pediatric GI. And it turned out we didn't have much 17 evidence to say that it needs to happen in an 18 efficient way. 19 Q. So in the evidence was low quality -- even 20 if it seemed common sense, if the evidence is low 21 quality, you would generally give only a conditional 22 recommendation? 23 MS. LEVI: Object as to form. 24 A. Yeah, no, there are really two different
Page 83 1 we were going to do. So that was all decided a 2 priori. 3 Q. If you back up to Page 36, Standard 32. 4 A. Yes. 5 Q. This standard says, "Pediatric endoscopic 6 procedures should be performed efficiently, within a 7 reasonable procedure time." 8 I take it, in layman's terms, that means 9 don't dawdle in your procedure. Am I understanding, 10 more or less, what it's telling us? 11 A. Yeah. 12 Q. And this also is a conditional 13 recommendation, and it states that there's very low 14 quality evidence, correct? 15 A. Yes. 16 Q. And indeed, the recommendation, only 37.5 17 percent of the participants strongly agreed with it; 18 am I right in understanding this correctly? 19 A. Yes. 20 Q. Now, the recommendation that you perform 21 these procedures efficiently within a reasonable 22 time off the cuff seems, to use a technical term, a 23 no-brainer. 24 Why was that recommendation only	Page 85 1 things. And so you sort of got to this, and then it 2 was like, "All right, are we ready to vote on this 3 recommendation?" 4 So, again, the conditional recommendation 5 is saying that we're going to recommend it, but we 6 appreciate that implementing it may be not something 7 you have to do; versus a strong recommendation was, 8 we actually think you need to do this, like, this is 9 from a safety and quality perspective. 10 So then the voting, you're just seeing that 11 it really -- and it really wasn't necessarily 12 everyone ready to say that time was important. But, 13 again, a priori we had said, "Well, what are we 14 going to say is a recommendation?" And it was 15 actually you had to combine the "strongly agree" and 16 "agree" and be, you know, on a certain level. 17 Q. Let me just put a caution out on the table. 18 We do this all the time in ordinary speech. You 19 began that answer, "Yeah, no." 20 A. Oh. 21 Q. And in a deposition, that doesn't work 22 terribly well. 23 A. I didn't hear it. I didn't hear it. Okay. 24 Q. You know what I mean.

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Page 86 1 A. Yeah. 2 Q. It's just sort of a thing. So let me -- 3 I'll just ask you a new question. It doesn't really 4 matter. I'll just caution you. 5 A. Okay. 6 Q. Am I correct that, most commonly, if all 7 you have is weak evidence for a recommendation, you 8 would expect that recommendation to be a conditional 9 or a weak -- a conditional recommendation or a 10 suggestion? 11 MS. LEVI: Object as to form. 12 A. I mean, I think we -- we would say it's 13 hard to make -- like, to have strong evidence and 14 then have a conditional recommendation. And I think 15 it's probably -- I mean, again, the low quality 16 evidence is not going to make it possible to have a 17 strong recommendation, usually. 18 Q. I can't promise we won't come back to that 19 again. I just love it so much. 20 MR. BROOKS: Let me ask the reporter to 21 mark as Exhibit 7 a paper from 2018, the lead author 22 Dayna Early, a number of authors including Dr. 23 Lightdale, entitled "Guidelines for sedation and 24 anesthesia in GI endoscopy."	Page 88 1 not for the procedure itself? 2 A. Right. 3 Q. And, again, in this set of guidelines, your 4 team used GRADE to rate the strength of the 5 supporting evidence; am I right? 6 Not a memory test. I think it says so at 7 the bottom of the first column on the first page. 8 A. I don't actually remember that we used 9 GRADE. 10 Q. Well, again, I'm not testing your -- first 11 page, first column, at the bottom of the -- 12 MS. LEVI: You can take your time to 13 read -- 14 THE WITNESS: Yeah, let me -- 15 MS. LEVI: -- and review your own article. 16 That's okay. 17 THE WITNESS: Yeah, no, this is part of the 18 evolution. 19 A. (Reviewing document) We used -- yeah. We 20 used GRADE criteria at the very end to talk about 21 the recommendations, but we didn't use GRADE 22 methodology. This is -- this was the state of the 23 art from, like, I don't know, 2010 to -- again, this 24 came out in 2018. We were probably working on this
Page 87 1 (Document marked as Lightdale 2 Exhibit 7 for identification) 3 Q. And, Dr. Lightdale, my first question is, 4 can you identify this document, this paper for the 5 record. 6 A. Yes. 7 Q. What is this? 8 A. So this was what we called a guideline for 9 sedation and anesthesia in GI endoscopy that I was 10 the second author on that came out of the Standards 11 of Practice Committee for the American Society of 12 Gastrointestinal Endoscopy. 13 Q. And "second author" implies that you -- 14 there's a lot of names there. 15 A. Yes. 16 Q. "Second author" implies that you were 17 substantially involved, more than many of those 18 authors? 19 A. I was substantially involved. 20 Q. All right. And this is a different set of 21 guidelines being created by a different team; am I 22 correct? 23 A. Yes. 24 Q. Specifically for sedation and anesthesia,	Page 89 1 one in 2016, you know. 2 So we were using GRADE criteria -- 3 actually, yes, published -- August 2017 is when we 4 started looking at things. 5 But we didn't actually use the GRADE 6 process. 7 Q. Well, let me ask this: The last line of 8 the first column -- I was going to say "abstract," 9 but it's not exactly an abstract, is it? 10 A. Yeah. 11 Q. Whatever it is, the first column, which is 12 in italics, reads, "The recommendations were based 13 on reviewed studies and were graded on the strength 14 of the supporting evidence by using the GRADE 15 criteria (Table 1)." 16 And if we turn to Table 1, that is headed 17 "System for rating the quality of evidence for 18 guidelines." It's footnoted, "Adapted from Guyatt 19 et al." And it has definitions which I -- we could 20 take the time -- it matches the list of previous 21 definitions in the table that we looked at earlier. 22 MS. LEVI: I'm going to ask, if you're 23 going to respond to that question, that you make 24 sure --

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Page 90 1 MR. BROOKS: That's a representation. 2 MS. LEVI: -- that you are familiar -- 3 Q. We can go back to my favorite document, 4 which is to say Exhibit 1 -- no, it's not. 5 Lightdale Exhibit 6 contains, on Page 404, the 6 definitions. 7 MS. LEVI: Take the time you need to 8 respond accurately to the question that may be 9 asked. 10 Q. And my only point -- and there is no 11 question at the moment -- my only point is that the 12 list of definitions contained in your paper from 13 2018 seems to correspond to the column labeled 14 "Previous definition" on Page 404 of Lightdale 15 Exhibit 6. 16 And if you'd like to check that, that's 17 fine. 18 A. Yes. It does. 19 Q. All right. And in the right-hand column in 20 your 2018 paper is -- it says "Symbol," and it shows 21 little circles with crosses. 22 Are those symbols widely used and 23 recognized in connection with GRADE ratings? 24 A. Not necessarily. So without a doubt --	Page 92 1 related to sedation and anesthesia, they're not 2 antique. 2018 is not that many years ago. 3 A. Correct. 4 Q. Why did your team not use a GRADE system 5 for rating the evidence in the course of developing 6 those guidelines? 7 A. So in 2017 -- again, my memory is probably 8 in 2016 I got assigned this with Dayna in the 9 Standards of Practice Committee that I was sitting 10 on. And we basically -- we were just, as a society 11 and as a group, and I would argue across most of 12 medicine, people were really not yet ready to put in 13 the tremendous effort it takes to do the GRADE 14 process. 15 And so it's being discussed by experts out 16 there and mentioned, and people are hearing the 17 term, but what it actually means to do it is a lot 18 of work. And that is not where we were at ASGE in, 19 you know, 2016, 2017, as we were doing this thing, 20 and it ultimately comes out in 2018. 21 MR. BROOKS: Okay. Let me ask the reporter 22 to mark as Exhibit 8 one of the GRADE Series papers, 23 No. 14, quote, "Going from evidence to 24 recommendations: the significance and presentation
Page 91 1 it's funny, I have strong memories of this paper. 2 We were not using the GRADE process, but 3 what we did at the end, and this is what ASGE was 4 doing at the time, is we used this GRADE criteria, 5 this previous definition of GRADE -- again, 6 everything has been an evolution, right? 7 Q. Right. 8 A. But this previous definition, we looked at 9 that as we looked at our recommendations. 10 In other words, we came up with the 11 recommendations and then we said, "Okay, how do we 12 feel?" 13 And this was not a Delphi process. There 14 was a lot to this that is really, frankly, just at a 15 different level than where we are now, like where my 16 PEnQuIN document is, let's say, in terms of the 17 rigor. 18 Q. Would you spell that for the reporter, 19 PEnQuIN. 20 A. Sure. P-E-n-Q-u-I-N, which is the 21 Pediatric Endoscopic Quality Improvement Network. 22 Q. Otherwise we're going get a transcript that 23 has "penguins" all over it. 24 Let me ask this, because the guidelines	Page 93 1 of recommendations." 2 (Document marked as Lightdale 3 Exhibit 8 for identification) 4 Q. And, again, Dr. Lightdale, do you think 5 that you've seen this paper before today? 6 A. No. 7 Q. Then I will ask you -- I mean to ask you 8 about your practices and understanding rather than 9 to interpret the meaning of the authors. 10 So let me ask you to turn to Page 720 11 and -- actually, why don't you read the abstract 12 just for context so you know what that paper is 13 about and we're not working in the dark. 14 A. (Reviewing document) Okay. 15 Q. Now let me ask you to turn to Page 720. 16 And the second column, beginning in the third text 17 line reads, "If the panel is highly confident of the 18 balance between desirable and undesirable 19 consequences, they make a strong recommendation 20 for.. or against... an intervention." 21 Do you see that? 22 A. Yes. 23 Q. And is that description of when a strong 24 recommendation is appropriate consistent with how

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Page 94 1 you have gone about deciding what merits or does not 2 merit a strong recommendation? 3 A. I mean, yes and no. 4 Q. Okay. 5 A. So I think -- I have not sat in a panel and 6 thought about this, you know, desirable, 7 undesirable. We haven't sat there and weighed that 8 kind of stuff. 9 But I would say, instinctively and 10 inherently, to make a strong recommendation, you 11 have brought into play discussions around desirable 12 and undesirable consequences. 13 So people are thinking about that, and that 14 could be either desirable health outcomes, or I 15 think there's a lot of, I would call it, risk/ 16 benefit weighing that's going on with 17 recommendations and what are the risks to making a 18 strong recommendation for or a strong recommendation 19 against something, what's the risk of that. 20 So strong recommendations are to be done 21 very carefully. 22 Q. Well, the next sentence reads, quote, "If 23 the panel has less confidence of the balance between 24 desirable and undesirable consequences, they offer a	Page 96 1 pushing us. In fact, the abstract that you asked me 2 to read says this. Don't shy away from not (sic) 3 making a recommendation. It's important to make 4 recommendations, because if you don't make a 5 recommendation, you still leave people in the dark. 6 So it is a grappling process to try to 7 figure out, okay, how do we make the recommendation. 8 Q. In that process, do you, as a physician -- 9 well, let's take it in a clinical process system 10 first. 11 Do you, as a physician, deciding on 12 treatment for a patient, have an obligation to 13 consider both long- and short-term consequences of 14 administering the treatment or withholding the 15 treatment? 16 MS. LEVI: Object as to form. 17 A. I would say not always, is the truth. 18 Q. In what context, if any, would you have no 19 obligation to consider the long-term consequences? 20 A. When there's life or death on the line. 21 Q. Okay. And have you yourself faced those 22 situations? 23 A. Yeah. 24 Q. And what degree of threat or imminence of
Page 95 1 weak recommendation." 2 Do you see that? 3 A. Yes. 4 Q. And is that relating to what you just 5 explained to me? 6 A. Yeah. I think, again, in practice that 7 kind of happens. 8 Q. So you need to be fairly confident that you 9 understand -- let me start again. 10 You need to have a fairly confident 11 evaluation of the upside of the treatment in 12 question and also a fairly confident understanding 13 of the risks or downside before you can offer a 14 strong recommendation; am I correct? 15 MS. LEVI: Object as to form. 16 A. I guess I'm not sure if you're restating 17 what I tried to state. 18 But I think a panel ultimately is -- 19 everybody in that panel is, in their head, weighing 20 what's good about making that recommendation and 21 what could be a downside or undesirable or a risk of 22 making a recommendation, or not making a 23 recommendation. 24 I think a lot of this GRADE stuff is really	Page 97 1 death, to your understanding, makes it appropriate 2 for you as a physician to put aside considerations 3 of long-term impacts? 4 A. So I'm in pediatric GI, so we certainly 5 encounter situations where, if we do not act within 6 the next 15 minutes, somebody will die, and you 7 actually do need to do something. 8 So, you know, not -- at that moment, I'm 9 not worrying about the long term. I'm worrying 10 about what needs to be solved at that moment to get 11 the patient out of the situation. 12 Q. Absent an imminent threat of death, do you 13 believe that you, as a physician, have an obligation 14 to consider both long-term and short-term 15 consequences of a potential treatment as you make 16 decisions for or with a patient? 17 A. I'm in pediatrics, so long-term discussions 18 of things is really tricky. You know, what are we 19 talking? Five years out? Ten years out? Fifty 20 years out? You know, that's -- no, I think we can't 21 always be fully sure of the long-term stuff, because 22 long term can be a very long time in pediatrics. 23 Q. It certainly can. 24 Do some of the types of treatments that

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Page 98 1 you, as a doctor, participate in deciding have 2 potential lifelong downside risks? 3 A. Sure. 4 Q. Give me an example. 5 A. We use biologics to treat inflammatory 6 bowel disease, and they can have cancer risks down 7 the line. 8 Q. So is that a context in which you do or you 9 don't consider the long-term risk as you talk with 10 parents? 11 A. I put it out there that there are potential 12 long-term risks. But then I weigh it against other 13 long-term risks, including not treating the disease 14 with the biologics, which still holds a cancer risk. 15 And there's almost no ways to really weigh these 16 things. But people try to imagine long term, and, 17 you know, I do my best to help them think about it. 18 I think about it, et cetera. 19 Q. Is there other any other example that comes 20 to mind of decisions you participate in that have 21 potential lifelong implications? 22 A. Sure. I'm going to have to think now. 23 That one came quickly. 24 Q. Go for it. Think.	Page 100 1 Q. Okay. 2 721, Column 2. 3 A. Okay. 4 Q. At the bottom is a section headed "Meaning 5 of recommendations in GRADE." We've talked earlier 6 about evaluating the strength of evidence, and now 7 we're talking about the GRADE labels for 8 recommendations. 9 And the first sentence in that section 10 reads, "Using the GRADE approach, guideline authors 11 make a strong recommendation when they believe that 12 all or almost all informed people would make the 13 recommendation choice for or against an 14 intervention." 15 Let me ask whether that understanding of a 16 strong recommendation is consistent with how you and 17 your colleagues have worked, for instance, in 18 creating the NASPGHAN guideline. 19 A. I don't know that we have used that exact 20 framework for talking about when to use a "strong 21 recommendation." So I hadn't read this before, and 22 I don't remember that that was what we said. 23 MR. BROOKS: Okay. Let me ask the reporter 24 to mark as Exhibit 9 GRADE Guidelines Paper Number
Page 99 1 A. Yes. I'll give you one. 2 So in the diagnosis of celiac disease, 3 there's a movement not to do endoscopy and get the 4 biopsies that we read about in our standards, 5 because that incurs risk to do that, especially in a 6 young child. 7 So there can be a discussion of, do we 8 really need to do the endoscopy? And the answer is, 9 well, if you -- this is my thinking; I'm not an 10 ethicist, but I explain that I think there is an 11 ethical question on the line -- which is, right now, 12 while the disease is not yet treated, if I do the 13 endoscopy, we will have evidence of the disease. 14 And in 20 years, after 20 years of treating the 15 disease, and now the child is an adult and they say, 16 you know, "I'm not sure I ever had celiac disease. 17 Maybe I don't need to be doing what I'm doing," that 18 is a long-term potential complication that could 19 come up. 20 So I say, "We better do the endoscopy, even 21 though it has risks right now, because in 20 years, 22 I want to give you what you need to assure your 23 child that you did the right things to make the 24 diagnosis."	Page 101 1 15, "Going from evidence to recommendation - 2 determinants of a recommendation's direction and 3 strength." 4 (Document marked as Lightdale 5 Exhibit 9 for identification) 6 Q. And, Dr. Lightdale, I assume, but correct 7 me if I'm wrong, you have not seen this particular 8 paper before today? 9 A. I have not. Shall I read the abstract? 10 Q. I'm going to take you -- you certainly may 11 read the abstract, or you can listen to my question 12 and then decide whether you want to read the 13 abstract. 14 A. Okay. Go ahead. 15 Q. If you turn to Page 731, there is, on the 16 first column, a heading "Confidence in estimates of 17 effect (quality of evidence)." Do you see that? 18 A. Yes. 19 Q. And if you go down, the third paragraph 20 below there begins, "For instance." Do you see 21 that? 22 A. Uh-huh. 23 Q. Let me read that short paragraph into the 24 record.

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Page 102 1 "For instance, the GRADE approach provides 2 insight into how guideline panels should have 3 handled the decision regarding hormone replacement 4 therapy (HRT) in postmenopausal women in the 1990s 5 when observational studies suggested a substantial 6 reduction in cardiovascular risk (which randomized 7 trials subsequently proved false, at least in women 8 appreciably past menopause), and equally low 9 evidence quality suggested an increase in the risk 10 of breast cancer (which proved true)," close quote. 11 Really my opening question is, do you have 12 some familiarity with the narrative in the medical 13 field of a period of time in which doctors and 14 indeed guidelines were recommending post-menopause 15 hormone therapy for women, and subsequently those 16 recommendations were changed? 17 A. Only vaguely. 18 Q. Okay. That's not a case study that -- 19 A. No. 20 Q. -- you've been through in either school or 21 in any sort of conference? 22 A. I went to pediatrics, and so by, you know, 23 1995 I was really in pediatrics and frankly not yet 24 myself in menopause. So...	Page 104 1 indeed testimony last Friday has confirmed that the 2 12-point plan was written by Dr. Coleman, Eli 3 Coleman. Is that a name that means anything to you? 4 A. No. 5 Q. I will also represent to you that he was 6 the chair of both the SOC-7 development project for 7 WPATH and the SOC-8 development project. He's 8 testified about the substance. 9 I want to take you, though, specifically to 10 Page -- and he's testified that he is the author of 11 this entire 12-point plan written in February of 12 2023. My representation. 13 I want to take you to Page -- we call these 14 things at the bottom production numbers or Bates 15 numbers -- ending in 216. 16 A. Okay. 17 MS. LEVI: It ends in 216. 18 THE WITNESS: Okay. Got it. 19 Q. And actually, the sentence at the top of 20 the page begins at the bottom of 215 where he wrote, 21 "As a result our methodology evolved and was 22 improved - however, we were not able to be as 23 systematic as we could have been (e.g., we did not 24 use GRADE explicitly)."
Page 103 1 Q. Not a focus of concern. Fair enough. I 2 didn't mean to get personal. 3 A. That's all right. I brought it up. 4 Sometimes that's what you pay attention to. 5 MR. BROOKS: I'm going to ask the reporter 6 to mark as Exhibit 10 a document bearing Bates 7 Numbers BOEAL_WPATH_91211 through 91218, which is an 8 email dated February 23 -- February of 2023, 9 February 7, attaching a "Draft 12-point Strategic 10 Plan," and designated confidential. Let me be clear 11 on the record. 12 (Document marked as Lightdale 13 Exhibit 10 for identification) 14 MS. LEVI: Roger, we're going to designate 15 the transcript as confidential. 16 MR. BROOKS: And I will ask you to follow 17 up with specific designations within that. I think 18 this may be the only confidential document we'll 19 look at. 20 MS. LEVI: Okay. 21 Q. Dr. Lightdale, I'm confident you have not 22 seen this before. 23 A. No. 24 Q. I will represent to you that discovery and	Page 105 1 Do you see that? 2 A. Yes. 3 Q. Now, the chairman of the SOC-8 project has 4 written, after the completion of that project, that 5 the team did not use GRADE explicitly. 6 Do you have any basis to disagree with him 7 in that regard? 8 A. Obviously, I'm, like, just looking at this 9 thing. But that is what is written there. 10 Q. He goes on to say, under "Research 11 Agenda" -- pardon me. Let me just draw your 12 attention to the first full paragraph on the page 13 ending in 216, where he says, quote, "I think it 14 would be helpful to engage a guideline development 15 expert or experts to examine what we have done and 16 help us form a clear narrative and justification for 17 what we have done." And he goes on a little farther 18 to say, "We need to sharpen our method about 19 strengths. At the same time, we need to know its 20 limitations." 21 Do you see that? 22 A. Yes. 23 Q. Do you consider it good practice to develop 24 and publish guidelines and afterwards bring in an

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Page 106 1 expert to help you know the limitations of what 2 you've done? 3 MS. LEVI: Object as to form. 4 A. I think I need to understand the context of 5 this. Is he talking about -- "We were not able to 6 be as systematic as we could have been," is he 7 talking about SOC-7, and now they're trying to say 8 how are they going to improve things with SOC-8? 9 Q. If you look at the beginning of that 10 paragraph, I believe -- this is my understanding, 11 not a representation -- that this is discussing what 12 was actually done in SOC-8. 13 A. Okay. Yes. So -- 14 Q. Do you want to hear my question back? 15 MS. LEVI: And also you should take the 16 time if you need to review the document. 17 THE WITNESS: Yeah, yeah. Let me 18 understand where this is, because obviously I'm, 19 like -- I don't know timelines, et cetera. 20 A. (Reviewing document) 21 Q. As far as timeline, I will represent to you 22 that this is written after SOC-8 has been published. 23 A. Okay. (Reviewing document) Can you repeat 24 your question.	Page 108 1 So what they seem to be saying here is that 2 Hopkins was helpful, but also constraining, and it's 3 like, "Oh, maybe we could have gone about this a 4 different way." 5 And so now they're saying, you know -- I 6 mean, he's saying, "We're being attacked for the 7 methodology." Obviously I'm sitting here today 8 trying to understand what we're being asked -- but 9 they said, "Okay, how can we continue to think about 10 what we've done." 11 So I don't think it's wrong to bring in 12 somebody to say, "Okay, here's what we've done. 13 What do you think of it? And can you" -- you know, 14 I guess here they're saying, "Can you help us feel 15 good about what we did, because we were trying to be 16 as robust as we possibly could be," which takes a 17 lot of work. 18 Q. Understood. 19 MR. BROOKS: Let me ask the reporter to 20 mark as Exhibit 11 a paper by Taylor and others 21 entitled "Clinical guidelines for children and 22 adolescents experiencing gender dysphoria," dated 23 2024. 24
Page 107 1 Q. Yes. Do you consider it good practice for 2 a team to develop, finalize and publish guidelines 3 and then seek expert input to understand the 4 limitations of the methodology that they used? 5 MS. LEVI: Object as to form. 6 A. To be honest, there could be even more 7 rigor around what happened. But as I'm reading 8 this -- and you start at the beginning of, I don't 9 know, Point 6, I guess, where it says, you know, "we 10 had to rely on Johns Hopkins," which I'll assume was 11 the methodologist, "which while some degree helpful, 12 was very constraining." And I think that is what 13 many people find. I don't know what Johns Hopkins 14 did. 15 But if you try, and even -- I feel like 16 even in -- you've been giving me some of this GRADE 17 stuff. There is this concern -- and I think I wrote 18 about this in my own thing -- there is this concern 19 that GRADE itself, especially in pediatrics, can 20 lead us to almost not give the right strong 21 recommendations we need to, because we just don't 22 have the evidence that GRADE is assuming is on the 23 table, and most of what we do in pediatrics doesn't 24 have that type of evidence.	Page 109 1 (Document marked as Lightdale 2 Exhibit 11 for identification) 3 Q. Dr. Lightdale, this is obviously a recently 4 published paper, which purports to evaluate the 5 quality of a number of different guidelines relating 6 to gender dysphoria in children and adolescents and 7 goes through various detail and comes to various 8 conclusions. 9 Let me ask you this. And I can represent 10 to you or you can turn to any of several pages and 11 see that they refer to the AGREE II -- well, turn to 12 Page 5, if you would, and you will see in the first 13 column, the first full paragraph describes the kind 14 of punchline table of this paper, and it says it 15 shows "the AGREE II domain scores for the appraised 16 guidelines." 17 Now, you looked at a methodology web page, 18 but just to be clear on the record, you have not 19 undertaken any attempt to apply the AGREE II 20 methodologies -- or I should say criteria -- to 21 evaluate the WPATH guidelines, correct? 22 A. Correct. 23 Q. Nor any other guidelines relating to 24 treatment of gender dysphoria in minors?

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Page 110 1 A. Correct. 2 Q. Okay. Then I will not ask you to read that 3 one. 4 And certainly you have not attempted to 5 evaluate the body of evidence relied on for any 6 recommendation in SOC-8 to form your own view as to 7 whether that body of evidence is strong, moderate, 8 weak or very weak, have you? 9 A. No. 10 Q. Do clinical practice guidelines themselves 11 constitute scientific evidence? 12 MS. LEVI: Object as to form. 13 A. No, not per se. 14 Q. I will not take your time further with that 15 document. 16 MR. BROOKS: I'm going to ask the reporter 17 to mark as Exhibit 12 a paper, the first author 18 Saunders and the last author Lightdale -- you've 19 moved into the senior slot there -- entitled 20 "Patient safety during procedural sedation," and it 21 goes on, published in BMJ -- 22 Q. Am I correct that's the British Medical 23 Journal -- 24 A. Yes.	Page 112 1 safety discussions. 2 So it was doing a systematic review of 3 anything out there, and then a meta-analysis of the 4 randomized controlled trials that did exist around 5 capnography, to begin to understand just how big a 6 study you'd need to do to show somebody dying, 7 basically, and in the process also showing, across 8 all the studies, that monitoring with capnography 9 does lead to less oxygen desaturation. 10 Q. And so underlying this paper, your team did 11 a formal systematic review? 12 A. Yes. 13 Q. And you disclosed the -- I'm not even sure 14 of the right term, but the PICO, population -- I 15 think you said it earlier, but can I get you to 16 spell out what PICO stands for. 17 A. PICO is the population, the intervention -- 18 what's the C -- and then O is outcomes. 19 Q. All right. And did you make available, 20 either in the paper or in publicly available 21 supplemental material, evidence tables? 22 MS. LEVI: Object as to form. 23 A. The truth is, I don't remember. I will 24 tell you the first author, who I worked with very
Page 111 1 MR. BROOKS: -- in 2017. 2 (Document marked as Lightdale 3 Exhibit 12 for identification) 4 Q. And, Dr. Lightdale, for context, am I 5 correct that the BMJ is really in the very top tier 6 of respected medical journals in the world? 7 A. I would like to think so. I felt that 8 about getting the paper accepted. 9 Q. That's nice to say, but more generally, am I 10 correct that it is widely recognized as one of the 11 most respected medical journals? 12 MS. LEVI: Object as to form. 13 A. Uh-huh. 14 Q. And explain to me the nature of your 15 involvement in this paper. 16 A. So I served as the senior author on this 17 paper that involved several experts, as well as 18 myself, in a particular monitoring technique called 19 capnography that clearly shows -- I mean, there are 20 many studies out there that have shown that it can 21 pick up patients who are starting to desaturate in 22 terms of oxygen. But, thankfully, none of the 23 studies alone have been big enough that anybody has 24 become truly injured or died, you know, real patient	Page 113 1 closely on this, was a -- he's not a physician. He 2 just does health economics and systematic reviews. 3 Q. On Page 2, you identify -- let me take you 4 down to the "Methods." You identified which 5 databases you searched in, correct? 6 A. Yes. 7 Q. And there's only three, but are these three 8 so extensive that that represents a rather 9 comprehensive search? 10 A. Yeah. 11 Q. And it goes on to say that the searches 12 aimed to identify, quote, "all literature reporting 13 on randomized, controlled trials," close quote. 14 Let me ask, why did you limit the search to 15 controlled trials? 16 A. So at the time that we did this, there had, 17 at that point, been a number of randomized 18 controlled trials on capnography. I was actually 19 the first to do a randomized controlled trial of 20 capnography, and people didn't want to put it into 21 their guidelines, which was frustrating for me at 22 the time. I was very young and idealistic. I 23 thought it would be a New England Journal of 24 Medicine paper, but it wasn't, it was pediatrics. It

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Page 114 1 was okay. I learned a lot. 2 But I will tell you then people when on 3 and used my methodology and tried randomized -- you 4 know, did randomized controlled trials in a number 5 of other populations. And this study took basically 6 any randomized controlled trial we could find and 7 was able to do a meta-analysis, so look at all the 8 data across all the different trials. 9 Q. Is it in fact the case, in your judgment, 10 that uncontrolled studies are known to be at risk of 11 serious bias as a result of effects such as the 12 placebo affect or confounding variables? 13 MS. LEVI: Object as to form. 14 A. So study design is obviously critical to 15 trying to get at whether or not intervention is 16 going to be -- you know, can lead to the clinical 17 outcome you're looking for. And there are different 18 study designs you could use to try to mitigate bias. 19 I think the randomized controlled trial 20 design in this question was able to get away from 21 the question of bias in terms of there are other 22 ways to assess whether or not a patient's in 23 trouble. 24 So, really, you had to do a randomized	Page 116 1 that are equally good at mitigating bias. So... 2 Q. Equally good? 3 A. Yeah. Maybe even better. So randomized 4 controlled trials can introduce systematic biases if 5 you're not careful. I mean, just because something 6 is controlled doesn't mean it gets away from, you 7 said, the placebo effect or other things like that. 8 It doesn't -- it's one way of designing a trial to 9 try to mitigate that, but there's lots of ways to do 10 it. 11 Q. It says, a little bit lower down, quote, 12 "'Grey' or unpublished literature (including 13 Congress abstracts) was included in the search 14 strategy." 15 Do you see that? 16 A. Yes. 17 Q. Now, am I correct that grey literature are 18 publications that are -- have not been peer 19 reviewed? Is that what the term refers to? 20 A. There is a definition for it, but, you 21 know, for me, it's -- yes, for me, it's stuff that 22 hasn't yet gone through the peer review process. 23 Q. Why did you consider it appropriate to 24 include grey literature in your search, if it has
Page 115 1 controlled trial in a creative way, which, again, I 2 was able to come up with a methodology that then 3 other people were able to use, where you could sort 4 of still have all the regular ways of monitoring 5 patients -- nobody wants to have a procedure without 6 being monitored to make sure they don't, you know, 7 die -- and so we basically needed a randomized 8 controlled trial to get at the question of whether 9 you needed to add capnography in as another means of 10 monitoring to get even safer. 11 Q. My question was perhaps simpler, which is, 12 isn't it the case that it's well known that 13 uncontrolled studies are at risk of serious bias as 14 a result of effects such as confounding variables or 15 the placebo effect? 16 A. No, not necessarily. 17 MS. LEVI: Object as to form. 18 THE WITNESS: Oh, sorry. 19 MS. LEVI: Just give me a second. 20 Object as to form. 21 A. No, no. Not necessarily. In fact, there 22 are all kinds of ways now of designing trials that 23 are not randomized controlled trials that -- so I 24 guess are uncontrolled trials -- that are, you know,	Page 117 1 not yet been through the peer review process? 2 A. So this particular paper, we were 3 determined to be as inclusive as possible and 4 include anything that was out there that hadn't yet 5 made it all the way to publication. 6 Q. And is it in fact commonly done, in 7 systematic reviews, to include grey literature? 8 A. So actually, in one of the papers that you 9 showed me from the GRADE chapters, they actually 10 talk about it. But, yeah, I mean, it's an option. 11 You can include grey literature if that's 12 appropriate for your question. 13 Q. If you turn to -- well, turn -- the second 14 column on Page 2, towards the bottom is a heading 15 "Quality and potential bias." And there there's a 16 reference to using a modified Jadad score, because 17 we didn't have enough scores already. 18 What is the Jadad score? 19 A. You know, this was something that Roger 20 Saunders actually introduced to me. But it was a 21 way of looking at studies and deciding how they -- 22 you know, how to assess them. So it's just another 23 way of assessing evidence, if you will. 24 Q. It says in the second sentence there,

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Page 118 1 quote, "The Jadad score assesses studies based on 2 their design (randomized and blinded) and their 3 reporting (all patients accounted for), with a 4 maximal score of 5... and a low score of 0." 5 Am I correct that the Jadad system rates 6 more than simply whether it's randomized or blinded 7 and whether all patients are accounted for? Those 8 are just examples? 9 A. I think the Jadad score is a very specific 10 way of trying to assess a clinical trial design. 11 Q. Okay. Why is it important, in clinical 12 trial design, to know whether all patients are 13 accounted for in the experiment outcomes? 14 A. Sorry. Can you repeat that question. 15 Q. Yes. I'm just referring to the 16 parentheses -- the parenthetical that says "all 17 patients accounted for." And my question is, why is 18 it important, in evaluating the strength of a study, 19 to know whether all patients are accounted for? 20 A. Maybe I'm missing this. (Reviewing 21 document) Oh, "and their reporting." 22 I mean, I think you would -- it may or may 23 not be important. It's just -- again, the Jadad 24 score was a way of saying, "We're looking at a	Page 120 1 Do you know one way or the other? 2 A. I know nothing. All I'm thinking is that 3 this is 1996. So we talked about my medical school 4 graduation. This is as we're all trying to 5 understand is it important or not. 6 Q. Right. Okay. Fair enough. 7 It appears to describe the Jadad score 8 system that was referred to in your paper -- 9 A. Okay. 10 Q. -- albeit introduced to you by one of your 11 co-authors, I think you testified. And as you say, 12 in the introduction, this paper by Dr. Jadad, 13 Exhibit 13, begins "The use of reliable data to 14 support medical and public health decisions is 15 essential." 16 And am I correct that you've been telling 17 me that this was essentially a new focus of medicine 18 about the time you were graduating from medical 19 school? 20 A. Yes. 21 Q. Okay. If you turn to Page 11 -- you will 22 see that we are now in the Appendix, which is 23 "Instrument to Measure the Likelihood of Bias," and 24 we see on Page 11, "Guidelines for Assessment." And
Page 119 1 series of studies, and how do we want to rate those 2 studies?" 3 And, you know, you can -- we did this big 4 literature search, you're going to come up with a 5 bunch of study, and then you want to be able to say, 6 you know, "80 percent of the studies scored very 7 well on the Jadad score," or -- I mean, you're 8 trying to decide how to think about those in -- all 9 together. 10 I mean, that reporting is saying -- one of 11 the items in the Jadad score is just saying, are all 12 patients accounted for in what they added up. So... 13 Q. Well, let me break out a little more 14 detail. 15 MR. BROOKS: Let me ask the reporter to 16 mark a paper "Assessing the Quality of Reports of 17 Randomized Clinical Trials: Is Blinding Necessary?" 18 by Dr. Jadad and others from 1996. 19 (Document marked as Lightdale 20 Exhibit 13 for identification) 21 Q. Dr. Lightdale, all I can say is this paper 22 by Dr. Jadad sets out a method of evaluating. 23 Whether it is the only paper by Dr. Jadad on this 24 topic or the latest, I can't say.	Page 121 1 as you said, it's very narrow. It focuses on 2 randomization, blinding and withdrawals and 3 dropouts. 4 Let me ask you to read to yourself the 5 paragraph relating to withdrawals and dropouts. 6 A. (Reviewing document) Okay. 7 Q. Why, in evaluating the strength of a study, 8 is it important to know the number and reasons of 9 those who did not complete the study? 10 MS. LEVI: Object as to form. 11 A. There can be a number of reasons. It could 12 be interesting to understand withdrawals and 13 dropouts. I don't think it's, you know, in and of 14 itself -- it's just another way to think about what 15 happened with the trial. 16 And in 1996 they said, "Gee, maybe we'd 17 better pay attention to is it a trial where, you 18 know, people withdrew, and have they explained 19 that." And that would seem just logically 20 important. 21 Q. Why? 22 A. Well -- so put yourself back in 1996, when 23 we're first starting to realize, "Hmm, maybe we need 24 to pay attention to evidence." And you have, like,

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Page 122 1 a whole -- I mean, it's incredible, right? We were 2 practicing medicine. 3 Q. You're really harsh on the medical field. 4 But go ahead. 5 A. It's true. It's how I was taught, you 6 know. It's like nobody was saying, "Where's the 7 evidence?" And now we're starting to say, "Oh, 8 maybe we need to notice this." 9 So you can potentially have a trial where, 10 you know, the intervention leads everybody to, let's 11 say, I don't know -- like, it's too much. That's a 12 classic one that will happen, where it's just -- and 13 sometimes it's not the intervention. Sometimes it's 14 the study itself was designed in a way that is so 15 impossible for people to do: Come three times a 16 week from, you know, wherever you are in order to do 17 something. 18 People may simply not be able to do that 19 for a sustained period of time. And that, alone, 20 can lead to lots of dropouts, never mind the 21 treatment itself. 22 So I think understanding what is it, why 23 were there dropouts, why was there withdrawal is 24 sort of now something we take for granted. But in	Page 124 1 don't do that, we don't understand what we got out 2 of the trial. 3 And so, again, that concept is brand-new in 4 1996, you know. 5 Q. Let me flip it, flip the hypothetical, and 6 let's drop it to 30 percent -- 7 A. Okay. 8 Q. -- 30 percent who don't -- who just, over 9 the course of the study, stopped coming back for -- 10 maybe it's because it was a hassle, maybe it's 11 because they benefited, maybe it's because it hurt 12 them. We don't know. We have no information on why 13 they dropped out. 14 One thing that could be the case is that 15 they have -- the treatment has made them feel really 16 sick, and they just don't feel like doing it 17 anymore. They're upset, and they don't want to 18 follow through. 19 In that case, if you looked only at the 20 results for the 70 percent who kept coming, you 21 might get an unduly optimistic reading on the effect 22 of the treatment; am I correct? 23 MS. LEVI: Object as to form. 24 A. So once, in 1996, we started paying
Page 123 1 1996 Dr. Jadad is saying, "Let's pay attention to 2 this. This could be a piece of how to think about a 3 high quality study; not just did it happen, but did 4 someone explain to me why it happened." 5 Q. If you had -- and this is purely abstract. 6 If you had a study -- let's say it's a two-year 7 study; it's going to go on for a while -- and by the 8 end, 50 percent of the participants have dropped 9 out; they just haven't showed up. Hypothetically -- 10 and you just looked at the results for the 50 11 percent who remained. 12 Now, one possible explanation would be that 13 the 50 percent who stopped coming had benefited so 14 much they just didn't feel the need of treatment 15 anymore. And in that case, if you focused only on 16 those who continued coming, you would get an 17 inaccurately negative understanding of the effect of 18 the treatment, correct? 19 MS. LEVI: Object as to form. 20 A. I mean -- I don't know. I think that it's 21 very -- it's so hypothetical. 22 So I think what's important is to notice 23 that only 50 percent of the people finished the 24 trial and to be asking questions why. And if we	Page 125 1 attention to the fact that, "Oh, people withdraw or 2 drop out of studies," we started coming up with 3 statistical approaches to what you do to avoid that 4 particular, what you're bringing up, concern. 5 So certainly we want the investigators 6 themselves to notice that 30 percent of their, you 7 know, population didn't finish the study and say it. 8 I'm saying "We," by the way, very grandiose like. 9 But this is what you're looking for, right -- 10 Q. Right. 11 A. -- when you're trying to understand a 12 paper. 13 But actually there are methodologies that 14 you use -- they call them intention-to-treat 15 methodologies -- where you're going to basically, if 16 someone doesn't finish, that actually will go 17 against the study finding. So you're designing a 18 study and weighing it in a way that you're being 19 very conservative. 20 And so now I'm looking to understand, was 21 it an intention-to-treat methodology, were there 22 other statistical ways that somebody tried to 23 account for the fact that not everybody is going to 24 finish the study.

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Page 126 1 And I think these days we design trials 2 knowing not everybody is going to finish. So you 3 have to say, a priori, what you are going to do to 4 make sure that you don't bias your own study by 5 being left with your 70 percent. 6 Q. Okay. 7 MS. LEVI: We're close to noon. I'm not 8 asking for a lunch break, but it would be good to 9 take another break. 10 MR. BROOKS: Yeah. And my recommendation 11 would be we take a break, we do one more run, 12 because stopping at noon always makes the afternoon 13 rough. 14 MS. LEVI: Yeah. 15 MR. BROOKS: So, yeah. Now is a fine time 16 to stop. 17 (Recess) 18 MR. BROOKS: Let me ask the reporter to 19 mark as Lightdale Exhibit 14 a paper from 2001 20 titled "Effects of Intravenous Secretin on Language 21 and Behavior of Children with Autism." 22 (Document marked as Lightdale 23 Exhibit 14 for identification) 24 Q. And, Dr. Lightdale, is this a paper on	Page 128 1 study, but it's an extremely small sample, correct? 2 A. Yes. 3 Q. And your goal, it says, down in "Objective" 4 a little farther in the abstract, is to apply the 5 scientific method to assess the reproducibility of 6 those reported effects, correct? 7 A. Yes. 8 Q. And can you explain to me the distinction 9 between the scientific method that you're referring 10 to here and -- obviously you've described earlier 11 there's been a published paper describing these 12 three children's experiences. 13 What's the difference between that paper 14 that existed and the scientific method that you 15 referred to under "Objective"? 16 A. Can I take a look at it? I haven't seen it 17 in a long time. 18 Q. Of course you may. 19 A. (Reviewing document) Okay. Because I did 20 not remember that that was my objective. But I am 21 now, why did we phrase it that way? 22 What was your question? 23 Q. Again, the beginning of the abstract, and I 24 didn't read it all, but it points out that this case
Page 127 1 which you were the first author? 2 A. Yes. 3 Q. Indicating that you did most of the hard 4 work? 5 A. Yes. 6 Q. All right. I have a few questions about 7 it, but we kind of need to break out what it is. So 8 let me see if I, after reading it, understood 9 correctly. 10 The background situation was, at the time, 11 a widespread belief among parents that intravenous 12 secretin improved language skills in autistic 13 children, correct? 14 A. Yes. 15 Q. And that, according to the very beginning 16 of the abstract, was due to simply a three -- a 17 paper that described the experience of three 18 children -- correct? 19 A. Yes. 20 Q. -- and parental reports specifically about 21 the supposed effect of intravenous secretin on the 22 language skills of those three children. 23 A. (Nods head) 24 Q. And that's not quite a one-patient case	Page 129 1 study of three autistic children was based on 2 reports from their parents over a five-week period, 3 right? 4 A. This was an extraordinary moment in my 5 life, but -- I will tell you, I was very junior. So 6 the senior author is a long-time mentor of mine. 7 Q. I understand. 8 A. I was just getting interested in GI, and he 9 said, "I have a study for you to do," and I said, 10 "Okay." 11 And while we were trying to get it going at 12 UCSF, other groups, in particular a group at the 13 University of North Carolina, published a randomized 14 controlled trial. So the sense was that we had been 15 scooped. 16 And we said, "Well, what do we do now?", 17 because we were in the middle of our design. And we 18 decided that you could say that what we were doing 19 was still important because of the scientific 20 method, which means that you really ought to be 21 careful before you move to a randomized controlled 22 trial. You need to perform first an open-label 23 trial, and the goal was to basically try to be more 24 sensitive in what we were measuring.

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Page 130 1 So the open-label design, smaller study, 2 open label, allowed us to do a whole lot of 3 different measures on these kids that you could not 4 do in a randomized controlled trial, which is bigger 5 and wasn't based on -- it didn't have even the right 6 data to even do a sample size determination, is my 7 memory. 8 So, you know, we felt that they had moved 9 too quickly to the randomized controlled trial, and 10 we could make the argument that our study was still 11 important. 12 Q. So let me focus on one thing you just 13 mentioned. 14 If you turn to Page 2, the top of the 15 second column is a paragraph that begins, "To 16 formally answer these questions, it seems necessary 17 to observe the basic principles of scientific method 18 by prospectively investigating the reproducibility 19 of the reported effects," correct? 20 A. Yes. 21 Q. And what were you referring to as "the 22 basic principles of scientific method"? 23 A. So -- I don't actually quite remember 24 exactly, but I think the scientific method would	Page 132 1 But I can answer the question of why 2 prospective data can be important in a moment like 3 this. 4 Q. All right. 5 A. So, without a doubt, retrospective data is 6 going to be limited in different ways, because you 7 can -- you can only look at what was reported. 8 And, of course, if the retrospective data 9 involves, you know, basically, in this case, parents 10 describing that things have changed, there wasn't 11 necessarily good data captured on the baseline 12 before something happened. So all we're getting is, 13 after the fact, somebody saying, "Oh, something has 14 changed." 15 Prospectively we could really measure the 16 kids at their baseline, and then we could give them 17 the secretin, and then we could say, "Did something 18 change?" 19 Q. Okay. And looking at that, let's turn to 20 Page 3. There's a section headed "Measures," and 21 there you state that "Children's language level was 22 assessed using the PLS-3." 23 Is that a well-recognized, objective 24 measure of language skills?
Page 131 1 state that you need to really be clear what your 2 question is, and then you need to decide if you're 3 measuring what you need to to answer it. 4 And I think we decided that we still should 5 be doing this open-label trial, because this was 6 actually going to either be helpful for supporting 7 or refuting, you know, moving forward and doing more 8 studies with this. 9 So, again, I think we had to come up with 10 an objective that met the moment of somebody else 11 publishing a trial that almost seemed to obviate 12 what we had done. So... 13 Q. In the same sentence I've read, you said 14 you needed "to observe the basic principles of 15 scientific method by prospectively investigating." 16 A. Uh-huh. 17 Q. Why was it important -- why do you consider 18 that prospective investigation rather than, for 19 instance, a retrospective analysis is among the 20 basic principles of the scientific method? 21 A. It's funny, because I am not sure I can 22 tell you exactly what the scientific method is 23 anymore. It feels almost like something one does 24 learn in medical school or even in college.	Page 133 1 A. So I had a number of people involved in 2 this study, and a couple of them were experts in 3 measuring developmental behavioral pediatrics and 4 language and things like that. So they were the 5 ones that came up with the measures that way. 6 Q. Do you know whether PLS-3 was a 7 pre-existing objective measurement of language 8 skills? 9 A. My understanding is it's a validated scale. 10 Q. Dated or outdated, my question was, did you 11 understand it to be an objective measure of language 12 skills? 13 A. I think we picked a measure we thought was 14 going to be a good measure for understanding if the 15 language skills changed. 16 Q. And it did not, am I correct, depend on 17 parental reports? 18 A. Yeah, it's basically -- it's a very -- I 19 don't really -- again, I was not the person 20 administering these particular scales. But 21 basically, they were -- you know, we were going to 22 do a number of different measures, and one of them 23 was this PLS-3 was decided as the best measure. 24 Q. And if we look at the second column on Page

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Page 134 1 3, it says, in the first full paragraph, "Language 2 and behavioral measures were repeated at T2 to T5." 3 A. Where are you now? 4 Q. It's the first full paragraph at the top of 5 Column 2 of Page 3. 6 A. Oh, I see. Okay. 7 Q. And noticing the word "repeated," am I 8 correct that part of your protocol was that you did 9 this objective test of language skills at each of 10 T1, T2, T3, T4, T5? 11 MS. LEVI: Object as to form. 12 A. Yeah, so, in full disclosure, I haven't 13 really thought about this study in a very long time. 14 So I don't quite remember the whole bits to it. I 15 more remember what was going on around it. 16 But -- so I would have to honestly get into 17 this a little bit. 18 Q. Well, let me ask about -- 19 A. I mean, I can read it if you want -- 20 Q. No. Let me ask -- 21 A. -- to see what I wrote. 22 Q. Let me ask some big picture questions and 23 see if you recall at the big picture level. 24 A. Yes.	Page 136 1 A. Yes. 2 Q. And -- I'm sorry, I've taken things out of 3 order. If you back up to the bottom of the second 4 column on Page 3, it states, "Analyses revealed no 5 significant increases in children's language skills 6 from baseline following a single infusion of 7 secretin," correct? 8 A. Yes. 9 Q. Do you recall, at least, that the big 10 picture take-away from this paper was that secretin 11 did not improve children's language skills and 12 parents thought it did? 13 MS. LEVI: Object as to form. 14 A. My own -- when I tell the story of this 15 paper, the big take-away was secretin did nothing. 16 Q. But am I correct that another important 17 take-away was, notwithstanding it did nothing, that 18 many parents thought it was having a beneficial 19 effect on their children? 20 MS. LEVI: Object as to form. 21 A. The answer for me is, I didn't remember 22 that piece of it, but it is there. 23 Q. Okay. If you turn to Page 5, Column 1, 24 about an inch from the top, a sentence begins, "This
Page 135 1 Q. If you turn to Page 4 -- 2 MS. LEVI: If you want to take time to 3 review your study -- 4 MR. BROOKS: That's certainly true. 5 MS. LEVI: -- you should feel free -- 6 THE WITNESS: It's weird to see -- 7 MS. LEVI -- to take the time you need. 8 THE WITNESS: -- my own words. It's, like, 9 very, very -- 10 Q. I'm going to try back up to the high level, 11 and then you decide what you want to read. 12 A. Okay. Sounds good. 13 Q. If you turn to Page 4, Column 1, we are, as 14 you'll see, in the "Results" section. It says, 15 about an inch and a half from the bottom of the text 16 from the first column, quote, "No relationship was 17 found between parental reports of change and 18 observable improvement in the sample." 19 Do you see that? 20 A. Yes. 21 Q. And it says -- goes on to say that "70 22 percent" of parents "reported moderate to high 23 change." 24 Do you see that?	Page 137 1 pattern of parental response." Do you see that? 2 A. Uh-huh. 3 Q. It reads, "This pattern of parental 4 response is consistent with previously published 5 observations by others, and underscores the need for 6 carefully designed trials of any putative 7 therapeutic agent suggested by empirical or 8 anecdotal evidence." 9 So I want to ask a general question, based 10 on your studies, based on your professional 11 experience. Is it well known that self-reports or, 12 in the case of children, parental reports can be 13 highly inaccurate? 14 MS. LEVI: Object as to form. 15 A. Well, what I'll say is that I think it is 16 known that any self-report is always going to be 17 suspect. And certainly when parents are being 18 asked, there's this added level of, well, we don't 19 know what it means. 20 So you have to take, you know, basically 21 reported -- self-reports and then parental reports 22 of children's behavior just have to be held as a 23 different type of evidence. 24 It's funny, because reading even the next

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Page 138 1 line -- this was an extraordinary moment going on, 2 but there was a hysteria. And so we knew that part 3 of what was happening is parents at that point were 4 not thinking it was a single infusion; they were now 5 wanting multiple infusions. 6 So, you know, these are strong emotions 7 people are having, and they're ready to say things, 8 you know. 9 Q. Well, are there -- 10 A. And it just -- I think what we were saying 11 is, "You have to do this well." If we're going to 12 start talking about cures for autism, they have to 13 be designed very well. 14 Q. Are there recognized reasons why 15 self-reports and parental reports are commonly 16 unreliable? 17 MS. LEVI: Object as to form. 18 A. I mean, I think it's human nature not to be 19 able to objectively think about things. I mean, 20 it's part of being human. 21 So, you know, anybody makes a big -- I 22 don't know -- in this case says, "We've got a cure 23 for autism," based, you know, on self-reports only, 24 that would not be sufficient to move forward.	Page 140 1 Appendix A on Page S247, two inches down on the 2 first column, it says, "The process for development 3 of the SOC-8" -- let me see if you find that. 4 A. Okay. 5 Q. "The process for development of the SOC-8 6 incorporated recommendations on clinical practice 7 guideline development from the National Academies of 8 Medicine and The World Health Organization that 9 addressed transparency, the conflict-of-interest 10 policy, committee composition and group process," 11 and it then cites a document from the Institute of 12 Medicine and from The World Health Organization. 13 Do you see that? 14 A. Yes. 15 Q. Are you, yourself, familiar with a document 16 from the National Academies of Medicine or the 17 Institute of Medicine that sets out procedures for 18 developing guidelines? 19 A. I am familiar with it. It's a big 20 document. It's a book. 21 Q. Have you, yourself, consulted that -- such 22 a document from the Institute of Medicine? 23 A. Yeah. 24 MR. BROOKS: Let me ask the reporter to
Page 139 1 And I think at this point -- we were 2 contributing at this point to a body of evidence, 3 saying, "This is not a cure for autism, this 4 secretin." 5 Q. And is the end of the story a broad medical 6 conclusion that secretin did not help? 7 A. Yes. 8 MS. LEVI: Object as to form. 9 THE WITNESS: Sorry. 10 MS. LEVI: Make sure you give me a 11 chance -- 12 THE WITNESS: Apologies. I'm working on 13 it. 14 Q. When you referred to, quote, "underscoring 15 the need for carefully designed trials of any 16 therapeutic agent suggested by anecdotal 17 evidence" -- let me start again. Pardon me. I'll 18 skip over that. It's too hard to package. 19 I have put back in order your exhibits, and 20 I'm going to ask you to find Exhibit 5 again, which 21 is -- you can check me on this -- the methodology 22 appendix to SOC-8. Sorry. We've got all sorts of 23 numbers. 24 If you turn in that document back to	Page 141 1 mark as Exhibit 15 a document published by the 2 Institute of Medicine entitled "Clinical Practice 3 Guidelines We Can Trust." And I believe that this 4 is selected chapters of, as you say, a whole book. 5 (Document marked as Lightdale 6 Exhibit 15 for identification) 7 Q. Let me ask you to take a look at this. And 8 recognizing it is the cover page, the table of 9 contents and then selected chapters, does this 10 appear to be portions of the book that you have in 11 mind? 12 A. Yes. 13 Q. And you've cited this yourself, have you 14 not? 15 A. Yes. 16 Q. And is this a widely respected set of 17 criteria for good practices for developing 18 guidelines? 19 A. I think it's an important text in the 20 field, yeah. 21 Q. Is there any other that you consider to be 22 more authoritative in terms of good practice for 23 developing guidelines? 24 A. I mean, I'll just note it was 2011. We've

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Page 142 1 already changed things a number of time. I mean, 2 you really have -- in fact, you've brought it out. 3 We have AGREE II which comes out much later. 4 So at that time, in 2011, it was really 5 helpful that they created this text that you could 6 reference. 7 Q. Do you know whether the Institute of 8 Medicine has publish any more updated version of 9 this? 10 A. I don't think so. 11 Q. And we've seen together that this was cited 12 in the SOC-8 methodology, correct? 13 A. Yes. 14 Q. Do you believe that accepted good practice 15 for developing guidelines has become, shall I say, 16 tighter, more rigorous since 2011? 17 A. Yes. 18 Q. Not less? 19 A. Become tighter. Yes. 20 Q. In your report, which we've marked as 21 Exhibit 4, you wrote, in Paragraph 19 on Page 6, 22 quote, "WPATH's process for developing SOC-8, as 23 described at," and then you have the -- you have a 24 live link, actually, to the web page in question,	Page 144 1 that I can -- 2 Q. Here you are. You're an expert, here to 3 offer opinions. 4 A. I'm the expert, okay. 5 So I think we're all learning, still, as we 6 go. And so the transparency gets important, because 7 I need to understand, as a, you know, physician or 8 somebody who's going to potentially going to use a 9 guideline, how did it happen? 10 And actually in some ways it goes along 11 with -- like, I think we've talked a little bit 12 about this, but there was that discussion how AGREE 13 II starts talking about the funding source, right? 14 So we need to understand who is driving the 15 guideline, why is it happening, how did they do it. 16 And so that transparency has actually 17 become really important. And it's been a piece of 18 evolving and, again, something we're continuously 19 improving. I don't think anything's done yet. I 20 bet there's an AGREE III in a couple of years. 21 So, you know, it's just, like -- it's 22 constantly trying to get guidelines better. Is that 23 okay? 24 Q. Let me ask you to find that Institute of
Page 143 1 right? -- "is transparent, rigorous, and 2 methodologically sound." 3 Do you see that language? 4 A. Yes. 5 Q. And you were referring to what you read in 6 that web page, not to any actual knowledge of what 7 the WPATH team did, correct? 8 A. Right. 9 Q. And you said the process was transparent 10 and rigorous. Can you explain to me the meaning and 11 importance of transparency in guideline development. 12 A. So I think to be transparent and 13 methodologically rigorous, as AGREE II says, is the 14 goal these days of guidelines, and transparency is 15 in multiple different layers. 16 So you want to, I think -- in a very 17 general way, the most important transparent thing is 18 to say how you -- you know, what you were looking to 19 do and how you did it. And then, from there, 20 transparency plays out in lots of other ways. So... 21 Q. Provided that the team was careful and 22 rigorous, why does it matter whether they're 23 transparent? 24 A. Is that kind of my opinion? I don't	Page 145 1 Medicine document again, Exhibit 14 (sic), and I 2 want to ask you to turn in there to Page 42. 3 A. Hold on. 4 MS. LEVI: I think it's this (indicating). 5 Q. This is what it looks like (indicating). 6 A. Sorry. This one. 7 Q. And if you would turn to 42. 8 And just for clarity, we referred to the 9 Institute of Medicine. Am I correct that the 10 Institute of Medicine is also or now known as the 11 National Institutes of Health? 12 A. National Association of -- National Academy 13 of Sciences. 14 Q. National Academy -- 15 A. -- of Sciences. 16 Q. Is it governmental entity? 17 A. It is not, technically. It's, like -- it 18 is and it's not. So -- or I don't know. I don't 19 actually -- and I'm not in it is the truth. 20 Q. Let's not spend time parsing out it is and 21 it's not. 22 Let me ask you to turn to page, what did I 23 say, 42, and -- 24 A. I think -- if you don't mind, I think the

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Page 146 1 government commissions it. 2 Q. Okay. 3 42 begins, "Organizations in several 4 countries outside the U.S. also produce clinical 5 practice guidelines." 6 And it goes -- in the next paragraph it 7 begins, "For example, the National Institute for 8 Health and Clinical Excellence (NICE) is an 9 independent organization that advises the UK 10 National Health Service," and it continues. 11 Are you familiar with the reputation of the 12 UK NICE? 13 A. I know what the NICE is. 14 Q. Is it a respected source of analysis of 15 medical science? 16 MS. LEVI: Object as to form. 17 A. Respected by who, I guess? Like, by 18 Americans? We don't necessarily follow NICE stuff. 19 Q. Well, what does NICE do, to your knowledge? 20 A. Okay. So this is purely what I understand. 21 Q. That's all you can ever testify to. 22 A. But the UK, unlike the United States, in 23 around -- actually, around as I'm graduating from 24 medical school, forms the National Health Service	Page 148 1 produce clinical guidance." 2 Were you aware, before reading that, that 3 NICE conducts or contracts for systematic reviews? 4 A. What I -- I didn't know that specifically. 5 What I knew -- 6 MS. LEVI: That was the question. 7 Q. That was the question. 8 A. Okay. 9 Q. So you don't have any view as to the 10 reputation of NICE for performing thorough or 11 reliable systematic reviews? 12 A. No. 13 Q. Okay. 14 Do you agree that transparency in the 15 development of a -- appropriate transparency in 16 connection with a clinical practice guideline 17 includes disclosure of the design of any systematic 18 searches that were done, for instance, the PICO 19 criteria? 20 MS. LEVI: Object as to form. 21 A. Actually -- I apologize, because I am 22 getting a little tired. So can you repeat that 23 question? 24 MS. LEVI: Do you need a break?
Page 147 1 and puts in place, over time, this National 2 Institute for Health and Clinical Excellence, the 3 NICE, which basically -- that's what I call it -- 4 which basically comes up with standards of care and 5 guidelines that go across the UK. 6 Unfortunately, the United States didn't 7 have that. So we have had a system that hasn't had 8 single payer like the National Health Service, and 9 instead we have allowed guidelines -- or we've 10 actually basically made it in the United States that 11 if you're going to have guidelines, it's all these 12 independent groups that have to create them. 13 And so guidelines in the U.S. are not 14 coming from a -- you know, there's not a single 15 payer and a single way of developing guidelines. We 16 have different organizations: NASPGHAN doing its 17 guidelines, WPATH doing its guidelines. I mean, 18 everybody is doing their own guidelines. So... 19 Q. The next sentence in this second full 20 paragraph gives a little more detail about the 21 functions of NICE. It says, quote, "It conducts or 22 contracts for technology assessments of new 23 treatments and devices as well as systematic reviews 24 and comparative effectiveness studies used to	Page 149 1 THE WITNESS: Maybe. Maybe. 2 MS. LEVI: It's perfectly fine. 3 MR. BROOKS: We can break for lunch now. 4 MS. LEVI: Okay. Why don't we do that. 5 MR. BROOKS: Fine. 6 THE WITNESS: Is that okay? 7 MS. LEVI: Of course. Absolutely. You get 8 to -- absolutely. 9 THE WITNESS: Okay. 12:40. I might have 10 hit my, like, lunchtime. 11 MR. BROOKS: That is just fine. 12 MS. LEVI: It is close to 12:45. Shoot for 13 half an hour? 14 MR. BROOKS: That's fine. 15 (Luncheon recess taken at 12:42) 16 17 18 19 20 21 22 23 24

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Page 150 1 AFTERNOON SESSION 1:20 p.m. 2 MS. LEVI: I will take a rough. A couple 3 days is fine. 4 BY MR. BROOKS: 5 Q. Let me ask you, Dr. Lightdale, to find 6 Exhibit 15, the "Clinical Practice Guidelines We Can 7 Trust." If you would turn in that document to Page 8 2, which is a ways in, because it follows the 9 preface. 10 On Page 2 is the heading that says, "CPG," 11 Clinical Practice Guideline, "Development 12 Challenges." And an inch and a half down, two 13 inches down in that is the sentence that begins, 14 "Certain factors commonly undermine." Let me ask 15 you to find that. 16 A. Yes. 17 Q. It reads, "Certain factors commonly 18 undermine the quality and trustworthiness of 19 CPG's." And you understand that to refer to 20 clinical practice guidelines, correct? 21 A. Yes. 22 Q. And it goes on to list factors that 23 undermine quality and trustworthiness, including 24 "lack of transparency of development groups'	Page 152 1 searches that were done for scientific evidence? 2 MS. LEVI: Object as to form. 3 A. I think I need to understand better what 4 the -- like, what's not a systematic search, or 5 whatever. 6 I'm not sure exactly how to answer that, 7 because I think there's a lot of things you think 8 about when you're looking at clinical practice 9 guidelines. That's what I think this paragraph is 10 saying: There are a lot of things you have to think 11 about. 12 Q. I'm asking your opinion now, not what the 13 paragraph is saying. 14 If a group preparing a clinical practice 15 guideline performs systematic searches for relevant 16 evidence, do you agree that appropriate transparency 17 includes disclosing the nature of searches done? 18 MS. LEVI: Object. 19 A. So I think it's just -- again, for me, 20 these are, like, sort of abstract questions, and I 21 would need to get more specifics, I think, in order 22 to understand what we're trying to get at here, is 23 the bottom line. 24 So for me, there's lots of things you're
Page 151 1 methodologies (particularly with respect to evidence 2 quality and strength of recommendation appraisals)." 3 And then a few lines farther below, it refers to 4 "unmanaged conflicts of interest." 5 Do you see the various things I've pointed 6 to? 7 A. "Unmanaged conflicts of interest." Yes. 8 Q. Okay. On the lack of transparency as a 9 factor that can undermine the quality and 10 trustworthiness of a clinical practice guideline, do 11 you agree that suitable transparency in the 12 development of a reliable clinical practice 13 guideline includes disclosure of the design of 14 searches for evidence that were done, including, for 15 instance, the PICO factors? 16 MS. LEVI: Object as to form. 17 A. I think this is a list of things you have 18 to be thinking about, and there's not any one 19 absolute. So I'm not sure I totally agree that 20 that's how one defines a good clinical guideline. 21 Q. You would consider, would you not, that 22 appropriate transparency in connection with the 23 development of a clinical practice guideline will, 24 in fact, include disclosure of the systematic	Page 153 1 thinking about, and it's really important that 2 that's the way I'm approaching things. I'm thinking 3 about lots of different things, and I have to have 4 all of them in order to decide whether or not I'm 5 dealing with a good clinical practice guideline. 6 Q. Let's see if you want to stick with that. 7 * Do you have an opinion as to whether good 8 practice and transparency in connection with 9 preparing a clinical practice guideline includes 10 disclosure of the databases that the team has 11 searched for relevant evidence? 12 MS. LEVI: Object. 13 A. So the question that you are asking is, is 14 the definition of transparency of the systematic 15 search that they list the actual, whatever, PubMed, 16 Cochrane, whatever that they did, the MBase, the 17 different databases? 18 Q. No, that wasn't my question. 19 MR. BROOKS: Let me ask the reporter to 20 read back my question. 21 (* Question read) 22 A. I would say not in and of itself. That's 23 not the only definition of transparency. 24 Q. I didn't ask if that was the definition of

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Page 154 1 transparency. I asked you whether good practice 2 includes disclosing the databases that you searched 3 for relevant evidence. 4 MS. LEVI: Object as to form. 5 A. I'm getting lost in the question, but not 6 in and of itself is listing the places you searched. 7 Q. Would you agree that good practice in 8 connection with preparing a clinical practice 9 guideline includes, if the team has used established 10 criteria for rating the strength of evidence, 11 disclosing the ratings that were assigned? 12 MS. LEVI: Object as to form. 13 A. I think there are lots of ways to do 14 guidelines. So the important thing is that 15 you basically put out what your process is going to 16 be, and then you follow it. 17 Q. That's it? That's the sum total of your 18 opinion as to what constitutes good practice in 19 forming and creating a clinical practice guideline? 20 MS. LEVI: Object as to form. 21 A. I think there are now lots of groups, 22 including this group and including other groups, 23 that are saying, "Okay, let's go through different 24 ways of measuring guidelines in trying to decide."	Page 156 1 review? 2 A. So when I have done systematic reviews or 3 been a part of systematic reviews, generally we've 4 worked with somebody who's performed the systematic 5 review for us, usually a librarian. 6 And then what you've got is, Okay, we were 7 given this number of papers that might or might not 8 meet our criteria, and then we've gone through and 9 we've made decisions about which ones we're 10 including or not including, and we wind up with, in 11 the end, Okay, we included X number, and then you 12 move from there, where we've reviewed it. 13 And so you've sort of gone through a 14 process. So the systematic review starts the 15 process, and then you have to move through it. And 16 we've usually explained that in some place, you 17 know, either in a figure or in a paragraph, in text. 18 Q. * If a team developing clinical practice 19 guidelines has commissioned systematic reviews that 20 resulted in GRADE ratings of the quality of evidence 21 on certain topics relevant to the clinical practice 22 guideline, would you agree with me that it would 23 violate principles of transparency not to make those 24 ratings available publicly?
Page 155 1 But they're also aware of all the different 2 things that go into guidelines. So there isn't one 3 thing that you have to do that makes a good 4 guideline. It's you sort of look at the whole thing 5 that happened and then decide on the strength of the 6 guideline. 7 Q. So it's just kind of a gut check? 8 MS. LEVI: Object as to form. 9 A. I think it's complex. 10 Q. If a team, in connection with preparing 11 guidelines, commissioned the performance of 12 systematic reviews of certain topics, would you 13 agree that good practice with regard to transparency 14 requires that the results of those systematic 15 reviews be disclosed? 16 MS. LEVI: Object as to form. 17 A. I'm not sure what you mean by "results of 18 the systematic reviews." Like, what is that 19 "results of the systematic reviews"? 20 Q. You have performed systematic -- you've 21 participated in performing systematic reviews? 22 A. I have. 23 Q. And how would you describe the output of 24 what is now recognized as a formal systematic	Page 157 1 MS. LEVI: Object as to form. 2 A. I don't agree with that. I don't think it 3 violates principles. It's a decision that was made, 4 or, frankly, it may have been at a moment when 5 people were -- you know, didn't realize that it 6 would be important. 7 I think there's been a lot going on in the 8 field, and so there hasn't been this, You must give 9 the GRADE ratings exactly the way -- it's really not 10 where we are. It's just becoming something that 11 people are talking more about. 12 So, again, there are many different ways 13 people have put out guidelines and so many ways to 14 put out your recommendations and I think different 15 ways to do it. 16 So, again, without getting into the 17 specifics, I can't really understand what I'm going 18 to be commenting on here. So... 19 MR. BROOKS: Let me ask the reporter to read 20 back my question. 21 (* Question read) 22 A. It's a very long question. So there's 23 different pieces to it, and it seems to be ending 24 with, is it violating principle not to put the GRADE

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Page 158 1 ratings next to the recommendations. 2 Q. No. That's not my question. 3 A. Okay. So maybe I can -- 4 Q. Does it violate principles of transparency 5 not to disclose those GRADE ratings in any way, 6 shape or form? 7 MS. LEVI: Object as to form. 8 A. Not to my knowledge. 9 Q. If an organization, for the purposes of 10 preparing clinical practice guidelines, commissions 11 an independent team to conduct systematic reviews 12 for the purpose of informing those guidelines, is it 13 consistent with principles of transparency for that 14 sponsoring organization to prevent the publication 15 of the results of the systematic review? 16 MS. LEVI: Object as to form. 17 A. Not to my knowledge. 18 Q. * If an organization preparing clinical 19 practice guidelines commissions systematic reviews 20 on certain topics from an independent team and 21 receives those systematic reviews, is it consistent 22 with ethics and transparency, in your view, for that 23 organization to publicly deny that the systematic 24 reviews were done?	Page 160 1 I mean, there's lots of contexts in which 2 you might make a decision that a systematic review 3 didn't get what you needed and you would go back and 4 do it again. 5 So if that's what we're asking or -- I'm 6 not sure if that's what you're asking. I think 7 there are reasons that a systematic review is simply 8 not included in the guideline. 9 Q. That's not what I'm asking. 10 A. Okay. 11 Q. If an organization such as WPATH, preparing 12 clinical practice guidelines, commissioned 13 systematic reviews to be performed by a separate 14 entity, those reviews are done and delivered to the 15 sponsoring organization, is it, in your view, 16 consistent with ethics and transparency for the 17 sponsoring organization to publicly deny that the 18 systematic views were in fact done? 19 MS. LEVI: I'm going to object as to form. 20 And also the question has been asked a number of 21 times. 22 I just want to say, answer it if you can. 23 A. Yeah, I guess I'm having trouble 24 understanding what would be the context in which
Page 159 1 MS. LEVI: Object as to form. 2 A. Again, you're describing scenarios that I 3 almost can't imagine, so I am not sure the context 4 in which -- I mean, I don't know. I'm not exactly 5 sure what this would be. 6 My understanding is you have an independent 7 group that is now -- has done the systematic review, 8 and the other group doesn't -- wait. You explained 9 something, and you said the first group should now 10 deny? 11 MR. BROOKS: Let me ask the reporter to 12 read the question back. 13 (* Question read) 14 A. Which organization? The one that 15 commissioned it? 16 Q. Yes. 17 A. It wouldn't -- you don't have to use a 18 systematic review when you publish your guideline. 19 I actually think, no, that that -- in my opinion, 20 you've done a systematic review, you might say, 21 "Gee, that wasn't good enough," or "That didn't get 22 what we wanted to," or "It didn't" -- "Actually, we 23 forgot a search term. Let's go back and do it 24 again."	Page 161 1 they would be asked, "Did you do a systematic 2 review?", and then they would publicly deny it. 3 I just don't get what happened here. This 4 would -- this is -- guidelines are not usually any 5 need to deny anything. It's just -- 6 Q. Are you unable to answer your question? 7 A. I would be unable to answer your question. 8 Not following it. So... 9 MS. LEVI: You can only answer a question 10 if you can. 11 THE WITNESS: Okay. 12 MS. LEVI: It's fine. If not, if you can't 13 answer it, then respond as such. 14 Q. Let me ask you to find your expert report, 15 which is Exhibit 4. 16 There, in Paragraph 24 on Page 8, you 17 discuss the Delphi process, and you describe it as a 18 "well-established methodology." We've talked about 19 it a bit. We've discussed the voting process. 20 We've discussed anonymity. I don't want to rehash 21 all that. 22 In 23, you quote Dr. Laidlaw as saying 23 Delphi is not, quote, evidence based. Do you see 24 that?

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Page 162 1 A. Yes. 2 Q. Now, am I correct that Delphi is a process 3 which could be used to achieve consensus or to 4 attempt to achieve consensus on either evidence- 5 based recommendations or recommendations based 6 simply on expert opinion? It could be used for 7 either of those, correct? 8 A. That's my understanding. 9 Q. And in one case the output would be 10 evidence based, and in the other case the output 11 would not be evidence based, right? 12 A. I mean, Delphi, again, is a process for 13 developing consensus. 14 Q. And using Delphi doesn't tell you anything 15 one way or the other as to whether -- 16 A. Correct. 17 Q. -- the output is evidence based? 18 Okay. I just wanted to clarify that. 19 And you, yourself, have, on multiple 20 occasions, participated in Delphi processes? 21 A. Yes. 22 Q. Given the nature of a Delphi process and 23 the importance of anonymity as you've described it, 24 would it be appropriate for the leadership of a	Page 164 1 WPATH methodology web page that suggested to you 2 that WPATH leadership made substantive changes to 3 the guidelines after the completion of the Delphi 4 process that they describe? 5 MS. LEVI: Object as to form. 6 A. All I read was the website that explained 7 their process. I don't recall anything saying about 8 making any changes after the fact. 9 Q. As a scientist and clinician, if you read a 10 set of guidelines in which the methodology said that 11 all the recommendations were approved through a 12 Delphi process, and in fact some of those 13 recommendations had been materially altered through 14 a non-anonymous process after the Delphi process, 15 that would cause you serious concern, would it not? 16 MS. LEVI: Object as to form. 17 A. Not necessarily. Having been through it, 18 what I would need is an understanding, some context 19 around what changes were made and why. 20 Q. Why, given the importance of the Delphi 21 process and the anonymity of the Delphi process, do 22 you need more context to form an opinion as to 23 whether post hoc changes through a non-anonymous 24 process would violate principles and cause you
Page 163 1 clinical practice guideline project to make 2 substantive changes to guideline recommendations 3 after they have been approved through the Delphi 4 process? 5 MS. LEVI: Object. 6 A. So not -- I mean, there are little changes 7 people can make after you've gone through a Delphi 8 process. So, for instance, grammar can get changed. 9 Q. In my question I said "substantive 10 changes." 11 MS. LEVI: Object as to form. 12 A. That's what I think you said. So that's 13 what I thought you said. 14 So Delphi is a methodology, and ideally, if 15 you're going to follow it, you will come to a 16 consensus around a statement. And that's what 17 you're trying to explain that you did. So... 18 Q. Is your understanding, based on what you 19 read from the WPATH web page, that all the WPATH 20 recommendations and suggestions were approved 21 through a Delphi process? 22 A. I don't remember if it was all of them, but 23 they were definitely using a Delphi process. 24 Q. And do you recall seeing anything in the	Page 165 1 concern as a scientist and a clinician? 2 MS. LEVI: Object as to form. 3 A. So Delphi allows for some work to happen as 4 you're getting to the final bits. And in 5 particular -- I've been through the moment when you 6 realize you've got two statements that can be sort 7 of made into one, or things like that that basically 8 will help simplify your process. 9 So I think there are even allowances within 10 Delphi to be able to keep working after the 11 iterative process is done. 12 Q. Have you been involved in any Delphi 13 process where, at a late stage, a revised statement 14 or recommendation was sent back through the Delphi 15 process again? 16 MS. LEVI: Object as to form. 17 A. I personally have not. 18 Q. Okay. 19 Let me ask you to find Paragraph 31 of your 20 report. And there you stated, "Dr. Laidlaw also 21 erroneously suggests that merely being a provider 22 who treats gender dysphoria creates a 'conflict of 23 interest' with respect to participating in the 24 development of guidelines. This has no basis in

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Page 166 1 medical ethics or science," close quote. 2 Now, you would agree with me, would you 3 not, Dr. Lightdale, that being a provider who treats 4 gender dysphoria is likely to give a physician some 5 financial interest in -- some potential financial 6 interest in what procedures are or are not approved 7 by the guidelines? 8 MS. LEVI: Object as to form. 9 A. No. No. I don't agree with that 10 statement. 11 Q. Why is that? 12 A. I think physicians who treat conditions -- 13 I mean, we're talking here about gender dysphoria, 14 but I treat conditions. I am treating a patient for 15 what they have as a condition. That's what I'm 16 supposed to do as a health care provider. 17 So I don't think my financial interest is 18 in providing treatment to patients. It's my 19 profession. 20 Q. I could flip back to it, but let's see if 21 we can do it without. 22 You recall that we looked at the SOC-8 23 methodology appendix which had language that stated 24 that that team relied on recommendations developed	Page 168 1 and disclosing and managing conflicts of interest, 2 it's important to transparency that a clinical 3 practice guideline development team does follow the 4 protocols that they state that they followed? 5 MS. LEVI: Object as to form. 6 A. So -- right. So I think that there are -- 7 there's a framework here, and there's lots of 8 different ways that I can put that framework into 9 action. But I would say, if you're going to state 10 something, then you followed it. 11 Q. If you state that you followed it, you 12 should follow it; that's what you're saying, 13 correct? 14 MS. LEVI: Object as to form. 15 A. I mean, this is the methods of what they 16 did. So they are describing their methods. 17 Q. And my question is, if they describe their 18 methods as incorporating recommendations with 19 respect to conflict-of-interest policy from the 20 Institute of Medicine document, then it would 21 violate principles of transparency if in fact they 22 did not follow those conflict of interest 23 principles? 24 MS. LEVI: Object as to form.
Page 167 1 by the National Academy of Medicine and cited the 2 document we've looked at from the Institute of 3 Medicine in connection with both process and 4 conflict of interest. 5 Do you recall that, or do you want to go 6 back to it? 7 A. I don't -- 8 Q. Let's find the exhibit, which is Exhibit 5. 9 Can you turn to Page 247. Three inches 10 down in the first column is the language that reads, 11 "The process for development of the SOC-8 12 incorporated recommendations on clinical practice 13 guideline development from the National Academies of 14 Medicine and The World Health Organization that 15 addressed transparency, the conflict-of-interest 16 policy, committee composition and group process." 17 And then it cites the IOM document that we've looked 18 at, correct? 19 A. Yes. 20 Q. As well as a WHO document that I'm not 21 going to take your time with. 22 A. Okay. 23 Q. Now, would you agree with me that, while 24 there may be different protocols for dealing with	Page 169 1 A. I think there are lots of ways to do 2 conflicts of interest, and -- I've personally filled 3 out many conflict-of-interest forms, and there are 4 lots of different ways. 5 I don't think the IOM actually said there's 6 one way to do it, as far as I know. Again, maybe 7 it's in the book, but... 8 Q. Maybe it is. 9 Why don't you find Exhibit 14, the 10 Institute of Medicine -- 11 MS. LEVI: I think that's 15. 12 MR. BROOKS: How right you are. Pardon me. 13 Exhibit 15. Thank you for the correction. 14 Q. If you will turn to Page 76, you'll see the 15 heading, "Establishing Transparency." 16 A. Okay. 17 Q. And on the following page, 77, the 18 paragraph at the bottom of the page begins, quote, 19 "Transparency also requires statements regarding the 20 development team members' clinical experience, and 21 potential conflicts of interest, as well as the 22 guideline's funding source(s)." 23 Do you see that? 24 A. Yes.

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Page 170 1 Q. Do you agree with that statement? 2 A. Sure. 3 Q. And if you turn to Page 78, you'll see a 4 heading, "Management of Conflict of Interest," and 5 there, in the second full sentence, it states, "A 6 recent comprehensive review of conflict-of-interest 7 policies of guideline development organizations 8 yielded the following complementary descriptions of 9 conflict of interest," close quote, and it goes on 10 to quote two of what it's referred to as 11 "complementary descriptions." 12 I want to read to you the first. Quote, "A 13 divergence between an individual's private interests 14 and his or her professional obligations such that an 15 independent observer might reasonably question 16 whether the individual's professional actions or 17 decisions are motivated by personal gain, such as 18 financial, academic advancement, clinical revenue 19 streams or community standing." 20 Do you see that? 21 A. Yeah. 22 MS. LEVI: Take the time you need to review 23 the document. 24 Q. My question for you is whether that	Page 172 1 publication. 2 Do you see that language referring to 3 intellectual conflicts of interest? 4 A. Yes. 5 Q. And are you generally familiar with the 6 concept of intellectual as opposed to financial 7 conflicts of interest? 8 A. Yes. 9 Q. And you agree that intellectual conflicts 10 of interest can be among the types of conflict of 11 interest that should be disclosed in connection with 12 a clinical practice guideline project? 13 MS. LEVI: Object as to form. 14 A. I mean, I would say that is -- that's an 15 opinion, and one I think I've come to. But, you 16 know, it's an evolving area. That's the other thing 17 about that one. 18 Q. If you look at Page 79, six line down, at 19 the end of the line it begins a sentence as follows, 20 quote, "Direct financial commercial activities 21 include clinical services from which a committee 22 member derives a substantial portion of his or her 23 income; consulting; board membership for which 24 compensation of any type is received; serving as a
Page 171 1 definition of a conflict of interest that IOM has 2 quoted here is consistent with your understanding of 3 what constitutes a conflict of interest. 4 A. Yes, this is consistent with what I think, 5 which is really around this very important concept 6 of an independent observer might reasonably question 7 whether something is being motivated. 8 So for me -- and, again, it's got these 9 complementary descriptions. I mean, there's lots of 10 ways to think about it, but you have to think it's 11 reasonable to think that there's conflict of 12 interest. 13 Q. The language goes on there to refer, in the 14 next line, to, quote, "A financial or intellectual 15 relationship that may impact an individual's ability 16 to approach a scientific question with an open 17 mind." 18 And the following sentence says, quote, 19 "Finally, intellectual conflicts of interest 20 specific to clinical practice guidelines are defined 21 as 'academic activities that create the potential 22 for an attachment to a specific point of view that 23 could unduly affect on individual's judgment about a 24 specific recommendation," and it quotes a Guyatt	Page 173 1 paid expert witness," and it goes on. 2 Do you see that language? 3 A. Yes. 4 Q. And do you agree or disagree that a direct 5 financial commercial interest that can comprise a 6 conflict of interest includes providing clinical 7 services from which a committee member derives a 8 substantial portion of his or her income? 9 MS. LEVI: Object as to form. 10 A. So I disagree with, I think, how this is 11 being characterized. And I will tell you that I 12 think that many of us are salaried. So it doesn't 13 matter if I bill -- if I do a particular thing or 14 not, because I'm still going to get the same salary. 15 That's number one. 16 Number two is the way medicine works. 17 You're getting paid for encounters. You're not 18 getting paid for, you know, doing anything specific. 19 You're just getting paid to see the patient. 20 And then the third thing is, I don't think 21 that the National Academy of Sciences would have 22 taken us down a route that means that experts in an 23 area can't participate in guidelines, you know, that 24 that would make no sense.

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1 So I think we know we need experts in 2 guidelines and that those experts have to really be 3 doing the medicine in order to be able to be a part 4 of that process. 5 So I think what they're talking about there 6 is, if you are, and I do, do some consulting, or you 7 do have royalties or something like that, that's 8 where you must disclose, on a conflict-of-interest 9 form, that you work with a company that actually has 10 interest in a guideline going in a certain 11 direction. 12 It's not about the practice of medicine. 13 It's about what you're doing to the side of that 14 that they're worrying about. 15 Q. Let me break out a couple of things that 16 you said. 17 First, when it comes to fees for 18 procedures, is it your testimony that, when you 19 perform an endoscopic procedure, that there is not 20 separate billing tagged to that procedure? 21 MS. LEVI: Object as to form. 22 A. I mean, I submit a bill, but I myself will 23 get the same salary whether I've submitted the bill, 24 like -- or not. It's not -- I don't have -- like,	1 talks about management through disclosure and is not 2 saying that everybody who has a conflict of interest 3 is disqualified from participating in a guideline 4 development process? You understand that, correct? 5 A. Yes. 6 Q. Okay. Now, my question for you is, is it 7 consistent with your understanding that a physician, 8 who provides clinical services potentially affected 9 by the guideline from which that individual derives 10 a substantial proportion of his or her income, has a 11 financial conflict of interest of a type that needs 12 management, perhaps through disclosure? 13 MS. LEVI: Object as to form. 14 A. I don't think that's what they were trying 15 to get at here. I think they're assuming that the 16 people on a guideline committee are experts in their 17 field and do that type of medicine. So that was -- 18 that's sort of an assumption. There's no point in 19 being in a guideline-writing process if you don't 20 actually practice the medicine. 21 So I think what they're getting at here is, 22 are you going to be making money because you have 23 stocks in something or you consult for something and 24 you'll get more money if you, you know, continue to
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1 many of us, particularly in pediatrics and in 2 academic pediatrics, are not -- it has nothing to do 3 with how much or how little we bill. We're going to 4 get our salaries. So... 5 Q. Let's break that out. 6 It's the case, is it not, that in 7 connection with medical procedures, including or 8 perhaps particularly surgeries, bills are quite 9 specifically broken out by procedure? 10 MS. LEVI: Object as to form. 11 A. Our current health care system is 12 absolutely about patient-facing activities being 13 billed. 14 Q. Specific procedure -- 15 A. Specifically. 16 Q. By specific procedure? 17 A. Sure. 18 Q. Second, it's by no means the case, is it, 19 that all physicians are salaried, such that their 20 income does not depend on how many procedures they 21 perform? 22 A. This is true. 23 Q. And you also understand, do you not, that 24 the IOM conflict-of-interest policy in many cases	1 consult, and people will be happy with you. 2 Q. Dr. Coleman -- pardon me. That was Friday. 3 What is your understanding of the language 4 I directed you to that refers to providing, quote, 5 "clinical services from which a committee member 6 derives a substantial portion of his or her income"? 7 A. I mean, I think -- the sentence actually 8 starts with "Direct financial commercial 9 activities." And I would say, like everything in 10 all of these papers, "may include," and then they're 11 giving a whole list here of different things that it 12 may include. 13 And the first one that you're pointing to 14 is "clinical services from which [you get] a 15 substantial proportion of [your] income." 16 And I guess where I'm thinking is that -- 17 what they're talking about there, I think, is 18 someone who is going to make a lot of money if they 19 do something -- I mean, basically the guideline is 20 going to have them do something more, and so then 21 they're going to do more of it, and now they're 22 going to make a lot of money. 23 I don't -- I just don't think that they're 24 talking about providing clinical medicine. To me,

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Page 178 1 that's -- like, doesn't make any sense. It's about 2 commercialism, and we're talking -- I practice 3 medicine. 4 So I think what I can understand and what I 5 tend -- what I think of when I fill out a conflict- 6 of-interest form is, if I sit on a board, if I 7 consult, if I've been a paid witness, if I'm doing 8 industry-sponsored research, I have a financial 9 interest in that company, and so then I need to 10 disclose that on the disclosure form. 11 Q. So as you sit here today, you really can't 12 understand what the IOM was referring to when they 13 talk about clinical services? 14 A. I think they're talking about clinical 15 services that are affected when you sit on a board 16 or you consult or you -- I think that's what this is 17 all getting at. 18 It's not getting at do you practice 19 medicine. Like, do I practice pediatric GI? Yes, 20 of course. I sit on guidelines because I'm an 21 expert in that particular area. 22 So, you know -- and I'm trying to remember 23 where we started this, but financial conflict of 24 interest is not practicing medicine. It's not	Page 180 1 conflict of interest consistent with your 2 understanding? 3 A. I think so. 4 Q. And would you agree with me that, under 5 that definition of an intellectual conflict of 6 interest, when it comes to pediatric endoscopy, you 7 have an intellectual conflict of interest? 8 MS. LEVI: Object as to form. 9 A. There are areas of my field where I may 10 have intellectual conflict of interest, like within 11 it, that I have -- sure. 12 Q. Okay. 13 A. -- strong feelings on things, and I can -- 14 Q. And strong published positions? 15 A. Sure. 16 Q. Okay. 17 * For physicians who are compensated based 18 on the revenue they generate for their practice, is 19 it still your position that those physicians have no 20 conflict of interest, financial conflict of 21 interest, with respect to clinical practice 22 guidelines that may affect their practice? 23 MS. LEVI: Object as to form. 24 A. I may need the beginning of the question
Page 179 1 treating patients. I mean, otherwise, we're 2 going -- 3 MS. LEVI: You answered the question. 4 Q. Let me ask you to look a little further 5 down, at a sentence that begins, "A person whose 6 work or professional group fundamentally." 7 Do you see that? 8 A. Yes. 9 Q. Let me ask you to read that and the 10 following sentence. 11 A. "A person whose work or professional 12 group --" 13 MS. LEVI: Did you want her to read it for 14 record or -- 15 MR. BROOKS: Oh, might as well. 16 Q. Go for it. 17 A. It's actually easier for me, guys. 18 "-- fundamentally is jeopardized, or 19 enhanced, by a guideline recommendation is said to 20 have intellectual COI. Intellectual COI includes 21 authoring a publication or acting as an investigator 22 on a peer-reviewed grant directly related to 23 recommendations under consideration." 24 Q. Is that definition of an intellectual	Page 181 1 asked again. Sorry. 2 (* Question read) 3 A. So what we're asking is, would it be a 4 financial conflict of interest for a person in 5 so-called private practice to sit on a guideline 6 committee that may potentially recommend something 7 that they then would be using in their practice? Is 8 that what we're asking? 9 Q. Again, we've talked about how IOM -- 10 discussion of conflict of interest doesn't 11 necessarily require exclusion as far as management. 12 So my question isn't about any activity 13 we're going to take. It's simply, do you agree or 14 disagree that a physician whose income depends in 15 significant part on revenues brought in from 16 procedures performed has a financial conflict of 17 interest with respect to clinical practice 18 guidelines that may significantly affect that 19 physician's practice? 20 MS. LEVI: Object as to form. 21 A. So what I'm having trouble with is, they 22 would have a conflict of interest in terms of 23 participating in the guideline. They probably 24 should disclose, again, that they own a practice

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Page 182 1 where they are doing a lot of the procedure that's 2 going to be recommended in the guideline, or not 3 recommended in the guideline, that their practice 4 will be affected financially by that. 5 I do believe in conflict-of-interest forms. 6 You can be asked, "Do you own a practice?" I mean, 7 that's -- you know, that's a reasonable thing to 8 ask, "Do you own a company?" I think you get asked 9 that, "Do you own a company?", which private 10 practice technically would be. 11 Again, for me, the difference is that I 12 don't think this is about being an expert in the 13 field. Like, that's just not one thing -- I'm not 14 asked, when I do these guidelines, "Are you a 15 gastroenterologist who's going to get affected by 16 the guidelines?" 17 The answer is, of course, "Yes." Like, 18 everybody involved in the process is a 19 gastroenterologist who's going to get affected by 20 the guidelines. 21 So it's not a financial conflict of 22 interest, what I do. Does that make any sense? 23 Q. Dr. Lightdale, do you consider yourself to 24 be an expert in conflict-of-interest principles?	Page 184 1 that they had a process where they asked for both 2 financial and nonfinancial conflicts of interest. 3 I mean, again, most of us are just starting 4 to do this. 5 Q. What led you to believe that WPATH had a 6 process that included asking for intellectual 7 conflicts of interest? 8 A. It may have been talked about -- at some 9 point somebody brought it up. 10 Q. What do you mean by "somebody brought it 11 up"? 12 A. Isn't that here (indicating)? I don't 13 remember. 14 Q. Do you recall seeing any document in which 15 WPATH claims to have identified -- 16 A. Maybe it's in this thing right here, to be 17 honest, that we read it today. 18 (Reviewing document) I think -- (reviewing 19 document) 20 I'm actually getting all dizzy right now. 21 MS. LEVI: Do you want to take a break? 22 THE WITNESS: Well, yes. 23 A. But maybe I want to try to understand what 24 we were talking about. Maybe it was way back at the
Page 183 1 A. No. 2 Q. You, in fact -- and I think this follows 3 from your earlier testimony, but let me ask. 4 Am I correct that you have no knowledge as 5 to whether WPATH, in the course of creating SOC-8 or 6 SOC-7, followed the Institute of Medicine conflict- 7 of-interest principles spelled out in this document, 8 Exhibit 15? 9 A. The knowledge I have of what they did is 10 from reading the websites and now, today, reading 11 their methods, which sounded in line with what the 12 National Academy of Sciences recommends. 13 Q. But you haven't, for instance, seen any 14 disclosure forms that were circulated within WPATH? 15 A. No. 16 Q. And you haven't looked at the SOC-8 itself 17 to see what conflicts they in fact disclosed? 18 A. No. 19 Q. You don't know whether -- you don't know 20 what proportion of the participants in the SOC-8 21 development project had intellectual conflicts of 22 interest of the type that we've discussed? 23 MS. LEVI: Object as to form. 24 A. I don't. I did think it was impressive	Page 185 1 beginning of the morning when we talked about this 2 piece (indicating). 3 I can't remember. We were talking about -- 4 I know, because I'm really interested in this 5 intellectual conflict of interest discussion. So... 6 Anyway... 7 MR. BROOKS: Would you like to take a 8 break? 9 THE WITNESS: Yes. 10 (The witness and Ms. Levi leave the room) 11 THE COURT REPORTER: Ms. Levi has asked for 12 a rough. Would you like one as well? 13 MR. BROOKS: I would like a rough. 14 (Recess) 15 MS. LEVI: Dr. Lightdale wants to explain 16 an earlier answer, give a context. 17 THE WITNESS: Yes. So I want to make it 18 clear that, in preparing for today, I had seen a 19 document that was likely a conflict-of-interest 20 document, and I think, again, such stuff I'm 21 interested in intellectually, intellectual conflict 22 of interest around this discussion. 23 BY MR. BROOKS: 24 Q. Do you have any knowledge, Dr. Lightdale,

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Page 186 1 as to whether the chair of SOC-8 had either 2 intellectual or financial conflicts of interest 3 relevant -- relating to treatment of gender 4 dysphoria? 5 A. I have no idea. 6 Q. And likewise, am I correct that you have no 7 idea as to whether the co-chairs of that project 8 have financial or intellectual conflicts of 9 interest? 10 A. I don't know that, no. 11 Q. And the same is true with respect to the 12 chapter leads of each chapter team? 13 A. No idea. 14 Q. Just because of law, I'm ticking these 15 things off. 16 And you have not formed any opinion as to 17 the adequacy of the actual disclosures made by WPATH 18 of conflicts of interest that may exist with respect 19 to any participants in the process, have you? 20 A. I have no opinions. 21 Q. You get out of a whole lot of deposition by 22 just saying, "I have no opinions." 23 MR. BROOKS: Let me ask the reporter to 24 mark as Exhibit 16 an article from 2018 entitled	Page 188 1 Q. And this was in connection with sedation 2 generally? 3 A. Yeah. This was not GI per se. 4 Q. Okay. Let me ask you to turn to the second 5 page of the document. In the first column, four 6 inches down, there's a paragraph that begins, 7 "SCEPTER's previous study." 8 Do you see that? 9 A. Uh-huh. 10 Q. And what is SCEPTER? It sounds like 11 something from a Bond movie. 12 A. SCEPTER is Sedation Consortium on Endpoints 13 and Procedures for Treatment, Education and 14 Research. SCEPTER. 15 Q. Thank you. 16 Late in the paragraph is a sentence -- and 17 feel free to read the whole paragraph. I'm going to 18 call your attention to sentence that begins, "While 19 safety is arguably the most important of the 6 IOM 20 domains, its measurement in clinical trials presents 21 complex problems and dilemmas." 22 Do you see that language? 23 A. Yes. 24 Q. I'm going to ask you about that, and you
Page 187 1 "Evaluating Patient-Centered Outcomes in Clinical 2 Trials of Procedural Sedation, Part 2," authors -- 3 lead author Denham Ward, and many authors, one of 4 whom is Dr. Lightdale. 5 (Document marked as Lightdale 6 Exhibit 16 for identification) 7 Q. Dr. Lightdale, I'm going to ask you first 8 if you can identify this paper. 9 A. Yes. 10 Q. And can you explain to me your role in its 11 creation. 12 A. So I was invited to be in this committee -- 13 which was brought together by the FDA, but then 14 represented a whole lot of stakeholders -- to come 15 up with recommendations for what our endpoint -- 16 what endpoints should be around treatment. 17 This particular paper was around treatment, 18 education and research. So endpoints for trials. 19 Q. And for the record, for the layman, can you 20 explain to me what you mean by "endpoints." 21 A. Outcomes, what you could look at in a 22 trial. 23 Q. The things you're measuring, fundamentally? 24 A. Right.	Page 189 1 can look at anything surrounding you want. 2 The beginning of the paragraph refers to, I 3 think, a different document from the Institute of 4 Medicine, just to avoid any confusion. 5 Do you have an opinion as to -- well, are 6 you able to explain to me why it's the case, if it 7 is, that safety is arguably the most important 8 consideration being addressed here? 9 A. So the group took the tack of saying that 10 we were going to focus on safety, because, I think, 11 when you give sedation and anesthesia, you want to 12 avoid physical or psychological harm, and we thought 13 that was perhaps the most urgent thing you have to 14 think about with sedation, especially for 15 procedures. 16 Q. Does sedation risk both physical and 17 psychological harm? 18 A. Yes. 19 Q. Is one of those considered to be a more 20 serious problem than the other? 21 MS. LEVI: Object as to form. 22 A. I think we considered them both. I mean, 23 either was bad. 24 Q. Okay. And are you telling me that the

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Page 190 1 group simply chose to focus on safety, or is safety, 2 for some recognized reason, the most important 3 concern as physicians evaluate procedures? 4 MS. LEVI: Object as to form. 5 A. So SCEPTER was trying to decide what are 6 good things to measure, and safety -- what this 7 sentence is really saying is safety is actually, 8 whether or not -- I would actually say we agreed 9 that other people could probably put together an 10 argument that one or the other IOM six domains was 11 as important as safety. 12 But we said, "Okay, well, let's just assume 13 it's really important. Actually measuring it is 14 very hard." And so -- then that's what we said 15 we're really dealing with in this paper. 16 Q. Okay. In the second column on this same 17 page, the second paragraph that begins in that 18 column starts, "For the systematic review of safety 19 studies." 20 A. Uh-huh. 21 Q. And am I correct that this group 22 essentially commissioned an independent systematic 23 review of safety studies? 24 A. Yes.	Page 192 1 Q. And maybe it could be -- we can focus on 2 this article or not. Let me ask more general 3 question. 4 In your experience, is it commonly the case 5 that systematic review searches are limited to 6 articles published in English in the field of 7 medicine? 8 MS. LEVI: Object as to form. 9 A. So my own personal experience has been that 10 we always think about should we include other 11 languages, and then we make a tactical decision not 12 to. 13 Q. And is there a reason why it is generally 14 accepted in the field as adequate to search only 15 English language materials? 16 MS. LEVI: Object as to form. 17 A. I think there's actually always a little 18 bit of a discomfort with the fact that we're 19 limiting it just to English and that -- for example, 20 there are billions of people that live in China and 21 India, and we're not including any medical 22 literature that comes out of those places, which 23 doesn't feel particularly comfortable. But there's 24 just an economy of effort that you have to work
Page 191 1 Q. And it describes -- a few lines down it 2 says, quote, "Only prospective randomized double- 3 blind studies reported as full-text articles 4 published in English were included." And I'm not 5 going to ask you again about blinding and 6 randomizing. 7 Why did you consider it appropriate to 8 restrict the search only to articles published in 9 English? 10 A. First off, I personally did not make 11 decisions about this on my own. I was very much in 12 the center of -- I'm really a middle person here of 13 a very large group that was making decisions about 14 what we were going to do as a group. 15 But there was a feeling, at least across 16 all of sedation, procedural sedation and anesthesia, 17 that you could get -- what we needed to get to you 18 could get from randomized controlled trials. 19 And -- so, again, we made that decision 20 that that's how we are going to do this particular 21 systematic review. 22 Q. Sorry. My question was focused only on the 23 issue of language, and that was -- 24 A. Oh, the English?	Page 193 1 with, and... 2 Q. Is it also the case that, in many cases, 3 science from countries that -- where the native 4 tongue is other than English are nevertheless 5 published in English? 6 A. Not necessarily. 7 Q. I didn't say "necessarily." I said, is it 8 often the case? 9 MS. LEVI: Object as to form. 10 A. I don't actually know. I don't know. 11 Q. All right. 12 You mentioned India. Do you have reason to 13 believe that important medical science coming out of 14 India is published in any language other than 15 English? 16 A. I have no idea. 17 Q. Okay. There's a lot of people there, 18 but... 19 Let's go back, if we could, to the AGREE 20 document, Exhibit 2, and I want to take you to Page 21 24. 22 There, at the top, the heading is, under 23 "Rigour of Development," quote, "The health 24 benefits, side effects, and risks have been

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Page 194 1 considered in formulating the recommendations," 2 close quote. 3 Do you see that? 4 A. Yes. 5 Q. And do you agree that, before you relied on 6 a clinical practice guideline, you would want to 7 have good confidence that those who developed it had 8 considered not just benefits but also side effects 9 and risks in formulating their recommendations? 10 MS. LEVI: Object as to form. 11 A. I mean, I think it's pretty -- yeah, it's 12 pretty normal to think about all of that and to 13 assume it's been thought about. 14 Q. Again, that's not what I asked. 15 A. Okay. 16 Q. I said, before you rely on a clinical 17 practice guideline, would you want to have good 18 comfort that the team that developed it had 19 considered not just benefits of a procedure or 20 treatment but also the side effects and risks? 21 MS. LEVI: Object as to form. 22 A. So when I personally evaluate -- like, look 23 at a guideline, I want to feel comfortable that they 24 have done that.	Page 196 1 assuming that people are thinking about health 2 benefits, side effects. 3 I think -- well, I'll stop there. 4 Q. You testified earlier that there are a 5 number of guidelines out there in the world that are 6 not well done and perhaps not reliable, correct? 7 A. Yes. 8 Q. And so my question for you is, before you 9 rely on a guideline, do you want to see, in its 10 text, evidence that those who prepared it have 11 considered side effects and risks? 12 MS. LEVI: Object as to form. 13 A. I don't think, when I go just in an 14 informal way to look at a guideline for guidance on 15 what to do, that I am looking specifically to see 16 whether they -- what evidence that they've looked at 17 risks and benefits. That's not -- I'm not able to 18 be that granular at that moment that I need the 19 guideline. 20 Q. Fair enough. And so now let me take us to 21 the next step. 22 Would you agree that, at least according to 23 the AGREE II principles, that rigorous guidelines 24 should, on their face, show evidence that the
Page 195 1 Q. Thank you. 2 Under the "User's Manual Description," it 3 states, quote, "The guideline should consider health 4 benefits, side effects, and risks." And then it 5 goes on to say, "For example, a guideline on the 6 management of breast cancer may include a discussion 7 on the overall effects on various final outcomes." 8 And towards the end of that paragraph it reads, 9 quote, "There should be evidence that these issues 10 have been addressed." 11 So my question for you is, in a guideline 12 that you have confidence in, am I correct that you 13 want to see, on the face of the guidelines, evidence 14 that important side effects and risks have been 15 considered and weighed? 16 MS. LEVI: Object as to form. 17 A. So are we talking about what I want to see, 18 or we talking what this scale's about? 19 Q. We're talking about what you want to see. 20 A. So I don't know that I -- if I'm smart 21 enough that I'm looking carefully enough at 22 guidelines to be able to say, "Oh, I evaluated that 23 guideline because they gave me some evidence that 24 they thought about things." Again, I'm sort of	Page 197 1 authors considered side effects and risks, as well 2 as benefits, in connection with any particular 3 recommendation? 4 MS. LEVI: Object as to form. 5 A. Not exactly. I would say what AGREE II has 6 done has said there's going to be degrees to which 7 that evidence has -- you feel comfortable that that 8 evidence is there. 9 And so you're either going to strongly 10 agree or strongly disagree or somewhere in the 11 middle. And most people are going to -- most 12 guidelines are going to be right in the middle, you 13 know, that people have adequately addressed it and 14 they've shown you this evidence. 15 And, again, if you systematically look, 16 you'll be able to pick where a particular guideline 17 is in that. 18 Q. At the bottom of the page is a section that 19 says, "How to Rate." Do you see that? 20 A. Uh-huh. 21 Q. So, again, this is structure that I know 22 you testified earlier that your team used it as 23 guidance for how to do it? 24 A. Right.

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Page 198 1 Q. It's structured for somebody who's looking 2 at guidelines to rate them; am I correct? 3 A. Yes. 4 Q. And here, to inform the rater's decision 5 between, as you said, a spectrum from a weak 1 to a 6 strong 7, one of the items is "Reporting of the 7 balance/trade-off between benefits and harms/side 8 effects/risks." 9 Do you see that? 10 A. Yes. 11 Q. So you would agree with me that a set of 12 guidelines that rates strongly on this aspect of 13 rigour of development will in fact report in writing 14 the balance or trade-off between benefits and risks 15 or harms that the drafters have considered? 16 MS. LEVI: Object as to form. 17 A. So, I mean, again, this is a subjective 18 reading that you're going to use on whether I think 19 a particular guideline has done this. 20 And to be honest, in the context, it's not 21 just did they do it, but did they well write it, is 22 it clear and concise, is it -- you know, they're 23 sort of telling you all these ways you can think 24 about what was written. Yes.	Page 200 1 Q. I acknowledge that it's eleven years old. 2 I acknowledge that you're an internal author, 3 neither the lead nor the final. 4 Am I correct that the question that was 5 being addressed, however, is how serious is the risk 6 of thromboembolic events for children who are 7 hospitalized with inflammatory bowel disease? 8 A. Yes. 9 Q. And therefore, is it appropriate to take 10 prophylactic measures to prevent thromboembolic 11 events in the case of children? 12 A. Yes. 13 Q. What is a thromboembolic event, if I'm 14 saying that correctly? 15 A. You're saying it great. It's a stroke. 16 Q. Is there anything else that falls within 17 the category of a thromboembolic event? 18 A. Sure. Any blood clot. So it could be, you 19 know -- most of them, unfortunately, are going to 20 predispose to stroke, but you worry about venous 21 thromboemboli or, you know, DVT, deep venous 22 thromboses, pulmonary emboli. 23 Q. All these, very serious medical 24 occurrences?
Page 199 1 Q. There's many ways it could be written. 2 My question for you was, do you agree, 3 based on either this discussion of how to rate with 4 regard to Item 11 of the Rigour of Development, that 5 a guideline that rates "strongly" on this particular 6 point will be one which, perhaps among other things, 7 actually reports how the authors evaluated the 8 balance or trade-off between benefits and harms? 9 MS. LEVI: Object as to form. 10 A. I would agree, if you are giving a 11 "strongly agree" rating of a guideline on this 12 Number 11, that you have -- it would be able to meet 13 these particular rating guidelines. 14 MR. BROOKS: Let me ask the reporter to 15 mark as Exhibit 17 an article dated 2013, first 16 author Zitomersky, with Dr. Lightdale as an internal 17 author, entitled "Risk Factors, Morbidity, and 18 Treatment of Thrombosis in Children and Young 19 Adults." 20 (Document marked as Lightdale 21 Exhibit 17 for identification) 22 Q. Dr. Lightdale, I'm going to guess that this 23 is an article that you haven't read recently. 24 A. No, I haven't read this one recently.	Page 201 1 A. Blood clots, yes. 2 Q. Okay. Just so I'm clear -- I know that 3 we're stating things -- am I correct that, 4 categorically, thromboembolic events are considered 5 to pose a risk of serious harm? 6 A. Yes. 7 Q. And, indeed, if we turn to Page 344, under 8 "Results" at the bottom, in the first column it 9 states that "Of 532 patients" -- and correct me if 10 I'm wrong, these are all minors that were subject to 11 this study, right? 12 A. Children, yes. 13 Q. Of 532 patients who were admitted with 14 inflammatory bowel disease, almost 2 percent 15 suffered thromboembolic events, correct? 16 A. Yes. 17 Q. And that's during their period of 18 hospitalization? 19 A. These were all during the hospitalization, 20 yeah. 21 Q. Okay. And that's far above the rate you 22 would expect among normal, healthy children, 23 correct? 24 A. Yes.

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Page 202 1 Q. And in the second column of that same page, 2 it says that four of the 10 had cerebrovascular 3 thrombosis, which is to say a stroke; am I correct? 4 A. Correct. 5 Q. One of which resulted in permanent 6 cognitive defects, right? 7 A. Yes. 8 Q. And hemiparesis means partial paralysis? 9 A. Yes. 10 Q. Okay. Very serious. 11 One of those four patients required brain 12 surgery? Is that what intracranial vascular surgery 13 is? 14 A. I believe so. 15 THE WITNESS: Sorry, I will not -- 16 MS. LEVI: You should make sure you answer 17 his questions, and if you need to review it, take 18 the time to do that. 19 THE WITNESS: Yeah. 20 A. Well, in full disclosure, I don't -- 21 MS. LEVI: There's only one medical expert 22 in this room, as far as I can tell. 23 A. Yeah, so what I can tell you is we 24 described it as intracranial vascular surgery. So I	Page 204 1 retrospective review and contributes to the 2 literature of these type of retrospective reviews. 3 I think it can answer some questions. But 4 it also -- it's limited because it's a retrospective 5 review at a single center. 6 Q. It raised enough concerns or questions 7 that, based only on this small study, Boston 8 Children's Hospital changed its practices with 9 regard to children admitted with inflammatory bowel 10 disease, correct? 11 A. Yeah. We made a decision to do that. 12 Q. Dr. Lightdale, in weighing the risks and 13 benefits of a treatment for any condition in minors 14 that was not immediately life threatening, if the 15 best available evidence indicated that that 16 treatment increased the long-term risk of 17 thromboembolic events in neonatals by 20 percent, 18 you would consider that to be an adverse effect that 19 needed to be given serious weight in the treatment 20 decision, would you not? 21 MS. LEVI: Object as to form. 22 A. Not necessarily. I'd need to know a lot 23 more about what you're just explaining. I mean... 24 Q. I'm going to ask the reporter to read the
Page 203 1 don't know if it was catheterization. 2 I don't remember the patient. This was a 3 long time ago. 4 Q. I understand, but catheterization or buzz 5 saw, either way it counts as brain surgery, does it 6 not? 7 A. Not necessarily, but I'm not a brain 8 surgeon. 9 MS. LEVI: I object to the form of that 10 question. 11 Q. Now, am I correct that this sample size of 12 patients who suffered thromboembolic events is small 13 enough that this was not the type of study that 14 could or did predict an incidence rate in a 15 general -- in general among children suffering from 16 inflammatory bowel disease? 17 MS. LEVI: Object as to form. 18 A. Yeah, this is a single study retrospective 19 review of our population at our hospital. 20 Q. And am I correct that that very small 21 sample size can raise questions and concerns, but it 22 can't really answer questions? 23 MS. LEVI: Object as to form. 24 A. I think -- it was -- it's an important	Page 205 1 question back and see if you have a more precise 2 answer. 3 THE COURT REPORTER: "Dr. Lightdale, in 4 weighing the risks and benefits of a treatment for 5 any condition in minors that was not immediately 6 life threatening, does the best available 7 evidence" -- 8 MR. BROOKS: Let me re-ask it myself. 9 Q. Dr. Lightdale, in weighing the risks and 10 benefits of a treatment -- we'll stay abstract -- of 11 a condition in minors that is not immediately life 12 threatening, if it becomes known that that treatment 13 increases the long-term risk of thromboembolic 14 events in those children by 20 percent, you would 15 consider that an adverse effect that needs to be 16 given serious weight in the decision, would you not? 17 MS. LEVI: Object as to form. 18 A. To me that's just too abstract. Like, I 19 need to understand what we're comparing it to and 20 what the non-treated group looks like, and also why 21 are we treating. 22 So I don't know that you can answer that 23 question so -- like, I can't give a specific answer 24 to that.

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Page 206 1 Q. You cannot answer the question whether a 20 2 percent increase in risk of thromboembolic events or 3 strokes is an adverse effect that you would need to 4 at least give serious weight to? 5 MS. LEVI: I'm going to object as to form, 6 and also it's a re-characterization of the question. 7 You can answer it, if you can. 8 A. I mean, I think that when you do clinical 9 studies, you're looking at complications. And so 10 you want to understand what are the safety events, 11 and you're going to categorize them. And then 12 you're going to take that into account as you look 13 at everything. 14 It's just -- it's too -- I think to just go 15 after throm -- I mean, I don't know that I can 16 answer the question more than that, is the bottom 17 line. I just would need a lot more context around 18 it. So... 19 Q. If a treatment resulted in 40 percent 20 higher risk of thromboembolic events in the treated 21 population, as compared to the untreated population, 22 would you consider that an adverse effect that would 23 need to be given serious weight in the cost/benefit 24 analysis of a treatment for a condition that was not	Page 208 1 term complications, like a lasting effect on memory 2 is one of the complications I would want to be 3 factoring in to my thinking about whatever we're 4 measuring. 5 Q. And you're not willing to say, as you sit 6 here today, Dr. Lightdale, that a long-term effect 7 on that child's cognitive capabilities is a very 8 serious negative effect? 9 MS. LEVI: Object as to form. 10 A. It's still too abstract, the way we're 11 being asked this. 12 Q. Do you have any familiarity or general 13 familiarity with the IQ scale? 14 A. IQ? 15 Q. Yeah. 16 A. Only, like, to talk about IQ. 17 Q. Well, for instance, do you have a notion of 18 the cognitive level of somebody who has an IQ 19 measured at 80? 20 A. That is -- you are profoundly not high IQ. 21 Q. And -- do any of the conditions that you as 22 a professional treat and any of -- or any of the 23 treatments that you as a professional are involved 24 in raise any risk of harm to a child's cognitive
Page 207 1 immediately life threatening? 2 MS. LEVI: Object as to form. 3 A. I think all complications need to be 4 brought into the safety/benefit discussion of any 5 treatment. 6 Q. * If a treatment for a child that you were 7 considering -- if the best available evidence 8 suggested that that treatment would have a lasting 9 negative effect on the memory and learning 10 capability of that child, am I correct that you 11 would consider that to be a very serious harm as you 12 weighed the harms and benefits of treatments? 13 MS. LEVI: Object as to form. 14 A. I would agree that you have to think about 15 all complications and that you want to be 16 transparent about them and understand them and weigh 17 them. 18 Q. I didn't ask about all of them. 19 MR. BROOKS: I ask the reporter to read back 20 the question. 21 (* Question read) 22 MS. LEVI: Preserving my objection for the 23 record on rereading. 24 A. I mean, I would say, thinking about long-	Page 209 1 capabilities? 2 MS. LEVI: Object as to form. 3 A. Not directly. So -- I mean, not that I 4 know of. 5 I think that we worry about side effects. 6 I study sedation, so I worry about, you know, that's 7 going to potentially depress somebody's 8 neurocognitive potential and have an effect. I 9 worry about sedation. I worry about -- sure, I'm 10 worried about strokes in kids. 11 Q. Right. If a treatment that you were 12 involved in or a clinical situation that you were 13 involved in involved a risk of significant loss of 14 cognitive capability to the child, am I correct that 15 you would consider that to be an important risk, for 16 instance, to disclose to parents? 17 MS. LEVI: Object as to form. 18 A. I think that would be an important risk I 19 would disclose to parents. 20 Q. And if a guideline you were developing 21 involved a therapy which the best evidence suggested 22 posed some risk of lasting cognitive impairment, you 23 would expect to see that disclosed in the guideline, 24 would you not?

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Page 210 1 MS. LEVI: Object as to form. 2 A. Not necessarily in the guideline if it's 3 some risk. I need to understand just how much risk. 4 And then -- again, I believe in guidelines I trust 5 and trustworthiness of guidelines. So I assume it 6 would be covered. 7 Q. Do you know who Marci Bowers is? 8 A. (Shakes head) 9 That was "No." Sorry. 10 MS. LEVI: You have to say it audibly. 11 THE WITNESS: Yes. I apologize. 12 MS. LEVI: But if you need a break -- 13 THE WITNESS: I was waiting to see if 14 anyone told me to say "No." 15 MS. LEVI: Do you -- 16 THE WITNESS: I'm okay. 17 MS. LEVI: Are you sure? 18 THE WITNESS: Yes, I think so. 19 MS. LEVI: You should take a break when you 20 need it. 21 MR. BROOKS: We're going to be done 22 shortly. Normally I offer breaks, but we're going 23 to be done shortly. 24 MS. LEVI: Okay.	Page 212 1 BY MR. BROOKS: 2 Q. Dr. Lightdale, let me ask you to pick up 3 Exhibit 17 again, the "Risk Factors" document. 4 A. Yes. 5 Q. And I want to clear up one thing. And, 6 again, I'm not trying to trick you with memory 7 tests. 8 You said more than once that this was about 9 children, and if you turn to Page 345, there's a 10 list at the top of the 10 subjects who suffered 11 thromboembolic events, and all but one of them are 12 older than 10, and some of them are in their younger 13 20s. 14 I just wanted to call your attention to 15 that and to clarify for the record that am I correct 16 that the patients covered in this study were, for 17 the most part, teens or very young adults? 18 A. Yeah, this was -- yes. This was a 19 single-center study. And actually I saw somewhere 20 in it that we had -- the age range was 8 to 23, I 21 think. 22 Q. Okay. And given that there were just 10 23 patients who had thromboembolic events -- this is 24 going to be kind of a terminology question -- is
Page 211 1 BY MR. BROOKS: 2 Q. Do you agree with me that if a treatment 3 recommended in a set of clinical guidelines involves 4 a significant risk of permanent loss -- let me start 5 again. 6 Do you agree with me that if a treatment 7 for a minor recommended in clinical practice 8 guidelines raises a significant risk of permanent 9 loss of sexual response, that that would be a 10 serious harm to the affected child? 11 MS. LEVI: Object as to form. 12 A. So -- probably. You know, this is, like, a 13 probably. This is long-term stuff. I think it 14 probably comes up for oncologists around 15 chemotherapies. 16 Q. And in that context, it's recognized as a 17 serious adverse effect; am I correct? 18 A. Again, some -- I can think of treatments I 19 know of where this would be something you have to 20 talk about with the families. So... 21 MS. LEVI: I need a break. 22 MR. BROOKS: Fine. Pardon me. 23 (Recess) 24	Page 213 1 this what one would describe as anecdotal evidence, 2 or is it -- kind of rise to the level beyond that? 3 MS. LEVI: Object to the form. 4 A. This is not anecdotal. It's a 5 retrospective chart review of a cohort at our 6 hospital. 7 Q. Of a cohort? 8 A. It's a cohort study. 9 Q. Retrospective cohort study? 10 A. Uh-huh. 11 Q. If experience from a small number of 12 patients suggests that a particular treatment for 13 children poses a risk of lasting loss of sexual 14 response and no large, statistically significant 15 study has yet been done, would you expect that 16 clinical practice guidelines addressing that 17 treatment would -- should and would disclose that 18 risk as part of the discussion of risks and 19 benefits? 20 MS. LEVI: Object as to form. 21 A. I'm just finding the questions too 22 abstract. There are so many things you need to look 23 at, and so I can't just hear one outcome. I sort of 24 have to understand who is it compared to, and, you

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Page 214 1 know -- whatever. There's just a lot more details. 2 Like, what were the other outcomes? What exactly 3 were we treating? It's almost hard to answer this 4 in the abstract. So... 5 Q. If -- let me show you a document. 6 MR. BROOKS: Let me ask the reporter to 7 mark as Exhibit 18 an article from 1922 -- pardon 8 me, 2022 entitled "The Dutch Protocol for Juvenile 9 Transsexuals: Origins and Evidence," by Michael 10 Biggs. 11 (Document marked as Lightdale 12 Exhibit 18 for identification) 13 Q. Dr. Lightdale, can I say with some 14 confidence you haven't seen this one? 15 A. I definitely have not. 16 Q. And let me take you in this document to 17 Page -- I want to take you to Page 12. At the very 18 bottom of Page 12 is a paragraph that begins, "Even 19 less is known about the effects of puberty 20 suppression on sexual functioning." That's the 21 topic sentence. 22 And then you can turn over the page. Then 23 there's going to be a quote from Marci Bowers. Let 24 me make a representation to you who Marci Bowers is.	Page 216 1 honestly you're asking the question in ways that I'm 2 not sure what I'm answering. So I'd prefer not to 3 answer. 4 Q. What about -- 5 MS. LEVI: If you can't answer, you can say 6 you can't answer. 7 Q. What about my question is unclear to you? 8 A. Honestly, I'm not sure if you're -- I'm not 9 sure if you're asking for me, like, my reaction, 10 or -- you know, there's a lot of ifs in there. So I 11 actually don't understand the data in order to be 12 able to make any sort of, you know, useful 13 statement. 14 Q. Dr. Lightdale, you've offered opinions that 15 WPATH, in its preparation of their clinical practice 16 guidelines, were, quote, exemplary, right? 17 MS. LEVI: Answer a question if he's asked 18 one. 19 MR. BROOKS: I have asked one. 20 A. I gave an opinion that I thought the 21 process that they describe on their website looks 22 like what you would want a process to look like. 23 Q. Am I correct that you have not offered and 24 have not formed any opinion that WPATH's SOC-8 was
Page 215 1 She is a past president of WPATH and is a surgeon 2 who performs surgical procedures related to sex, 3 gender-affirming surgeries or sex change surgeries 4 on minors. And it indicates here, "Marci Bowers, 5 who has performed over 2,000 vaginoplasties." 6 And the quote here is, quote, "Every single 7 child... who was truly blocked at Tanner stage 2, 8 has never experienced orgasm. I mean, it's really 9 about zero." 10 Now, that's not a study. That's, what 11 shall we say, expert opinion, comment. 12 My question for you is, if it's the case 13 that children who are put on puberty blockers at an 14 early stage of adolescent development in many cases 15 fail to develop the ability to experience orgasm, 16 would you consider that responsible clinical 17 practice guidelines addressing use of puberty 18 blockers on minors would disclose that risk and 19 discuss how it had been weighed by the team in their 20 cost/benefit analysis? 21 MS. LEVI: Object as to form. 22 A. This is just so outside my own scope of 23 practice and knowledge. So I'm just in an area that 24 I know nothing about and have no context. And	Page 217 1 in fact developed and written in compliance with any 2 reliable or respected methodology for developing 3 evidence-based clinical practice guidelines? 4 MS. LEVI: Object as to form. 5 A. I have no opinion on the guidelines 6 themselves, because I didn't look at them, and I 7 frankly wouldn't understand them. So... 8 Q. And you have not formed any opinion as 9 to -- you have not formed any opinion that SOC-8 was 10 in fact developed and written in compliance with a 11 reliable methodology for developing evidence-based 12 clinical practice guidelines? 13 MS. LEVI: Object as to form. 14 A. I have formed an opinion that the website 15 and their discussion and description of the methods 16 that they used, and today actually looking, albeit 17 briefly, at the methods, looks, honestly, rigorous, 18 transparent and well thought out; that they put up a 19 process that they were -- that they say that they 20 followed. That's what I can form my opinion on. 21 Q. And the flip side of that is, you don't 22 have the information you would need to form an 23 opinion as to whether they actually followed the 24 process described in the methodology; am I correct?

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Page 218 1 A. Correct. Yes. 2 MR. BROOKS: I have no further questions 3 for the witness. 4 MS. LEVI: Okay. The witness will read and 5 sign. 6 (Whereupon the deposition 7 was concluded at 3:15 p.m.) 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Page 220 1 SUGGESTED CORRECTIONS 2 RE: Brianna Boe, et al., etc., vs. 3 Hon. Steve Marshall, etc., et al. 4 5 WITNESS: Jenifer Lightdale, M.D. , Vol. I 6 7 The above-named witness wishes to make the following 8 changes to the testimony as originally given: 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
Page 219 1 C E R T I F I C A T E 2 I, Jenifer Lightdale, M.D., do hereby certify 3 that I have read the foregoing transcript of my 4 testimony, and further certify, under the pains and 5 penalties of perjury, that said transcript 6 (with/without) suggested corrections is a true and 7 accurate record of said testimony. 8 Dated at _____, this ____ day of _____, 9 2023. 10 11 _____ 12 13 * * * * * 14 15 16 17 18 19 20 21 22 23 24	Page 221 1 COMMONWEALTH OF MASSACHUSETTS) 2 SUFFOLK, SS.) 3 I, Carol H. Kusnitz, RPR and Notary Public in 4 and for the Commonwealth of Massachusetts, do hereby 5 certify that there came before me on the 6th day of 6 May, 2023, at 9:12 a.m., the person hereinbefore 7 named, who was by me duly sworn to testify to the 8 truth and nothing but the truth of her knowledge 9 touching and concerning the matters in controversy 10 in this cause; that she was thereupon examined upon 11 her oath, and her examination reduced to typewriting 12 under my direction; and that the deposition is a 13 true record of the testimony given by the witness. 14 I further certify that I am neither attorney or 15 counsel for, nor related to or employed by, any 16 attorney or counsel employed by the parties hereto 17 or financially interested in the action. 18 19 20 21 22 23 24

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Page 222 1 Under Federal Rule 30: 2 X Reading and Signing was requested 3 Reading and Signing was waived 4 Reading and Signing was not requested. 5 6 In witness whereof, I have hereunto set my hand 7 and affixed my notarial seal this 14th day of May, 8 2023. 9 <i>Carol H. Kuusimäki</i> 10 Notary Public 11 Commission expires 5/20/27 12 13 14 15 16 17 18 19 20 21 22 23 24	Page 224 1 ERRATA for ASSIGNMENT #6671430 2 I, the undersigned, do hereby certify that I have read the 3 transcript of my testimony, and that 4 ___ There are no changes noted. 5 ___ The following changes are noted: 6 Pursuant to Civil Procedure, Rule 30. ALA. CODE § 5-30(e) 7 (2017). Rule 30(e) states any changes in form or 8 substance which you desire to make to your testimony shall 9 be entered upon the deposition with a statement of the 10 reasons given for making them. To assist you in making any 11 such corrections, please use the form below. If additional 12 pages are necessary, please furnish same and attach. 13 14 Page ___ Line ___ Change _____ 15 Reason for change _____ 16 Page ___ Line ___ Change _____ 17 Reason for change _____ 18 Page ___ Line ___ Change _____ 19 Reason for change _____ 20 Page ___ Line ___ Change _____ 21 Reason for change _____ 22 Page ___ Line ___ Change _____ 23 24
Page 223 1 To: Jennifer Levi, Esq. 2 Re: Signature of Deponent CONF Jenifer Lightdale, M.D. 3 Date Errata due back at our offices: 30 days 4 5 Greetings: 6 This deposition has been requested for read and sign by 7 the deponent. It is the deponent's responsibility to 8 review the transcript, noting any changes or corrections 9 on the attached PDF Errata. The deponent may fill 10 out the Errata electronically or print and fill out 11 manually. 12 Once the Errata is signed by the deponent and notarized, 13 please mail it to the offices of Veritext (below). 14 15 When the signed Errata is returned to us, we will seal 16 and forward to the taking attorney to file with the 17 original transcript. We will also send copies of the 18 Errata to all ordering parties. 19 20 If the signed Errata is not returned within the time 21 above, the original transcript may be filed with the 22 court without the signature of the deponent. 23 24 Please Email the completed errata/witness cert page to CS-SOUTHEAST@VERITEXT.COM or mail to Veritext Production Facility 2000A Southbridge Parkway, Suite 400 Birmingham, AL 35209 800-808-4958	Page 225 1 Page ___ Line ___ Change _____ 2 3 Reason for change _____ 4 Page ___ Line ___ Change _____ 5 6 Reason for change _____ 7 Page ___ Line ___ Change _____ 8 9 Reason for change _____ 10 Page ___ Line ___ Change _____ 11 12 Reason for change _____ 13 Page ___ Line ___ Change _____ 14 15 Reason for change _____ 16 17 18 _____ DEPONENT'S SIGNATURE 19 Sworn to and subscribed before me this ___ day of 20 _____, _____. 21 22 _____ 23 NOTARY PUBLIC / My Commission Expires: _____ 24