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Sherley v. Sebelius: Who Knew the Term "Research" Could Cause Such a Ruckus?

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I. Introduction

From heated controversies to unrivaled praise, stem cell research stimulates much discussion among the scientific and political communities as to its proper place in today's society. However, without federal funding, an overwhelming majority of stem cell research would not be possible. *Sherley v. Sebelius* centers on the plight of two scientists and their efforts to limit distribution of federal funds to research involving only adult stem cells, rather than human embryonic stem cells (ESCs).[1] The court considered whether the National Institutes of Health (NIH) violated the Dickey-Wicker Amendment by funding research projects using ESCs.[2]

The United States Court of Appeals for the District of Columbia vacated the district court's decision to enjoin the NIH from funding research using ESCs.[3] The court concluded that the plaintiffs were unlikely to prevail because the Dickey-Wicker Amendment's usage of "research" was ambiguous and the NIH was reasonable in concluding that the Amendment does not prohibit funding research projects using ESCs.[4] However, as the dissenting judge wrote, the term "research," as used in the Amendment, is not ambiguous.[5] A cursory look at previous case law demonstrates that context is indicative of whether a term's tense applies to the past.[6] Here, because the context clearly indicates applicability to the past tense, the Dickey-Wicker Amendment should bar federal funding for research using ESCs because the process involves the destruction of embryos.[7]

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1. Sherley v. Sebelius (*Sherley II*), 644 F.3d 388, 389-90 (D.C. Cir. 2011).
2. *Id.* at 390.
3. *Id.*
4. *Id.* (arguing that the Dickey-Wicker Amendment's usage of "research" only applied to present research and not past).
5. *Id.* at 400 (Henderson, J., dissenting).
6. *See* Lindh v. Murphy, 521 U.S. 320, 331 (1997); Bell v. Maryland, 378 U.S. 226, 236 (1964); Abercrombie v. Clarke, 920 F.2d 1351, 1359 (7th Cir. 1990); Coalition for Clean Air v. S. Cal. Edison Co., 971 F.2d 219, 225 (9th Cir. 1992); *see also* Guidiville Band of Pomo Indians v. NGV Gaming, Ltd., 531 F.3d 767, 776 (9th Cir. 2008) ("[O]n its own terms the Dictionary Act . . . looks first to 'context,' and only if the 'context' leaves the meaning open to interpretation does the default provision come into play." (quoting Rowland v. Cal. Men's Colony, 506 U.S. 194, 199–200 (1993))).
7. *Sherley II*, 644 F.3d at 400, 403 (Henderson, J., dissenting).

II. Facts of the Case

Plaintiffs Dr. James Sherley and Dr. Theresa Deisher are scientists who conduct research exclusively using adult stem cells.[8] "Adult stem cells can be found in the various tissues and organs of the human body."[9] On the other hand, ESCs are "found only in . . . human embryo[s]."[10] Isolating an ESC requires the removal of its inner cell mass; thereby destroying the embryo.[11] Subsequently, the stem cells harvested from the inner cell mass are placed in a culture, where they continuously divide without differentiation and create a "stem cell line of identical cells."[12] An individual ESC can be separated with minimal risk of disruption to the multiplication process or durability of the line.[13] The removed cell may then be used in further research.[14] Either way, the ESC will be manipulated and developed into a specific type of cell appropriate to the specific research."[15]

In 1996, Congress passed the Dickey-Wicker Amendment, which prohibited the NIH from funding:

(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 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act.[16]

In 1999, the General Counsel of the United States Department of Health and Human Services issued a memorandum concluding that the Dickey-Wicker Amendment "permit[ted] federal funding of research using ESCs . . . because ESCs are not embryos."[17] In 2009, President Obama signed an Executive Order permitting the NIH to support human ESC research, within the

8. *Id.* at 390 (majority opinion).

9. *Id.*; *What Are Adult Stem Cells?*, Nat'l Insts. of Health: Stem Cell Info., http://stemcells.nih.gov/info/basics/basics4.aspx (June 7, 2012).

10. *Sherley II*, 644 F.3d at 390.

11. *Id.*

12. *Id.*

13. *Id*

14. *Id.*

15. *Sherley II*, 644 F.3d at 390.

16. Consolidated Appropriations Act, 2010, Pub. L. No. 111-117, 123 Stat 3034, § 509(a)(2) (2010); *see also* Jack T. Mosher, *Viewpoint: Injunction Junction: Where Stem Cell Research and Politics Collide*, AAMC Rep. (2011), *available at* http://www.aamc.org/newsroom/reporter/170170/viewpoint.html (NIH funds more stem cell research than any other organization—private or public).

17. *Sherley II*, 644 F.3d at 391.

boundaries of the law.[18] The NIH then issued the 2009 Guidelines, which state that "funding of the derivation of stem cells from human embryos is prohibited by . . . the Dickey-Wicker Amendment."[19] In addition, the Guidelines further addressed the Amendment as follows:

> Since 1999, the Department of Health and Human Services (HHS) has consistently interpreted [Dickey-Wicker] as not applicable to research using [ESCs], because [ESCs] are not embryos as defined by Section 509. This longstanding interpretation has been left unchanged by Congress, which has annually reenacted the Dickey[-Wicker] Amendment with full knowledge that HHS has been funding [ESC] research since 2001. These guidelines therefore recognize the distinction, accepted by the Congress, between the derivation of stem cells from an embryo that results in the embryo's destruction, for which Federal funding is prohibited, and research involving [ESCs] that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted.[20]

Following the issuance of the Guidelines, Congress reenacted the Dickey-Wicker Amendment.[21]

III. Description of Plaintiffs' Claim

The plaintiffs filed this lawsuit in the United States District Court for the District of Columbia and moved for a preliminary injunction to prevent the NIH from funding research using ESCs.[22] The plaintiffs argued that the Dickey-Wicker Amendment clearly barred federal funding for projects using ESCs. Since, by definition, ESCs are produced through the destruction of embryos, any subsequent use of the ESCs was research that "result[ed] in an embryo's destruction.[23] Further, the plaintiffs advocated that the court interpret the term "research" broadly because Congress would have undoubtedly been more specific, analogous to subsection (1) of the Dickey-Wicker Amendment, if a narrow reading was intended.[24] Further, the plaintiffs ar-

18. Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

19. *Sherley II*, 644 F.3d at 391 (quoting National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170-02, at 32,175 (July 7, 2009)).

20. *Sherley II*, 644 F.3d at 391 (quoting National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. at 32,173).

21. *Sherley II*, 644 F.3d at 392.

22. *Id.* at 389.

23. *Id.* at 393–94.

24. *Id.* (Subsection (1) specifically "bars the 'creation' of an embryo for research purposes").

gued that the NIH was not entitled to *Chevron*[25] deference because no interpretation of the term "research" was offered.[26] Moreover, the NIH's reading of the Dickey-Wicker Amendment was unreasonable because the NIH interpreted "research" to encompass embryonic cell derivation, which should only be deemed "research" if it is part of a larger project.[27]

IV. Procedural and Substantive History

The Government's motion to dismiss was granted by the district court for want of standing.[28] The plaintiffs appealed, and the United States Court of Appeals for the District of Columbia Circuit ruled that plaintiffs had standing because they compete with ESC researchers for funding.[29] On remand, the district court issued the preliminary injunction sought by the plaintiffs that prohibited defendants from funding research involving ESCs.[30]

V. United States Court of Appeals for the District of Columbia Circuit

The circuit court disagreed with the district court's decision and vacated the preliminary injunction.[31] The court held that the NIH's interpretation of the Dickey-Wicker Amendment was entitled to *Chevron* deference, and that the balance of equities tilted away from granting a preliminary injunction.[32] The plaintiffs were unlikely to succeed due to the ambiguity of the Dickey-Wicker Amendment and the reasonableness of the NIH's determination that funding research project using ESCs was not prohibited.[33]

VI. Court's Rationale

The court began its analysis by looking at the first factor a plaintiff must show in an action for a preliminary injunction—likelihood of success on the

25. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984).

26. *Sherley II*, 644 F.3d at 395.

27. *Id.* (analyzing under *Chevron*).

28. *Id.* at 392.

29. *Id.*

30. *Id.*

31. *Id.* at 390.

32. *Sherley II*, 644 F.3d at 388, 390, 399 ("'A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.'" (quoting Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008))).

33. *Id.* at 390.

merits.[34] The court then approached this issue under the two-step *Chevron* framework.[35] Under the framework, "[i]f . . . Congress has directly spoken to the precise question at issue, then [a court] must give effect to the unambiguous expressed intent of Congress."[36] If the "statute is silent or ambiguous with respect to the issue, then [a court] must defer to the administering agency's interpretation as long as it reflects a permissible construction of the statute."[37]

Under the first step of its *Chevron* analysis, the court agreed that the text of the Dickey-Wicker Amendment was not an "unambiguous ban on research using [ESCs]" because it was present tense and addressed research where embryos "are" destroyed; not research where embryos "were" destroyed.[38] The court reasoned that "[t]he use of the present tense in a statute strongly suggests it does not extend to past actions."[39] As evidence, the court looked to the Dictionary Act; it provided that "unless the context indicates otherwise . . . words used in the present tense include the future, as well as the present."[40] The court also gave great weight to the Supreme Court's interpretation to mean "the present tense generally does not include the past."[41] Because there was no indication of a different interpretation of "research," and because "the definition of research is flexible enough to describe either a discrete project or an extended process," the court found the text of the Dickey-Wicker Amendment to be ambiguous.[42]

Under the second step of *Chevron*, the NIH's interpretation of the Dickey-Wicker Amendment was found to be reasonable.[43] Contrary to the plaintiffs' argument, the court found that the NIH made clear that "research involving ESCs does not necessarily include the antecedent process of deriving the cells" because the NIH's Guidelines distinguished the derivation of ESCs from "research involving ESCs that does not involve an embryo nor result in an embryo's destruction."[44] While the Government admitted that

34. *Id.* at 393.

35. *Id.* (citing *Chevron*, 467 U.S. at 842–43).

36. *Id.*

37. *Id.*

38. *Sherley II*, 644 F.3d. at 393–94.

39. *Id.* at 394.

40. *Id.* (quoting 1 U.S.C. § 1).

41. *Id.* (quoting Carr v. United States, 130 S. Ct. 2229, 2236 (2010)).

42. *Id.*

43. *Id.*

44. *Sherley II*, 644 F.3d at 395 (quoting National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. at 32,173).

"derivation is research," the court debated "whether the act of derivation, by itself, comes within a standard definition of research."[45]

Because the statute was imprecisely worded, the court broadened its focus.[46] It concluded that Congress "wrote with particularity" and the statute uses the present tense "in which" and "are," as opposed to the past tense "for which" and "were"; therefore, it was entirely reasonable for the NIH to understand the amendment as permitting funding for ESC research.[47] Further supporting the reasonableness of the NIH's interpretation, Congress "has reenacted Dickey-Wicker unchanged year after year with full knowledge that HHS has been funding [ESC] research since 2001."[48]

The plaintiffs then presented their challenges to the validity of the Guidelines; however, these were quickly dismissed because the plaintiffs could not establish that there were no "circumstances exist[ing] under which the Guidelines would be valid."[49] The plaintiffs then argued that the Guidelines "transgress the prohibition in Dickey-Wicker against research in which a human embryo or embryos are . . . knowingly subjected to risk of injury or death."[50] The court found no merit in the plaintiffs' argument because it relied on the idea that ESC research "creat[es] demand for human embryonic stem cells, which *necessitate[s]* the destruction of embryos."[51] Furthermore, because the district court did not address this theory, the D.C. Circuit chose to ignore such arguments.[52]

The court then attempted to "balance the equities" and determine whether the three other factors for granting a preliminary injunction "favor the plaintiffs [so much] that they need only have raised a 'serious legal question' on the merits."[53] The court reasoned that the plaintiffs, at a minimum, "raised a 'serious legal [challenge]' on the merits."[54] However, the court was not satisfied that plaintiffs "compete with ESC researchers for funding," and

45. *Id.* at 396 (internal quotation marks omitted). The plaintiffs argue that "because the standard definition of 'research' requires some kind of scientific inquiry, and deriving ESCs, standing alone, involves no such inquiry, then the act of derivation can be deemed 'research' only if it is part of a larger project." *Id.* at 395.

46. *Id.* at 396.

47. *Id.*

48. *Id.* (quoting National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. at 32,173).

49. *Sherley II*, 644 F.3d at 397 (quoting Reno v. Flores, 507 U.S. 292, 301 (1993)).

50. *Id.*

51. *Id.*

52. *Id.* at 398.

53. *Id.*; *see also* Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C. Cir. 1977).

54. *Sherley II*, 644 F.3d at 398.

held that the plaintiffs failed to prove they would prevail on the merits of the case.[55] The court mentioned that the plaintiffs have been competing for funding since 2001 and "it is necessarily uncertain whether invalidating the Guidelines would result in the plaintiffs getting any more grant money from the NIH."[56]

Instead, the court found that the hardship placed on ESC researchers would be "certain and substantial."[57] An injunction would preclude the NIH from funding worthy ESC projects and "bar further disbursements to ESC researchers who have already begun multi-year projects in reliance upon a grant from the NIH."[58] As a result, the court decided that it did not need to evaluate the other two factors because the balancing of irreparable harm did not tip in the favor of the plaintiffs.[59]

VII. Critique

While the majority opinion makes a few good points, I strongly side with the dissenting opinion in this case and firmly believe the plaintiffs would be able to succeed on the merits.[60] The majority obliviously butchered the laws of statutory construction.[61] As Judge Henderson points out, the majority opinion "produced a result that would make Rube Goldberg tip his hat" and essentially accomplished "linguistic jujitsu," so as to shape an interpretation the majority thought best.[62] And in this instance, the majority thought it best to manipulate the term "research" in such a way to justify their decision instead of tailoring a decision in congruence with their findings.

First, evaluating whether ESC research is "research in which a human embryo or embryos are destroyed," begins by "determining the meaning of research."[63] The dictionary defines "research" as "'diligent and systemic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc."[64] Thus, research includes "systematic inquiry or investigation."[65] Further, "systematic" is another word for sequenced ac-

55. *Id.* at 398–99 (holding that the balancing of equities did not tilt in the plaintiffs' favor).

56. *Id.* at 398.

57. *Id.*

58. *Id.* at 398–99.

59. *Id.* at 399.

60. *See Sherley II*, 644 F.3d at 399–406 (Henderson, J., dissenting).

61. *See id.* at 399 (citing majority opinion at 391, 396).

62. *Id.*

63. *Id.* at 400.

64. Sherley v. Sebelius (*Sherley I*), 704 F. Supp. 2d 63, 70 (D.C. Cir. 2010)).

65. *Id.*

tion.[66] As a result, "[t]he first sequence of ESC research is the derivation of stem cells from the human embryo. . . .[which] destroys the embryo and therefore cannot be federally funded."[67] Similarly, as advocated by Judge Henderson, the succeeding steps of ESC research should be "banned by the [Dickey-Wicker] Amendment because . . . they continue the systematic inquiry or investigation."[68]

Moreover, one must assume that Congress considered ESC research when it enacted the Dickey-Wicker Amendment in 1996.[69] Although the amendment prohibits federal funding for the "creation of a human embryo . . . for research purposes," it does not use similar language with respect to the destruction of embryos.[70] Thus, research must be the explicit "target of the ban Congress imposed [on] the destruction of a human embryo."[71] As a result, analysis should stop at the first step under *Chevron* "[b]ecause the meaning of research is plain, and the intent of the Congress to ban the federal funding of ESC research is equally plain."[72]

However, in the event uncertainty exists regarding the extent of the Dickey-Wicker Amendment's ban, Judge Henderson notes that it could be remedied by reading the Dickey-Wicker Amendment in full.[73] Such a reading reveals that Congress unambiguously intended that the term "research" is to have same meaning as "research" found in Section 46.204(b).[74] Research, in that context, means "a *systematic investigation, including research development*, testing, and evaluation, designed to develop and contribute to generalizable knowledge."[75] Further, if the same term is used throughout a statute, it is presumed to have the same meaning; which is exactly the situation here.[76]

The government's interpretation of the Dickey-Wicker Amendment to be present- and future-looking, rather than past-looking, is in contrast with the context of the amendment.[77] The context necessitates that "research" not

66. *Sherley II*, 644 F.3d at 401 (citation omitted).

67. *Id.* at 400.

68. *Id.* at 401.

69. *Id.*

70. *Id.* (internal quotation marks omitted).

71. *Id.*

72. *Sherley II*, 644 F.3d at 401.

73. *Id.* ("[R]esearch 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 C.F.R. 46.204(b) and section 498(b) of the Public Health Service Act" is not permitted.).

74. *Id.* at 402.

75. *Id.* at 401–02 (quoting 45 C.F.R. § 46.102(d)).

76. *Id.* (citing Brown v. Gardner, 513 U.S. 115, 118).

77. *Id.* at 403–04.

be treated as "free-standing pieces," with only one piece being banned while the other pieces remained undisturbed.[78] This technical twisting reinforces the notion that the majority was performing linguistic acrobatics in order to catch a glimpse of justification for their decision.

In addition, the majority was wrong to downplay the irreparable harm the plaintiffs have suffered; NIH funding is highly competitive, and provides the largest amount of funding for stem cell research.[79] It is of no consequence that a disruption may occur in ongoing ESC research projects that have been funded or will receive funding in the future.[80] As the dissent adequately describes, two scientists should have been successful, because they made an incredibly "strong showing of likelihood of success on the merits."[81]

VIII. Conclusion

In summary, the United States Court of Appeals for the District of Columbia Circuit's holding in *Sherley* halted the scientists' efforts to simply enforce the long standing Dickey-Wicker Amendment and ban funding for (essentially) the destruction of human embryos. The majority's decision creates a slippery slope, not only for statutory interpretation, but also for other issues, including abortion. Determining where to draw the proverbial line in the sand has been a staple in the United States' legal history. Sadly, the line in *Sherley* was drawn in the wrong location.

78. *Sherley II*, 644 F.3d at 403–04.

79. *Id.* at 405; Mosher, *supra* note 18.

80. *Sherley II*, 644 F.3d at 405.

81. *Id.* at 406 ("If the movant makes an usually strong showing on one of the factors, then it does not necessarily have to make a strong a showing on another factor." (internal quotation marks omitted)).