amendment.

Thanks to the efforts of state regulatory agencies, such as the California Air Resources Board, the region has seen a marked improvement in air quality and other environmental indicators. The number of air quality alerts has fallen from over 200 per year in the 1970s to less than 10 per year today.

For 17 years, the Air Resources Board has regulated and monitored oil and gas operations near my district. The standards they employ were developed over nearly 5 decades of experience, and, most importantly, they remain directly accountable to the people and communities of California.

Mr. Chair, I believe that if a state invests time and money towards establishing high standards and creating innovative solutions to a problem, they ought to enjoy the full support of the law.

I urge my colleagues to support the Capps amendment.

HONORING U.S. MERCHANT MARINE

HON. TOM REED
OF NEW YORK
IN THE HOUSE OF REPRESENTATIVES
Thursday, June 23, 2011

Mr. REED. Mr. Speaker, I rise today to acknowledge the tremendous work accomplished by the U.S. Merchant Marine during World War II.

Those who served on ships in the Merchant Marine risked their lives and welfare during World War II to protect our country. Like our other service members, the Merchant Marine members served in both theaters of war. They faced enemy fire, floating mines and other dangerous conditions. Unfortunately the risks faced by these brave men have often been forgotten.

Mr. Speaker, one of my constituents, Jacena Brahm, wrote me a letter to tell me about her husband, Vernon Lee Brahm, who served in the U.S. Merchant Marine. I’m proud to recognize Mr. Brahm and all the brave men who served in the Merchant Marine during World War II. These men committed their lives to America’s cause by leaving their families and their homes and putting themselves in harm’s way to help win the war. I commend these brave souls for all that they did to ensure our freedom. The Merchant Marine helped lead us to victory.

The sacrifices of our veterans have been appreciated throughout the history of our nation, and that demonstration of respect should not be denied to those in Merchant Marine who also defended our nations’ interests in World War II.

HONORING JEANETTE SUTHERLIN

HON. JEFF DENHAM
OF CALIFORNIA
IN THE HOUSE OF REPRESENTATIVES
Thursday, June 23, 2011

Mr. DENHAM. Mr. Speaker, I rise today to acknowledge and honor Jeanette Sutherlin on her retirement from the University of California Cooperative Extension; and to thank her for her dedicated, lifelong spirit of community service.

Since joining the University of California Cooperative Extension in 1973, Jeanette has been a leading advocate for nutrition and agricultural education, working tirelessly to implement nutrition education and youth development programs throughout Fresno County.

Jeanette began her career at the University of California Cooperative Extension in Fresno County as the 4-H Advisor. She later took over the role of Nutrition, Family and Consumer Sciences Advisor where she focused on providing nutrition education and access to healthy nutrition for low-income families in Fresno County. In addition, she successfully secured more than a half-million dollars in grants each year to fund multiple projects related to nutrition and agricultural education.

Jeanette’s hard work in the Fresno County agriculture industry is deeply valued by those who have worked with her. One of Jeanette’s main focuses was strengthening a nearly decade-long relationship between the University of California Cooperative Extension and the Fresno County Farm Bureau. President Brian Pacheco commended Jeanette’s contributions to the Fresno County Farm Bureau, stating, “Jeanette’s expertise in nutrition education, youth development and administration has been an asset to the Fresno County Farm Bureau, and her services will not be soon forgotten.”

Beyond her work at the University of California Cooperative Extension and Fresno County Farm Bureau, Jeanette has volunteered much of her time to philanthropic endeavors. She currently serves as Chairperson of the Board for the Trauma Intervention Program, providing emotional aid and practical support to victims of traumatic events and their families in the hours following a tragedy.

Mr. Speaker, please join me in honoring Jeanette Sutherlin on her retirement and wishing her the best of luck and health in her future endeavors.

SUPPORT OF A NATIONAL WORLD WAR I MEMORIAL

HON. ELEANOR HOLMES NORTON
OF THE DISTRICT OF COLUMBIA
IN THE HOUSE OF REPRESENTATIVES
Thursday, June 23, 2011

Ms. NORTON. Mr. Speaker, I submit the following:

Whereas, the year 2014 marks the centennial of World War I, often referred to as the “Great War;”

Whereas, the National Mall is home to memorials for America’s major 20th century conflicts—the World War II Memorial, the Korean War Veterans Memorial, and the Vietnam Veterans Memorial, with the exception of a World War I Memorial;

Whereas, the District of Columbia War Memorial, managed by the National Park Service, was dedicated to the more than 26,000 District residents who, without a vote in Congress, served bravely in World War I, including 499 who were killed;

Whereas, a memorial dedicated to all Americans who served in World War I should be located in our nation’s capital, in a well-traveled area commensurate with the importance of World War I in the nation’s history;

Whereas, members of Congress and other Americans desire to establish a commission to ensure a suitable observance of the World War I centennial;

Whereas, the National Park Service, the National Capital Memorial Advisory Commission, and the American Battle Monuments Commission have specifically determined that either adding a new National World War I Memorial in the vicinity of the District of Columbia War Memorial or re-designating the District of Columbia Memorial as a National World War I Memorial would violate the Commemorative Works Act; be it therefore

Resolved that, the District of Columbia War Memorial should remain a memorial dedicated solely to the D.C. residents who served in World War I; and, be it therefore

Resolved that, a proper location for a memorial dedicated to all Americans who served in World War I shall be determined; and, be it therefore

Resolved that, Congress should authorize a study or commission to determine a proper location for a memorial dedicated to all Americans who served in World War I.

AMERICA INVENTS ACT

HON. CHRISTOPHER H. SMITH
OF NEW JERSEY
IN THE HOUSE OF REPRESENTATIVES
Wednesday, June 22, 2011

The House in Committee of the Whole House on the State of the Union had under consideration the bill (H.R. 1249) to amend title 35, United States Code, to provide for patent reform:

Mr. SMITH of New Jersey. Madam Chair, for over two decades, USPTO has had an internal policy that human beings at any stage of development are not patentable subject matter under 35 U.S.C. Section 101. I commend Chairman Lamar Smith for including in the manager’s amendment to H.R. 1249, the America Invents Act, a provision that will codify an existing pro-life policy rider included in the CJS Appropriations bill since FY2004. This amendment, commonly known as the Weldon amendment, ensures the U.S. Patent and Trade Office, USPTO, does not issue patents that are directed to or encompassing a human organism.

Codifying the Weldon amendment simply continues to put the weight of law behind the USPTO policy.

This amendment and USPTO policy reflect a commonsense understanding that no member of the human species is an “invention,” or properly to be licensed for financial gain. Patients on human organisms commodify life and allow profiteers to financially gain from the biologic and life of another human person.

Codifying a ban on patenting of humans would not violate international obligations under the TRIPs agreement with the WTO, in which member countries can exclude from patentability subject matter to prevent commercial exploitation which is “necessary to protect public morality, [and] to protect human, animal or plant life.” (The Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27, Section 5)
Even the European Union prevents patents on human embryos on the basis of morality and public order without conflicting with the TRIPs agreement. (See Guidelines for Substantive Examination. European Patent Office. Part C, Chapter IV, Section 4.5, iii (Rule 28c))

Long-standing American patent and trademark policy states that human beings at any stage of development are not patentable, subject to matters under 35 U.S.C. section 101. Though some policy would not issue patents on human embryos, Congress has remained silent on this subject. Though this amendment would not actually ban this practice of the Patent Office, it should simply reaffirm current U.S. patent policy and ensure there is not financial gain or ownership of human beings by those who engage in this commerce.

This amendment simply mirrors the current patent policy concerning patenting human beings. The Patent Office has, since 1980, aggressively rejected patent claims subject to the morality in the area of biotechnological inventions which concern:

- uses of human embryos for industrial or commercial purposes;
- the exclusion of the use of human embryos for industrial or commercial purposes does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are not directed to a product, process, or method that will add further clarification to the intent of this important provision.

SPEECH OF HON. DAVE WELDON OF FLORIDA IN THE HOUSE OF REPRESENTATIVES, JULY 22, 2001

Mr. WELDON of Florida. Mr. Chairman, I offer an amendment.

Mr. CHAIRMAN pro tempore. The Clerk will designate the amendment.

Mr. WELDON of Florida. None of the funds appropriated or otherwise made available under the act may be used to issue patents on claims directed to or encompassing a human organism.

Mr. WELDON of Florida. Mr. Chairman, technology proceeds at a rapid rate, bringing great entrepreneurial opportunities and new technology that will add further clarification to the intent of this important provision.

Mr. WELDON of Florida. Mr. Chairman, I yield to the gentleman from Florida (Mr. WELDON).

Mr. TERRY. Mr. Chairman, I yield back.

Mr. WELDON of Florida. Mr. Chairman, I thank the gentleman for yielding to me. I think I heard the gentleman say this, but I want it repeated again so it is clear. I yield to the gentleman from Florida (Mr. WELDON) who is about to make an amendment adding the language of the current Patent Office (USPTO) against patenting human beings. However, they oppose this amendment, saying it would have a far broader scope—potentially prohibiting patents on stem cell lines, cloning for research purposes, creating human embryos, prosthetic devices, and in short almost any drug or product that might be used in or for human beings.

Mr. WELDON of Florida. Mr. Chairman, the absurdity of these claims is apparent when one compares the language of the amendment with the language of the current USPTO policy that these groups claim to support.

The House-approved amendment reads: "None of the funds appropriated or otherwise made available under the act may be used to issue patents on claims directed to or encompassing a human organism."

The current USPTO policy is set forth in two internal documents:


"The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any application for a patent on any non-plant multicellular organism which would include a human being within its scope includes the limitation ‘‘non-human’’ to avoid the ground of rejection."

This noticed response to the Supreme Court’s 1980 decision in Chakrabarty concludes that a modified oyster, a bacterium, could be patented, and a subsequent decision by the USPTO’s own Board of Appeals in Ex parte Allen that a multicellular organism such as a modified oyster is therefore patentable as well. The USPTO sought to ensure that these policy conclusions would not be misconstrued as allowing a patent on a human organism.


"If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under section 101 must be made. It is the recommendation that the claimed invention is directed to non-statutory subject matter."

In other words, the USPTO clearly distinguishes between organisms that are non-human and therefore are patentable and those organisms that are human and therefore not patentable subject matter.

As a USPTO official testified recently to the President’s Council on Bioethics:

"When a patent claim includes or covers a human being, the USPTO will reject the claim on the grounds that it is directed to non-statutory subject matter. When examining a patent application, a patent examiner must construe the claim presented as broadly as is reasonable in light of the application’s specification. If the examiner determines that a claim is directed to a human being at any stage of development, such as a product, the examiner rejects the claims on the grounds that it includes non-statutory subject matter and provides the applicant with an explanation."

Bio and CAMR claim to support the current policy of the U.S. Patent and Trademark Office (USPTO) against patenting human beings. However, they oppose this amendment, saying it would have a far broader scope—potentially prohibiting patents on stem cell lines, cloning for research purposes, creating human embryos, prosthetic devices, and in short almost any drug or product that might be used in or for human beings.

Mr. WELDON of Florida: Mr. Chairman, I think it is about time that Congress starts to speak up and take a stand on this issue. We have been silent for far too long on this issue. However, they oppose this amendment, saying it would have a far broader scope—potentially prohibiting patents on stem cell lines, cloning for research purposes, creating human embryos, prosthetic devices, and in short almost any drug or product that might be used in or for human beings.
being and reject the claims as directed to non-statutory subject matter.” (Testimony of Karen Hauda on behalf of USPTO to the President’s Council on Bioethics, June 20, 2002, http://bioethics.gov/transcripts/jun02/jun2I session5.html)

Current USPTO policy, then, is that any claim that can be interpreted as directed to or encompassing a human being, and any claim reaching beyond “nonhuman” organisms to cover human organisms (including human embryos) should be rejected. My amendment simply restates this policy, providing congressional support so that federal courts will not invalidate the USPTO interpretation beyond the Congress (as they invalidated the earlier USPTO policy against patenting living organisms in general). Literally the only difference the amendment makes to any of these USPTO documents is that the amendment uses the term “human organism,” while the USPTO usually speaks of the non-patentability of anything that can be biologically construed as “a human being.” But “human organism” is more politically neutral and more precise, having a long history of clear definition in Federal law.

Since 1996, Congress has annually approved a rider to the Labor/HHS appropriations bill that prohibits funding of research in which human embryos are created or destroyed—and this rider defines a human embryo as “a human organism” not already protected by Federal regulations on fetal research. In December 1998 testimony before the Senate Appropriations Sub-committee on Labor/HHS/Education, a wide array of expert witnesses—including NIH Director Harold Varmus and the head of a leading company in BIO—testified that this rider does not forbid funding research on embryonic cells or stem cells, but that what is an “organism” but a stem cell clearly is not (see S. Hrg. 105-939, December 2, 1998). That same conclusion was later reached by HHS general counsel Harriet Rabb, in arguing that the Clinton administration’s guidelines on stem cell research were in accord with statutory law; this same legal opinion was accepted by the Bush administration when it issued its more limited guidelines for funding stem cell research (Legal memorandum of HHS general counsel, Harriet R. Rabb, “Feeder Research Involving Human Pluripotent Stem Cells,” January 15, 1999). To argue now that a ban on patenting “human organisms” somehow bans patenting embryonic cells or stem cell lines is run counter to years of legal history, and would undermine the legal validity of any federal funding for embryonic stem cell research.

BIO also claims that the amendment raises new and difficult questions about “mixing” human and nonhuman species. What is a species? What is an animal that is modified to include a few human genes so that it can produce a human protein or antibody? What about a human-animal hybrid? How do we define an embryo, that is, a “human, half animal?” The fact is, these questions are not new. The USPTO has already granted patents on the former (see U.S. patent nos. 5,625,128 and 5,693,306). It has also thus far rejected patents on the latter, the half-human embryo (see Biotechnology Law Report, July–August 1998, p. 256), because the latter can broadly but reasonably be construed as a human organism. The Weldon amendment does nothing to change this, but leaves the USPTO free to address new or borderlining cases on the same case–by-case basis as it already does.

In short, my amendment has exactly the same scope as the current USPTO policy, and only restates with the proper emphasis of policy that BIO and its allies claim. In reality, BIO opposes this amendment because it opposes the current USPTO policy as well, and has a better chance of nullifying this policy in court (or having courts reinterpret it into uselessness) if it lacks support from Congress. This goal is apparent from BIO’s own “fact sheet” opposing the amendment (see www.bio.org/wp/cloning/factsheet.asp). There is no evidence that the USPTO would invalidate any “conventional reproduction” or have any “physical characteristics resulting from human reproduction.” In other words, humans should be seen as “inventions” and thus be patentable on exactly the same grounds as animals are now.

The logic of the USPTO’s position reaches beyond the human embryo, because an embryo who resulted from reproductive technology or received any physical or genetic modification presumably remains just as invented throughout his or her existence, no matter what stage of development he or she reaches. The USPTO’s position must therefore be rejected on grounds that it undermines the U.S. Patent and Trademark Office’s commitment to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim directed to an organism of the species Homo sapiens at any stage of development. It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus; hence claims directed to living “organisms” are to be rejected unless they include the adjective “nonhuman.”

The USPTO’s policy of rejecting patent application claims that encompass human lifeforms, which the Weldon Amendment elevates to an unequivocal prohibition, applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., nuclear transfer, in vitro fertilization, pathogenensis). If a patent examiner determines that a claim is directed to a human life-form at any stage of development, the claim is rejected as non-statutory subject matter and will not be issued in a patent as such.

As indicated in Representative Weldon’s remarks in the Congressional Record of November 5, 2003 the referenced language precludes the patenting of human organisms, including human embryos. He further indicated that the amendment’s goal was “to elevate the same scope as the current USPTO policy,” which assures that any claim that can be broadly construed as a human being, including a human embryo or fetus, is not patentable subject matter. Therefore, our understanding of the plain language of the Weldon Amendment is fully consistent with the detailed statements that the author of the amendment, Representative Weldon, has made in the Congressional Record regarding the meaning and intent of his amendment.

While the USPTO’s interpretation of the Weldon Amendment does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development, the amendment is fully consistent with our policy, and we support its enactment. With best personal regards, I remain Sincerely,

JAMES E. ROGAN,
Under Secretary and Director.

SPEECH OF HON. DAVE WELDON OF FLORIDA IN THE HOUSE OF REPRESENTATIVES FRIDAY, NOVEMBER 21, 2003

AMENDMENT TO SUPPORT CURRENT U.S. PATENT AND TRADEMARK OFFICE POLICY AGAINST PATENTING HUMAN ORGANISMS—EXTENSIONS OF REMARKS—NOVEMBER 22, 2003

Mr. WELDON of Florida. Mr. Speaker, this summer I introduced an amendment that provides congressional support for the current U.S. Patent and Trademark Office policy against patenting human organisms, including human embryos. This amendment was approved by the House of Representatives with bipartisan support on July 22, 2003, as Sec. 801 of the Commerce/Justice/State Appropriations Bill. On November 5th of this year, I submitted to the Congressional Record an analysis of my amendment that offers a more complete elaboration of what I stated on July 22nd, namely, that this amendment “has no bearing on stem cell research or patent genes, it only affects patenting human organisms, human embryos, human fetuses or human beings.”

However, some have continued to misrepresent my amendment by claiming it would apply to methods directed to produce human organisms. Moreover, some incorrectly claim that my amendment would prohibit patents on claims directed to human organisms. This is simply untrue.

What I want to point out is that the U.S. Patent Office has already issued patents on genes, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos. This amendment would not affect the former, but would simply affirm the latter. This position is reaffirmed in the following U.S. Patent Office letter of November 20, 2003:

I submit to the Record a letter from James Rogan, Undersecretary and Director of the U.S. Patent office, that supports the enactment of my amendment because it “is fully consistent with our policy.”

U.S. PATENT AND TRADEMARK OFFICE,
November 20, 2003

Hon. Ted STEVENS,
Chairman, Committee on Appropriations, U.S. Senate, Washington, DC.

Dear Mr. Chairman: Thank you for the opportunity to present my position on the Weldon amendment adopted by the House during consideration of H.R. 2799, the Commerce-Justice-State Appropriations bill FY 2004, and the effect it would have on the United States Patent and Trade Mark Office (USPTO) policy on patenting human organisms which was outlined below, we view the Weldon amendment as fully consistent with USPTO’s policy on the non-patentability of human life-forms.

The USPTO understands that the Weldon Amendment is intended to provide unequivocal congressional backing for the long-standing USPTO policy of refusing to grant any patent containing a claim directed to an organism of the species Homo sapiens at any stage of development. It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus; hence claims directed to living ‘organisms’ are to be rejected unless they include the adjective ‘nonhuman.’

The USPTO’s policy of rejecting patent application claims that encompass human lifeforms, which the Weldon Amendment elevates to an unequivocal prohibition, applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., nuclear transfer, in vitro fertilization, pathogenensis). If a patent examiner determines that a claim is directed to a human life-form at any stage of development, the claim is rejected as non-statutory subject matter and will not be issued in a patent as such.

As indicated in Representative Weldon’s remarks in the Congressional Record of November 22, 2003 the referenced language precludes the patenting of human organisms, including human embryos. He further indicated that the amendment’s goal was “to elevate the same scope as the current USPTO policy,” which assures that any claim that can be broadly construed as a human being, including a human embryo or fetus, is not patentable subject matter. Therefore, our understanding of the plain language of the Weldon Amendment is fully consistent with the detailed statements that the author of the amendment, Representative Weldon, has made in the Congressional Record regarding the meaning and intent of his amendment.

While the USPTO’s interpretation of the Weldon Amendment does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development, the amendment is fully consistent with our policy, and we support its enactment. With best personal regards, I remain Sincerely,

JAMES E. ROGAN,
Under Secretary and Director.

SPEECH OF HON. DAVE WELDON OF FLORIDA IN THE HOUSE OF REPRESENTATIVES MONDAY, DECEMBER 8, 2003

CONFERENCE REPORT ON H.R. 2673, CONSOLIDATED APPROPRIATIONS ACT, 2004—HOUSE OF REPRESENTATIVES—DECEMBER 8, 2003

Mr. WELDON of Florida. Mr. Speaker, on July 22, 2003, I introduced an amendment to provide congressional support for the current U.S. Patent and Trademark Office (USPTO) policy on patenting human organisms. Against this amendment, 279 claims directed to human organisms, including human embryos and human fetuses. The House of Representatives approved the amendment without objection on July 22, 2003, as section 801 of the Fiscal Year 2004 Commerce/Justice/State Appropriations Bill. The amendment, now included in the Omnibus Appropriations Bill for Fiscal Year 2004, as section 801 of the Commerce/Justice/State Appropriations Bill, H.R. 2673, reads as follows: “None of the funds appropriated or otherwise made available...
under this Act may be used to issue patents on claims directed to or encompassing a human organism.

The current Patent Office policy is that "non-human organisms, including animals" are patentable subject matter under 35 U.S.C. 101, but that human organisms, including humans and human fetuses, are not patentable. Therefore, any claim directed to a living organism must include the qualification "non-human" to avoid rejection.

This amendment provides unequivocal congressional support for this current practice of the U.S. patent office.

House and Senate appropriators agreed on report language in the manager's statement on section 634. The statement reads: "The conferees have included a provision prohibiting funding to process patents of human organisms. The conferees concur with the intent of this provision as expressed in the colloquy between the provision's sponsor in the House and the ranking minority member of the House Committee on Appropriations as occurred on July 22, 2003, with respect to any existing patents on stem cells."

The manager's statement refers to my discussion with Chairman DAVID OBEY, when I explained that the amendment "only affects patenting human organisms, human embryos, or human fetuses." In response to Chairman OBEY's inquiry, I pointed out that there are existing patents on stem cells, and that this amendment would affect solvent's patents.

Here I wish to elaborate further on the exact scope of this amendment. The amendment applies to patents on claims directed to or encompassing a human organism at any stage of development, including a human embryo, fetus, infant, child, adolescent, or adult, regardless of whether the organism was produced by natural or technological methods (including, but not limited to, in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis). This amendment applies to patents on human organisms regardless of where the organism is located, including, but not limited to, a laboratory or a human, animal, or artificial uterus.

Some have questioned whether the term "organism" could include "stem cells". The answer is no. While stem cells can be found in human organisms (at every stage of development), they are not themselves human organisms. This was considered the "key question" by Senator HARKIN at a December 2, 1998 hearing before the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education regarding embryonic stem cell research. Dr. Harold Varmus, then director of the NIH testified "that pluripotent stem cells are not organisms and are not embryos. ... Senator HARKIN noted: "I asked all of the scientists who were here before the question of whether the human stem cell lines be on or not these stem cells are organisms. And I believe the record will show they all said no, it is not an organism." Dr. Thomas Okarma of the NIH testified: "My view is it is not an organism."

The advance of biotechnology provides enormous potential for developing innovative science and therapies for a host of medical needs. However, it is inappropriate to turn nascent individuals of the human species into profitable commodities to be owned, licensed, marketed and sold.

Congressional action is needed not to change the Patent Office's current policy and practice, but precisely to uphold it against any threat of legal challenge. A previous Patent Office policy of granting patents on human organisms in general was invalidated by the U.S. Supreme Court in 1980, on the grounds that the policy has no explicit support from Congress. In an age when the irresponsible use of biotechnology threatens to make humans themselves into items of property, of manufacture and commerce, Congress cannot let this happen again in the case of human organisms.

I urge my colleagues to support this Omnibus in defense of this important provision against human patenting.