Washington Insider

With the end of December 2011, the first session of the 112th Congress came to a close. Pending bills that have not received a final vote will carry over into 2012.

One of the last bills enacted in 2011 was a Consolidated Appropriations Act to keep most federal programs funded through fiscal year 2012, which ends September 30, 2012.[1] Final negotiations between House and Senate produced a final package that retains all existing appropriations riders on abortion and rights of conscience. All restrictions on use of federally appropriated funds for abortion survived (including the ban on use of any public funds for elective abortion in the District of Columbia, an issue that had sharply divided House and Senate negotiators). The ban on use of federal funds for harmful research using human embryos remained intact. The Federal Employees Health Benefits Program retained its mandate for coverage of prescription contraceptives, but also retained its conscience provision exempting religiously affiliated health plans with a religious objection as well as individual health professionals in other plans who have a moral or religious objection. And the Hyde/Weldon amendment, which since 2004 has forbidden governmental discrimination against individual or institutional health care providers who do not provide, refer for, or pay for abortions, remained in law.

With a Senate majority and a President committed to a "pro-choice" agenda, even maintaining the status quo on such issues was a difficult and time-consuming task for Catholic and other organizations committed to life-affirming bioethics policies. Unfortunately, the end-of-year rush of legislative activity failed to address two conscience issues that have become increasingly urgent: shortcomings in the Hyde/Weldon amendment that may allow some discrimination to go unpunished, and the prospect of a new federal mandate for sterilization and prescription contraception

[1] Consolidated Appropriations Act of 2012 (H.R. 2055), signed into law December 23, 2011, as Public Law 112-74.

coverage in almost all health plans nationwide, without conscience protection even for many religious organizations. The only significant legislative advance on federal bioethics issues in 2011 was the codification in permanent law of a ban on patenting human organisms, including human embryos. These and other matters are discussed below.

Rights of Conscience in Health Care: The Unmet Need

Every year since 2004, Congress has approved the Hyde/Weldon amendment as a rider to the Labor/Health and Human Services appropriations bill. The amendment forbids federal agencies, and state and local governments receiving federal funds, to discriminate against institutional or individual health care providers who decline to provide, pay for, or refer for abortions.[2] In recent years, however, problems or deficiencies have become apparent in this provision.

Several problems arise from the fact that this rider to the Labor/HHS bill had to be framed as a "limitation of funds," to withstand a parliamentary objection that it constitutes "legislating on an appropriations bill." The amendment technically does not forbid discrimination, but asserts that no funds appropriated under this bill may be disbursed to a governmental body that discriminates. Thus, the only penalty explicitly established for cases where a state discriminates against health care providers is the complete loss of all federal health, labor, and education funding for that state. The state of California and others have pursued lawsuits claiming that this massive penalty is unconstitutional. And while those suits have been dismissed for the time being because a specific controversy has not come before the courts,[3] California officials have told Catholic health care organizations in the state that they do not believe the federal government would ever impose such a massive penalty on the entire state of California. In addition, the state's Department of Managed Health Care has told local Catholic health systems to include abortion coverage in their employee health plans, claiming that their actions are not forbidden by the current Weldon amendment because this particular department of the state government does not directly receive federal funds.[4]

Enforcement of the conscience law is also stymied by the absence of explicit language on how victims can file a complaint to vindicate their rights. By regulation, the Obama administration has instructed victims to file a complaint with the Office for Civil Rights at the Department of Health and Human Services. But it is increasingly clear that in this administration, at least, HHS may be one of the perpetrators that need to be restrained by the law. In an egregious instance of discrimination, the HHS

[2] The version currently in effect is section 507(d) of division F of H.R. 2055.

[3] See *California v. United States*, 2008 WL 744840 (N.D. Cal. 2008).

[4] See letter to members of Congress from Cardinal Daniel N. DiNardo, chairman of the USCCB Committee on Pro-Life Activities, December 7, 2011, http://www.usccb.org/issues-and-action/religious-liberty/conscience-protection/upload/DiNardo-Letter-to-Congress-Regarding-ANDA_Dec_2011.pdf.

Office of Refugee Resettlement (ORR) recently eliminated the role of the Catholic bishops' Migration and Refugee Services (MRS) in managing a government program for serving the victims of human trafficking.[5] Under oath at a congressional oversight hearing, ORR officials admitted that MRS had done an excellent job managing the program for the previous five years—but the grant was transferred to three other organizations, two of which received far lower scores than MRS from independent reviewers, solely because those groups agreed to send clients only to health care providers who will help them obtain abortions and contraceptives. The officials insisted that HHS attorneys had assured them this discrimination is completely legal.[6]

In response to these growing problems, the Catholic bishops' conference urged congressional leaders to include in their final appropriations package the text of the Abortion Non-Discrimination Act (ANDA),[7] a proposed law to make the Weldon protections permanent and correct the flaws described above. ANDA would make it clear that subunits of state and local governments that receive federal funds are covered by the nondiscrimination policy; it would provide for a "private right of action" so that victims can go to federal court with complaints and courts can issue injunctions and provide other relief to end the discrimination without defunding entire governmental bodies. Pursuing this effort with the bishops were the Alliance for Catholic Health Care, representing over four dozen Catholic hospitals in California, and other concerned religious, pro-life, and medical groups. ANDA was ultimately included in the House's draft Labor/HHS appropriations bill that became the basis for negotiations with the Senate, but it did not survive in the final appropriations package. One problem faced by House leadership in this negotiation was that dozens of fiscally conservative House Republicans threatened to oppose the final package unless it made more drastic cuts in federal spending; politically, then, in the final face-off with the Senate, that issue became a more nonnegotiable demand for the House than the demand for better conscience protection.

Also unresolved at the end of 2011 was the dispute over the Department of Health and Human Services' new nationwide mandate for almost all health plans to cover sterilization and the full range of FDA-approved contraceptives (including drugs approved for "emergency contraception" that can induce an early abortion).[8] Catholic and other groups were especially appalled that the mandate's incredibly narrow religious exemption would not exempt even most kinds of religious employers, or religiously

[5] See Michael Gerson, "Obama Turns His Back on Catholics," *Washington Post*, November 14, 2011, http://www.washingtonpost.com/opinions/obama-turns-his-back-on-catholics/2011/11/14/gIQABHCKMN_story.html.

[6] See "HHS and the Catholic Church: Examining the Politicization of Grants," hearing of the House Committee on Oversight and Government Reform, December 1, 2011, http://oversight.house.gov/index.php?option=com_content&view=article&id=1522%3A12-1-2011-qhhs-and-the-catholic-church-examining-the-politicization-of-grantsq&catid=12&Itemid=20.

[7] H.R. 361 and S. 165. By end of 2011, the legislation had 108 sponsors in the House and 9 in the Senate.

[8] See William Saunders' "Washington Insider" in the Winter 2011 issue, 637–641.

affiliated educational institutions with student health plans.[9] After it became public that President Obama had expressed a willingness to consider a broader exemption, pro-abortion groups launched a new offensive to condemn any such move and to insist on removing even the narrow exemption already in place, so that even clergy and the employees of houses of worship would be forced to purchase contraceptive coverage.[10] The Catholic community responded with full-page newspaper ads signed by over a hundred leaders of Catholic health care, charitable, and educational organizations, urging the President and Congress to support conscience protection for all involved in providing, sponsoring, and purchasing health insurance.[11] As of this writing no new policy had been announced, and calls for Congress to address the problem through a rider to the final consolidated appropriations act had gone unheeded. Without new action by Congress or the administration, the mandate as currently written will take full effect in August 2012.

Progress on Patenting

Given the lack of decisive action on the issues discussed above, the one notable bioethics advance by Congress in 2011 was the enactment in permanent law of a ban on human patenting. The annual rider first establishing this ban—known as the Weldon amendment after its sponsor, former Rep. Dave Weldon (R-FL)—was approved by Congress in 2004, after researchers began to discuss the prospects for patenting human embryos made to various specifications for research use; it has been maintained by an annual appropriations rider ever since. With the enactment of the America Invents Act on September 16, 2011,[12] this policy was codified as part of permanent federal law governing patents. Section 33 of the act reads,

> SEC. 33. LIMITATION ON ISSUANCE OF PATENTS.
> (a) Limitation.— Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

[9] See the news releases and letters of the U.S. Conference of Catholic Bishops from July through December 2011, at http://www.usccb.org/issues-and-action/religious-liberty/conscience-protection/.

[10] See, for example, Laura Bassett, "Will Obama Back Down on Birth Control?" Huffington Post, November 18, 2011, http://www.huffingtonpost.com/2011/11/18/lawmakers-worry-obama-will-cave-to-bishops-on-birth-control_n_1102077.html, and Robert Pear, "Democrats Urge Obama to Protect Contraceptive Coverage in Health Plans," New York Times, November 20, 2011, A16, http:// www.nytimes.com/2011/11/20/us/politics/democrats-urge-obama-to-defend-birth-control-rules.html.

[11] For the text of the full-page ad that appeared in the *Washington Post* and *New York Times* on December 21, 2011, see http://www.usccb.org/issues-and-action/religious-liberty/conscience-protection/upload/Catholic-Leaders_Protect-Conscience-Rights_12-21-11-pdf.pdf. By early January 2012, the statement had been signed by 434 Catholic leaders. An up-to-date list of signers can be found at http://www.usccb.org/issues-and-action/religious-liberty/conscience-protection/.

[12] H.R. 1249, enacted as Public Law 112-29. For more background on the congressional debate on this issue, see my "Washington Insider" in the Autumn 2011 issue, 425–426.

> (b) Effective Date.—
>
> (1) IN GENERAL.—Subsection (a) shall apply to any application for patent that is pending on, or filed on or after, the date of the enactment of this Act.
> (2) PRIOR APPLICATIONS.—Subsection (a) shall not affect the validity of any patent issued on an application to which paragraph (1) does not apply.

Notwithstanding the continuing federal policy of funding stem cell research that involves the destruction of "spare" human embryos, then, at least United States law firmly rejects the idea that the embryonic human being is merely a commodity to be manufactured and patented for profit.

European policy has taken a far broader step. On October 18, 2011, the European Court of Justice issued a final ruling that stem cell lines arising from destruction of human embryos, including cell lines already in existence and procedures or products based on them, may not be patented in the twenty-seven countries of the European Union.

Reactions of some embryonic stem cell researchers were characteristically exaggerated, with one German researcher whose patent had been rejected by the court calling the decision "a disaster for Europe."[13] A more informed analysis was offered by bioethics commentator Wesley J. Smith. He pointed out that the court simply interpreted and applied a European law forbidding EU nations to issue patents involving "uses of human embryos for industrial or commercial purposes" on the grounds that such use is "contrary to *ordre public* or morality." Smith observes that the suit against patenting embryonic stem cells had been brought not by pro-life groups but by the environmentalist group Greenpeace. However, pro-life advocates may be interested in the court's response to the claim that the word "embryo" in the European law should apply only after implantation in the uterus. The court replied that "respect for human dignity" requires one to recognize "any human ovum … as soon as fertilized" as a human embryo, "since that fertilization is such as to commence the process of development of a human being." Smith says the ruling discourages venture capitalists from putting significant money into embryonic stem cell-derived products, by reducing their profit motive; it also "boosts normal adult stem cell research and induced pluripotent stem cell experiments—in which a skin cell can be reprogrammed into a stem cell—because they and products derived from these sources *can* be patented in Europe."[14]

Stem Cells and Human Cloning

Since federal courts rejected a suit against federal funding of embryonic stem cell research in the summer of 2011, no significant policy development has taken

[13] Ewen Callaway, "European Court Bans Patents Based on Embryonic Stem Cells," *Nature News*, published online October 18, 2011, http://www.nature.com/news/2011/111018/full/news.2011.597.html.

[14] Wesley Smith, "A European Victory for Ethical Stem Cell Research," *On the Square* (*First Things*), November 8, 2011, http://www.firstthings.com/onthesquare/2011/11/a-european-victory-for-ethical-stem-cell-research.

place in Washington on this issue.[15] Even as the Obama administration brought the total number of embryonic stem cell lines eligible for federally funded research up to 143 as of January 2012,[16] major developments in the scientific community provided further evidence of the obsolescence of this avenue of research.

The most striking news was that Geron Corporation, the nation's leader in pursuing therapies from embryonic stem cells, announced that it was discontinuing its first-ever human trial in therapeutic use of these cells and "leaving the stem cell business entirely." Geron cut 38 percent of its work force and said it would concentrate on trials using its experimental cancer drugs in the near future.[17] The announcement crystallized a growing realization among American researchers that any therapeutic promise from these cells may be a very long way off.

Meanwhile, progress toward expanded therapeutic use of adult stem cells and other non-destructive approaches continued. For example, a number of researchers reported progress in making ordinary adult cells convert directly to other cell types, "avoiding the tumor-causing pluripotent stage associated with stem cells."[18] In October 2011, researchers announced progress in improving the condition of cystic fibrosis patients using adult stem cells.[19] And scientists at the University of Pittsburgh showed that prematurely aging mice became healthier and lived much longer after being injected with adult stem cells from the muscles of young, healthy mice. The healthy stem cells seemed not so much to replace aging cells as to secrete rejuvenating factors that corrected dysfunction in the cells around them. This suggests that "it might be possible one day to forestall the biological declines associated with aging by delivering a shot of youthful vigor, particularly if specific rejuvenating proteins or molecules produced by the stem cells could be identified and isolated."[20]

---

[15] To be sure, we have not seen the end of this lawsuit. The plaintiffs are appealing their case to a new three-judge panel of the D.C. Circuit Court of Appeals, with oral argument expected April 23, 2012. See Jocelyn Kaiser, "Dates, Judges Set in Appeal of Stem Cell Suit," *ScienceInsider*, December 9, 2011, http://news.sciencemag.org/scienceinsider/2011/12/dates-judges-set-in-appeal-of-st.html.

[16] See National Institutes of Health, *Human Embryonic Stem Cell Registry*, updated July 13, 2011, http://grants.nih.gov/stem_cells/registry/current.htm.

[17] Andrew Pollack, "Geron is Shutting Down Its Stem Cell Clinical Trial," *New York Times*, November 15, 2011, B2, http://www.nytimes.com/2011/11/15/business/geron-is-shutting-down-its-stem-cell-clinical-trial.html?_r=1.

[18] Jef Akst, "Skipping Pluripotency," *The Scientist*, September 14, 2011, http://the-scientist.com/2011/09/14/skipping-pluripotency/.

[19] Alliance for the Advancement of Adult Stem Cell Therapy and Research, "Cystic Fibrosis Patients See Significant Results with Regenocyte Adult Stem Cell Therapy," news release, *Market Watch* (*Wall Street Journal*), October 26, 2011, http://www.marketwatch.com/story/cystic-fibrosis-patients-see-significant-results-with-regenocyte-adult-stem-cell-therapy-2011-10-26.

[20] University of Pittsburgh Schools of the Health Sciences, "Shot of Young Stem Cells Makes Rapidly Aging Mice Live Much Longer and Healthier, Researchers Report,"

Loosening Organ Transplant Rules?

Near the end of 2011, the National Catholic Bioethics Center managed to help stall a proposed loosening of national protocols for removing vital organs from patients who no longer have a heartbeat. The issue is sure to return in 2012 after an opportunity is provided for more complete public comment.

The change was proposed by the United Network for Organ Sharing (UNOS), a nonprofit organization that since 1986 has held the federal grant for coordinating the nationwide Organ Procurement and Transplantation Network (OPTN) established by Congress under the National Organ Transplant Act of 1984. Since 2007, UNOS/OPTN has proposed "model elements" (guidelines) on the donation of organs after cardiac death. The new proposal, originally scheduled for approval at a November 14–15 meeting of the UNOS/OPTN board of directors, would make these guidelines "requirements" while dropping many specific safeguards.[21] One University of Washington bioethicist observed, "By this document, every hospital in America can now develop its own definition of 'dead,' and that is profoundly disturbing. … We are, it seems, admitting that we are willing to take the chance of procuring organs from someone who is not dead yet."[22] Dr. John Haas, president of the National Catholic Bioethics Center, wrote to the board on November 11 to point out a number of specific problems, including these: the new proposal drops the older "model elements" sections on how to define irreversibility and how to determine the permanent absence of circulation, in effect allowing each hospital to decide how long after circulation ceases a patient can be declared dead; it broadens the criteria for donor candidates to include patients with "permanent and irreversible neurological injury" without clearly defining that term; and it removes a requirement that, before a patient can be considered a candidate for future organ removal, the patient's family and primary health care provider must first decide that removal of life-sustaining treatment is appropriate on other grounds.[23]

---

news release, *ScienceDaily*, January 3, 2012, http://www.sciencedaily.com/releases/2012/01/120103135131.htm. The research is reported in full in Mitra Lavasani et al., "Muscle-Derived Stem/Progenitor Cell Dysfunction Limits Healthspan and Lifespan in a Murine Progeria Model," *Nature Communications*, January 3, 2012, http://www.nature.com/ncomms/journal/v3/n1/full/ncomms1611.html.

[21] The 2007 "Model Elements for Controlled DCD Recovery Protocols" (attachment III to appendix B of the OPTN bylaws) can be found at http://optn.transplant.hrsa.gov/search.asp?qu=bylaws. The "Proposal to Update and Clarify Language in the DCD Model Elements" (proposal 25) can be found at http://optn.transplant.hrsa.gov/policiesAndBylaws?publicComment/proposals.asp.

[22] See Rob Stein, "Changes in Controversial Organ Donation Method Stir Fears," *Washington Post*, September 19, 2011, http://www.washingtonpost.com/national/health-science/changes-in-controversial-organ-donation-method-stir-fears/2011/09/15/gIQAlY9agK_story.html.

[23] Letter to John R. Lake, president of OPTN/UNOS board of directors, from John M. Haas, November 11, 2011, http://www.ncbcenter.org/document.doc?id=214.

In this instance, informed criticism of a federal proposal prevailed, at least for the time being. The OPTN/UNOS executive committee instructed the committee developing the proposal to withdraw it from consideration at the board's November 14–15 meeting, and resubmit it for broader public comment at a later time.[24] So on this issue as well, one can expect to see further developments in the new year.

Looking Ahead to 2012

The second session of the 112th Congress, running through 2012, has a good deal of unfinished business on these issues. Efforts to pass the Abortion Non-Discrimination Act and to protect conscience rights threatened by the new federal contraceptive mandate will continue. Supporters of two other House-passed pro-life bills will also seek ways to bring them before the Senate for an up-or-down vote. These are the No Taxpayer Funding for Abortion Act,[25] to establish a permanent and government-wide policy against federal funding of abortion, and the Protect Life Act,[26] to bring the new health care reform law into compliance with policies on abortion funding and conscience rights governing other federal health programs. There may be new developments in the continuing law suit against federal funding of embryonic stem cell research, and in the dispute over organ transplant protocols. It should be a year worth watching.

Richard M. Doerflinger

[24] Executive summary of the minutes, OPTN/UNOS board of directors meeting, November 14–15, 2011, http://optn.transplant.hrsa.gov/SharedContentDocuments/ExecutiveSummary_1111.pdf. See also NCBC news release of December 5, 2011, http://www.ncbcenter.org/page.aspx?pid=482.

[25] H.R. 3, approved by the House of Representatives on a vote of 251 to 175 on May 4, 2011.

[26] H.R. 358, approved by the House of Representatives on a vote of 251 to 172 on October 13, 2011.