

Section 1102 of S. 1004 amends OPA '90 so that the National Pollution Funds Center will make payments directly to the OSRI for these activities, rather than through the National Oceanic and Atmospheric Administration or annual appropriations. The OSRI will conduct its mission over the next 10 years using annual interest from \$22.5 million that was transferred from the Trans-Alaska Liability Pipeline Fund to the Oil Spill Liability Trust Fund. The initial payment to OSRI, which will occur within 60 days after the enactment of S. 1004, will include the interest that has accrued from the date of the first transfer of funds from the Trans-Alaska Pipeline Fund to the Oil Spill Liability Trust Fund pursuant to section 8102(a)(2)(B)(i) of OPA '90.

Section 1102 makes other changes to enhance the effectiveness of the OSRI. It reduces the size and changes the composition of the OSRI Advisory Board, broadens the OSRI's mission, and allows the OSRI Advisory Board to request a scientific review every 5 years by the National Academy of Sciences to be performed by the Academy in carrying out section 7001(b)(2) of OPA '90.

The conferees intend for the Interagency Coordinating Committee on Oil Pollution Research (established under section 7001 of OPA '90) to coordinate with the OSRI and the Arctic Research Commission in developing and overseeing the national oil spill research plan. By involving these two entities, the Interagency Committee will be able to ensure that Arctic and Subarctic prevention and mitigation research needs are being fully identified and met. The Interagency Committee should include relevant recommendations of the OSRI in its reports to Congress, and should include OSRI representatives in meetings and other activities regarding oil pollution.

#### REGARDING S. RES. 304

• Mr. LOTT. Mr. President, I would like to make some clarifying remarks regarding the resolution recently agreed to by the Senate, S. Res. 304. This resolution will approve certain regulations to implement provisions of the Congressional Accountability Act. These regulations are approved to the extent they are consistent with the Congressional Accountability Act. In that regard, section 220(c)(3) of that act allows for judicial review of negotiability issues, although it limits who may seek review. Also, the term "any matter" under section 220(c)(1) of that act clearly includes any and all petitions and other submissions submitted to the board under section 220(c)(1) of the act. •

#### ANNIVERSARY

• Mr. ASHCROFT. Mr. President, families are the cornerstone of America. The data are undeniable: Individuals from strong families contribute to the

society. In an era when nearly half of all couples married today will see their union dissolve into divorce, I believe it is both instructive and important to honor those who have taken the commitment of "till death us do part" seriously, demonstrating successfully the timeless principles of love, honor, and fidelity. These characteristics make our country strong.

For these important reasons, I rise today to honor Bill and Alice Wynkoop of Aldrich, Missouri who on Saturday, October 26, 1996 will celebrate their 50th wedding anniversary. My wife, Janet, and I look forward to the day we can celebrate a similar milestone. Bill and Alice's commitment to the principles and values of their marriage deserves to be saluted and recognized. •

#### CONGRATULATIONS TO LAWRENCE SMITHSON CELEBRATING HIS 100TH BIRTHDAY

• Mr. ASHCROFT. Mr. President, I rise today to encourage my colleagues to join me in congratulating Lawrence Smithson of Chilhowee, Missouri who celebrated his 100th birthday on Wednesday, October 16, 1996. Lawrence is a truly remarkable individual. He has witnessed many of the events that have shaped our Nation into the greatest the world has ever known. The longevity of his life has meant much more, however, to the many relatives and friends whose lives he has touched over the last 100 years.

Lawrence's celebration of 100 years of life is a testament to me and all Missourians. His achievements are significant and deserve to be recognized. I would like to join Lawrence's many friends and relatives in wishing him health and happiness in the future. •

#### HEARTFELT THANKS

• Mrs. FRAHM. Mr. President, I want to take just a moment to extend my heartfelt thanks to Chairman MURKOWSKI, Senator JOHNSTON, and their respective staffs on the Energy and Natural Resources Committee for including the designation of Nicodemus, KS, as a national historic site in the omnibus parks bill.

During the 1870's, Kansas was the scene of a great migration of southern blacks seeking their fortune in what some African-American leaders described as the "Promised Land." One of the most important settlements founded during that time was Nicodemus. From sod "burrows" carved out of the prairie by the original "colonists," Nicodemus flourished into a leading center of black culture and society through the turn of the century.

Today, a cluster of five buildings is all that remains of that once vibrant community. National historic landmark status has not halted the gradual decay of this monument to the struggle of African-Americans for freedom and equality. In fact, in its report entitled "Nicodemus, Kansas Special Resource

Study," the National Park Service indicated that "[i]f Nicodemus is not protected and preserved by a public or private entity, it seems inevitable that the historic structures will continue to deteriorate and eventually be razed." It was that finding that prompted Senator Dole's original legislation granting the town of Nicodemus, KS, national historic site status.

Senators Dole and KASSEBAUM and Representative ROBERTS pursued historic site status for Nicodemus for years. As Kansans, they recognized that this little-known oasis of hope for blacks on the long road to true emancipation was on the verge of being lost forever to the ravages of time. Progress, however, was agonizingly slow. Familiar as I was with Nicodemus—it is located in my old Kansas senate district—I vowed to continue the fight. Aply assisted by Janet Sena, whom I was lucky enough to briefly inherit from Senator Dole, we piggybacked our freestanding bill onto the larger omnibus parks package to get it through the Senate and succeeded in incorporating it into the conference report to assure passage in the House.

Now, after a long and arduous struggle, the fight is won and we have taken the essential step toward saving this unique piece of American history. Descendants of the original Nicodemus settlers are convinced that historic site status will give the town the prestige necessary to raise preservation funds. I agree. For them, and for myself, let me once again offer my thanks to all who made the inclusion of Nicodemus possible. •

#### OMNIBUS PARKS BILL

• Mr. SMITH. Mr. President, I rise to speak in support of the Omnibus Parks and Public Lands Management Act, which was adopted unanimously by the Senate. This legislation contains numerous provisions affecting 41 States to preserve and protect our Nation's scenic rivers and historic land areas. I am pleased that, after many days of negotiations, we have reached agreement on this important environmental legislation.

Included in this comprehensive package is legislation that Senator GREGG and I introduced on August 10, 1995, to designate the Lamprey River in New Hampshire as part of the National Wild and Scenic Rivers System. The Lamprey Wild and Scenic River Act, S. 1174, will designate an 11.5-mile segment of the Lamprey River as wild and scenic. Following introduction, the Senate Energy and Natural Resources Committee held a hearing on the Lamprey bill, which was later approved unanimously by the committee.

The history of this legislation goes back almost 5 years when Senator Rudman and I introduced the Lamprey River study bill in February 1991, which was signed into law by President Bush later that year. Once the National Park Service determined the

Lamprey River's eligibility for the National Wild and Scenic Rivers System, a local advisory committee was formed to work with local communities, landowners, the National Park Service, and New Hampshire's Environment Department in preparing a comprehensive management plan. This management plan was completed in January 1995.

The Lamprey River management plan was subsequently endorsed by the advisory committee as well as the local governments affected by this designation. The primary criteria for my sponsorship of this legislation was the support of the local communities. After the towns of Lee, Durham, and Newmarket all voted in favor of this designation, it received my enthusiastic support.

The Lamprey River is well deserving of this designation for a number of reasons. Not only is the river listed on the 1982 National Park Service's inventory of outstanding rivers, but it has almost been recognized by the State of New Hampshire as the "most important coastal river for anadromous fish in the State." Herring, shad, and salmon are among the anadromous species found in the river. In fact, New Hampshire fishing maps describe the Lamprey as "a truly exceptional river offering a vast variety of fishing. It contains every type of stream and river fish you could expect to find in New England."

The Lamprey is approximately 60 miles in length and serves as the major tributary for the Great Bay, which is part of the National Estuarine Research Reserve System. The Great Bay Refuge is also nearby, which was established several years ago following the closure of Pease Air Force Base. The preservation of the Lamprey is a significant component to protecting this entire ecosystem.

The 11.5-mile segment, as proposed by our legislation, has been the focus of local protection efforts for many years. The towns of Lee, Durham, and Newmarket, local conservationists, the State government, as well as the congressional delegation have all come together in support of this legislation. I believe the management philosophy adopted by the advisory committee best articulates our goals for this legislation: " \* \* \* management of the river must strike a balance among desires to protect the river as an ecosystem, maintain the river for legitimate community use, and protect the interests and property rights of those who own its shorelands."

In conclusion, Mr. President, I congratulate Senate majority leader LOTT, Senator MURKOWSKI and others in negotiating an agreement on this comprehensive legislation. In addition, I commend all of the members of the Lamprey River Advisory Committee, especially Sharon Meeker of Lee, who served as committee chair, Judith Spang of Durham, and Richard Wellington of Lee. All have worked very hard on the Lamprey River legislation

and have traveled to Washington to testify on its behalf. I am extremely pleased that, at last, the fruits of their labor will be rewarded with the adoption of the omnibus parks bill—one of the most significant environmental accomplishments of the 104th Congress. •

#### HUMAN TISSUES SAFETY ACT OF 1996

• Mr. WYDEN. Mr. President, I inadvertently neglected to ask that a copy of legislation I introduced with Senators DODD and SIMON be printed in the October 3, 1996, CONGRESSIONAL RECORD.

I request that this bill, the Human Tissues Safety Act of 1996, be printed in the CONGRESSIONAL RECORD to be dated October 21, 1996.

The bill follows:

S. 2195

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. HUMAN TISSUE.

(a) IN GENERAL.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

"(hh)(1) The term 'human tissue' means a collection of similar human cells which—

"(A) is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or condition in a human or for reproduction;

"(B) achieves its primary intended purpose through repair or replacement of bodily tissue by structural support or cellular function;

"(C) may have been propagated or otherwise processed before use;

"(D) may be combined with substances that are safe under conditions of intended use and not intended to provide a therapeutic effect; and

"(E) includes reproductive tissue, demineralized bone, heart valves, dura mater, and manipulated autologous cells.

"(2) The term 'human tissue' does not include vascularized human organs, gene therapy, blood, soluble blood components, milk, or products made by combining human tissue with biomaterials.

"(3) Human tissue is not a drug, biological product, or device unless reclassified by the Secretary pursuant to section 352A of the Public Health Service Act."

(b) REGULATION OF HUMAN TISSUE.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following section:

#### "REGULATION OF HUMAN TISSUE

"SEC. 352A. (a) SUBJECT TO REGULATION.—

"(1) IN GENERAL.—Human tissue shall be subject to regulation under this section only if the Secretary publishes a finding in the Federal Register, after a hearing before the Commissioner, that voluntary regulation under generally accepted scientific standards is inadequate to protect the public health with respect to any particular type of human tissue or human tissue generally.

"(2) EXCEPTION.—Human tissue shall not be subject to regulation as a drug, biological product, or device unless it is reclassified under subsection (f).

"(b) REGISTRATION.—

"(1) IN GENERAL.—Any person subject to regulation under this section who recovers, processes, stores, or distributes human tis-

sue for transplantation or implantation in the United States shall register in accordance with the registration procedures established for drugs under section 510 of the Federal Food, Drug, and Cosmetic Act. Such registration shall contain the name of the person, the location of its facilities, a list of the types of human tissue recovered, processed, stored, or distributed by such person, and a brief description of the basic method or methods of processing of such tissue.

"(2) AUTHORIZED ACTIVITIES.—A person registered in accordance with paragraph (1) shall be deemed to be authorized to conduct human tissue recovery, processing, storage, and distribution activities as identified in the applicable registration unless—

"(A)(i) the Secretary determines, upon inspection, that such person fails to meet applicable operating standards under subsection (c);

"(ii) the Secretary notifies such person of a determination under clause (i), advises the person of the steps necessary to meet such standards, and provides the person with a reasonable opportunity to establish compliance with the standards;

"(iii) the Secretary determines, after an opportunity for an informal hearing, that the person has failed to establish compliance as provided for in clause (ii) within the applicable period and such failure constitutes a threat to the public health; and

"(iv) the Secretary suspends or revokes the authority to conduct such activities;

"(B) the Secretary determines, after an opportunity for an informal hearing, that such person has failed to comply with any patient registry or other retrospective patient data requirement, and the Secretary suspends or revokes the authority to conduct such activities; or

"(C) the Secretary determines that such person presents an immediate or substantial danger to the public health, and the Secretary suspends or revokes the authority to conduct such activities, in which case an informal hearing shall be conducted within 5 business days of the date of such suspension or revocation.

"(c) OPERATING STANDARDS.—The Secretary may establish, after notice and opportunity for comment, operating standards for human tissue that shall be limited to the following general requirements for the recovery, processing, storage, and shipment of human tissue.

"(1) Requirements for infection control designed to prevent transmission of disease.

"(2) Requirements for processing practices that assure the safety of, and prevent damage to, human tissue.

"(3) Requirements for labeling and record-keeping to identify the type of tissue and any added foreign substance and to permit tracing.

"(d) LABELING AND ADVERTISING.—Statements made in labeling, advertising or promotional materials regarding clinical benefit with respect to human tissue shall consist only of accurate and balanced representations that are consistent with sound scientific information, including current data from a registry required or established under subsection (e), if available.

"(e) REGISTRY.—A person registered under subsection (b) may be required by the Secretary to maintain a patient registry or meet other retrospective patient data requirements if, after notice and an opportunity for comment, the Secretary determines that such tissue has been commercially available within the United States for a period of less than 5 years and that such data requirement is necessary to protect the public health.

"(f) RECLASSIFICATIONS.—

"(1) HUMAN TISSUE.—The Secretary may reclassify a particular type of human tissue as