IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JAMES L. SHERLEY, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 1:09-cv-01575-RCL
	)	
KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

DEFENDANTS' RESPONSE TO PLAINTIFFS' STATEMENT OF MATERIAL FACTS

Defendants hereby file this Response to Plaintiffs' Statement of Material Facts as to Which There is No Genuine Dispute. (Doc. 55). Defendants submit, at the outset, that Plaintiffs' statement of facts is inconsistent with the Local Rules and the deferential standard of review applicable to this case, which is brought under the Administrative Procedure Act (APA). Where, as here, review is based on the administrative record and the grounds for decision invoked by the agency, "the court is not called upon to determine whether there is a genuine issue of material fact, but rather to test the agency action against the administrative record." *See* Comment to LCvR 7(h). For that reason, the Local Rules direct moving parties to provide a statement of facts with references to the administrative record, rather than a statement of material facts as to which the party contends that there is no dispute.[1] *See* LCvR 7(h)(2). Although nothing in the Local Rules requires parties to submit a response to a statement of facts filed in an APA case, *see* LCvR 7(h)(2), defendants file this response in an abundance of caution to address

[1] Defendants include the statement of facts with citations to the administrative record as required by LCvR 7(h)(2) in the factual background section of their memorandum in support of their Motion for Summary Judgment.

plaintiffs' assertions and to make clear that the majority of supposed material facts on which they rely are not relevant and immaterial to the narrow set of issues before the Court.

Such irrelevant assertions include plaintiffs' repeated efforts to have this Court adopt incorrect and misleading statements about the science of stem cell research. Even if such statements were relevant, record review "does not require [judicial] fact finding. . . ," *Northwest Motorcycle Ass'n v. United States Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994), as this Court is well aware, *see Cape Cod Hosp. v. Sebelius*, 677 F. Supp. 2d 18, 29 (D.D.C. 2009). Accordingly, while defendants – and the scientific community at large – disagree with plaintiffs' assertions of scientific fact, *see* Declaration of Francis Collins ("Collins Decl.") (attached as Ex. A to Defendants' Motion to Stay Preliminary Injunction), Declaration of Dr. Story Landis ("Landis Decl.") (attached as Ex. A to Defendants' Motion for Summary Judgment), that is not an issue that should be decided here.

Defendants respond individually to plaintiffs' asserted material, undisputed facts as follows:

1. *Plaintiff Dr. James L. Sherley is an adult stem cell researcher. (Declaration of Dr. James L. Sherley in Support of Pls.' Mot. for Summary Judgment ("Sherley Decl.") ¶ 2.)*

   Response: Undisputed

   a. *Dr. Sherley currently works at the Boston Biomedical Research Institute. (Sherley Decl. ¶ 2.)*

      Response: Undisputed

   b. *Dr. Sherley does not conduct research on embryos or human embryonic stem cells. (Sherley Decl. ¶ 2.)*

      Response: Undisputed

   c. *Dr. Sherley relies exclusively on research grants for funding. (Sherley Decl. ¶ 3.) The "vast majority" of grants he receives are from NIH. (Id.)*

Response: Undisputed

d. *Since 1999, Dr. Sherley has applied for NIH funding approximately 42 times. (Sherley Decl. ¶ 3.)*

Response: Defendants do not dispute that Dr. Sherley has submitted 42 applications, a number which include applications to transfer funds from one institution to another and applications for non-competing incremental grants. Dr. Sherley submitted 34 unfunded applications in that time, of which 10 were revisions. *See* Ex. A to Sherley Decl.

e. *Fourteen of Dr. Sherley's research proposals have received NIH funding. (Sherley Decl. ¶ 3.)*

Response: Defendants do not dispute that fourteen of Dr. Sherley's applications have been awarded NIH funding since 1999, including applications to transfer funds from one institution to another and applications for non-competing incremental grants. Of those, 4 were new awards, 7 were non-competing continuations, and one was a supplement. *See* Ex. A to Sherley Decl.

f. *Two of Dr. Sherley's research proposals in which he is a principal investigator are currently pending. (Sherley Decl. ¶¶ 3, 4.)*

Response: It is undisputed that Dr. Sherley has at least two research proposals in which he is a principal investigator currently pending.

g. *Since 1999, Dr. Sherley has received only one significant private research award. (Sherley Decl. ¶ 3.)*

Response: The term "significant" is vague and undefined. In any event, the statements in this paragraph are not material to the issues before the Court.

h. *Dr. Sherley has been a co-investigator on two other NIH grants providing minor funding for his adult stem cell studies. (Sherley Decl. ¶ 3.)*

Response: Undisputed

i. *Dr. Sherley will continue to apply for NIH grants in the future. (Sherley Decl. ¶ 5; see also Sherley v. Sebelius, 610 F.3d 69, 71 (D.C. Cir. 2010) (attached as Declaration of Steven H. Aden in Support of Pls.' Mot. for Summary Judgment ("Aden Decl."), Ex. N).)*

Response: Undisputed

j. *Dr. Sherley will likely be unable to continue his research without NIH funding. (Sherley Decl. ¶ 5.)*

Response: This paragraph is vague and ambiguous as to what "research" is being discussed. Dr. Sherley is expected, at a minimum, to continue to receive extramural research funding from NIH into 2011, regardless of the outcome of his pending applications. Collins Decl. ¶ 23.

2. *Plaintiff Dr. Theresa Deisher is an adult stem cell researcher. (Declaration of Dr. Theresa Deisher in Support of Pls.' Mot. for Summary Judgment ("Deisher Decl.") ¶ 2.)*

Response: Undisputed

a. *Dr. Deisher is the founder, managing member, and research and development director of AVM Biotechnology. (Deisher Decl. ¶ 3.)*

Response: Undisputed

b. *Dr. Deisher works exclusively with adult stem cells. (Deisher Decl. ¶ 2.)*

Response: Undisputed

c. *Dr. Deisher does not conduct research on embryos or embryonic stem cells. (Deisher Decl. ¶ 2.)*

Response: Undisputed

d. *Dr. Deisher can continue her research only if she obtains funding from NIH. (Deisher Decl. ¶ 3.)*

Response: Disputed. To date, Dr. Deisher has conducted her research without the aid of NIH extramural funds. Collins Decl. ¶ 24. Indeed, she has never applied for such funds. *Id.*; *see also* Deisher Decl. ¶ 3.

e. *Dr. Deisher is in the process of applying for NIH funding and will continue to seek NIH grants in the future. (Deisher Decl. ¶ 3; see also Sherley, 610 F.3d at 71 (attached as Aden Decl., Ex. N).)*

Response: This assertion is vague and ambiguous, insofar as Dr. Deisher has claimed to be "in the process" of applying for NIH funding for more than a year. *Compare* Declaration of Teresa Deisher in Support of Plaintiffs' Motion for Summary Judgment, Sept. 2, 2010 *with* Declaration of Teresa Deisher, August 16, 2009. Defendants further dispute that Dr. Deisher will "continue" to seek NIH grants, insofar as she has not previously applied for any such grants.

3. *Applicants for NIH research funding undergo evaluation through two-tier peer review. (Aden Decl., Ex. J [Decl. of Sarah Jean Rockey, Ph.D., in Support of Defs.' Opp'n to Pls.' Mot. for Prelim. Inj.] ¶ 8.)*

   Response: Undisputed.

4. *A grant applicant submits the application to the Center for Scientific Review (CSR) at NIH; CSR then refers the application to one or more Institutes or Centers (ICs) at NIH depending on the subject area of the application. (Aden Decl., Ex. J ¶ 9.)*

   Response: Undisputed.

5. *Each Institute or Center has "an independent budget" to fund research particular to its subject area. (Aden Decl., Ex. J ¶ 5.)*

   Response: Undisputed

   a. *Congress sets each IC's individual budget. (Aden Decl., Ex. J ¶ 15.)*

      Response: Undisputed

   b. *Most ICs then establish a "'payline' for the overall amount they will spend on research grants. The 'payline' is a percentile-based funding cutoff point determined at the beginning of a fiscal year." (Aden Decl., Ex. J ¶ 15.)*

      Response: Undisputed

   c. *"[S]tem cell research . . . is included within the overall payline and funded . . . according to the particular proposals received and the funding available to the particular IC." (Aden Decl., Ex. J ¶ 16.)*

      Response: Undisputed.

   d. *"[I]n the short run, the amount of money available from NIH for research grants is fixed notwithstanding the greater range of stem cell projects made eligible for funding by the Guidelines." Sherley, 610 F.3d at 73 (attached as Aden Decl., Ex. N); see also Aden Decl., Ex. J at ¶¶ 15-16.*

      Response: Defendants do not dispute that, in the short run, the amount of money available from NIH for research grants is fixed, regardless of the number of applicants for funding. Defendants dispute that the eligibility of hESC researchers has a direct impact on the ability of adult stem researchers to obtain funds. *See* Rockey Decl. ¶ 16; Collins Decl. ¶ 22.

6. *Each application receives a preliminary score; in general, only the applications in the*

top half of all preliminary scores are discussed at the first level of peer review. (Aden Decl., Ex. J ¶ 11.)

Response: Undisputed. Applications scoring in the bottom half may also be considered on the motion of a reviewer. Decl. of Sally Rockey ¶ 11.

7. *An application that is considered receives an actual score. (Aden Decl., Ex. J ¶ 11.) Based on this score "and the needs and mission of the particular funding component . . . , the Council or Board then recommends certain applications for funding." (Id. ¶ 12.)*

Response: Undisputed

8. *NIH "uses specific funding or 'targeted' announcements to stimulate research in particular areas of science through use of an announcement called a 'Request for Applications' (RFA)." (Aden Decl., Ex. J ¶ 6.)*

Response: Undisputed.

9. *The grant-application process is competitive, such that "[o]nly about 20 percent of applicants are successful in having their research proposals funded by NIH." (Aden Decl., Ex. J ¶ 14.)*

Response: Undisputed.

10. *The NIH Guidelines for Human Stem Cell Research ("Guidelines") "have intensified the competition for a share in a fixed amount of money." Sherley, 610 F.3d at 74 (attached as Aden Decl., Ex. N); see also Sherley Decl. ¶ 5; Deisher Decl. ¶ 4.*

Response: Disputed. *See* Rockey Decl. ¶¶ 4, 11, 14-16; Collins Decl. ¶ 22.

11. *As a result of the intensified competition caused by the Guidelines, "the plaintiffs will have to invest more time and resources to craft a successful grant application." Sherley, 610 F.3d at 74 (attached as Aden Decl., Ex. N); see also Sherley Decl. ¶ 5; Deisher Decl. ¶ 4.*

Response: Disputed. *See* Rockey Decl. ¶¶ 4, 11, 14-16; Collins Decl. ¶¶ 22-23. *See generally* Sherley Decl. and Deisher Decl.

12. *"[Adult stem cells] and [embryonic stem cells] are substitutes in some uses." Sherley, 610 F.3d at 74 (attached as Aden Decl., Ex. N); see generally Aden Decl., Ex. D at 9-10.*

Response: Defendants are unable to respond to the statements in this paragraph, as they are vague and ambiguous. Defendants dispute that hESC and adult stem cell research are in direct competition with one another for NIH funds. Collins Decl. ¶ 22. Defendants further dispute that adult stem cell researchers are more likely to lose funding to projects

involving hESCs than are researchers who do not work with stem cells. Rockey Decl. ¶¶ 15-16; Collins Decl. ¶ 22.

13. *The Dickey-Wicker Amendment provides that: "None of the funds made available in this Act may be used for—(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, 123 Stat. 3034, 3280-81, § 509(a).*

Response: Undisputed

14. *The Dickey-Wicker Amendment was enacted in direct response to efforts on the part of the National Institutes of Health (NIH) to begin funding research entailing the destruction of or undue risk to human embryos. (Aden Decl., Ex. D at 7.)*

Response: The statements in this paragraph constitute a legal conclusion rather than a statement of fact.

15. *In early 1993, NIH Director Harold Varmus convened the Human Embryo Research Panel, which recommended that NIH fund research entailing risks to human embryos. (See Aden Decl., Ex. D at 6.)*

Response: The statements in this paragraph are not relevant to NIH's promulgation of the guidelines; the Human Embryo Research Panel had no connection to hESC research.

16. *Before NIH could approve any grants for human embryonic stem cell research, Congress passed the Dickey-Wicker Amendment for the first time. (Aden Decl., Ex. D at E-6.)*

Response: Defendants dispute the implication that there was any causal connection between efforts by NIH to approve grants for human embryonic stem cell research and the passage of the Dickey-Wicker Amendment for the first time. At the time the Dickey-Wicker Amendment was passed in 1996, human embryonic stem cells had not yet even been isolated. *See* Collins Decl. ¶ 6.

17. *Congress has included the Dickey-Wicker Amendment without material change in every Health and Human Services ("HHS") appropriations bill since 1996. (See Aden Decl., Ex. D at 7-8; see also Defs.' Memo. in Support of Mot. to Dismiss at 37 [Dkt. #23].)*

Response: Undisputed.

18. *NIH attempted to fund embryonic stem cell research in 2000, when it finalized and made effective "Guidelines for Research Using Human Pluripotent Stem Cells" ("2000 Guidelines"). 65 Fed. Reg. 51,976 (Aug. 25, 2000).*

Response: Undisputed that in 2000, after notice and comment, NIH issued "Guidelines for Research Using Human Pluripotent Stem Cells" ("2000 Guidelines"), which set forth policies and procedures for the funding of human embryonic stem cell research. 65 Fed. Reg. 51,976 (Aug. 25, 2000).

19. *In 2001, NIH formally withdrew the 2000 Guidelines, which had never been implemented. 66 Fed. Reg. 57,107 (Nov. 14, 2001); Aden Decl., Ex. D at E-*2.

Response: Undisputed that in 2001, without notice and comment, NIH withdrew the 2000 Guidelines as they pertained to human pluripotent stem cells derived from human embryos.

20. *Executive Order 13,505 provided that NIH "may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law," and that "[w]ithin 120 days . . . [HHS and NIH] shall review existing NIH guidance and other widely recognized guidelines on human stem cell research . . . and issue new NIH guidance on such research that is consistent with this order." 74 Fed. Reg. 10,667 (Mar. 11, 2009) (attached as Aden Decl., Ex. A).*

Response: Undisputed. However, this statement selectively quotes from the Executive Order, which also states that "[t]he purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind." Exec. Order No. 13,505 § 1. This Court is referred to the Executive Order for a full statement of its contents.

21. *The Executive Order also required that it "be implemented consistent with applicable law." 74 Fed. Reg. 10,667 (Mar. 11, 2009) (attached as Aden Decl., Ex. A).*

Response: Undisputed

22. *On April 23, 2009, NIH issued and requested comment on draft guidelines ("Draft Guidelines") for human stem cell research. 74 Fed. Reg. 18,578 (Apr. 23, 2009) (attached as Aden Decl., Ex. B).*

Response: Undisputed

23. *The Draft Guidelines' stated purpose was "to help ensure that NIH-funded research [involving human embryonic stem cells] is ethically responsible, scientifically worthy, and conducted in accordance with applicable law." 74 Fed. Reg. 18,578.*

Response: Undisputed that this was one of the stated purposes of the Draft Guidelines.

24. *The Draft Guidelines proposed the authorization of federal funding of human embryonic*

stem cell research. 74 Fed. Reg. 18,578.

Response: Defendants dispute this characterization of the Draft Guidelines to the extent that it suggests that no human embryonic stem cell research had previously been authorized to receive federal funding or that limitations on such research had not already been withdrawn by the President's Executive Order.

25. *In a telephone briefing with reporters after the Draft Guidelines were issued, Acting NIH Director Raynard Kington stated: "We will expand greatly the number of cell lines eligible for funding . . . . We know of several hundred cell lines that will meet the guideline standards." (Aden Decl., Ex. I [Gautam Naik, NIH Offers Rules for Embryonic Stem Cell Research, Wall St. J., Apr. 17, 2009].)*

Response: The statements in this paragraph are not relevant to NIH's promulgation of the guidelines and not material to the issues before the Court.

26. *In response to the Draft Guidelines, Do No Harm, et al., submitted Comments that detailed numerous scientific flaws associated with human embryonic stem cell research. (Aden Decl., Ex. D.)*

Response: Defendants do not dispute that, in response to the Draft Guidelines, Do No Harm, et al., submitted comments that addressed the scientific merit of hESC research. The scientific merit of hESC research as a whole was not relevant or material to the promulgation of the Guidelines. Instead, the merits of each application for research funds, regardless of the type of research proposed, is done through the established peer review process. In any event, defendants dispute that the Comments identified "scientific flaws" associated with hESC research.

27. *Defendants received the Comments submitted by Do No Harm, et al., detailing the scientific problems associated with human embryonic stem cell research, and they are part of the administrative record. (Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm ?StartID=47017 (last visited Aug. 16, 2010).)*

Response: Defendants do not dispute that they received the comments submitted by Do No Harm, *et al.*, and that they are part of the administrative record. Defendants dispute that the Comments identified "scientific flaws" associated with hESC research, and note that the scientific merit of hESC research as a whole was neither relevant to the passage of the Guidelines nor material to the issues before this Court.

28. *The administrative record establishes the following scientific facts, as shown by the Do No Harm Comments:*

Response: The statements in this paragraph, including its sub-parts, are neither relevant to NIH's promulgation of the guidelines nor material to the issues before the Court. The

role of the Court is not to determine whether the administrative record "establishes" any "scientific facts." *See Northwest Motorcycle Ass'n v. United States Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994) (record review "does not require fact finding on behalf of this court"). Moreover, as explained in Defendants' Opposition to Plaintiffs' Motion for Summary Judgment, the scientific merit of hESC research as a whole was neither relevant to the promulgation of the Guidelines nor material to this case.

29. *In promulgating the Guidelines, Defendants failed to address or respond to the scientific problems identified in the Comments of Do No Harm, et al., and failed to explain [sic].*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the guidelines nor material to the issues before the Court. Defendants had no obligation to respond to comments about the scientific merits of hESC research generally.

30. *In response to the Draft Guidelines, Do No Harm, et al., submitted Comments that detailed numerous ethical flaws associated with human embryonic stem cell research. (Aden Decl., Ex. D.)*

Response: Defendants do not dispute that Do No Harm, et al., submitted comments in response to the Guidelines that raised ethical objections to hESC research. Defendants dispute that there are "numerous ethical flaws" associated with hESC research as outlined in the Guidelines, although that issue is neither relevant to the promulgation of the Guidelines nor material to the Court's review in this case.

31. *Defendants received the Comments of Do No Harm, et al., detailing the ethical flaws associated with human embryonic stem cell research, and they are part of the administrative record. (Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/ stem_cells/web_listing.htm? StartID=47017 (last visited Aug. 16, 2010).)*

Response: Defendants do not dispute that they received the comments submitted by Do No Harm, *et al.*, and they are part of the administrative record. Defendants dispute that there are "ethical flaws" associated with hESC research as outlined in the Guidelines, although that issue is neither relevant to the promulgation of the guidelines nor material to the Court's review in this case.

32. *The administrative record establishes the following ethical flaws with the Guidelines, as shown by the Do No Harm Comments:*

Response: The statements in this paragraph, including its sub-parts, are neither relevant to NIH's promulgation of the guidelines nor material to the issues before the Court. The role of the Court is not to determine whether the administrative record "establishes" any "ethical flaws." *See Northwest Motorcycle Ass'n v. United States Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994) (record review "does not require fact finding on behalf of this court").

33. *In promulgating the Guidelines, Defendants failed to address or respond to the ethical concerns raised in the Comments of Do No Harm, et al., and failed to explain Defendants' decision to authorize the federal funding of embryonic stem cell research in view of the ethical flaws Do No Harm identified. See 74 Fed. Reg. 32,170 (attached as Aden Decl. Ex. C).*

Response: Defendants dispute that they did not address any comments from Do No Harm, *et al.*, that raised ethical concerns. *See* 74 Fed. Reg. 32,170 (addressing concerns about conflicts of interest between the reproductive facility and the research facility). Further, it is immaterial whether Defendants addressed comments that raised categorical ethical objections to the funding of hESC research, as these were neither relevant to the promulgation of the guidelines nor material to the issues before the Court in this case.

34. *The Do No Harm Comments also expressed concern that NIH Acting Director Raynard Kington had entered the rulemaking proceeding with "an unalterably closed mind" regarding the merits of the Guidelines and urged that he be excluded from the decisionmaking process. (Aden Decl., Ex. D at 19.)*

Response: It is undisputed that the comments make this suggestion; however, that fact is neither relevant to the promulgation of the guidelines nor material to the present case.

35. *Defendants received the comment referenced in ¶ 34, which is part of the administrative record. (Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm?StartID=47017 (last visited Aug. 16, 2010).)*

Response: Undisputed; however, that fact is immaterial to the present case.

36. *Defendants ignored the comment referenced in ¶ 34 and failed to explain their decision to permit Acting Director Kington to participate in the decisionmaking process despite his professed bias and unalterably closed mind. See 74 Fed. Reg. 32,170.*

Response: The statements in this paragraph are neither relevant to the promulgation of the Guidelines nor material to the present case. Furthermore, the statements are disputed. *See* Landis Decl. ¶ 9 ("All of the comments were reviewed"); *see also* Defs' Memo in Support of Mot. for Summary Judgment at 38-40.

37. *NIH received 49,015 public comments on the Guidelines. (See Nat'l Institutes of Health, Listing of Comments on Draft NIH Human Stem Cell Guidelines, http://grants.nih.gov/stem_cells/web_listing.htm? (last visited Aug. 16, 2010).)*

Response: Undisputed.

38. *NIH disregarded as "unresponsive" about 30,000 such comments, which opposed federal funding for embryonic stem cell research on ethical and scientific grounds. (Aden. Decl.,*

[sic].

Response: Defendants do not dispute that they deemed comments advocating a blanket ban on all funding for hESC research rather than responding to the specific topics for which comments were requested not relevant to the promulgation of the Guidelines.

a. *Explaining NIH's decision to disregard these comments, Acting NIH Director Raynard Kington stated, "We actually did not ask the public whether we should fund research on human embryonic stem cells. We asked the public how we should fund human embryonic stem cell research." (Aden Decl., Ex. F at 2.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

b. *Kington also stated, "We clearly predict that the opportunities for research will greatly expand" with respect to human embryonic stem cell research. (Aden Decl., Ex. F at 2.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

c. *Kington's statements regarding NIH's decision to disregard comments opposed to embryonic stem cell funding were accurately reported in the article referenced in ¶ 38.*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

39. *Defendants ignored comments addressing the merits of human embryonic stem cell research. (See Defs.' Memo. in Support of Mot. to Dismiss at 44 [Dkt. #23] (NIH "properly ignored . . . the relative merits" of embryonic stem cell research); see also Defs.' Reply in Support of Mot. to Dismiss at 20 [Dkt. #32] ("NIH responded appropriately to comments that were relevant to the formulation of the Guidelines, namely, comments that addressed the substance of the informed consent procedures that NIH proposed to establish.").)*

Response: Defendants dispute that they "ignored" comments addressing the categorical merit of hESC research; rather, Defendants reviewed those comments and deemed them irrelevant to the issues facing the agency. *See* Landis Decl. ¶¶ 11, 13.

40. *On July 7, 2009, NIH issued "Guidelines for Human Stem Cell Research," which authorized federal funding of embryonic stem cell research utilizing live human embryos that were "created . . . for reproductive purposes" but are "no longer needed for [that] purpose." 74 Fed. Reg. at 32,170, 32,174 (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants further dispute this characterization. Research using embryonic stem cells does not utilize human embryos. 74 Fed. Reg. 32,173 ("research involving hESCs . . . does not involve an embryo nor result in an embryo's destruction").

41. *The Guidelines require applicant institutions proposing research using human embryonic stem cells to ensure that the process by which the embryonic stem cells were derived from human embryos was in accordance with the Guidelines. 74 Fed. Reg. at 32,174-75 (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants further dispute this characterization. A researcher may use hESC lines that are posted on the NIH Registry. 74 Fed. Reg. at 32,174.

42. *The Guidelines permit the same researcher both to derive stem cells from an embryo and to receive federal funding for all research activities involving those cells. 74 Fed. Reg. at 32,174 ("The attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize [human embryonic stem cells] should not have been the same person unless separation was not practicable") (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph are not material to the issues before the Court. The statements in this paragraph also constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants further dispute this characterization.

43. *The Guidelines categorically prohibit the use of any funds for cloning or breeding of animals. 74 Fed. Reg. at 32,175 §§ IV, V (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph are not material to the issues before the Court. The statements in this paragraph also constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants further dispute this characterization of the Guidelines as overbroad. 74 Fed. Reg. at 32,175 §§ IV, V.

44. *The Guidelines categorically prohibit the offering of "payments, cash or in kind," for "donated embryos." 74 Fed. Reg. at 32,174 § II.A.3.b (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants dispute that the Guidelines regulate the process of deriving stem cells from embryos. The Guidelines set forth criteria for determining which human embryonic stem cell lines may be used in NIH-funded research; one aspect of that

eligibility involves the manner in which embryos used to create the stem cell line used in that research were donated. 74 Fed. Reg. at 32,170.

45. *The Guidelines regulate the process by which embryos must be obtained if they are to be used in government-funded research. 74 Fed. Reg. at 32,174-32,175 (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants further dispute that the Guidelines regulate the process of deriving stem cells from embryos. The Guidelines set forth criteria for determining which human embryonic stem cell lines may be used in NIH-funded research; one aspect of that eligibility involves the manner in which embryos used to create the stem cell line used in that research were donated. 74 Fed. Reg. at 32,174-75.

a. *"[T]he Guidelines pertain primarily to the donation of embryos for the derivation of [human embryonic stem cells]." 74 Fed. Reg. 32,170 (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants do not dispute that the Guidelines address criteria for the types of hESCs that may be used in federally-funded research, including the voluntary and informed donation of embryos from which hESCs are derived.

b. *The Guidelines require that individuals donating "human embryos for research purposes" be informed of "[w]hat would happen to the embryos in the derivation of [the stem cells]." 74 Fed. Reg. at 32,174 (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants dispute this characterization. The Guidelines do not regulate the process of deriving stem cells from embryos, but provide guidelines for the eligibility for funds for research using stem cells derived from a human embryo. 74 Fed. Reg. at 32,174

c. *"To conduct [embryonic stem cell] research, [embryonic stem cells] must be derived from an embryo. The process of deriving [embryonic stem cells] from an embryo results in the destruction of the embryo." (Order of Aug. 23, 2010, at 12 [Dkt. #44]; see also Aden Decl., Ex. D at 5, E-3.)*

Response: The statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. It is undisputed that the derivation of a stem

cell results in the destruction of an embryo. Defendants dispute that the derivation process is a part of all hESC research. Defendants also dispute that an embryo is destroyed to create each stem cell used in hESC research. *See* 65 Fed. Reg. at 51,979 (noting that hESCs are "self-replicating").

46. *In the Human Subject Protection Regulations, incorporated in the Dickey-Wicker Amendment, NIH defined "research" as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d); see also § 509(a)(2)(b), 123 Stat. at 3281.*

Response: The statements in this paragraph constitute a legal conclusion rather than a statement of fact.

47. *HHS guidance documents on the Human Subject Protection Regulations state that an institution that receives federal funding is generally engaged in human subjects research "even where all activities involving human subjects are carried out by employees or agents of another institution." (Dep't of Health & Human Servs., Guidance on Engagement of Institutions in Human Subjects Research (Oct. 16, 2008), available at http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court. The statements in this paragraph also constitute plaintiffs' characterization of the Human Subject Protection Regulations, to which the Court is respectfully referred for a full and accurate statement of their contents.

48. *The Guidelines do not prohibit a privately funded researcher from destroying an embryo at a publicly funded researcher's behest. See 74 Fed. Reg. at 32,174 (discussing limitations on eligibility for embryonic stem cell funding) (attached as Aden Decl., Ex. C).*

Response: The statements in this paragraph are not material to the issues before the Court. Furthermore, the statements in this paragraph constitute plaintiffs' characterization of the Guidelines, to which the Court is respectfully referred for a full and accurate statement of their contents. Defendants dispute the statements as a mischaracterization of the manner in which typical hESC research is conducted.

49. *Defendants never have set forth an interpretation of the word "research" as used in the Dickey-Wicker Amendment.*

Response: Disputed. NIH's interpretation of the Dickey-Wicker Amendment reflects its consistent interpretation of the term "research" as used in the context of the Amendment.

a. *Defendants never have interpreted "research" to mean a "piece of research" in an official agency statement promulgated through notice-and-comment*

procedures.

Response: Disputed to the extent it suggests that NIH's interpretation of Dickey-Wicker, including the use of the term "research" in the context of the Amendment, has not been issued through notice and comment. *See* 74 Fed. Reg. 32.173. Moreover, this statement is immaterial.

50. *The removal of the inner cell mass of a human embryo generates the embryonic stem cell, but in order to extract the stem cell, the human embryo must be destroyed. See 74 Fed. Reg. at 32,171 (defining human embryonic stem cells as "cells that are derived from the inner cell mass of blastocyst stage human embryos") (attached as Aden Decl., Ex. C); Aden Decl., Ex. D at E-3 ("[t]he process by which human embryonic stem cells are extracted from human embryos necessarily destroys the human embryos").*

Response: Undisputed, except to the extent that this paragraph suggests that an embryo is destroyed each time that a stem cell is used in hESC research.

51. *Mouse embryonic stem cells were first isolated and successfully grown in the laboratory in 1981, while the first mouse adult stem cell was successfully isolated and purified in the laboratory in 1988. (Aden Decl., Ex. Q [Declaration of Dr. Theresa Deisher in Support of Pls.' Opp'n to a Stay of the Prelim. Inj.] ¶ 7.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

52. *Human embryonic stem cells were first isolated and grown briefly in the laboratory in 1994, and were first successfully maintained long-term in the laboratory in 1998. (Aden Decl., Ex. Q ¶ 7.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

53. *The first human adult stem cell was first isolated in the laboratory in 1992. (Aden Decl., Ex. Q. ¶ 7.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

54. *Although many researchers predicted that embryonic stem cell research would lead to the cure of diseases such as Parkinson's, Alzheimer's, and diabetes, those predictions have not come to pass. (Aden Decl., Ex. G [Bernadine Healy, M.D., Why Embryonic Stem Cells Are Obsolete, U.S. News & World Report, Mar. 4, 2009, http://health.usnews.com/blogs/heart-to-heart/2009/03/04/why-embryonic-stem-cells-are-obsolete.html]; see also Aden. Decl., Ex. D at A-2.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

55. *No patients have been injected with human embryonic stem cells. (Aden Decl., Ex. Q. ¶ 11.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

56. *Even many human embryonic stem cell research proponents are concerned that a clinical trial of a human embryonic stem cell-derived therapy is not safe to proceed despite having received FDA approval to begin enrolling certain patients. (Aden Decl., Ex. Q ¶11.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

57. *As of September 3, 2010, 1,973 adult stem cell interventional trials were listed at ClinicalTrials.gov, a website developed and maintained by NIH. (Aden Decl., Ex. Q ¶ 12.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

58. *As of September 3, 2010, zero interventional clinical trials with embryonic stem cells were listed on ClinicalTrials.gov. (Aden Decl., Ex. Q ¶ 12.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

59. *The published literature contains . . . examples of adult stem cells that can differentiate into cell types different from their tissue of origin, including recently-discovered very small embryonic-like ('VSEL') cells from adult bone marrow, and demonstrates that these bone marrow-derived cells can repair cardiac damage. (Aden Decl., Ex. Q ¶ 14.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

60. *Bone marrow stem cells can form neurons, as even NIH as noted. (Aden Decl., Ex. Q ¶ 15.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

61. *Adult neural stem cells can be obtained from the post-mortem human brain and yield*

nerve cells. (Aden Decl., Ex. Q ¶ 16.)

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

62. *The technique used to generate induced pluipotent [sic] stem cells was originally discovered using knowledge from mouse embryonic stem cells; that same technique was used to create the first human induced pluripotent stem cell. (Aden Decl., Ex. Q ¶ 17.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

63. *Recently published literature confirms that human embryonic stem cells and induced pluripotent stem cells are "virtually identical." (Aden Decl., Ex. Q ¶ 18 & n.21.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

64. *Induced pluripotent stem cells probably avoid rejection by the immune system. (Nat'l Institutes of Health, Stem Cell Basics 14 (2009), available at http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf; see also Aden Decl., Ex. D at 10.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

65. *Standard cell culture technique involves freezing (cryopreservation) of cell stocks from the very inception of a cell culture and cell line. (Aden Decl., Ex. Q. ¶ 19.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

66. *Cryopreserved cells are stored in liquid nitrogen at –196° C, at which temperature they can be maintained indefinitely; methods have been refined specifically for human embryonic stem cells. (Aden Decl., Ex. Q ¶ 19.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

67. *In 2006, a total of 50,417 transplants were performed worldwide using hematopoietic (blood-forming) adult stem cells. (Aden Decl., Ex. Q ¶ 20.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

a. *Almost half (48%) of such transplants took place in Europe. (Aden Decl., Ex. Q ¶*

20.)

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

b. *Only 36% took place in all of the Americas. (Aden Decl., Ex. Q ¶ 20.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

68. *Adult stem cell transplants have become the standard of care for many patients with blood disorders and malignancies, though they are starting to be used for other conditions including autoimmune disorders and heart disease. (Aden Decl., Ex. Q ¶ 20.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

69. *Adult stem cell therapy is an accepted therapy worldwide. (Aden Decl., Ex. Q ¶ 20.)*

Response: The statements in this paragraph are neither relevant to NIH's promulgation of the Guidelines nor material to the issues before the Court.

Dated: September 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2010, I caused a true and correct copy of the foregoing Response to be served on Plaintiffs' counsel electronically by means of the Court's ECF system.

/s/ Eric Womack
ERIC R. WOMACK