



Summary of Issues Related to NIH Funding Freeze

On October 19-20 the Interstate Alliance on Stem Cell Research sponsored a workshop designed to provide in-depth analysis of the legal and policy considerations surrounding the *Sherley v. Sebelius* case. IASCR received three separate briefings from legal and policy experts. The following themes emerged from the briefings.

Sherley v. Sebelius: Summary and Legal Analysis

- **Timeline of the Case Thus Far:**

- **August 19, 2009:** Two researchers working with adult stem cells, certain religious groups and others, file a lawsuit seeking to enjoin NIH funding of human embryonic stem cell (“hESC”) research pursuant to the NIH Guidelines (the “Guidelines”).
- **October 27, 2009:** Judge Lamberth of the Federal District Court dismisses the case for lack of standing.
- **August 19, 2010:** The Appeals Court reverses with respect to the stem cell researchers only and remands to the Federal District Court for further proceedings.
- **August 23, 2010:** Judge Lamberth of the Federal District Court determines that NIH funding policy violates Dickey-Wicker Amendment and enjoins NIH from funding hESC research.
- **August 30, 2010:** NIH issues a [Notice](#) to suspend all hESC funding activities pursuant to the NIH Guidelines.
- **September 7, 2010:** Judge Lamberth of the Federal District Court denies HHS emergency motion to stay the preliminary injunction, and suggests that preliminary injunction does not address Bush lines or previously funded research.
- **September 9, 2010:** Appeals Court imposes stay of the Federal Court injunction, allowing NIH to resume hESC funding activities temporarily.
- **September 10, 2010:** NIH issues a [Notice](#) lifting its August 30th suspension of hESC funding activities pursuant to the NIH Guidelines.
- **September 28, 2010:** Appeals Court issues a durable stay of the Federal District Court injunction, allowing NIH to resume hESC funding activities pending its decision on the appeal of the preliminary injunction.

Legal Analysis: The legal analysis centers on three main issues: (1) whether the stem cell researchers who initiated this legal challenge have legal standing to proceed, (2) whether the Dickey-Wicker Amendment (“DWA”) clearly prohibits federal funding of human embryonic stem cell (“hESC”) research, (3) whether NIH followed correct federal procedures when issuing the Guidelines.

- **Plaintiff Standing:** To proceed with a lawsuit to challenge a federal law or agency action, such as the NIH Guidelines, an individual must demonstrate that he or she is affected or harmed by the law or agency action. This is referred to as standing.
 - **Not a Settled Issue:** On appeal from the Federal District Court’s dismissal of this case, the Appeals Court determined that stem cell researchers who brought the case had standing to proceed to the next stage in the litigation. However, the question of standing can be raised at any stage of litigation, and becomes progressively more difficult to meet as the litigation progresses.
 - **UC Amicus Argument:** On appeal, the Regents of the University of California have offered a particularly powerful argument against plaintiff standing in this case. The brief states that:
 - Plaintiffs’ Injury is Not Personal to Them
 - NIH grants are awarded to institutions, not principal investigators such as the Plaintiffs.
 - Plaintiffs have no independent legal right to assert competitive injury to their institution-grantees
 - The institution-grantee that Plaintiff works for states on its website that Plaintiff’s position neither represents nor reflects that of the institution-grantee.
 - There exists no individualized legal right to compete for federal funding
 - Plaintiffs Failed to Identify a Relevant Market for their Competitive Standing Theory.
 - To establish harm, the plaintiffs must identify the market they compete in. NIH does not have an iPSC or hESC market, it has 28 funding markets and nearly 180 regular study sections.
 - Plaintiffs Cannot Establish Redressability of their alleged competitive injury.
 - Invalidating the NIH Guidelines will not end funding of hESC research.
 - **Practical Effect of HHS Winning on Standing Issue:**
 - The Plaintiffs may not proceed with their challenge of the NIH Guidelines on DWA or APA grounds. The NIH

Guidelines remain in effect and a standing precedent is established for future challenges to federal funding.

- **DWA Considerations** The Dickey-Wicker Amendment is a rider to the annual Appropriations Act that has been renewed every year since 1996. The DWA prohibits the use of federal funds for:

(1) the creation of a human embryo or embryos for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

This DWA defines “embryo” as “any organism, not protected as a human subject under 45 CFR 46 [the human subjects regulations] as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.”

- **Ambiguous/Unambiguous Language:** The plaintiffs case rests on the proposition that DWA unambiguously prohibits federal funding of hESC research despite the fact that the language predated the first human application of embryonic stem cells and that the language does not explicitly mention hESCs. If the court rules that the DWA language is ambiguous with regards to federal funding of hESCs, the court will defer to NIH authority, if reasonable (examine whether the rule-making is consistent with prior legislative and interpretive history).
 - **Consistency in Interpretation:** The NIH Guidelines reflect an interpretation of DWA that has remained consistent through three successive Administrations: (a) The Rabb memorandum, issued during the Clinton Administration, distinguished between embryos and hESCs and determined that hESCs are not embryos subject to the DWA (b) The Congressional Record through the Bush and Obama Administrations demonstrated support for the Rabb distinction (passage of two stem cell bills and a committee report supporting the Obama Executive Order), (c) Federal funding of hESC research during the Bush Administration, though limited, implemented the Rabb distinction (Bush interpretation adopted the Rabb distinction), and (d) The Obama Administration recognizes NIH’s authority to fund hESC research through Executive Order.

- **Practical Effect of HHS Losing on DWA grounds:** Legal experts suggest the HHS position is strong on the merits and the appeals process represents an effective strategy going forward. However, should NIH be judged to be in violation of the DWA, federal funding of hESC research could abruptly terminate. This would likely push any legislative effort to the top of the Congressional priority list. Additionally, experts suggest that the Supreme Court would be more likely to grant cert and hear this case if the federal government loses on appeal, due to historical trends.
- **Procedural Considerations:**
 - **Administrative Procedure Act (“APA”):** The Administrative Procedure Act governs how federal agencies such as the NIH issue regulations and creates procedures for federal court review of agency decision-making.
 - **Practical Effect of HHS Losing on APA grounds:** Observers believe NIH promulgated the guidelines consistent with APA requirements. However, should NIH be judged in violation of the APA (and not DWA), NIH would simply have to re-promulgate the guidelines. A “do-over” approach would likely be faster than prolonged litigation and provide opportunities to improve any technical drafting errors.

Legislative Policy Analysis and Summary

In light of the uncertainty wrought by the litigation and its attendant funding freezes, there have been calls for legislative intervention along two alternative paths:

1. **Affirm the NIH Guidelines through legislation to: (a) demonstrate Congressional support for the federal funding of hESC research and (b) protect hESC research from future executive actions that could restrict federal funding. (DeGette approach).**
 - a. This approach seeks to codify President Obama’s Executive Order and NIH hESC research policies for future Administrations without the downside risk associated with legislation targeting the DWA. Legislative staff has been “working” the legislation and cite a number of co-authors.
 - b. One fundamental issue is the ability to advance companion legislation in the Senate given competing priorities and the filibuster potential.

2. Amend DWA to remove restrictions on embryo research.

- a. Legislation Targeting DWA (aka “the third rail approach”): Any effort to address the constraints imposed by the DWA involves extreme downside risk. Any legislation would be subject to hostile amendment. Given NIH’s comparatively strong legal position and the fact that the DeGette approach achieves a positive outcome, no action on DWA is advisable.
- b. **Window of Opportunity:** The Senate still must pass an appropriations bill after the November elections. Although this bill is likely to contain the DWA language, the committee reports supporting the legislation provide an opportunity to reiterate Congressional support for the current NIH approach.

Summary

Given the strength of the current HHS position, legal remedies appear to be the most promising for sustained NIH funding. However, it is important to note that there may be further hiccups in federal funding during the course of the litigation, depending on the outcomes at each stage. Because of the on-going litigation, the short-term benefits associated with the DeGette approach are unclear. The DeGette approach may, however, prove useful in the long-term, as a vehicle to protect the existing NIH funding framework, and the NIH Guidelines issued pursuant to President Obama’s Executive Order, from shifting policy proclamations of future Administrations. Any legislation directed at the DWA simultaneously involves risk of a negative policy outcome and may compromise the existing framework.

Given the dynamic nature of federal funding policy, the above issues should be subject to ongoing evaluation.