Sherley v. Sebelius, Ambiguity and "Linguistic Jujitsu" in Federal Court over the Funding of Human Embryonic Stem Cell Research?

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On August 24, 2012, the District of Columbia Circuit Court validated the legality of the National Institutes of Health guidelines[1] for the funding of human embryonic stem cell ("hESC") research.[2] The use of hESCs is complex and controversial. The complexity of the issues is highlighted by the difference in opinions put forth in the three concurring judgments comprising the Circuit Court's August decision in *Sherley v. Sebelius*, and, additionally, by the fact that the federal courts issued six substantive judgments in this case to date, including two decisions by the Circuit Court overruling the District Court. This article will overview the history of embryonic stem cell research and regulations, and provides an analysis of the federal court decisions in *Sherley*.

hESCs are of great interest to scientific research due to their ability to continually replicate themselves and to differentiate into all of the types of cells in the human body.[3] Their ability to differentiate into any cell type distinguish hESCs[4] from adult stem cells ("ASCs") which are only able to differentiate into a restricted number of cells and therefore have a more limited potential for use in research.

In 1975, the Departments of Health, Education and Welfare issued guidelines on the federal funding of research using embryos.[5] These guidelines required all research using ex utero IVF embryos to be approved by an Ethics Advisory Board ("EAB"). The EAB was created in 1979, and expired in 1980; this expiry prevented further approval of embryo research ending the funding of such research.[6]

The National Institutes of Health Revitalization Act of 1993[7] reopened the door to potential funding of research involving embryos by ending the EAB requirements and by giving the National Institutes of Health ("NIH") authority to fund research using human fetal tissue from a spontaneous or induced abortion. The NIH subsequently convened a Human Embryo Research Panel, which recommended that

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[1] National Institutes of Health Guidelines for Research Using Human Stem Cells ("Guidelines"), 74 Fed. Reg. 32170, (July 7, 2009).
[2] Sherley v. Sebelius, ("Sherley VI"), 689 F.3d 776, 785 (D.C. Cir. 2012), *aff'g* 776 F. Supp. 2d 1 (D.D.C. 2011).
[3] Tahereh Tavakoli et al., *Self-renewal and Differentiation Capabilities Are Variable Between Human Embryonic Stem Cell, 13, 16 and; BG01V*, 10 BMC Cell Biology 44 (2009).
[4] *Derivation, Propagation and Differentiation of Human Embryonic Stem Cells*, 36 INT'L J. BIOCH. & CELL BIO. 555, 556-7 (2004). (hESCs are derived from an early-stage embryo termed a blastocyst. In order to isolate hESCs, the inner cell mass of the blastocyst is mechanically or surgically separated from the other cells and transferred to culture dishes where the hESCs continue to replicate. All cells that are derivative of one blastocyst are referred to as a cell line. hESCs continue to replicate and therefore may be used in a multitude of research projects); Tavakoli, *supra* note 3 (hESC lines differ in their genetic makeup, cell shape, replication rate, gene expression and ability to more readily differentiate into certain cell types, as a result different lines are useful for different research projects.)
[5] Emilie W. Clemmens, *Creating Human Embryos for Research: A Scientist's Perspective on managing the Legal and Ethical Issues*, 2 IND. HEALTH L. REV. 95, 103 (2005), *available at* http://www.guttmacher.org/pubs/tgr/04/1/gr040103.html; Office for Human Research Protections; *Institutional Review Board Guidebook* (1993), *available at* http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm#g2;
[6] *Id.*
[7] Pub. L. No. 103-43, 111, 107 Stat. 122, 129 (1993) (codified at 42 U.S.C.§§ 289g-1, 289g-2) (2012).

the NIH fund human embryo research on embryos created through in vitro fertilization for fertility or research purposes.[8]

Both President Clinton[9] and Congress, through the passage of the Dickey-Wicker Amendment ("DWA")[10] in 1995, demonstrated their opposition to the federal funding of the creation of human embryos for research purposes. The DWA is a rider that has been attached to every appropriations bill for Health and Human Services since 1996, and prohibits the federal funding of "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 …"[11]

Since 1999, the NIH has asserted its opinion that the DWA does not bar it from providing federal funds to experiments using embryonic stem cells as long as the funds were not used to derive the hESCs.[12] The NIH asserts that hESCs are not embryos within the DWA statutory definition, and therefore the DWA does not apply to the funding of research involving them.[13]

In 2001, President Bush limited the funding of hESC research to the use of the 22 hESC lines that had been created prior to that date.[14] President Obama withdrew these restrictions on March 9, 2009 and directed the NIH to issue new guidelines for the funding of hESC research.[15] The NIH published the final "National Institutes of Health Guidelines for Human Stem Cell Research" ("Guidelines") on July 7, 2009, detailing eligibility requirements for NIH funding of research projects involving hESCs.[16] The eligibility requirement included that the hESCs be from previously approved hESC lines or that the researchers demonstrate that the hESCs were derived from embryos "that were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose."[17] The Guidelines expressly prohibited NIH funding of the derivation of stem cells from human embryos contrary to the DWA.[18]

On August 19, 2009 the *Sherley v. Sebelius* action was commenced by a group of eight Plaintiffs, alleging that the Guidelines were contrary to the DWA and seeking to enjoin the NIH from funding hESC research.[19] The government brought a motion to dismiss for lack of standing, which was granted by the United States District Court for the District of Columbia (the "District Court").[20] Two plaintiff researchers successfully appealed the district court's denial of standing to the United States Court of

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[8] *Report of the Human Embryo Research Panel*, x-xii (Ad Hoc Group of Consultants to the Advisory Committee to the Director, NIH, 1994), *available at* http://bioethics.georgetown.edu/pcbe/reports/past_commissions/human_embryo_vol_1.pdf.

[9] United States, Office of the Federal Register, Public Papers of the Presidents of the United States, William J. Clinton 2142 (1993) ("I do not believer that Federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research.")

[10] Pub. L. No. 104-99, § 128, 110 Stat. 26, 4 (1996).

[11] Consolidated Appropriations Act, 2012, Pub. L. No. 112-74, § 508 (current version of DWA)

[12] National Institutes of Health, *Proceedings of the 78th Meeting of the Advisory Committee to the Director* (June 3, 1999), available at http://acd.od.nih.gov/06031999minutes.htm; Harold Varmus, *NIH Director's Statement on Research Using Embryonic Stem Cells* (January 26, 1999), *available at* http://stemcells.nih.gov/policy/statements/statement.asp; Guidelines, *supra* note 1 at 32174.

[13] *Id*.

[14] Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (Aug. 9, 2001); Proclamation No. 13,435, 72 Fed. Reg. 34,591 (August 9, 2001).

[15] Proclamation No. 13505, 74 Fed. Reg. 10667 (March 9, 2009).

[16] *Surpa* note 1.

[17] *Id.* at 32174.

[18] *Id.* at 32.

[19] Complaint, Sherley v. Sebelius, No. 1:09-CV-01575 (D.D.C., Aug 19, 2009).

[20] Sherley v. Sebelius ("Sherley #1"), 686 F. Supp. 2d 1 (D.D.C. 2009), *rev'd by* 610 F.3d 69 (D.C. Cir. 2010).

Appeals for the District of Columbia Circuit (the "D.C. Circuit") and were granted competitor standing on the basis that the DWA could be interpreted as limiting hESC research.[21]

The D.C. Circuit's 2009 decision was significant as it extended the doctrine of competitor standing to apply to situations of increased competition for government research funding. Specifically the D.C. Circuit found that the plaintiffs, who conducted ASC research, would face an "actual or imminent increase in competition" as a result of the increased number of grant applications that would be put forward to the NIH for hESC research as a result of the Guidelines.[22]

After issues of standing were resolved, the District Court granted the plaintiff's motion for a preliminary injunction.[23] The Court held that the NIH's interpretation of the DWA was not entitled to deference based on the application of the two-step test articulated in *Chevron U.S.A. Inc. v. Natural Resources Defense Counsel Inc*,[24] and therefore the plaintiff had demonstrated a strong likelihood of success and met the requirements for a preliminary injunction.[25] In *Chevron* the Supreme Court articulated a two-step test for whether an administrative agency's interpretation of a statute is entitled to deference. The issue to be determined at the first step is whether the language in the statute is unambiguous, if the language is clear the intent of the statute must be followed no matter what the agency's interpretation is.[26] However, if the statute is silent or ambiguous, then the court will, in step two of the test, defer to the agency's interpretation provided that it is "based on a permissible construction of the statute."[27] The District Court rejected the government's claim that the term 'research' in the statute was ambiguous, as it could be read as prohibiting the funding of research involving derivation of hESCs from embryos but not prohibiting the funding of research using established hESCs, and held that the Guidelines violated the DWA.[28]

On appeal, the D.C. Circuit reversed the District Court's decision, vacating the preliminary injunction granted by the lower court.[29] The majority of the D.C. Circuit accepted the government's argument that the term "research" in the DWA was ambiguous. The majority based its finding of ambiguity on the fact that the banned 'research' was defined in the DWA in the present tense as "research <u>in which</u> … embryos <u>are</u> destroyed."[30] The majority held that because Congress could have used a 'past tense' definition of research, such as "research for <u>which</u> … embryos <u>were</u> destroyed" which would have demonstrated an intention that the ban applied to past action and thus to all hESC research, the use of the present tense was ambiguous.[31] In step two of the *Chevron* test, the majority concluded that the NIH's interpretation of the DWA in the Guidelines, that funding of research projects using hESC was permissible because hESCs are not embryos, was reasonable.[32] Support for the reasonableness of the Guidelines included the use of the present tense in the DWA and that Congress had reenacted the DWA year to year, even after the NIH began funding hESC research in 2001.[33] The majority thus concluded that the plaintiffs were not likely to succeed on the merits of the case and therefore were not entitled to an injunction.[34]

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[21] Sherley v. Sebelius ("Sherley II"), 610 F.3d 69, 74-75 (D.C. Cir. 2010), *rev'g* 686 F. Supp. 2d 1 (D.D.C. 2009).
[22] *Id.* at 73-74.
[23] Sherley v. Sebelius ("Sherley III"), 704 F.Supp.2d 63, 72-73 (D.D.C. 2010), *rev'd by* 644 F.3d 388 (D.C. Cir. 2011).
[24] 467 U.S. 837, 843 (1984)
[25] Sherley III at 71.
[26] *Chevron*, 467 U.S. 837, 843
[27] *Id*.
[28] Sherley III at 70-71.
[29] Sherley v. Sebelius ("Sherley IV), 644 F.3d 388, 399 (D.C. Cir. 2011), *rev'g* 704 F.Supp.2d 63, 65 (D.D.C. 2010).
[30] *Id.* at 394.
[31] *Id.*
[32] *Id.*
[33] *Id.* at 395-98.
[34] *Id.*at 399.

The D.C. Circuit's 2011 circuit decision was instrumental in the ultimate disposition of this matter. The majority holding that the DWA was ambiguous and the Guideline's interpretation was reasonable established precedent that the both the District Court and D.C. Circuit itself were unable to vary.[35]

Following the dismissal of the preliminary injunction by the D.C. Circuit, both sides brought opposing motions for summary judgment in district court, these motions were granted in favor of the government.[36] The District Court held that it was bound to the D.C. Circuit's decision that the NIH's interpretation of the destruction of embryos provision in the DWA was entitled to deference.[37] At this juncture, the Plaintiffs also put forward a new argument that the Guidelines violated also both the DWA's prohibition on "research in which a human embryo or embryos are… knowingly subjected to risk of injury or death…". The District Court held that although the D.C. Circuit had not previously ruled on the NIH's interpretation of 'research' and the risk of injury to embryos, that based on analogous reasoning, the definition of research was ambiguous and the NIH's opinion in the Guidelines were reasonable and therefore entitled to deference.[38]

The D.C. Circuit upheld the lower court's decision granting summary judgment for the government, however, even though the panel agreed in the result, the Justices differed in their reasoning and thus the decision was written as three concurring judgments. Chief Justice Sentelle and Justice Henderson held the law-of-the-case doctrine[39] governed the issue of whether Guidelines violated the DWA. As a result, the Court was bound by its previous decision that the NIHs interpretation of the DWA, permitting the funding of hESC research not including derivation, was entitled to deference under a *Chevron* analysis.[40]

Although Justice Henderson agreed with Chief Justice Sentelle that the DWA issue was ultimately determined by the law-of-the-case doctrine, she nonetheless concurred with Justice Brown in finding that the court should not have afforded *Chevron* deference to the NIH's interpretation of the DWA in the first place.[41] An agency is only entitled to *Chevron* deference when it interprets a statue that it is entrusted to administer, Justice Brown further stated that the "NIH was not charged with administering the Amendment, as is obvious from both its language and its substance".[42] Although further guidance is not provided regarding what in the 'language and substance' makes it *obvious* that the NIH was not charged with its administration, this reference to obviousness likely arises from the fact that the DWA applies generally to all "funds made available by Public Law 104-91" and that section 101 of Public Law 104-91 applies to funds for "departments, agencies, corporations and other organizational units of Government…".[43]

Justices Henderson and Brown differed as to their opinions of what the result would have been were *Chevron* deference not applied. Justice Henderson held that because *Chevron* deference did not apply the court should have interpreted the statute de novo; based on a plain meaning of the DWA all hESC research included derivation and therefore the Guidelines permitting the funding of hESC research

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[35] Sherley v. Sebelius ("Sherley V"), 776 F.Supp.2d 1, 15-16 (D.D.C. 2011), *aff'd by* 689 F.3d 776 (D.C. Cir. 2012); Sherley VI at 780.
[36] Sherley V at 24.
[37] *Id.* at 15-16.
[38] *Id.* at 18-21.
[39] Sherley VI at 780 ("The purpose of the law-of-the-case doctrine is to ensure that "the same issue presented a second time in the same case in the same court should lead to the same result").
[40] *Id.* at 9-10; *id.* at 787 (Henderson J, concurring).
[41] *Id.* at 785-6 (Henderson J., concurring); *Id.* at 788 (Brown J., concurring).
[42] *Id.* at 785-6 (Henderson J., concurring).
[43] Pub. L. No. 104-99, § 128 (1996); Pub. L. No. 104-91, § 101 (1996).

violated the DWA.[44] Conversely, Justice Brown found that the standard of review of the de novo review would be that of "clear error." Although Justice Brown questioned the adequacy of the DWA, given the complex issues at state, she nonetheless held that the NIH's interpretation of the DWA was to be upheld based both on the facts in evidence and the fact that the Chevron standard was used for so long in this case, the NIH's interpretation was not clearly in error.[45]

The saga of federal court decisions in the *Sherley v. Sebelius* action highlights both the complexity and controversy surrounding the issues of funding hESC research as well as the difficulty courts face when in determining the deference entitled to administrative agency opinins. Although the most recent decision from the D.C. Circuit permits the continuation of NIH funding for hESC research in accordance with the Guidelines, the fact that the outcome hinged on the 'law of the case' doctrine is concerning. But for a majority of the Justices holding that they were bound to their own Court's 2011 decision granting *Chevron* style deference to the NIH, the disposition of the summary judgment motion in this case would have been different. It remains to be seen how cases involving administrative agencies interpretation of the DWA will be resolved in the future, particularly if they are litigated in other jurisdictions.

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[44] *Id.* at 787 (Henderson J., concurring).
[45] *Id.* at 789 (Brown J., concurring).