

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

JAMES L. SHERLEY et al.,

Plaintiffs,

v.

KATHLEEN SEBELIUS, in her official  
capacity as Secretary of the Department of  
Health and Human Services, et al.,

Defendants.

No. 09-cv-1575 (RCL)

**Memorandum of the Genetics Policy Institute  
as Amicus Curiae in Opposition  
to the Plaintiffs' Motion for Summary Judgment**

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## Contents

Table of Authorities.....	ii
Interest of Amicus.....	1
Introduction.....	1
Argument .....	2
I. The word <i>research</i> can be understood to refer to pieces of research rather than to research in general. ....	2
A. As used in the definition advanced by the government, “piece of research” means RESEARCH PROJECT, not A PHASE OR PIECE OF A RESEARCH PROJECT. ....	3
B. The Dickey-Wicker Amendment can reasonably be read to incorporate the RESEARCH PROJECT interpretation. ....	6
1. The definition in 45 C.F.R. § 46.102(d) is not controlling, and in any event it is not inconsistent with RESEARCH PROJECT interpretation. ....	7
2. Disregarding the definition advanced by the government cannot be justified by the fact that some dictionaries do not list it. ....	9
3. Accepting the RESEARCH PROJECT interpretation would not entail that funding is prohibited only for the specific acts that cause destruction of an embryo.....	11
C. The word research is inherently ambiguous. ....	12
II. The NIH guidelines do not contemplate funding research “in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death[.]” .....	15
A. The government’s conceptualization results in an interpretation that gives the Dickey-Wicker Amendment’s language its natural and ordinary meaning.....	16
B. The interpretation in the Court’s preliminary-injunction decision is inconsistent with the Dickey-Wicker Amendment’s use of the present tense. ....	19
C. The NIH guidelines do not violate the prohibition against funding research in which embryos are subjected to risk of injury or death greater than allowed for research on fetuses in utero. ....	21
III. If funding is allowed for research on existing stem cell lines, as suggested by the order denying a stay pending appeal, the NIH guidelines do not facially violate the Dickey-Wicker Amendment.....	24
Conclusion .....	27

## Table of Authorities

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<i>Carr v. United States</i> , 130 S. Ct. 2229 (2010) .....	19, 20, 21
<i>Jama v. Immigration &amp; Customs Enforcement</i> , 543 U.S. 335 (2005) .....	7–8
<i>Omni Capital Int’l, Ltd. v. Rudolf Wolff &amp; Co.</i> , 484 U.S. 97 (1987).....	8

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18 U.S.C. § 2550.....	20
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42 U.S.C. 289g(b) .....	22
45 C.F.R. § 46.102 .....	7
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45 C.F.R. §46.204(b).....	7, 22, 23

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## **Interest of Amicus**

The Genetics Policy Institute, Inc. is a not-for-profit corporation devoted to promoting and defending stem-cell research (including hESC research) and other cutting-edge medical research. The Institute's activities include co-sponsoring the World Stem Cell Summit, an annual conference that brings together researchers, industry leaders, policymakers, advocates, patients, and others; publishing the *World Stem Cell Report*, an annual collection of articles dealing with a wide range of issues relating to stem-cell research; promoting education about stem-cell research; and engaging in other public-outreach activities.

## **Introduction**

This memorandum will focus on the textual issues raised by the claim that hESC funding is prohibited by the Dickey-Wicker Amendment. We will show that, contrary to the plaintiff's contention and the Court's conclusion in its preliminary-injunction hearing, Dickey-Wicker does not unambiguously mean what the plaintiffs say it does. On the contrary, to the extent that the Amendment's meaning is plain, its meaning is that funding of hESC research is permitted.

We show that as used in the Dickey-Wicker Amendment, the word *research* can in fact be interpreted in accordance with the "piece of research" definition advanced by the government. However, the plaintiffs' characterization of that definition is misleading. The definition does not say that *research* can mean "a piece of research"; it says it can mean "a particular *instance or piece* of research." Thus, the meaning described by this definition is not PHASE OR PORTION OF A RESEARCH PROJECT, as the plaintiffs contend, but simply RESEARCH PROJECT. When *research* is used in this sense, a research project is a piece of research in the same way that a song is a piece of music and a statute is a piece of sculpture. This is a very different meaning than the one at which the plaintiffs have been directing their arguments.

In addition, we will show that the Dickey-Wicker Amendment can reasonably be interpreted in such a way that it does not invalidate the NIH guidelines. Indeed, that represents the more natural interpretation. But at a minimum, Dickey-Wicker does not unambiguously prohibit NIH from funding hESC research. That being so, the government's interpretation is entitled to deference and the plaintiffs' claim under Dickey-Wicker must be rejected.

Finally, we will show that under an interpretation under which the Bush-era policy was permissible under Dickey-Wicker, research on virtually all currently-existing cell lines may lawfully be funded.

### **Argument**

#### **I. The word *research* can be understood to refer to pieces of research rather than to research in general.**

The government argues that “the term ‘research,’ standing alone, may be defined as a ‘piece of research,’ meaning that ‘research can be segmented into discrete parts.’”<sup>1</sup> But in granting a preliminary injunction, the Court rejected this reading and held that the statutory language had only one possible meaning—a meaning that the Court went on to rely on in holding that NIH funding of hESC research is prohibited by the Dickey-Wicker Amendment. We would respectfully submit that the Court was mistaken.

*First*, the Court's conclusion seems to have been based on a mistaken understanding of what the government's definition means. The Court apparently interpreted “piece of research” to mean something like PHASE OR PIECE OF A RESEARCH PROJECT. But in fact a “piece of research” in the sense given in the government's definition is the whole of a particular research project. This significantly affects the analysis, because it makes clear that accepting this interpretation would

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1. DE 23 at 31.

not entail that the only thing prohibited by the Dickey-Wicker Amendment is the specific act that causes the destruction of an embryo.

*Second*, the Dickey-Wicker Amendment can reasonably be interpreted as using the word *research* in the sense described by the government's definition. Contrary to what the plaintiffs contend, the definition in 45 C.F.R. § 45.102(d) is not incorporated in the Dickey-Wicker Amendment and therefore is not controlling. And in any event that definition is not inconsistent with the definition advanced by the government.

Furthermore, there was no valid basis for rejecting the government's definition. The fact that the plaintiffs' preferred definition may be more common is meaningless. It is not at all uncommon for dictionaries not to list all meanings of a word, so no conclusion can be drawn from the failure to include a given definition, other than that those who wrote the dictionary made an editorial decision.

*Third*, the word *research* is inherently and unavoidably ambiguous. The ambiguity arises because the activity that it denotes can be conceptualized in indefinitely many different ways, depending on where one focuses along the continuum between the generic and the specific and the one between the broad and the narrow. In this case, the government conceptualizes the research activity that Dickey-Wicker refers to in one way and the plaintiffs conceptualize it in a different way. And that difference in conceptualizations is what drives the different conclusions that the respective parties argue for. As a result, the meaning of *research* is anything but plain.

***A. As used in the definition advanced by the government, "piece of research" means RESEARCH PROJECT, not A PHASE OR PIECE OF A RESEARCH PROJECT.***

1. The first step in deciding whether the definition advanced by the government is pertinent here is to be clear on what the definition actually means. The plaintiffs assume that it means something like PHASE OR PIECE OF A RESEARCH PROJECT. Thus, they argue that the Dickey-

Wicker Amendment “necessarily encompasses all of the research project at issue, not merely a selected ‘phase’ or ‘piece of the research.’”<sup>2</sup> But that understanding is demonstrably wrong. A “piece of research” in the sense given in the definition that the government relies on is the whole of a particular research project.

This is clear from the definition itself, which defines *research* not simply as “a particular piece of research.” but as “a particular *instance* or piece of research.”<sup>3</sup> An instance of something is not a portion of that thing but an example of it. Thus, the dictionary cited by the government gives as the first definition of *instance*, “a case or occurrence of anything[.]”<sup>4</sup> Similarly, the first definition in *The New Oxford American Dictionary* is “an example or single occurrence of something[.]”<sup>5</sup> So when the definition is read as a whole, the word *piece* in the phrase *piece of research* is used in the sense of “an example, specimen, or instance of something” or “an individual thing of a particular class or kind,” not in the sense of “a separate or limited portion or quantity of something[.]”<sup>6</sup>

The INSTANCE OF RESEARCH sense of the word *research* is also given in *Webster’s Third New International Dictionary*:

2a: a studious investigation or examination...b (1): *a particular investigation of such a character: a piece of research[.]*<sup>7</sup>

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2. Memo in Sup. of Pltfs.’ Mtn. for Sum. J. 16 (DE 55).
  3. *Id.* The government cited to an internet source for this definition; the definition can be found in RANDOM HOUSE WEBSTER’S UNABRIDGED DICTIONARY 1637 (2d ed. 1997) (emphasis added) (hereinafter, “RANDOM HOUSE UNABRIDGED DICTIONARY”).
  4. RANDOM HOUSE UNABRIDGED DICTIONARY 988.
  5. THE NEW OXFORD AMERICAN DICTIONARY 873 (2d ed. 2005)
  6. RANDOM HOUSE UNABRIDGED DICTIONARY 1466 (definitions of *piece*). *See also, e.g.*, THE NEW OXFORD AMERICAN DICTIONARY 1285 (“an item of a particular type”; “an instance or example”).
  7. WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1930 (2002) (emphasis added).

This definition is essentially the same as the one advanced by the government, the main difference being that this one uses the phrase “a particular investigation of such a character” instead of “a particular instance...of research,” which means pretty much the same thing. Moreover, *Webster’s Third* provides a definition of the noun *project* that underlines our point here: “a planned undertaking: as a: a definitely formulated *piece of research*.”<sup>8</sup>

Our point here is confirmed by looking at how the phrase is used in the real world. Several instances are set out in examples (1)–(4), immediately below.

- (1) “One of the most important jobs in planning a piece of research is to list and schedule all the tasks that are going to have to be undertaken.”<sup>9</sup>
- (2) “The preceding discussion has revealed the complexity of planning a piece of research, yet it should not be assumed that research will always go according to plan!”<sup>10</sup>
- (3) “The research design is the basic plan for a piece of research, and includes four main ideas.”<sup>11</sup>
- (4) “In a revealing new piece of research, Jeffrey Fagan of Columbia University and Tom Tyler of New York University set out to find answers to two basic questions.”<sup>12</sup>

What we have said so far shows that the sense that is intended to be conveyed by the definition cited by the government can be described in a variety of different ways. Some of these ways are listed in (5):

- (5) a. a particular piece of research  
b. a particular instance of research  
c. a particular example of research

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8. *Id.* at 1813.

9. Graham Birley & Neil Moreland, *A PRACTICAL GUIDE TO ACADEMIC RESEARCH* 6 (1998).

10. Louis Cohen, Lawrence Manion & Keith R. B. Morrison, *RESEARCH METHODS IN EDUCATION* 88 (2000).

11. Keith Punch, *INTRODUCTION TO SOCIAL RESEARCH: QUANTITATIVE AND QUALITATIVE APPROACHES* 63 (2005).

12. David A. Harris, *How Accountability-Based Policing Can Reinforce—or Replace—the Fourth Amendment Exclusionary Rule*, 7 *Ohio State J. Crim. L.* 149, 162 (2009).

- d. a particular occurrence of research
- e. a particular studios investigation or examination
- f. a research project

What is important, however, is not the precise wording of the descriptions, but the fact is that the plaintiffs have put a “spin” on the government’s interpretation that is highly misleading. In an effort to counteract that spin, we will refer to the interpretation advocated by the government, not as the PIECE OF RESEARCH interpretation, but as “the RESEARCH PROJECT interpretation.”<sup>13</sup>

***B. The Dickey-Wicker Amendment can reasonably be read to incorporate the RESEARCH PROJECT interpretation.***

The RESEARCH PROJECT interpretation of the word *research* represents a perfectly ordinary meaning of the word. This is clear from how the word is actually used, as shown by the examples of the word being used in this sense in (6)–(8).

- (6) [*From the complaint:*]  
“Dr. Sherley has received funding from NIH for research aimed at developing new methods for identification and production of human adult stem cells that have the potential for human cell therapy.”<sup>14</sup>
- (7) “Haidt has conducted research in which liberals and conservatives were asked to project themselves into the minds of their opponents and answer questions about their moral reasoning.”<sup>15</sup>
- (8) “Dan Ariely of Duke University in Durham, North Carolina, accepts the [IgNobel] Medicine Prize for research showing that expensive fake medicine works better than cheap fake medicine.”<sup>16</sup>

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13. However, we want to caution about taking this label too literally. The use of the word that we are describing with this label is not limited to instances in which the word refers to a single research project. It can also be used to refer to a particular body of research, which can comprise a number of different projects. For example, the phrase *Dr. Sherley’s research* is understood to refer to the overall body of research whose components are individual research projects. That usage is similar to the use of *research* to refer to a single research project, because in both cases, the word is used to denote some specific chunk of research as distinguished from research in general.

14. Compl. ¶ 6 [DE 1].

15. Judith Warner, *No Laughing Matter*, Opinionator Blog, New York Times Online, <http://opinionator.blogs.nytimes.com/2008/09/11/no-laughing-matter/> (Sept. 11, 2008).

One must therefore start from the position that the Dickey-Wicker Amendment can reasonably be understood as using the word in this way. A number of arguments against that position have been made in this case, but they are unpersuasive.

1. *The definition in 45 C.F.R. § 46.102(d) is not controlling, and in any event it is not inconsistent with RESEARCH PROJECT interpretation.*

The plaintiffs argue that the meaning of the word *research* as used in the Dickey-Wicker Amendment is controlled by the definition of that word in 45 C.F.R. § 46.102(d): “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” But that definition is not controlling here, and even if it were, it is fully compatible with the RESEARCH PROJECT interpretation.

a. Contrary to what the plaintiffs contend, the Dickey-Wicker Amendment does not incorporate the definition in 45 C.F.R. § 46.102(d); indeed, that regulation is not even mentioned.

In contrast, the Amendment does refer to a *different* regulation:

None of the funds made available in this Act may be used for... research in which a human embryo or embryos are... 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)).<sup>17</sup>

This express reference to § 46.204 shows (if any demonstration is needed) that Congress knows how to incorporate specific regulations into a statute when it wishes to do so. Congress’s failure to similarly refer to § 46.102 in the Dickey-Wicker Amendment therefore means that the statute does not incorporate the latter section. As the Supreme Court has said, “We do not lightly assume

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16. Steve Nadis, *An Ig Nobel diary: Nature reports from the awards that celebrate the silliest science around*, Nature News, <http://www.nature.com/news/2008/081003/full/news.2008.1150.html> (Oct. 3, 2008) (footnote omitted).

17. Consolidated Appropriations Act, 2010, § 509, Pub. L. No. 111-117, 123 Stat 3034, 3280–81 (2009) (paragraph breaks omitted). This citation is to the iteration of the Dickey-Wicker Amendment currently in effect, which was enacted after the Court’s initial decision dismissing the complaint for lack of standing.

that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.”<sup>18</sup>

In saying this, we do not intend to suggest that the definition in § 46.102 must be disregarded in interpreting the Dickey-Wicker Amendment. Rather, our point is that this regulatory definition is merely one piece of evidence and is therefore not entitled to decisive weight.

**b.** Even if the Dickey-Wicker Amendment incorporated the definition in § 46.102, that would not preclude the Amendment from being understood according to the RESEARCH PROJECT interpretation. The two definitions are entirely consistent with one another, in that a particular research project can satisfy all the elements spelled out in § 46.102(d). Indeed, NIH presumably does not fund proposed projects that would not constitute a systematic investigation designed to develop or contribute to generalizable knowledge.

Furthermore, the most natural reading of § 46.102(d) is one that is consistent with the RESEARCH PROJECT interpretation. The definition in § 46.102(d) begins with the noun phrase *a systematic investigation*, which is similar to the language of the definition in *Webster’s Third* that gives the RESEARCH PROJECT sense of the word:

2a: a studious investigation or examination...b (1): *a particular investigation of such a character: a piece of research[.]*<sup>19</sup>

This similarity is not surprising, since an investigation is merely a particular kind of project.

Although the plaintiffs have asserted that the PIECE OF RESEARCH interpretation is inconsistent with the definition in § 46.102(d), they have never backed that claim up with any

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18. *Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005). See also, e.g., *Omni Capital Int’l, Ltd. v. Rudolf Wolff & Co.*, 484 U.S. 97, 106 (1987); *American Forest & Paper Ass’n v. FERC*, 550 F.3d 1179, 1181 (D.C. Cir. 2008).

19. WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY 1930 (2002) (emphasis added).

reasoned explanation. The discussion here shows that no such explanation is possible, because the plaintiffs' assertion is simply wrong.<sup>20</sup>

2. *Disregarding the definition advanced by the government cannot be justified by the fact that some dictionaries do not list it.*

In rejecting the government's argument about the meaning of RESEARCH, the Court said that "the term 'research' as used in the Dickey-Wicker amendment has only one meaning[.]"<sup>21</sup> in the Court's view that meaning was the meaning set out in 45 C.F.R. § 46.102(d), which the Court said was "the most common definition."<sup>22</sup> But even if the Court is correct on that point (the decision cites no supporting evidence), the fact that one definition is more common than another provides no basis for rejecting the less common one.

The decision whether to include a particular sense of a word in a dictionary is governed by many factors unrelated to the question of how the word can actually be used. These include the length of the dictionary (which governs the amount of space available for each entry) and

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20. Our conclusion here is not changed by the fact that § 46.102 defines *research* to include "research development." That phrase is most naturally interpreted to refer to the process of planning a particular research project, and it is reasonable to conclude that it does not refer to the creation of the materials that will be used in carrying out the project. Even if a contrary interpretation is possible, the availability of more than one interpretation plausible interpretation would render the definition ambiguous.

21. Mem. Op. at 10 ( DE 44), 2010 WL 3296974 at \*6.

22. Mem. Op. at 10 (DE 44), 2010 WL 3296974 at \*6. It is not clear whether the Court agreed with the plaintiffs' argument that the definition in § 46.102 is incorporated in the Dickey-Wicker Amendment. One hint that the Court might not have reached that conclusion is that the Court also quoted the first definition of *research* in the *Random House Dictionary*: "diligent and systematic inquiry or investigation into a subject in order to discover or revise facts, theories, applications, etc." That definition would have been irrelevant if the Court had regarded the definition in § 46.102(d) as legally binding.

Note that while the Random House definition is certainly similar to the definition in § 46.102, it is not identical. (For example, the Random House definition does not incorporate or refer to the concept of **generalizable** knowledge.) The question therefore arises as to how to square the conclusion that *research* has only one meaning with the fact that the two definitions are different. The solution, we would suggest, is to recognize that dictionary definitions are imperfect and that they should not be relied on to the exclusion of other sources of evidence about what words mean and how they are used.

lexicographic judgment calls such as whether to lump senses together or split them into separate entries.<sup>23</sup> Thus, dictionaries do not attempt to include every possible way in which a word can be used.<sup>24</sup> For example, most dictionaries have no entry indicating that *research* can be used to refer to the results or findings of a particular piece of research. But as is shown by examples (9) and (10), below, that is a perfectly ordinary and acceptable use of the word:

- (9) “To ensure permanence and high visibility, research published in *Stem Cell Research & Therapy* will also be deposited in several international bibliographic databases.”<sup>25</sup>
- (10) “In research published in the April 30th edition of *Cell*, a team of Whitehead Institute researchers describes a pausing step in the transcription process that serves to regulate expression of as many as 80% of the genes in mammalian cells.”<sup>26</sup>

The phenomenon of dictionaries not including well-established meanings is not unusual. A particularly relevant example concerns the fact that word denoting a particular type of food or beverage can be used (especially in the context of ordering in a restaurant) to mean A SERVING OF [THE FOOD OR BEVERAGE]:

- (11) I’d like two beers.
- (12) We’ll have a club soda, one tea, and two chocolate milks.
- (13) [Waitress to cook:] Ordering! Two oatmeals, a grits, three chocolate cakes, and an apple pie.

While this use may be listed in a dictionary for some words (e.g., *beer*), for many others it typically is not (e.g., *tea*, *milk*, *soda*, *seltzer*, *lemonade*, *oatmeal*, *grits*). This example is pertinent

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23. See, e.g., Henri Béjoint, *THE LEXICOGRAPHY OF ENGLISH* 293–96 (2010).

24. *Id.* at 298–300; B.T. Sue Atkins & Michael Rundell, *THE OXFORD HANDBOOK OF PRACTICAL LEXICOGRAPHY* 430 (2008).

25. Ann Donnelly et al., *Welcome to Stem Cell Research & Therapy*, 1 *STEM CELL RESEARCH & THERAPY* 1 (March 15, 2010), available at <http://stemcellres.com/content/1/1/1>.

26. Whitehead Institute for Biomedical Research, *Embryonic stem cells reveal oncogene’s secret growth formula*, [http://www.wi.mit.edu/news/archives/2010/ry\\_0429.html](http://www.wi.mit.edu/news/archives/2010/ry_0429.html) (April 29, 2010).

here because the semantic relationship between BEVERAGE and SERVING OF BEVERAGE is the same as that between RESEARCH and PIECE OF RESEARCH: each of these pairs represents an instance of the more general semantic relationship between STUFF and UNIT OF STUFF.<sup>27</sup> So the fact that some dictionaries do not include “a piece of research” as a definition for *research* has no more significance than the fact that they don’t include “a cup of tea” as a definition for *tea* or “a piece of pie” as a definition for *pie*.

3. *Accepting the RESEARCH PROJECT interpretation would not entail that funding is prohibited only for the specific acts that cause destruction of an embryo.*

In its decision granting a preliminary injunction, the Court apparently acted on the assumption that accepting the definition advanced by the government would lead to the conclusion that under the Dickey-Wicker Amendment, funding is prohibited for “only those discrete acts that result in the destruction of an embryo[.]”<sup>28</sup> That assumption was mistaken; the government has never suggested (nor do we) that the Dickey-Wicker Amendment prohibits funding only of the specific acts resulting in the destruction or discarding of an embryo. For an example, if a grant proposal included the derivation of hES cells as one of the steps for which funding was sought, the **entire** proposal would be ineligible for funding.

Thus, everyone agrees that NIH is not only prohibited from funding the act of destroying or discarding embryos, but also from funding any research project in which embryos are destroyed or discarded. The disagreement is about what it means to say that destroying or discarding embryos occurs “in” the research funded by NIH.

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27. *See generally, e.g.*, Rodney Huddleston & Geoffrey K. Pullum, THE CAMBRIDGE GRAMMAR OF THE ENGLISH LANGUAGE 334–40 (2002).

28. Mem. Op. at 11 (DE 44); 2010 WL 3296974 at \*6.

As a result, it is entirely beside the point that Congress could, if had wanted, have drafted the Dickey-Wicker Amendment to apply only to the specific act of destroying an embryo. More to the point is the fact that if Congress had wanted to prohibit federal funding of human embryonic stem-cell research, it could have used language far more explicit than that of the Dickey-Wicker Amendment—for example, the alternatives in (14):

- (14) None of the funds made available in this Act may be used...
- ...for research involving human embryonic stem cells.
  - ...for research dependent on the destruction of a human embryo or embryos.
  - ...for research that creates an incentive for the destruction of human embryos.

If Congress had used any of these formulations, the dispute in this case could not have arisen

**C. *The word research is inherently ambiguous.***

The discussion so far has shown that the word *research* is ambiguous between a generic sense and a sense that can be used to refer to a particular research project. That ambiguity is just one aspect of a broader ambiguity that is inherent in what the word means.

The ambiguity arises because the activity denoted by the word *research* is not something that has a definite size or shape. Rather, the word can be used to denote research activity that is viewed in broad generic terms, or to denote research activity that is viewed narrowly and with great specificity, or to denote research activity anywhere between those extremes. For example, consider the examples in (15), in which research activity is conceptualized in a range of different ways, starting with a very broad conceptualization and ending with a very narrow one.

- (15) a. scientific research  
b. biological research  
c. cell-biology research  
d. stem-cell research (of all kinds)  
e. human embryonic stem-cell research  
f. human embryonic stem-cell research in Massachusetts  
g. human embryonic stem-cell research at Harvard

- h. human embryonic stem-cell research in a particular lab at Harvard
- i. human embryonic stem-cell research in a particular lab at Harvard for which NIH provides funding

It is the ability to construe the concept RESEARCH at different levels of generality that makes the word *research* ambiguous, and therefore makes it possible to interpret the Dickey-Wicker Amendment in different ways. This ambiguity is reflected in the parties' conflicting interpretations. The government zooms in and focuses on the level of individual projects for which funding is sought. Those projects—the “research” at issue—do not seek funding for the derivation of embryonic stem cells, so the research is conceptualized as being separate from the derivation. This is shown visually in Figure 1 on the next page.

The plaintiffs, on the other hand, focus on the field of stem-cell research as a whole, which they conceptualize as including the derivation of embryonic stem cells: “Dickey-Wicker unambiguously prohibits the federal funding of research—such as embryonic stem cell research—that requires and induces the destruction of human embryos.”<sup>29</sup> This interpretation (depicted in Figure 2) was adopted by the Court in its preliminary-injunction decision:

ESC research is clearly research in which an embryo is destroyed. To conduct ESC research, ESC's must be derived from an embryo. The process of deriving ESCs from an embryo results in the destruction of the embryo. Thus, ESC research necessarily depends on the destruction of a human embryo.<sup>30</sup>

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29. Mem. in Sup. of Pltfs.' Mtn. for Sum. J. 14 (DE 55).

30. Mem. Op. at 12 (DE 44), 2010 WL 3296974 at \*7. In addition to viewing the field of embryonic stem-cell research as a whole, this interpretation seems to view that field generically, from what could be described as a “timeless” perspective that lumped together past, present, and future. In passage quoted in the text, the Court ascribes to hESC research the property of depending on the derivation of embryonic stem cells and therefore on the destruction of embryos. The Court presumably viewed that property not only as a property that exists in the present but also that one existed in the past and that will continue to exist in the future.

However, the decision denying the government's motion for a stay seemed to take a different approach—an approach that would allow NIH funding of research on “existing stem cell lines.” (Order denying motion for stay at 1 [DE 53].) In this section of the memorandum, we deal only with the “timeless” interpretation reflected in the preliminary-injunction decision. The different approach reflected in the order denying a stay will be addressed in a subsequent section.

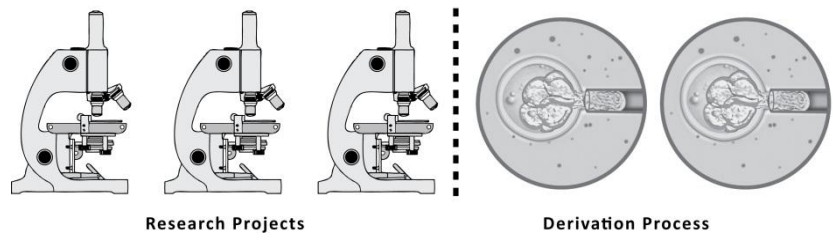


Figure 1

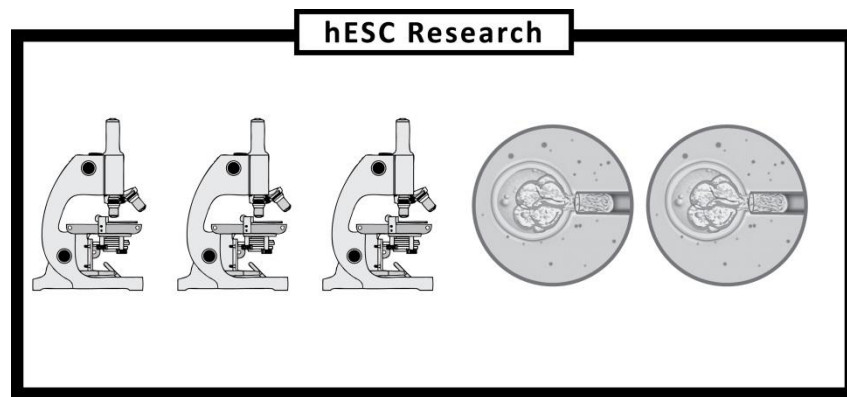


Figure 2

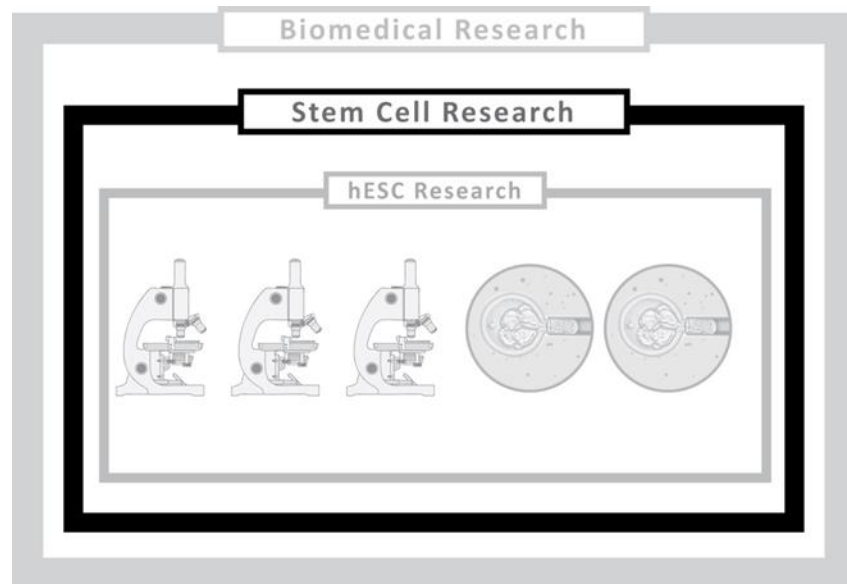


Figure 3

However, these are not the only possible interpretations. As previously discussed, *research* can be conceptualized even more broadly than in the plaintiffs’ interpretation. For example, it can be conceptualized as stem-cell research generally, which includes research on adult stem cells and induced-pluripotent stem cells. It can also be conceptualized as biomedical research, as biological research, and so forth. Figure 3 depicts an interpretation in which *research* is understood to mean “stem-cell research generally”

This depiction shows both the possibility of alternative conceptualizations (represented by the inclusion of boxes for narrower and broader levels of focus), and the selection of “stem-cell research” as the salient conceptualization (indicated by the visual emphasis on the box for that level).

The interpretation shown in Figure 3 would lead to the result that NIH could not fund *any* stem-cell research, including research on adult stem cells and induced-pluripotent stem cells. That would of course be absurd. But it is an absurdity that is not ruled out by either the literal meaning of the Dickey-Wicker Amendment or anything inherent in the activity that falls into the category “research.”

**II. The NIH guidelines do not contemplate funding research “in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death[.]”**

The discussion in the previous section has shown that the answer to the ultimate issue here—whether the NIH guidelines contemplate funding research “in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death”—depends to a great extent on how one conceptualizes the “research” to which the Dickey-Wicker Amendment refers. And the particular conceptualization one chooses will obviously affect one’s view of the “boundaries” of the research, by which we mean the conceptual line between what is

regarded as occurring **in** the research and what is regarded as occurring **outside** the research. And that, in turn, will control the determination of the ultimate issue in this case.

In this section, we will show that the government’s conceptualization—which essentially sees the boundaries of the relevant research as being set by the research plan in the applicant’s grant proposal—comes easily within the natural meaning of the Dickey-Wicker Amendment’s language, while the plaintiffs’ does not. The government’s conceptualization is also supported by a number of practical considerations.

We also show that the “timeless” perspective that the Court seems to have taken in its preliminary-injunction decision is inconsistent with the Dickey-Wicker Amendment’s use of the present tense (“research in which a human embryo or embryos **are** destroyed or discarded” as opposed to “research in which a human embryo or embryos **are or were** destroyed or discarded”). Finally, we refute the plaintiffs’ argument that the NIH guidelines violate Dickey-Wicker because they supposedly create an incentive for the destruction of additional embryos.

***A. The government’s conceptualization results in an interpretation that gives the Dickey-Wicker Amendment’s language its natural and ordinary meaning.***

Under the government’s interpretation of the Dickey-Wicker Amendment, the focus is on the specific projects for which NIH funding is sought, and the question is whether embryonic stem cells will be destroyed, discarded, or endangered in the specific work for which funding is sought. From that perspective, the work that funding is sought for does not constitute research in which embryos are destroyed, discarded, or endangered. Indeed, embryos presumably are not involved in the research at all, in that they are not manipulated or otherwise subjected to procedures in the course of the work that NIH would fund. As far as we know, this point is undisputed.

The government's interpretation has the virtue of closely paralleling the way in which NIH reviews and acts on grant proposals. NIH focuses on the specifics of the proposed research, and the question whether funding is allowed under the Dickey-Wicker Amendment is decided case by case, just like the question of the proposal's scientific merit. And the decision is based on each proposal's specifics, rather than on the basis of broad generalizations about the field of hESC research as a whole.

The government's interpretation is also consistent with the most natural reading of the Dickey-Wicker Amendment's language. If one says regarding a scientist that some action is performed "in his research," that is ordinarily intended (and understood) to mean that the action is performed by the scientist or those working under him as part of his experiments. The quotes in (16–19) illustrate this usage.

- (16) "In his research, Biehl often proceeds like a detective, finding clues and gathering evidence to help him understand the reality of what he is investigating."<sup>31</sup>
- (17) "The council said he had shown 'a callous disregard' for the suffering of children involved in his research."<sup>32</sup>
- (18) "In research involving 30,065 athletes, electrocardiograms taken during exercise showed that 4.9 percent of participants had abnormal heart activity."<sup>33</sup>

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31. Karin Dienst, Investigating clues to a life, Biehl discovers larger reality, <http://www.princeton.edu/main/news/archive/S17/06/97S70/?section=featured> (Feb. 5, 2007)

32. John F. Burns, British Medical Council Bars Doctor Who Linked Vaccine With Autism, New York Times, <http://www.nytimes.com/2010/05/25/health/policy/25autism.html> (May 24, 2010)

33. Howard Mustoe, Heart Tests May Cut Deaths in Competitive Athletes, Study Says, Bloomberg, <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=amegqDt28OC&refer=uk> (July 4, 2008).

- (19) “In research involving 50,000 men over 20 years, scientists led by Kathryn Wilson at Harvard’s Channing Laboratory found that the 5 percent of men who drank 6 or more cups a day had a 60 percent lower risk of developing the advanced form of the disease than those who didn’t consume any.”<sup>34</sup>

Furthermore, there are functional characteristics that support the conclusion that the derivation of hES cells does not invariably constitute part of a research project that uses the resulting stem cells. A single line of stem cells can be used in many different research projects, including projects conducted by different people, at different institutions, and even in different countries. Conversely, a single research project might use two or more different cell lines, with each line coming from a different source. It is therefore more natural to say that the derivation of hES cells is not necessarily part of the research project in which the cells are used.

Nevertheless, the plaintiffs argue that the derivation of stem cells occurs “in” hESC research because “the funded research *necessarily requires* the destruction of embryos.”<sup>35</sup> Underlying the contention that the derivation of human embryonic stem cells occurs in hESC research is a particular conception of what it means to say that some act or process happens “in” a particular type of research. Under this conception, the act or process happens “in” the research if its occurrence is a necessary precondition for the research taking place. But that view is inconsistent with how the English language is ordinarily used and understood.

hESC research requires the use of electricity and petri dishes, yet nobody would say that the generation of electricity and the manufacturing of petri dishes are processes that occur “in” that research. Nor would anybody accept the following statements as correct:

- (20) Geologists study rocks. Their research requires the existence of rocks. Therefore, geologists make rocks in their research.

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34. Simeon Bennett, Coffee May Reduce Risk of Deadly Prostate Cancer, Bloomberg, <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=alAhmT2SZ8Yg> (December 8, 2009).

35. Mem. In Sup. of Pltfs.’ Mtn. for Sum. J. 14 (DE 55) (emphasis in the original).

- (21) Neuroscientists study brains. Their research requires the existence of brains. Therefore, neuroscientists make brains in their research.
- (22) Carpenters use lumber. Their work requires that lumber be made by cutting down trees and milling them into boards. Therefore, carpenters cut down trees in their work and mill them into boards in their work.

These statements provide evidence of what it means to say that an action or process occurs “in” a particular activity. And the statements’ absurdity provides evidence that the fact that an action or process is a necessary precondition of an activity does not, by itself, mean that the action or process occurs **in** the activity. At a minimum, they show that the plaintiffs’ interpretation represents only one possible interpretation, not the only possible interpretation.

***B. The interpretation in the Court’s preliminary-injunction decision is inconsistent with the Dickey-Wicker Amendment’s use of the present tense.***

We have described the Court’s decision granting a preliminary injunction as interpreting the Dickey-Wicker Amendment from a “timeless” viewpoint that takes no account of whether the research for which funding is sought would involve the use of preexisting stem-cell lines. But that mode of interpretation is inconsistent with the Dictionary Act<sup>36</sup> and with the Supreme Court’s recent decision in *Carr v. United States*.<sup>37</sup>

The statutory language at issue here is written in the present tense: “None of the funds made available in this Act may be used for... research in which a human embryo or embryos *are* destroyed, discarded, or knowingly subjected to risk of injury or death....”<sup>38</sup> This use of the present tense is important in interpreting the Dickey-Wicker Amendment; as the Supreme Court

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36. 1 U.S.C. § 1.

37. 130 S. Ct. 2229 (2010).

38. Pub. L. No. 111-117, § 509(b), 123 Stat. 3034, 3280–81 (2009) (emphasis added).

said in *Carr*, “Consistent with normal usage, we have frequently looked to Congress' choice of verb tense to ascertain a statute's temporal reach.”<sup>39</sup>

In *Carr*, the Court was dealing with the Sex Offenders Registration and Notification Act (“SORNA”),<sup>40</sup> which makes enacts criminal penalties for anyone who (a) is required under SORNA to register as a sex offender with local authorities, (b) “travels in interstate or foreign commerce,” and (c) knowingly fails to register. Several circuits had held upheld convictions for failure to register by sex offenders whose interstate travel had occurred before SORNA was enacted. (Those holdings are analogous to the Court’s implicit holding here that the Dickey-Wicker Amendment prohibits federal funding of hESC research even where the research will use preexisting stem-cell lines.) The Supreme Court held otherwise, and it based its decision in part on the statute’s use of the present tense.

The Court noted the requirement in the Dictionary Act that “[i]n determining the meaning of any Act of Congress, unless the context indicates otherwise[,] . . . words used in the present tense include the future as well as the present.” In interpreting this language, the Supreme Court said that “[b]y implication . . . the Dictionary Act instructs that the present tense generally does not include the past.”<sup>41</sup> The Court therefore held that “a statute that regulates a person who ‘travels’ is not readily understood to encompass a person whose only travel occurred before the statute took effect.”<sup>42</sup> Moreover, it held that when a statute is written in the present tense, it is ordinarily inappropriate to interpret it in a way that takes no account of when the relevant conduct occurred:

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39. 130 S. Ct. at 2236.

40. 18 U.S.C. § 2550.

41. 130 S. Ct. at 2236.

42. *Id.*

The Court of Appeals quoted a Ninth Circuit decision for the proposition that “the present tense is commonly used to refer to past, present, and future all at the same time.” ... Perhaps, as the Dictionary Act itself recognizes, there may be instances in which “context” supports this sort of omnitemporality, but it is not the typical understanding of the present tense in either normal discourse or statutory construction.<sup>43</sup>

In referring in this passage to the notion of “omnitemporality,” the Court is invoking the same concept that we have invoked in speaking of the “timeless” interpretation reflected in the Court’s preliminary-injunction decision.

*Carr* and the Dictionary Act establish that the latter interpretation is, at least prima facie, mistaken. And while a timeless/omnitemporal interpretation might be warranted in an appropriate context, nothing about the context here militates in favor of such an interpretation.

***C. The NIH guidelines do not violate the prohibition against funding research in which embryos are subjected to risk of injury or death greater than allowed for research on fetuses in utero.***

The plaintiffs argue that even if the NIH guidelines do not allow funding of research in which human embryos are destroyed or discarded, the guidelines nevertheless violate the Dickey-Wicker’s prohibition against funding research in which embryos “are knowingly subjected to risk of injury of 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 (42 U.S.C. § 289g(b)).” In making this argument, the plaintiffs do not contend that stem-cell researchers physically do things to embryos that endanger them; indeed, they accept the proposition that hES cells are not embryos and do not contend that hESC research involves the use of embryos other than as sources for deriving stem cells. Rather, they argue (a) that embryonic stem-cell research creates a demand for additional stem cells, (b) that this demand creates the incentive to derive

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43. *Id.* n.5.

more lines of stem cells and therefore destroy more embryos, (c) that this incentive puts embryos at risk of injury or death, and (c) that all stem-cell researchers know all of this.

This is a decidedly strange notion of what it means to say that an activity subjects something to risk of injury or death. In ordinary English usage, the concept of subjecting someone or something to a risk entails that if the risk comes to fruition, the causal link between the risk-creating conduct and the resulting harm will be relatively short and direct. But the chain of causation that the plaintiffs hypothesize is lengthy and indirect.

It is quite clear that this is not the kind of risk that Congress had in mind when it enacted Dickey-Wicker. This is clear from the fact that the risk referred to in the Amendment is not simply “risk of injury or death,” it is “risk of injury of 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 (42 U.S.C. § 289g(b)).*” Thus, the italicized language provides guidance about the kind of risk that Congress had in mind. The plaintiffs entirely ignore this language—their discussion of this aspect of the Dickey-Wicker does not even mention it. Their reason for sweeping this language under the rug is obvious: it undermines their argument completely.

The language that the plaintiffs ignore refers to 45 C.F.R. § 46.204(b) and to 42 U.S.C. § 289g(b). The latter provision merely requires that the risk standard for research on fetuses intended to be aborted be the same as the risk standard for research on fetuses intended to be carried to term; therefore, the key provision for purposes of this case is 45 C.F.R. § 46.204(b):

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

...

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

The risks that this regulation deals with are the risks associated with being a research subject. *Those* are the kinds of risks that the Dickey-Wicker Amendment is meant to address—not the remote and indirect risks that might result from market incentives supposedly generated by a field of research.

If there is any doubt about this, it is dispelled once one considers the intractable issues that this Court would face if the plaintiffs' interpretation were to be accepted.

To begin with, it would be necessary to somehow quantify the risk supposedly created by hESC research, in order to determine whether that risk is greater than the entirely different kind of risk referred to in § 46.204(b). But that would be only the first step. The embryos that hESC research supposedly puts at risk—those that were created for reproductive purposes by in-vitro fertilization but not used for that purpose—are already subject to a host of other risks: the risk that the donors will choose to discard them, the risk that they will not be in good enough condition to be frozen and will have to be discarded, the risk that they will be frozen but will not survive being thawed, the risk that they will be frozen, thawed, and implanted but without a full-term pregnancy resulting, the risk of being used in research funded by non-federal sources. Thus, the question for the courts would be to quantify the *incremental* risk created by hESC research, which would require quantifying all the other risks.

Furthermore, the overwhelming majority of unused embryos are destined to remain in frozen limbo, never to be implanted in someone's womb and therefore never to become more than a tiny blob of cells. If measured against what counts as injury to a person *after* birth, this in itself is a serious injury. Yet under the plaintiffs' argument, courts would have to determine whether being used as a source of stem cells is a worse fate for an embryo than being stored in a tank of liquid nitrogen at -196° Celsius.

These are only some of the issues that would arise. But what we have said is enough to show that the inquiry that the plaintiffs' argument would require this Court to conduct would not only be unmanageable, but would call on the Court to decide ethical issues for which there is no governing legal standard. Nothing in the Dickey-Wicker Amendment requires an interpretation that would lead to such extreme consequences.

**III. If funding is allowed for research on existing stem cell lines, as suggested by the order denying a stay pending appeal, the NIH guidelines do not facially violate the Dickey-Wicker Amendment.**

As has been noted, the Court's decision denying a stay pending appeal seems to have deviated from the timeless perspective reflected in the preliminary-injunction decision. In the decision denying a stay, the Court suggested (or at least raised the possibility) that the Dickey-Wicker Amendment might not prohibit funding of research on the stem-cell lines for which funding was allowed under the Bush administration guidelines, which "allowed research only on existing stem cell lines, foreclosing additional destruction of embryos."<sup>44</sup> If, as we believe, this does represent a deviation from the Court's original interpretation, the new interpretation is more consistent with the Dickey-Wicker Amendment's use of the present tense than the original interpretation was.

As discussed below, the new interpretation would compel the conclusion that Dickey-Wicker does not prohibit funding of research on existing cell lines, even if it prohibits funding of research on lines created in the future. Moreover, the line between existing lines and future lines would have to be re-set every time a new iteration of the Dickey-Wicker Amendment is enacted, with funding being allowed for research on all cell lines then in existence.

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44. Order denying stay 1 (DE 53).

A. An interpretation allowing NIH to fund research on existing cell lines cannot logically be applied only to the lines for which funding was allowed under the Bush guidelines. During the nine years after the Bush policy was announced, many new hESC lines have been created. Of these new lines, almost 75 have been added to the NIH Registry under the current guidelines.<sup>45</sup> All of these are now “existing stem cell lines.” What is more, most of them were in existence before the preliminary injunction was entered in this case and even before the current administration’s stem-cell policy was announced.<sup>46</sup> And most important, most of these lines were in existence before the currently-effective iteration of the Dickey-Wicker Amendment was enacted. If the permissibility of federal funding turns on whether the research involves existing stem cell lines, there is no basis for distinguishing any of these new lines from the handful of lines for which funding was allowed under the Bush guidelines.

We said above that most of the existing lines predate the enactment of the iteration of the Dickey-Wicker Amendment that is currently in effect, and we said that this was the most important fact relating to when the lines were created. The reason for the latter statement is that for each new budget year, the dividing line between “existing” stem-cell line and subsequently created lines gets moved to the date when the appropriations act for that year act becomes law. Prior iterations of the Dickey-Wicker Amendment have no effect during the new fiscal year, because the Dickey-Wicker language by its own terms merely restricts the use of funds appropriated under the act that contains that language. For each new fiscal year, all the stem-cell lines that have been created during the prior fiscal year will be existing stem-cell lines. Thus,

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45. Decl. of Story Landis ¶ 14.

46. *Id.*

under the reasoning reflected in the order denying a stay, NIH will be permitted to fund research on those lines, as well as on all previously-created lines.

The iteration of the Dickey-Wicker Amendment currently in effect, which governs fiscal year 2010, became law on December 16, 2009.<sup>47</sup> Thus, *at a minimum*, Dickey-Wicker permits NIH to fund research on all hESC lines that were created before that date. This means that the plaintiffs' facial attack on the NIH guidelines cannot possibly succeed. At worst (or, from the plaintiffs' viewpoint, at best), funding would be prohibited for research on subsequently-created lines. In that event, an injunction with the same broad scope as the preliminary injunction would be grossly overinclusive, and any relief would have to be narrowly tailored to fit the narrow scope in which Dickey-Wicker's prohibition could still operate.

And by the time the Court decides the plaintiffs' summary-judgment motion, the legal environment will have changed, to the government's benefit. The federal government's 2010 fiscal year will end on September 30, 2010—two days after this memorandum is filed. The appropriations act for FY 2010 will have expired, and with it the iteration of the Dickey-Wicker Amendment now (September 28, 2010) in effect. Assuming that the appropriations bill for FY 2011 includes the Dickey-Wicker language, every hES line now in existence will qualify as an existing line for which, under the reasoning in the decision denying a stay, funding would be available. At that point, the only relief the plaintiffs could conceivably obtain under the Dickey-Wicker Amendment would be an injunction against funding research on hESC lines created after the new appropriations act became law.

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47. Consolidated Appropriations Act, 2010, § 509, Pub. L. No. 111-117, 123 Stat 3034, 3280–81 (2009).

## Conclusion

For the foregoing reasons, the Court should hold that the NIH guidelines are consistent with the Dickey-Wicker Amendment. In the alternative, the Court should hold that the guidelines are consistent with the Dickey-Wicker Amendment with respect to any stem-cell lines that were derived before the enactment of the applicable iteration of the Dickey-Wicker Amendment.

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Respectfully submitted,

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