The 111th Congress adjourned just before Christmas 2010. Although the first three months of 2010 were dominated by debates over health care reform, bioethics issues played little role in legislation enacted later in the year. Even a final continuing resolution, passed to keep federal agencies and programs funded until March 4, 2011, simply maintained all policies in previous appropriations bills—including policy riders on abortion, embryo research, the patenting of human embryos, and other issues.

The most significant development in Washington on bioethics issues late in 2010 therefore came not from Congress but from a federal court, which found that the policy under which the Obama administration has been funding human embryonic stem cell research may well be illegal. Other developments included a renewed attack on the conscience rights of Catholic hospitals and a report from President Obama's bioethics commission on synthetic biology.

Lawsuit on Embryonic Stem Cell Research

Sherley v. Sibelius, the lawsuit against federal funding of human embryonic stem cell research, dates back to August 2009. Suit was brought in a U.S. district court by Nightlight Christian Adoptions (which arranges the adoption of frozen human embryos by couples), the Christian Medical Association, and two adult-stem-cell researchers. They argued that President Obama's executive order of March 2009, and the guidelines for funding stem cell research that were issued by the National Institutes of Health in furtherance of that order, violate statutory law on embryo research as well as requirements of the Administrative Procedures Act.

On October 27, 2009, U.S. District Judge Royce Lamberth dismissed the suit, ruling that none of the plaintiffs had standing to bring such a suit. (It is important to understand in this context that the issue of "standing" is quite separate from the substantive issue of whether a given action or policy is illegal—"standing" concerns which individuals or groups have a right to raise the issue in court.) At that point most

observers simply assumed the lawsuit would vanish, as had a similar suit against the Clinton administration's embryonic stem cell policy almost a decade earlier.

However, the suit was revived by the U.S. Court of Appeals for the District of Columbia, which ruled on June 25, 2010, that the two stem cell researchers did have standing. The court found that Dr. James Sherley of the Boston Biomedical Research Institute and Dr. Theresa Deisher of AVM Biotechnology were placed at a "competitive disadvantage" by federal funding of human embryonic stem cell research, as that policy diverts limited NIH funds away from the adult stem cell research that they wish to pursue. This decision about standing, of course, simply allowed the researchers' substantive claims about the legal status of the policy to be heard in court.

The case therefore went back to Judge Lamberth for consideration on the merits. And on August 23, surprising many observers, he handed down a preliminary injunction that blocked the NIH from pursuing human embryonic stem cell research on its premises or issuing any further grants for such research to outside scientists. By the end of the month, the Justice Department on behalf of the NIH had asked the D.C. Circuit Court of Appeals for an emergency stay of this order, claiming (without evidence) that allowing the injunction to remain in place would cause "irrevocable harm to the millions of extremely sick or injured people who stand to benefit from continuing [human embryonic stem cell] research." The appeals court granted the emergency stay in September, pending its review of the arguments for and against reinstating the injunction. According to one respected science magazine, the NIH immediately took advantage of this temporary reprieve by "scrambling to get money out the door" to embryonic stem cell researchers in case it loses the next stage of the dispute. Meanwhile, plaintiffs and the government filed lengthy briefs on the merits of the case in Judge Lamberth's court, and the appellate court heard oral arguments in December on whether to reinstate the preliminary injunction. There the matter remains as of this writing.[1]

The chief legal claim at issue is whether current NIH guidelines violate statutory law—specifically, the appropriations rider known as the Dickey-Wicker amendment, which Congress first approved for fiscal year 1996 as part of a Labor/HHS appropriations bill and has renewed every year since then. The current version of the amendment states:

> (a) None of the funds made available in this Act may be used for—
>
> (1) the creation of a human embryo or embryos for research purposes; or
>
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g (b)).
>
> (b) For purposes of this section, the term ''human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR 46

[1] A chronology of the case, with links to key documents, can be found on the Web site of Advocates International, part of the public interest legal team pursuing the lawsuit, at http://www.advocatesinternational.org/content/step-step-cause-life-being-upheld-sherley-v-sebelius.

> 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.[2]

When he granted his preliminary injunction against the NIH's guidelines for funding human embryonic stem cell research, Judge Lamberth found (among other things) that plaintiffs Sherley and Deisher had "demonstrated a strong likelihood of success" for their claim that the guidelines violate the Dickey-Wicker amendment.

Since 1999, when the Clinton administration was considering federal support for human embryonic stem cell research, the NIH (guided by a legal opinion from the general counsel of the Department of Health and Human Services at the time) has held that paragraph (a)(2) of the amendment bars only federal funding of the act of destroying a human embryo for stem cell research. As long as such destructive "derivation" of stem cells is carried out with nonfederal funds, federal grants may support research using the stem cells that result from this act. But Judge Lamberth disagreed, saying that "the language of the statute reflects the unambiguous intent of Congress to enact a broad prohibition of funding research in which a human embryo is destroyed." He continued,

> This prohibition encompasses *all* "research in which" an embryo is destroyed, not just the "piece of research" in which the embryo is destroyed. Had Congress intended to limit the Dickey-Wicker to only those discrete acts that result in the destruction of an embryo, like the derivation of [embryonic stem cells], or to research on the embryo itself, Congress could have written the statute that way. Congress, however, has not written the statute that way, and this Court is bound to apply the law as it is written.[3]

Judge Lamberth's broader reading of the amendment is, in fact, the only one consistent with long-standing judicial rules for the interpretation of federal statutes. Clearly, paragraph (a)(1) of the amendment bans funding "the creation of" embryos for research purposes; but instead of banning merely funding of "the destruction of" embryos, it pointedly words paragraph (a)(2) more broadly to prevent funding of *any* part of a research project that requires or involves the destruction of human embryos. Critics have pointed this out since the NIH first came up with its narrow interpretation in 1999. As the U.S. Conference of Catholic Bishops said in its comments on the Clinton administration's guidelines for human embryonic stem cell research,

> NIH's interpretation, limiting the funding ban only to the act of destruction itself, violates two principles of statutory construction. First, a statute must be construed to avoid rendering any of its words superfluous. *Walters v. Metropolitan Educational Enterprises*, 519 U.S. 202, 209-10 (1997); *United States v. Menasche*, 348 U.S. 528, 538-39 (1955). NIH's interpretation renders the

---

[2] Section 509, Title V, of Division D of the Consolidated Appropriations Act of 2010 (Public Law 111-117), enacted December 16, 2009; authority extended by continuing appropriations, most recently by Public Law 111-322, enacted December 22, 2010, and extending to March 4, 2011.

[3] *Sherley v. Sebelius*, case 1:09-cv-1585 (D.D.C. August 23, 2010), 10–11, https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv1575-44.

> words "research in which" superfluous. Second, when Congress chooses different language in proximate subsections of the same statute—one narrow, the other broad—the statute must be construed to give effect to those differences. *Russello v. United States*, 464 U.S. 16, 23 (1983), and cases cited therein.[4]

Once these rules of interpretation are followed, it becomes clear that federal funding of human embryonic stem cell research violates the Dickey-Wicker amendment. Indeed, that position has always been taken by those who authored and sponsored the amendment. The amendment's co-author, Rep. Jay Dickey, testified against the NIH's narrow interpretation in 1999: "While the act of destroying or injuring a human embryo would certainly be ineligible for Federal funding, the law has much broader application. It also bans the use of tax dollars to fund research which follows or depends upon the destruction of or injury to a human embryo."[5] As Judge Lamberth said in granting his injunction, "[Embryonic stem cell] research is clearly research in which an embryo is destroyed. To conduct ESC research, ESCs 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 upon the destruction of a human embryo."[6]

The NIH and its defenders have charged that by this interpretation, even the Bush administration policy accepted by many pro-life groups would be illegal. That policy allowed use of embryonic stem cells if the cells had been derived prior to the date the policy was issued. President Bush and others argued that this created a sufficient separation between the decision to destroy a human embryo and the decision to use the resulting stem cells, so that such destruction is not truly a part of the funded research project and could not have been done for the sake of such funding. Judge Lamberth has declined comment on whether he would agree with this claim, stating that the Obama policy is the only policy before his court.

The NIH's strongest argument for its interpretation of the Dickey-Wicker amendment is that, even while renewing the amendment every year since 1996, Congress has also indicated support for federal funding of human embryonic stem cell research in various ways during the same period—twice approving legislation to authorize such funding at the statutory level, only to see these bills vetoed by President Bush because they went beyond his own more limited policy. But post-enactment legislative history, particularly a history dominated by committee chairs and congressional leaders who personally oppose the policy of the Dickey-Wicker amendment itself, is of limited use here, especially if courts find that the language of the amendment itself is clear. It could equally be claimed that if Congress believed the

---

[4] "Bishops' Conference Comments on NIH Guidelines for Embryonic Stem Cell Research," January 31, 2000, part II, http://www.usccb.org/prolife/issues/bioethic/comments.shtml.

[5] Statement of Rep. Jay Dickey before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education, November 4, 1999, Senate Hearing 106-413, "Stem Cell Research, Part 2," 9, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_senate_hearings&docid=f:61422.wais.pdf.

[6] *Sherley v. Sebelius* (August 23, 2010), 12.

amendment should not mean what its sponsors and strongest supporters have always insisted it means, Congress has had ample opportunities to change the amendment to make this clear and has never done so.

Those opportunities to weaken the amendment certainly existed throughout the 111th Congress, when the President and majorities in both chambers of Congress presumably supported federal funding of human embryonic stem cell research. From the time Judge Lamberth issued his preliminary injunction in August, sponsors of legislation to provide statutory authorization for such funding urged Congress to approve their proposals and make the current legal challenge moot. This did not occur, for a number of reasons. Congressional leadership had other priorities, chiefly on jobs and the economy, during a contentious election year when public trust in Congress seemed to be at a low ebb; a committed minority may have been able to block such legislation in the Senate by procedural maneuvers, or at least make the Senate spend a long time on the issue; and the appellate court's emergency stay temporarily restored the status quo, reducing the urgency of congressional action. The bills' sponsors may also have miscalculated, by proposing legislation that goes beyond the Obama administration policy to set the stage for more controversial funding of human cloning research.[7]

Members of Congress may also finally be waking up to the fact that human embryonic stem cell research is unlikely to be the path to miracle cures that lobbying groups have irresponsibly made it out to be for many years. Clinical progress in treating illnesses and injuries has been emerging chiefly from work with adult stem cells, while more and more attention once devoted to human embryonic stem cells is turning instead to induced pluripotent stem (iPS) cells, which are easier to obtain and use as well as less controversial. Most recently, researchers seem to have found a way to reprogram one adult cell type into another directly, without the cell's passing through the pluripotent state that could pose a risk of tumor formation.[8]

In deciding whether to issue a preliminary injunction, Judge Lamberth noted that the "balance of hardships" favors the plaintiffs in the suit: continued funding of human embryonic stem cell research will certainly divert resources away from adult stem cell research here and now, while any claim that an injunction would deprive patients

---

[7]For example, the Stem Cell Research Advancement Act proposed by Rep. Diana DeGette, HR 4808, states, "*Notwithstanding any other provision of law*, the Secretary shall conduct and support research that utilizes human stem cells, including human embryonic stem cells" (emphasis added). The bill states that such research will "include" research that meets the basic requirements of the Obama policy, but it allows the NIH to expand its guidelines later if it sees this as "scientifically warranted." It also prohibits funding for "human cloning," but defines "human cloning" as the "implantation" of the product of the cloning process into "a uterus or the functional equivalent of a uterus"—leaving the door wide open to the cloning and destruction of human embryos for their stem cells in the laboratory. The text of the bill is available at http://www.gpo.gov/fdsys/pkg/BILLS-111hr4808ih/pdf/BILLS-111hr4808ih.pdf.

[8]See Ewen Callaway, "Cellular 'Alchemy' Transforms Skin into Blood," *Nature News*, published online November 7, 2010, http://www.nature.com/news/2010/101107/full/news.2010.588.html.

of needed treatments is "speculative."[9] That judgment is much better grounded than the NIH's irresponsible claim that using these federal funds for avenues other than human embryonic stem cell research would harm "millions" of patients in need.

In fact, the only federal legislation on stem cell research to be approved by the 111th Congress was a much-needed reauthorization of the federal program to promote public banking and use of umbilical-cord-blood stem cells. The program was first established in 2005, largely through the efforts of House pro-life caucus chair Rep. Chris Smith. The reauthorization updates the program, promotes innovative ways to promote collection of cord blood at a wider range of hospitals, and authorizes $153 million in funding over the next five years. These stem cells have saved many thousands of lives already, and clearly could save many more if they were collected and banked more often instead of being discarded after live births. To its credit, Congress passed this reauthorization in late September without audible dissent—by unanimous consent in the Senate, and by a "suspension of the rules" requiring two-thirds support in the House—and without attaching any hostile amendments promoting human embryonic stem cell research. It was signed into law by President Obama on October 8.[10]

With the end of the 111th Congress and the arrival of a new Congress expected to show higher levels of support for protecting unborn human life, the opportunity for enacting legislation supporting human embryonic stem cell research may now be past for the time being. If Judge Lamberth issues a final ruling against the Obama administration policy and that is upheld on appeal, and the new Congress does not pursue legislation to reverse or weaken the Dickey-Wicker amendment, we may see the end of federally funded human embryonic stem cell research for years to come.

Conscience Rights under Renewed Attack

The American Civil Liberties Union has renewed its demand that the federal government force Catholic hospitals to perform abortions in "emergency" cases—a category the ACLU does not define, except to suggest that it includes both "life-saving" and "health-saving" abortions.[11] In short, the ACLU wants the Obama administration to forbid Catholic hospitals to exist, since hospitals performing abortions cannot meet an essential ethical requirement for Catholic health care.

The ACLU first presented its claim to the Department of Health and Human Services (HHS) in a letter of July 1, 2010. It said that "religiously affiliated hospitals" were violating requirements in federal law that pregnant women receive "emergency" abortions, citing an article prepared under the aegis of a major abortion training center. That article specifically charged "Catholic-owned hospitals" with endangering

[9] *Sherley v. Sebelius* (August 23, 2010), 14.

[10] Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111-264, *U.S. Statutes at Large* 124 (October 8, 2010): 2789, http://www.gpo.gov/fdsys/pkg/PLAW-111publ264/pdf/PLAW-111publ264.pdf.

[11] See Brigitte Amiri and Alexa Kolbi-Molinas, "The Obama Administration Must Ensure That Hospitals Provide Emergency Abortion Care," *ACLU Blog of Rights*, December 22, 2010, http://www.aclu.org/blog/religion-belief-reproductive-freedom/obama-administration-must-ensure-hospitals-provide-emergen.

women's health, basing the charge on anecdotes it published without documentation, identification, or cited sources. The ACLU letter claims that hospitals are required to perform abortions in such cases under the Emergency Medical Treatment and Active Labor Act (EMTALA) and under the conditions for participation in Medicaid and Medicare, and urged HHS to enforce these laws.[12]

The ACLU's distorted claims were comprehensively rebutted in an August 19 letter to HHS from the Becket Fund for Religious Liberty. The Becket Fund pointed out that the cited federal laws nowhere require any health care provider to perform abortions, and EMTALA's provisions on emergency care for pregnant women explicitly call on providers to stabilize the condition of both mother and "unborn child." Moreover, several long-standing federal laws protect the right of health care providers to decline involvement in abortion in all circumstances.[13]

However, the ACLU repeated its charges to HHS on December 22, the day after the Catholic Bishop of Phoenix informed St. Joseph's Hospital in his diocese that it can no longer identify itself as a Catholic hospital. The bishop took this action after St. Joseph's refused to assure him that it would not perform procedures that in his judgment violate the *Ethical and Religious Directives for Catholic Health Care Services*, the national code for Catholic health care that each diocesan bishop has the authority to interpret and apply in his diocese. The controversy with St. Joseph's arose after the hospital agreed to terminate the pregnancy of a woman with severe hypertension in November 2009, in a procedure that the hospital claimed (without the input or consent of the bishop) did not constitute a direct abortion in Catholic teaching.[14]

The ACLU now warns that such actions by bishops send "a chilling message" to Catholic hospitals that if they provide abortions in such cases "there will be consequences," and it urges the federal government to remedy this situation.[15] But since the only "consequence" here is that a hospital may no longer be able to identify itself

---

[12] ACLU to Marilyn Tavenner, acting administrator of the HHS Centers for Medicare and Medicaid Services, July 1, 2010, http://www.aclu.org/files/assets/Letter_to_CMS_Final_PDF.pdf. The article about alleged incidents at Catholic hospitals is "When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals," by L. Freedman et al., *American Journal of Public Health* 98.10 (October 2008): 1774–1778. The authors note that their research was "sponsored by the Kenneth J. Ryan Residency Training Program in Abortion and Family Planning at the Bixby Center, University of California, San Francisco" (1778).

[13] Kevin J. Hasson, president of Becket Fund for Religious Liberty, to Marilyn Tavenner, HHS Centers for Medicare and Medicaid Services, August 19, 2010, http://www.becketfund.org/files/response%20to%20aclu%20letter%20-%20final0001.pdf.

[14] See R. Stein, "Abortion Fight at Catholic Hospital Pushes ACLU to Seek Federal Help," *Washington Post*, December 22, 2010. The version of this article posted on the Web site of the *Arizona Republic* includes links to key documents in the Phoenix case: http://www.azcentral.com/community/phoenix/articles/2010/12/22/20101222phoenix-catholic-abortion-fight-aclu.html.

[15] ACLU to Donald Berwick, MD, administrator, and Marilyn Tavenner, HHS Centers for Medicare and Medicaid Services, December 22, 2010, http://www.aclu.org/files/assets/EMTALA-_ACLU_CMS_Follow_Up_Letter-St__Joseph-_12-22-2010_FINAL.pdf.

as a *Catholic* hospital, the ACLU's proposal essentially suggests that the Obama administration should overrule Catholic bishops in determining which hospitals are Catholic—an "entanglement with religion" nightmare that the ACLU's own First Amendment experts should have foreseen.

Despite the heavy-handed and poorly researched nature of the ACLU's campaign, its insistence that the government must increase pressures on pro-life health care providers is a reminder that clarifying and strengthening federal laws protecting conscience rights should be a priority in the new Congress.

Bioethics Commission Reports on Synthetic Biology

As reported in the Autumn 2010 *Washington Insider*, President Obama in May 2010 asked his presidential commission on bioethical issues to review the implications of recent developments in "synthetic biology." His request was prompted by the news that scientists have created a bacterial cell whose development is entirely directed by synthetic DNA.

The Presidential Commission for the Study of Bioethical Issues released its report on this matter on December 16. Commission chair Dr. Amy Guttman says the commission chose a "middle course" between "allowing unfettered freedom with minimal oversight," and "prohibiting experiments until they can be ruled completely safe beyond a reasonable doubt." Commission recommendations include White House–level coordination among agencies involved in such research, a "risk assessment" prior to field release of synthetic organisms, and better education of scientists and the general public on the benefits and risks of synthetic biology.[16]

The commission's call for "prudent vigilance," unaccompanied by significant new regulatory limits or safeguards, disappointed some observers. Saying that the final report is "very thin gruel," molecular biologist Richard Ebright of Rutgers University observed that it "suggests no substantive oversight" and is "fundamentally empty."[17] Bioethics commentator Wesley Smith agreed, saying that the commission "punted" on the need to set limits. "There is no reason to wait before beginning to regulate the field," he wrote. "Indeed, when better to do it than before anyone has a vested interest in crossing reasonable boundaries? For example, I think the government should outlaw using this technique on sentient life."[18] As this field moves forward, there will be many opportunities to debate whether the commission's generally rosy view of this technology is warranted.

Richard M. Doerflinger

---

[16] For the commission's press release and full report, see the news listing for December 2010 at http://www.bioethics.gov/news/.

[17] Quoted in Meredith Wadman, "U.S. Report Sets Ground Rules for Artificial Life," *Nature News,* December 16, 2010, http://www.nature.com/news/2010/101216/full/news.2010.680.html.

[18] Wesley J. Smith, "Obamaethics: Disappointing Bioethics Commission Report Punts on Regulating 'Synthetic Life,'" *Secondhand Smoke*, December 16, 2010, http://www.firstthings.com/blogs/secondhandsmoke/2010/12/16/obamaethics-disappointing-bioethics-commission-report-punts-on-regulating-synthetic-life/.