APPENDIX E

Selections from Excerpts of Record

study can.
Q. Do you think this pyramid is saying that a randomized controlled trial is of higher quality than a cohort study?
A. I think that's a broad oversimplification, but I think what it's saying is that if you had a single randomized controlled trial that was well conducted, it would likely give you more information than a cohort study.
Q. Because it's of higher quality?
A. Not necessary -- what do you mean by "higher quality"?
Q. Because that study design is of higher quality than a cohort study.
A. I would say because it has the benefit of having a control group, medical cohort study does not, which gives you additional information about whether or not your outcome would have improved whether or not the introduction was given. It gives you more information.
A single randomized controlled trial, when well conducted, can give more information than a cohort study.
Q. What about -- and I know this is -- I'm not -- this question is not about a specific

study. It's more about methodology in theory.
And so my question is looking at this, in theory you have a group of four cohort studies. And if you have a group of four randomized controlled trials, all else being equal, based on the design of those studies, are the randomized controlled trials of higher quality than the cohort studies?
MS. NOWLIN-SOHL: Object to form.
THE WITNESS: It's hard to say all else being equal because there are so many variables that go into how you design a cohort study or how you design a randomized controlled trial, so I would really need you to kind of give me specific studies to answer that question.
Q. (BY MR. RAMER) Well, no. It's a hypothetical about the theory and the method of it, and so the hypothetical is all else being equal -- they have the exact same inputs, the exact same outputs, one is a randomized controlled trial; one is a group of cohort studies.
And my question is is the group of randomized controlled trials of higher quality than the group of cohort studies?
MS. NOWLIN-SOHL: Object to form.

THE WITNESS: Again, with all due respect, I think your question is implying lack of understanding of how the studies are designed. You can't put the exact same inputs into a cohort study and a randomized controlled trial because they're different study designs.
So when you're saying "all else being equal," I really don't know what you -- I need you to be more specific.
Q. (BY MR. RAMER) And when you say they're a different study design, does the design of one lead to a higher quality study than the design of the other?
MS. NOWLIN-SOHL: Object to the form.
THE WITNESS: I believe I answered that question.
Q. (BY MR. RAMER) Could you remind me what your answer was?
MS. NOWLIN-SOHL: Same objection.
THE WITNESS: So they're different study designs. A cohort study tells you whether or not an outcome changes before and after the intervention. It does not have a control group.
So you could be left with the question of whether or not your outcome improved because of

the intervention or because it was going to improve anyway over time.
A randomized controlled trial generally has two groups. One group gets intervention; one group doesn't. So you can see maybe the treatment group improves and the other group, which could be many different groups -- let's say it's a placebo in this case -- does not improve, and then that would tell you, okay. It probably wasn't that they improved just because of time.
So in that case, a randomized controlled trial can give you more information than a cohort study wouldn't. So it has the potential to give you more information certainly.
Q. And on this pyramid, on the left side of it, the arrow that's adjacent that refers to quality, what do you think that's referring to?
A. I think it's just a vague reference to the fact that -- these are all different study designs as you go up the pyramid.
And as you go up the pyramid, you get -- the study designs have the potential to answer other kinds of questions, right?
So the cohort study can't tell you about whether or not mental health would have improved

without the treatment. The randomized controlled trial tells you that.

And then all randomized controlled trials are going to have strengths and benefits, right? They may have different patient populations. They might have different study outcomes. They may have different blinding procedures.

And so a systematic review and meta-analysis would tell you instead of like, oh, look, I only have this one study I'm looking at, you would look at all of them, and that would give you more and more richer information.

Q. Okay. I'd like to go back to Turban Exhibit 4, which is the Users' Guide to the Medical Literature.

And I would like to go to page 6 in the document. I think it's 35 in the PDF.

A. Yes.

Q. And I'm just going to read the -- it's the sentence at the very bottom that carries over on to page 7. And I'll just read it and ask if I read it correctly.

It says "In our discussions of systematic reviews and guidelines, we introduce the GRADE (Grading of Recommendations Assessment,

Development, and Evaluation) approach to summarizing evidence and developing recommendations, an approach that we believe represents a major advance in EBM," parentheses, cross-reference to chapter 15.

Did I read that correctly?

A. Yes.

Q. And are you familiar with the GRADE approach that's referenced here?

A. Broadly, yes.

Q. And could you explain your understanding of that approach?

A. Yes. So GRADE generally involves looking at the research literature. And then there's some subjectivity to it, but they provide you with general guidelines about how you would -- like, great level of confidence in the research itself.

Then there's a -- and then each of those get GRADE scores. I think it's something like low, very low, high, very high. I could be wrong about the exact names of the categories.

And then there's a separate set of factors that are applied about strength of recommendation. So it takes into account both what the research literature is, but then makes

several other factors that would be important to consider when -- whether or not to recommend a treatment.

But it has two steps in that way. It has kind of the grading of the evidence and then determining strength of recommendations.

Q. And have you ever attempted to apply the criteria specified by GRADE to assess a study?

A. It's generally recommended that one do that as part of, like, a full research group. And I've not been on one of those groups.

Q. And so then you -- you've also never attempted to do that for any of the studies that you cite in your declaration, correct?

A. No, not apply specific GRADE criteria. Generally GRADE criteria is used when one is writing guidelines.

Q. I'm sorry. Say that again?

A. GRADE is typically used when one is writing clinical practice guidelines.

Q. Is GRADE ever used in a systematic review?

A. Some people might. I have not.

Q. How many systematic reviews have you done?

A. Just one.

Q. Can you explain how those who would use GRADE in a systematic review would use it in the process of creating the systematic review?

MS. NOWLIN-SOHL: Object to the form; foundation.

THE WITNESS: Yeah, I don't think they would GRADE the systematic review. I think they would have different research questions, and there would be a body of literature they would identify through their search that they would then look at in their specific tables that give you, like, a rough general sense of how to apply the GRADE criteria to different conclusions.

Q. (BY MR. RAMER) And then sticking with this document, I'd like to go to page 273, which is 302 in the PDF, I believe.

Are you there?

A. Yes.

Q. Okay. And then the -- well, the only full paragraph on the page, it's a little long, but I'm going to read it and ask if I read it correctly.

It says "In contrast to systematic reviews, traditional narrative reviews typically

gender-affirming medical interventions."

Did I read that correctly?

A. Yes.

Q. And what do you mean when you say "studies have demonstrated improvements following gender-affirming medical interventions"?

A. So through various statistical methods, they have shown to correlate the gender-affirming medical intervention with improvements in mental health.

Q. In your opinion, have you concluded that gender-affirming medical care causes improvements in mental health?

A. The research shows that. And clinically that is what I have seen, so yes.

Q. The research shows causation?

A. Not causation, but the statistical data that is presented plus my clinical experience leads me to say yes.

Q. So the research did not show causation, but when you personally combine the research with your clinical experience, you have concluded that gender-affirming medical care causes improvements in mental health; is that right?

MS. NOWLIN-SOHL: Object to form.

THE WITNESS: I believe that it leads to improvements in mental health, yes.

Q. (BY MR. RAMER) I asked the question with the verb "cause" for a reason. And I think in your answer you switched to "lead."

And I'm just trying to -- you know, I think in this context the word "cause" -- just to be clear, have you concluded that gender-affirming medical care causes improvements in mental health?

A. And I can share why I'm avoiding the word "cause" in this case.

So for me, causation is specifically a statistical term that is very difficult, even in our randomized control trials, to prove because there are so many other variables that account for change.

And so to the best of their scientific ability, I believe these studies to be robust but aren't statistically showing causation. And so that's why I'm saying "leads to."

Q. So just to clarify, you are declining to say that gender-affirming medical care causes improvements in mental health; is that right?

A. From a statistical perspective, yes.

Q. As opposed to what's a non-statistical

perspective?

MS. NOWLIN-SOHL: Object to form.

THE WITNESS: So -- which is why I'm using "clinically" also. Clinically I have seen A to B and B to C, and, you know, I've not conducted this research myself to be able to show that statistically. But clinically I do see that it is directly linked to gender-affirming medical care that I'm seeing these improvements.

Q. (BY MR. RAMER) Back on your declaration, on this page, you list a number of articles in footnote 16.

Are these articles the basis for your conclusion that studies have demonstrated improvements following gender-affirming medical care?

A. They are samples of those studies, yes.

Q. There are other articles?

A. Yes.

Q. Do you cite them in your declaration?

A. No.

Q. Is there a reason you didn't?

A. I just felt like these were the best representation, and they summarized the previous studies within them as well.