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 tissue 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 recordkeeping 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

a drug, biological product or device if, after notice and an opportunity for comment, the Secretary determines that—

''(A) with respect to the particular type of human tissue—

''(i) the tissue is subject to a patient registry or other retrospective data requirement under which the collection of information has been required for at least 5 years (or such other time period as agreed to by the Secretary and the registered person); and

''(ii) the information received from such patient registry or other retrospective data requirement is insufficient to confirm the safety and clinical benefit from the use of such tissue; or

''(B) a particular type of human tissue should be reclassified because it presents an imminent hazard to public health.

''(2) UPON SECRETARIAL ACTION.—The Secretary may reclassify a human drug, biological product or medical device as human tissue if the Secretary determines, after notice and an opportunity for comment, that such previous classification is not necessary to protect public health.

''(3) UPON PETITION.—The Secretary may reclassify a drug, biological product, medical device, or human tissue upon the petition of the sponsor of such drug, biological product or device, or the registered person for such human tissue, if, after notice and an opportunity to comment, the Secretary finds that such reclassification is consistent with the protection of public health.

''(g) ENFORCEMENT.—

''(1) IN GENERAL.—If the Secretary determines that any person has violated any provision of this section or any regulations promulgated under this section, and the Secretary determines that the violation constitutes a significant risk to the public health, the Secretary may issue an order that such person cease distribution of human tissue, or that human tissue recovered, processed, stored or distributed by such person be retained, recalled, or destroyed. After receipt of such an order, the person in possession of the human tissue shall not distribute or dispose of the human tissue in any manner inconsistent with the provisions of the order.

''(2) HEARING.—A person subject to the order under paragraph (1) may obtain an informal hearing regarding the order if the person requests such a hearing not later than 5 days after receiving the order. If the person does make such a request within such period, the Secretary shall conduct the hearing within 30 days after receiving the request and shall issue an order not later than 15 days after the hearing is conducted. Such order shall be considered a final order of the Secretary.

''(h) INSPECTION.—Each person registered under subsection (b) shall be subject to inspection under section 704 of the Federal Food, Drug, and Cosmetic Act. The Secretary may, with the concurrence of the registered person, authorize an inspection be conducted by any person specifically accredited by the Secretary to conduct such inspection under section 712 of such Act.

''(i) CORD BLOOD.—

''(1) IN GENERAL.—This section (including provisions regarding reclassification) shall apply with respect to cord blood to the same extent and in the same manner as this section applies with respect to human tissue.

''(2) IMPLEMENTATION.—The Secretary shall implement this section with respect to cord blood under regulations promulgated after notice and opportunity to comment.

''(j) EYES.—The Secretary shall not regulate eyes until such time as the Secretary makes a finding under this section that voluntary regulation under generally accepted standards is inadequate to protect the public health.''.

(c) TRANSITION.—The requirements of the interim regulation, promulgated by the Secretary of Health and Human Services on December 11, 1993, shall remain in effect until amended or withdrawn by the Secretary. Any modifications to such regulations after the date of the enactment of this Act are subject to this Act and the amendments made by this Act.

(d) EFFECTIVE DATE.—The amendment made by subsection (c) shall take effect on June 30, 1997.

(e) CONFORMING AMENDMENTS.—

(1) ADULTERATION PROVISION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended—

(A) in the first sentence by striking ''drug or device'' and inserting ''drug, device or human tissue''; and

(B) by adding at the end thereof the following:

''(j) if it is human tissue and it is recovered, processed, stored, or distributed by—

''(1) a registered person under section 352A of the Public Health Service Act whose failure to comply with standards constitutes a threat to public health; or

''(2) a person who is required under such section to register but has failed to do so.''.

(2) MISBRANDING PROVISIONS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended:

(A) in the section heading, by striking ''MISBRANDED DRUGS AND DEVICES'' and inserting the following: ''MISBRANDED DRUGS, DEVICES, AND HUMAN TISSUE''; and

(B) in the first sentence, by striking ''drug or device'' and inserting ''drug, device or human tissue''.

(3) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end thereof the following:

''(v) The adulteration or misbranding of any human tissue.''.

(4) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended

(A) in subsection (a)(2)(D), by inserting ''or human tissue'' after ''device''; and

(B) in the first sentence of subsection (d)(1), by striking ''or cosmetic'' and inserting ''cosmetic, or human tissue''.

(5) INSPECTION.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended—

(A) in the first sentence, by inserting ''human tissue,'' after ''device,'' each place such appears; and

(B) in the second sentence, by inserting ''human tissue,'' after ''drugs,'' each place such appears.

THE NEED FOR BALLAST MANAGEMENT—H.R. 4283

● Mr. GLENN. I thank the Senator from South Dakota for his efforts in responding to the urgent national need for ballast management to prevent unintentional introduction of nonnative species into U.S. waters. As you know, some Senators raised concerns about the initial House-passed version of the National Invasive Species Act [H.R. 3217] because it does not give assurance that onerous requirements will not be imposed upon vessels that exercise the safety exemption from national ballast exchange requirements. This version, [H.R. 4283], rectifies that problem. The Great Lakes Program which already leaves sole discretion over safety to the ship master, and already requires alternatives if high seas exchange is not possible, will not be affected by this amendment. I ask the Senator, is it his opinion that the Coast Guard will actively seek to identify alternatives of which vessels may avail themselves in other coastal regions, and will it request vessels to conduct these alternative precautions on a voluntary basis in the new national program?

Mr. PRESSLER. As Chairman of the Senate Committee on Commerce, Science and Transportation that has jurisdiction of the U.S. Coast Guard, I would expect the Coast Guard to actively seek alternatives applicable to other regions, routinely identify those alternatives to ballast exchange for vessels which use the safety exemption, and encourage their use prior to discharging unexchanged water in the port of call.

Mr. GLENN. I also ask the Senator, if he believes that the Coast Guard will keep careful records regarding the extent to which the safety exemption is utilized, under what circumstances, and the extent to which vessels attempt in good faith to use alternatives that may be identified?

Mr. PRESSLER. Yes, I expect the Coast Guard to include each of those items in its reporting requirements, and to include a careful assessment of those matters in its report to Congress so that Congress can make decisions regarding the impact of this exemption and the need for revision of the law.

Mr. GLENN. As I mentioned, the Great Lakes Program currently requires alternatives to ballast exchange if high seas exchange is not possible due to safety concerns. While these alternatives are not overly onerous, I can understand industry's concern in other regions where the alternatives have not yet been developed.

A cooperative relationship between the Committee of Environment and Public Works at the Committee on Commerce, Science and Transportation is crucial to the passage of this legislation and its effective implementation. I hope that these two Committees that share jurisdiction over this issue continue to work together to evaluate progress under the National Invasive Species Act.

Mr. PRESSLER. I look forward to a continued cooperative relationship between the two committees as well as with the bill author and cosponsors.

Mr. GLENN. H.R. 4283 includes an exemption from the National Ballast Management Program for crude oil tankers engaged in coastwise trade. While the majority of this trade is conducted between Hawaii and Alaska, the risk to receiving waters of ballast water from these vessels may be significant. As the Senator knows, there is concern that fish pathogens may have been transported to Alaskan waters via this trade. I would hope that every effort will be made to study the baseline conditions of the Prince William Sound ecosystem to assure that invasive species problems in fact have