

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

ALINA BOYDEN and
SHANNON ANDREWS,

Plaintiffs,

v.

Case No. 17-CV-0264

STATE OF WISCONSIN DEPARTMENT
OF EMPLOYEE TRUST FUNDS, et al.,

Defendants.

**DECLARATION OF COLIN ROTH
IN SUPPORT OF STATE DEFENDANTS'
RULE 37 MOTION TO STRIKE PLAINTIFFS' SUPPLEMENTAL
EXPERT WITNESS REPORTS OF DRS. BUDGE AND SCHECHTER**

I, **COLIN ROTH**, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am employed as an Assistant Attorney General at the Wisconsin Department of Justice (DOJ). I am one of the attorneys for the State of Wisconsin Department of Employee Trust Funds, State of Wisconsin Group Health Insurance Board, and Robert J. Conlin in the above-captioned matter.

2. This declaration is based on my personal knowledge.

3. On February 19, 2018, Plaintiffs disclosed to State Defendants an expert report from Dr. Stephanie Budge.

4. On April 19, 2018, State Defendants disclosed to Plaintiffs rebuttal expert reports from Dr. Lawrence Mayer and David Williams.

5. On May 31, 2018, Plaintiffs disclosed to State Defendants rebuttal/reply expert reports from Dr. Loren Schechter and Joan Barrett. Plaintiffs did not disclose a rebuttal/reply report from Dr. Budge on this date.

6. Plaintiffs deposed both of State Defendants' experts, Dr. Mayer and David Williams, on June 15, 2018.

7. Attached as Exhibit A to this declaration is a true and correct copy of an email chain between Plaintiffs' counsel and State Defendants' counsel regarding deposition scheduling. I received the top-most email from Plaintiffs' counsel on May 18, 2018. Plaintiffs' counsel asked to depose Dr. Mayer on June 19, 2018.

8. Attached as Exhibit B to this declaration is a true and correct copy of a rough draft of a report from Dr. Mayer, received on July 8, 2018, responding to the opinions expressed in Plaintiffs' supplemental expert reports. Dr. Mayer informed me that he intends to continue his work on this draft and will submit a finalized report to this Court, if given leave to do so.

I declare under penalty of perjury that the forgoing is true and correct.

Executed on July 9, 2018.

s/ Colin T. Roth
COLIN ROTH

Roth, Colin T.

From: John Knight <jknight@ACLU-il.org>
Sent: Friday, May 18, 2018 3:11 PM
To: Roth, Colin T.; Jeannine Anderson; Nicholas Fairweather; Mike Godbe; Caitlin Madden; 'Larry Dupuis'; 'Asma Kadri'
Cc: Kilpatrick, Steven C.; Schmelzer, Jody J.
Subject: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Ok. Could you check about the following dates for us to depose Mayer and Williams?

For Williams, we could do June 14, 15, 18 or 19. For Mayer, we'd prefer June 19, if he is available then. We assume that we will travel to their locations to depose them. Please let us know where they are going to be at that point, so that we can find a place for the deposition and plan our travel.

John

From: Roth, Colin T. [mailto:rothct@doj.state.wi.us]
Sent: Friday, May 18, 2018 8:37 AM
To: John Knight <jknight@ACLU-il.org>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>
Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>
Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

A quick followup – Nancy Thompson cannot start until 9:30 on May 25, so let's plan to begin then.

Thanks,
Colin

From: John Knight [mailto:jknight@ACLU-il.org]
Sent: Wednesday, May 16, 2018 3:46 PM
To: Roth, Colin T. <rothct@doj.state.wi.us>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>
Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>
Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Let's go with 5/30. We were trying to make sure that we could make this work.

From: Roth, Colin T. [mailto:rothct@doj.state.wi.us]
Sent: Wednesday, May 16, 2018 3:37 PM
To: John Knight <jknight@ACLU-il.org>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>
Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>
Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Counsel -

I'm following up on this scheduling issue. To be clear, we are not intending to produce JP for a deposition this Friday. Please let us know which of the 29th or 30th will work.

Thanks,
Colin

From: Roth, Colin T.
Sent: Monday, May 14, 2018 3:28 PM
To: 'John Knight' <jknight@ACLU-il.org>; 'Jeannine Anderson' <janderson@hq-law.com>; 'Nicholas Fairweather' <nfairweather@hq-law.com>; 'Mike Godbe' <mgodbe@hq-law.com>; 'Caitlin Madden' <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>
Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>
Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Sorry, I meant to raise this scheduling issue on our call, too. Please let us know which of 29th or 30th will work for JP's deposition.

Thanks,
Colin

From: Roth, Colin T.
Sent: Friday, May 11, 2018 2:33 PM
To: 'John Knight' <jknight@ACLU-il.org>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>
Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>
Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

How about May 29 or 30, instead? I'd rather not set for the 18th or 21st and then have to reschedule if the motion to compel is still out there, but I imagine we'll have an answer by the 29th or 30th.

Thanks,
Colin

From: John Knight [<mailto:jknight@ACLU-il.org>]
Sent: Friday, May 11, 2018 12:04 PM
To: Roth, Colin T. <rothct@doj.state.wi.us>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>
Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>
Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Please go ahead and schedule it. However, we may have to move it or reopen the deposition, depending on when the court rules on the pending motion to compel. Thanks - John

From: Roth, Colin T. [<mailto:rothct@doj.state.wi.us>]
Sent: Friday, May 11, 2018 11:49 AM
To: John Knight <jknight@ACLU-il.org>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry

Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>

Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>

Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Can you please let us know whether the 18th would work for JP's deposition? If so, we need to get it reserved on his calendar as soon as possible.

Thanks,
Colin

From: Roth, Colin T.

Sent: Thursday, May 10, 2018 2:20 PM

To: 'John Knight' <jknight@ACLU-il.org>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>

Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>

Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Would May 18 work for JP, instead? He can give a full day starting at 9:00 am.

Also, I heard back from Nancy Thompson – she is available May 25, so we can confirm that date.

Thanks,
Colin

From: John Knight [<mailto:jknight@ACLU-il.org>]

Sent: Thursday, May 10, 2018 10:57 AM

To: Roth, Colin T. <rothct@doj.state.wi.us>; Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'Asma Kadri' <akadri@aclu-wi.org>

Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>

Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

If 5/21 is the only day he can be available, we'll have to make it work. However, we'll need him for the day, so starting at 11 will mean we might not finish until fairly late. Please let us know when you hear from Ms. Thompson.

From: Roth, Colin T. [<mailto:rothct@doj.state.wi.us>]

Sent: Wednesday, May 09, 2018 9:36 AM

To: Jeannine Anderson <janderson@hq-law.com>; Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; John Knight <jknight@ACLU-il.org>; 'Asma Kadri' <akadri@aclu-wi.org>

Cc: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>

Subject: RE: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Counsel –

May 24 will not work for JP. His only substantial availability that week or the next is May 21 at 11:00. Will that work?

I have not yet heard back from Nancy Thompson regarding her availability on May 25.

Thanks,

Colin T. Roth

Assistant Attorney General
Wisconsin Department of Justice
P.O. Box 7857
Madison, WI 53707-7857
Direct: (608) 264-6219
Fax: (608) 267-2223

From: Jeannine Anderson [<mailto:janderson@hq-law.com>]

Sent: Tuesday, May 08, 2018 4:30 PM

To: Kilpatrick, Steven C. <kilpatricksc@doj.state.wi.us>; Roth, Colin T. <rothct@doj.state.wi.us>; Schmelzer, Jody J. <SchmelzerJJ@DOJ.STATE.WI.US>

Cc: Nicholas Fairweather <nfairweather@hq-law.com>; Mike Godbe <mgodbe@hq-law.com>; Caitlin Madden <cmadden@hq-law.com>; 'Larry Dupuis' <ldupuis@aclu-wi.org>; 'John Knight' <jknight@ACLU-il.org>; 'Asma Kadri' <akadri@aclu-wi.org>

Subject: Boyden, et al. v. State of Wisconsin Department of Employee Trust Funds, et al. - W.D. Case No. 17-cv-264

Dear Counsel,
Please see attached.
Thank you.

Jeannine L. Anderson
Paralegal



409 E Main Street • P.O. Box 2155 • Madison, WI 53701
Phone: (608) 257-0040 • Fax: (608) 256-0236 • www.hq-law.com

PLEASE NOTE: If you receive this email in error, use or disclosure is prohibited. Please notify me of the error by email and delete this email. Thank you.

July 9th, 2018

In light of new documents which have been provided to me, I have been asked to elaborate on item 6 in my Summary of Opinions from my April 18, 2018 report. In that report I stated, “Medical and surgical treatments have not been demonstrated to be safe and effective for gender dysphoria.”

I endorse my opinion that medical and surgical treatments have not been demonstrated to be safe and effective for gender dysphoria. There is almost no evidence, primary or secondary, that surgery reduces the risk of gender dysphoria. There is no primary evidence, but may be some secondary evidence, that hormone treatment significantly effects the incidence of gender dysphoria.

There appear to be some points of confusion, evidenced by recent documents submitted to the court, and I hope that I might clarify these points by detailing them below.

The basis of my opinion is as a research physician not a clinician.

1. As a biostatistician and epidemiologist, I have devoted the last 50 years of my career to developing, applying, and evaluating the degree of statistical evidence contained in research studies conducted in medicine and public health.
2. As a research physician, I focus on the evaluation of studies which are complex medically and biologically, interdisciplinary or multi-specialty, and have implications for clinical decision making.
3. For 30 years, my teaching in medical schools has focused on clinical epidemiology, the translation of published statistical results into decision making at the bedside.
4. As a professor at Princeton, University of Pennsylvania, Stanford, Johns Hopkins and the Mayo Clinic and during my work as the System Director for Research for Banner Health, the largest non-profit system in the West, I have reviewed thousands of statistical studies, a majority of which were estimating the effect of treatments, or other input factors, on incidence or severity of the disease - as is the case in the

present study. Over 1000 of these reviews were conducted for government agencies including the FDA, NIH, editors of leading medical journals including the New England Journal of Medicine and Lancet, industries testing new treatments, and parties involved legal proceedings in federal and state courts, as well as administrative hearings.

There are established standards and criteria for the evaluation of treatment for a given disease.

5. All of the reviews I conduct, whether for hospitals, journals, the FDA, or as an expert witness start by examining the primary studies, the studies that contain direct statistical evidence, including direct statistical analysis of primary data and gives the details of the statistical analysis used, that the treatment effects the outcome in terms of incidence or severity.
6. I do not review abstracts, opinion pieces, clinical guidelines, ethical reviews, anecdotal reports or case series. These may be valuable for other reasons but they give no estimate the actual effect of the treatment on the disease of interest.
7. At the bare minimum, every evaluation I have performed has at its focal point at least one study which at the highest possible level of evidence possible shows the treatment is effective for the primary outcome, the incidence or severity of disease.
8. The primary outcome of a treatment is understood to be the disease, and only the disease, being treated. For example, were we to examine the use of aspirin (acetylsalicylic acid) as a treatment for a particular class of inflammation, then we are interested in measuring that inflammation as our primary outcome. It may be the case that there is evidence that aspirin has certain benefits to heart attack victims as well, and it would be useful to provide this evidence as supplementary to a primary outcome, but measuring the cardiovascular benefits of taking aspirin does not inform the question at hand, “is aspirin a safe and efficacious treatment for the particular inflammation under study?”
9. When reviewing the evidence for a given treatment, I apply paradigms of analysis that are well established in the academic scientific community. These paradigms are the pillars upon which my analysis is based, and include the Hierarchy of Statistical

Evidence presented by the Cambridge University Program in Evidence Based Medicine, the CONSORT documents, the Federal Reference Guide, and the Bradford Hill Criteria.

- a. The Hierarchy of Evidence is a system for weighting the degree of evidence contained in a statistical study. At the highest end are double-blind randomized clinical trials. These are the gold standard. When feasible every treatment should be evaluated by this type of trial but they are often not possible because of ethical and financial constraints. In lieu of such studies, it may be possible to examine other research that may be at the next lowest level of evidence. Examples of these studies are case control studies, cohort studies, and matched observational studies. These studies must contain explicit analysis of the data and be related to the issue at hand. Generally, they are used to increase the statistical power of the primary study, but at times when the evidence is powerful and studies are constrained, these kinds of studies may be used as a primary evidence. If this is done, such studies must provide replicable statistical analysis of primary data. I can evaluate what was done if I can't see what was done. It must be clear how the research data and statistical analysis demonstrate and isolate the effect of treatment on the incidence and severity of disease. I find for the matter at hand that both the highest level of evidence, and this lower level of evidence are entirely missing for the case of surgical intervention and are provide weak secondary evidence in the case of medical interventions ,
- b. Documents which are not identified on one of these two higher levels of evidence according to the hierarchy of evidence can and often do accompany a submission I might receive. These include editorials, abstracts, clinical guidelines, clinical reports, ethics statements, secondary statistical analyses, case series and other similar documents, like reviews and related studies. While these documents may be useful in providing context for the treatment under scrutiny, they typically, if ever, contribute any statistical power or useable information for estimating the effect of treatment on the primary outcome.

- c. The works of Drs. David Sackett, Alvan Feinstein, and Archie Cochrane refined the practice of evidence based medicine by employing these principles of evidence. A former Johns Hopkins University colleague of mine, Dr. David Sackett published more than 30 papers that are considered by epidemiologists worldwide to be fundamental to the understanding and practice of clinical epidemiology. I follow his work and guidelines closely.
- d. Another pillar of this kind of analysis is the CONSORT documents (KF Schulz, 2010), which give guidelines for evaluating the highest form of statistical evidence, the double blind randomized clinical trial. Virtually every biostatistician uses these guidelines in assessing the quality of a clinical trial.
- e. In the case that there is no double blind clinical trial, I look for the next highest form of evidence. For non-controlled studies I focus on use of the Bradford Hill criteria (Hill, 1965) to evaluate the strength of evidence between the treatment and the primary outcome in a non-controlled study. In these situations where less-than-ideal research data is available, general paradigms presented in *Modern Epidemiology*, 3rd Ed., the definitive treatise on epidemiology by Rothman, Lash, and Greenland, are used to guide this kind of work.
- f. Lastly, the Federal Reference Guide covers the entire exercise of evaluating the uses of scientific studies in federal courts. (Committee on Science, National Academy of Science, 2011) This document was made for judges to evaluate statistical evidence, and is used as a guideline by others in evaluating scientific research.

Since filing my first report, I have been sent several documents to evaluate as evidence that the treatments in question are effective for treating gender dysphoria.

- 10. Employing the standards of evidence outlined in (8) I find that not a single one of these supports the assertions of the report in which they are cited. Not one of them identifies gender dysphoria as a primary outcome, and not one of them finds statistical significance for incidence or severity of gender dysphoria. In fact, some of

these documents are ethical statements and abstracts, and have no meaningful value in evidence based inquiry. None of the more recently reviewed documents are suitable as a primary study.

The following are some examples of my findings from the most recent documents I have reviewed:

11. The document by Garcia is not a scientific study, it is an abstract and contains no details, data, or analysis. It is a measurement validation exercise. It provides no evidence for or against medical or surgical intervention as a treatment for gender dysphoria.

- a. Further, the author endorses the opinion I provided in my earlier report:

“... to date, no inventory that measures/quantifies the degree of gender dysphoria a patient associates with his or her body has been described. Furthermore, no inventory for gender dysphoria allows for pre and post-surgery assessment of gender dysphoria, to allow measurement of the effect of specific gender affirming surgeries to reduce gender dysphoria for transgender patients.”

Garcia & Karasic, 2018

12. The document by Glynn is a study which uses a community-based design, one of the weakest statistical designs, to examine psychological well-being of transgender sex workers. It is appropriate only as a secondary piece of evidence. It does not measure the primary outcome, gender dysphoria, only associated outcomes such as depressive symptoms, self-esteem, and suicide ideation.

13. The document by Fisher is not a scientific study, it is another abstract. The author of this abstract writes:

“To date, no study investigating the effects of crosshormonal treatment (CHT) alone-w/o the use of genital reassignment surgery (GRS) e on Gender Dysphoria (GD) is Available.”

Fisher et al., 2016

- a. The author's assertion that there are no studies investigating treatments for GD as an outcome, without the use of CHT, is in agreement with my original opinion.

14. The document by van de Grift is a study which measures the effect of satisfaction with surgery on quality of life - not the effect of surgery on the incidence or severity of gender dysphoria. Quality of life is a secondary outcome for the evaluation of gender dysphoria. This paper does employ a variable as a measure for variability in gender dysphoria measured against surgical satisfaction, however the author finds no statistical significance when doing this analysis.

The above 4 documents were provided to me to evaluate whether it is the case that they are examples of

“studies that measure gender dysphoria as a specific outcome of transition-related care”

and whether they demonstrate with a meaningful level of evidence that the studies

“have found that gender dysphoria is significantly reduced after the medical interventions.”

I find for both questions that the above four documents are lacking in meaningful statistical information, and do not directly test the effect of medical and surgical care on the incidence or severity of gender dysphoria.

There are further documents I have been asked to evaluate since filing my original report. Several of these most recent documents are ethical statements, review papers, studies of comorbidities to the disease under examination, or simply statements of guidelines. None of them provide useful statistical data or analysis that informs the question at hand - “Can medical and surgical interventions reduce the incidence and severity of gender dysphoria?”

15. The document from Costa and Colizzi is a review paper that provides no primary statistical evidence.
16. The document from Kuzon is an ethics paper about military decision making and has no relevant statistical data regarding the efficacy of treatment.
17. The 2018 Witcomb study contains important findings for the measurement of depression, which is a secondary outcome. This study appears to be of high quality and I would consider it to be an important supplemental document to a primary study. (Witcomb, 2018)
18. Keo-Meier -- a very complex analysis of secondary outcomes.
19. Deutsch - This is another paper on ethics, and concerns the creation of clinical guidelines. It contains no statistical analysis that informs a primary outcome.