majority of small webcasters feared that it would lead to their demise? As the distinguished chairman of the Senate Judiciary Committee stated at a May 2002 hearing on this subject, Congress did not intend to bankrupt small webcasters when it created this new royalty.

It would be a mistake for someone to construe the Helms-Leahy bill as a criticism of the arbitrators decision. Rather, I consider this legislation to be an indictment of the process, with unintended consequences flowing from the framework that Congress set forth in the DMCA.

It is impossible for arbitrators to appreciate the full implications of their determinations if significant industry participants cannot afford to appear before them or if those with disproportionate control over the outcome refuse to deal in good faith. I understand that Senator LEAHY intends to pursue comprehensive CARP reform in the Judiciary Committee next Congress. Though I will no longer be serving in the U.S. Senate next year, I hope that the chairman and ranking members of both Judiciary Committees will follow through on this commitment, working constructively to quickly remedy the concerns expressed about the current CARP process.

There was not time to fully reform CARP this fall but I considered it essential that Congress move swiftly to ensure that small webcasters not be bankrupted by unfair arbitration outcomes. An equally important goal was to ensure that settlement agreements negotiated by recording companies and small webcasters facing bankruptcy not unfairly impact non-participating third parties—such as larger webcasters and broadcasters, or even the recording companies. Moreover, I consider it critically important to underline that nothing in this bill should be construed as affecting the outcome of any pending litigation.

I commend Chairman SENSENBRENNER for focusing attention on this issue and commencing the process that ultimately led to the passage of this critically-needed legislation. I respect that there was a difference of opinion on the precedential value of H.R. 5469, as originally passed by the House. Nevertheless, beyond dispute is the fact that numerous stakeholders had expressed serious reservations that the original House-passed bill could unintentionally and negatively influence future rate setting proceedings.

The Helms-Leahy bill removes that concern, helps ensure that small webcasters will not be forced into bankruptcy, provides non-commercial webcasters with additional flexibility, and accomplishes several other goals on which the stakeholders and the Judiciary Committee leadership could agree.

The deductibility provision contained in section 5(b) of the bill is one that was viewed as important to several parties. The final provision is intended to encourage competition among agents designated to distribute royalties. While I ultimately agreed to this provision, I wish to make it clear that I would consider it unconscionable if the provision were used to justify higher royalty rates for users of sound recordings.

The ability to deduct these fees is premised on a balance of interests, owners of sound recordings should not be prejudiced by a process that precludes effective legal representation, designated agents should be incentivized to quickly and fairly conclude settlement agreements rather than engage in protracted and expensive legal and arbitration proceedings, and music services and other users of sound recordings should pay a fairly negotiated fee that is not impacted by the costs of litigation, arbitration, and legal expenses incurred by the designated agents.

Users already bear their own litigation, expert fee and legal representation costs for participating in the CARP process and the resources of the Copyright Office are taxed when fair settlements are not reached among the parties.

In my view, the public interest would not be well served if the deductibility provision were interpreted in a manner that had the effect of diluting the payout to copyright owners, reducing the incentives for negotiating settlements, and/or increasing the fees paid by consumers for the use of sound recordings. To avoid these clearly undesirable and unintended outcomes, I believe it would be unwise to take these costs into account in any arbitration or other proceeding to set royalty fees.

I expect this to be the final piece of legislation I author in my career as a United States Senator. I particularly wish to thank Senators LEAHY and HATCH and their superb staffs for their expertise and assistance in ensuring the quick approval of the U.S. Senate. Additionally, I want to recognize the substantial contributions of the Senate and House leadership as well as the leaders of the House Judiciary Committee, for their continued assistance and cooperation as we worked through these difficult issues over the past several weeks.

Finally, I also wish to thank David Whitney, Joe Lanier, Wayne Boyles and David Crotts of my staff, the leaders of the affected industry and artist organizations who assisted me so greatly in negotiating this compromise legislation and a young lady entrepreneur of whom I am extremely proud, Deb Proctor of WCPE–FM in Raleigh, NC who first brought this issue to my attention.

PERFORMANCE GOALS FOR THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002

Mr. KENNEDY. Mr. President, on October 17, 2002, the Senate passed the Medical Device User Fee and Modernization Act of 2002, ''MDUFMA''. Included in Title I of this bill is the authorization of medical device user fees.

Performance goals, existing outside of the statute, accompany the authorization of medical device user fees. These goals represent a realistic projection of what the Food and Drug Administration's Center for Devices and Radiological Health and Center for Biologics Evaluation and Research can accomplish with industry cooperation. The Secretary of Health and Human Services forwarded these goals to the chairmen of the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate, in a document entitled ''MDUFMA PERFORMANCE GOALS AND PROCEDURES.'' According to Section 101 of Title I of MDUFMA, ''the fees authorized by this title will be dedicated to meeting the goals set forth in the CONGRESSIONAL RECORD.''

Today I am submitting for the RECORD this document, which was forwarded to the Committee on Health, Education, Labor and Pensions on November 14, 2002, as well as the letter from Secretary Thompson that accompanied the transmittal of this document.

I ask unanimous consent to print those items.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

MDUFMA PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures of the FDA Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), as agreed to under the medical device user fee program in the Medical Device User Fee and Modernization Act of 2002, are summarized as follows:

I. REVIEW PERFORMANCE GOALS—FISCAL YEAR 2003 THROUGH 2007

All references to ''days'' mean ''FDA days.''

A. ORIGINAL PREMARKET APPROVAL (PMA), PANEL-PMATRACK SUPPLEMENT, AND PREMARKET REPORT SUBMISSIONS

1. The following cycle goals apply to: 75% of submission received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action major deficiency letters will issue within 150 days.

(b) All other first action letters (approval, approvable, approvable pending good manufacturing practices (GMP) inspection, not approvable, or denial) will issue within 180 days.

(c) Second or later action major deficiency letters will issue within 120 days.

(d) Amendments containing a complete response to major deficiency or not approvable letters will be acted on within 180 days.

2. Decision Goals:

(a) 80% of submissions received in fiscal year 2006 will have an FDA decision in 320 days.

(b) 90% of submissions received in fiscal year 2007 will have an FDA decision in 320 days.

3. Subject to the following paragraph, 50% of submissions received in fiscal year 2007 will have an FDA decision in 180 days.

This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal.

4. 90% of amendments containing a complete response to an approvable letter received in fiscal years 2003 through 2007 will be acted on within 30 days.

B. EXPEDITED ORIGINAL PMA SUBMISSIONS

1. The following goals apply to PMA submissions where:

(a) FDA has granted the application expedited status;

(b) The applicant has requested and attended a pre-filing review meeting with FDA;

(c) The applicant's manufacturing facilities are prepared for inspection upon submission of the application; and

(d) The application is substantively complete, as defined at the pre-filing review meeting.

2. The following cycle goals apply to: 70% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action major deficiency letters will issue within 120 days.

(b) All other first action letters (approval, approvable, approvable pending GMP inspection, not approvable, or denial) will issue within 170 days.

(c) Second or later action major deficiency letters will issue within 100 days.

(d) Amendments containing a complete response to major deficiency or not approvable letters will be acted on within 170 days.

3. Decision Goals:

(a) 70% of submissions received in fiscal year 2005 will have an FDA decision in 300 days.

(b) 80% of submissions received in fiscal year 2006 will have an FDA decision in 300 days.

(c) 90% of submissions received in fiscal year 2007 will have an FDA decision in 300 days.

4. 90% of amendments containing a complete response to an approvable letter received in fiscal years 2003 through 2007 will be acted on within 30 days.

C 180-DAY PMA SUPPLEMENT SUBMISSIONS

1. The following goals apply to: 80% of submissions in fiscal year 2005; 85% of submissions in fiscal year 2006; 90% of submissions in fiscal year 2007.

(a) First action not approvable letters will issue within 120 days.

(b) All other first action letters (approval, approvable, approvable pending GMP inspection, not approvable or denial) will issue within 180 days.

(c) Amendments containing a complete response to a not approvable letter will be acted on within 160 days.

2. Decision Goals:

(a) 80% of submissions received in fiscal year 2005 will have an FDA decision in 180 days.

(b) 80% of submissions received in fiscal year 2006 will have an FDA decision in 180 days.

(c) 90% of submissions received in fiscal year 2007 will have an FDA decision in 180 days.

3. Current performance for real-time review PMA supplement submissions will be maintained.

D. 510(K) SUBMISSIONS

1. The following goals apply to: 70% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

(a) First action additional information letters will issue within 75 days.

(b) Subsequent action letters will issue within 60 days.

2. Decision Goals:

(a) 75% of submissions received in fiscal years 2005 and 2006 will have an FDA decision in 90 days.

3. Subject to the following paragraph, 80% of submissions received in fiscal year 2007 will have an FDA decision in 90 days.

This goal will be re-evaluated following the end of fiscal year 2005. FDA will hold a public meeting to consult with its stakeholders and to determine whether this goal is appropriate for implementation in fiscal year 2007. If FDA determines that the goal is not appropriate, prior to August 1, 2006, the Secretary will send a letter to the Committee on Health, Education, Labor and Pensions of the Senate and to the Energy and Commerce Committee, Subcommittee on Health of the House of Representatives stating that the goal will not be implemented and the rationale for its removal, and that the goal for fiscal year 2006 will be implemented for fiscal year 2007.

E. ORIGINAL BIOLOGICS LICENSING APPLICATIONS (BLAS)

The following goals apply to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on standard original BLA submissions within 10 months of receipt.

2. Review and act on priority original BLA submissions within 6 months of receipt.

F. BLA EFFICACY SUPPLEMENTS

The following goals apply to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on standard BLA efficacy supplement submissions within 10 months of receipt.

2. Review and act on priority BLA efficacy supplement submissions within 6 months of receipt.

G. ORIGINAL BLA AND BLA EFFICACY SUPPLEMENT RESUBMISSIONS

The following goals apply to: 75% of submissions received in fiscal year 2005; 80% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

1. Review and act on Class 1 original BLA and BLA efficacy supplement resubmissions within 2 months of receipt.

2. Review and act on Class 2 original BLA and BLA efficacy supplement resubmissions within 6 months of receipt.

H. BLA MANUFACTURING SUPPLEMENTS REQUIRING PRIOR APPROVAL

The following goal applies to: 75% of submissions received in fiscal year 2006; 90% of submissions received in fiscal year 2007.

Review and act on BLA manufacturing supplements requiring prior approval within 4 months of receipt.

I. ADDITIONAL EFFORTS RELATED TO PERFORMANCE GOALS

The Agency and the regulated industry agree that the use of both informal and formal meetings (e.g., determination and agreement meetings, informal pre-investigational device exemption (IDE) meetings, pre-PMA meetings, pre-PMA filing meetings) by both parties is critical to ensure high application quality such that the above performance goals can be achieved.

J. MAINTENANCE OF CURRENT PERFORMANCE

It is the intent of the Agency that in review areas where specific performance goals have not been identified, current performance will be maintained.

K. APPLICATION OF USER FEE REVENUES

The Agency intends to apply significant user fee revenues to support reviewer training and hiring and/or outside contracting to achieve the identified performance goals in a responsible and efficient manner.

L. MODULAR PMA REVIEW PROGRAM

The Agency intends to issue guidance regarding the implementation of new section 515(c)(3) of the Federal Food, Drug, and Cosmetic Act. It is the intent of the Agency that once this program is implemented, the Agency will work with its stakeholders to develop appropriate performance goals for this program. Until such time, the Agency intends to review and close complete modules that are submitted well in advance of the PMA submission as expeditiously as possible.

M. ''FOLLOW-ON'' LICENSED DEVICES

The Center for Biologics Evaluation and Research will, if feasible, identify a category of ''follow-on'' licensed devices and collect information to determine whether alternative performance goals for such a category are appropriate.

N. BUNDLING POLICY

The Agency will, in consultation with its stakeholders, consider the issue of bundling for products with multiple related submissions. After such consultation, the Agency will either issue guidance on bundling or publish a notice explaining why it has determined that bundling is inappropriate.

O. ELECTRONIC REVIEW OF APPLICATIONS

The Agency will continue its efforts toward development of electronic receipt and review of applications, as expeditiously as possible, acknowledging that insufficient funding is included in the user fee program for this effort.

P. PREAPPROVAL INSPECTIONS

The Agency will plan to improve the scheduling and timeliness of preapproval inspections. The Agency will monitor the progress of these efforts and provide such information in the annual performance report.

II. ANNUAL STAKEHOLDER MEETING

Beginning in fiscal year 2004, FDA will hold annual public meetings to review and evaluate the implementation of this program in consultation with its stakeholders.

III. DEFINITIONS AND EXPLANATION OF TERMS

A. For original PMA submissions, Panel-Track PMA supplement submissions, expedited original PMA submissions, 180-day supplement submissions, and premarket report submissions, issuance of one of the following letters is considered to be an FDA decision:

1. approval
2. approvable
3. approvable pending GMP inspection
4. not approvable
5. denial

B. For 510(k) submissions, issuance of one of the following letters is considered to be an FDA decision:

1. substantially equivalent (SE)
2. not substantially equivalent (NSE)

C. Submission of an unsolicited major amendment to an original PMA submission, Panel-Track PMA supplement submission, expedited original PMA submission, 180-day supplement submission, or premarket report submission extends the FDA decision goal date by the number of days equal to 75% of the difference between the filing date and the date of receipt of the amendment. The submission of the unsolicited major amendment is also considered an action that satisfies the first or later action goal, as applicable.

D. For BLA (original, efficacy supplement, or manufacturing supplement) submissions, the term ''review and act on'' is understood to mean the issuance of a complete action letter after the complete review of a filed

complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

E. For original BLA and BLA efficacy supplement resubmissions:

1. Class 1 resubmitted applications are applications resubmitted after a complete response letter that include the following items only (or combinations of these items):

(a) Final printed labeling

(b) Draft labeling

(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)

(d) Stability updates to support provisional or final dating periods

(e) Commitments to perform Phase 4 studies, including proposals for such studies

(f) Assay validation data

(g) Final release testing on the last 1–2 lots used to support approval

(h) A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the Class 1 category)

(i) Other minor clarifying information (determined by the Agency as fitting the Class 1 category)

(j) Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

2. Class 2 resubmissions are resubmissions that include any other items, including any item that would require presentation to an advisory committee.

THE SECRETARY OF HEALTH AND HUMAN SERVICES,
Washington, DC, November 14, 2002.

Hon. EDWARD KENNEDY,
U.S. Senate,
Washington, DC.

DEAR MR. CHAIRMAN. As you are aware, the Medical Device User Fee and Modernization Act of 2002 was signed by the President on October 26, 2002. Under Title I, the additional revenues generated from fees paid by the medical device industry will be used to expedite the medical device review process, in accordance with performance goals that were developed by the Food and Drug Administration (FDA) in consultation with the industry.

FDA has worked with various stakeholders, including representatives from consumer, patient, and health provider groups, and the medical device industry to develop legislation and goals that would enhance the success of the device review program. Title I of the Medical Device User Fee and Modernization Act of 2002 reflects the fee mechanisms and other improvements developed in these discussions. The performance goals referenced in Section 101 are specified in the enclosure to this letter, entitled ''Performance Goals and Procedures.'' I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources identified in the bill.

This letter and the enclosed goals document pertain only to title I (Fees Related to Medical Devices) of Public Law 107–250, Medical Device User Fee and Modernization Act of 2002. OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in the authorization of this vital program.

Sincerely,

TOMMY G. THOMPSON.

LOCAL LAW ENFORCEMENT ACT OF 2001

Mr. SMITH of Oregon. Mr. President, I rise today to speak about hate crimes legislation I introduced with Senator KENNEDY in March of last year. The Local Law Enforcement Act of 2001 would add new categories to current hate crimes legislation sending a signal that violence of any kind is unacceptable in our society.

I would like to describe a terrible crime that occurred September 6, 2001in Madison, WI. Two men were arrested on the University of Wisconsin campus for attempting to strangle a gay man. The attackers were part of a visiting group on campus to talk about homosexuality. The attackers approached the victim, told him that it was his time to go to hell, then began choking him.

I believe that government's first duty is to defend its citizens, to defend them against the harms that come out of hate. The Local Law Enforcement Enhancement Act of 2001 is now a symbol that can become substance. I believe that by passing this legislation and changing current law, we can change hearts and minds as well.

ELECTRIC ASSISTED LOW-SPEED BICYCLES

Mr. JEFFORDS. Mr. President, I am very pleased that H.R. 727 will soon be on its way to the President for signature.

This bill, which passed the other body by a 401 to 1 margin on March 6, 2002, will help promote the use of electric-assisted low-speed bicycles and will help seniors participate in cycling related activities. For many of our seniors, long-distance bicycle rides or participation in bicycle clubs in areas with extensive hills, can present an unfair challenge.

Simply put, this bill will allow seniors to more fully participate in these events while, at the same time, providing solid exercise for them. I believe that in states, such as my home state of Vermont, our senior citizens may derive benefits from using these low-speed pedal-assisted electric bicycles for help getting up our steep terrain.

Not only will these bikes improve mobility options for seniors, they will also help to reduce congestion on our roads and air pollution when used for commuting purposes. Since these bikes produce no noise or exhaust because they are powered by small batteries rather than gasoline powered engines, they provide an environmentally friendly transportation option to our citizens and should be treated as bicycles and not as motor vehicles.

H.R. 727 states that these low-speed pedal-assisted electric bikes, as defined in very detailed Consumer Product Safety Commission, CPSC, rules—found at 16 CFR 1512—shall be considered bikes and not motor vehicles.

These detailed existing safety standards for bicycles should be applied in every state, as in current law, and as would be required under the bill for these low-speed pedal-assisted electric bikes. The existing safety rules are based on extensive experience and tests done on material strength, stem and fork torque resistance, pedal design and the like and should apply throughout the nation. The existing rules, referenced in H.R. 727, set the requirements for such things as: handlebar stem insertions; pedal construction; chain guards; handlebar stem tests; stem-to-fork clamp tests; bicycle design; handlebar strength; front hub retention; attachment hardware; hand levers for brakes; reflectors; pedal reflectors; seat size; maximum seat height; and the like.

To assure the safety of these bicycles, the bill provides for federal preemption of State law or requirements—as provided in section 1(d) of the bill—regarding those detailed CPSC safety rules. The CPSC would have the authority to issue additional federal rules regarding the construction and physical properties of these low-speed bicycles to ensure safety.

Obviously, local regulation of where these low-power bicycles can be ridden, such as not on sidewalks if that is the state or local rule, or not on high-speed thruways, or whether helmets are required, would still be a local matter. Local or state governments would continue to regulate the use of these and other bikes, who could ride the bikes, and where they could be ridden, but they could not alter the safety rules for the construction of the bikes, or the metals or materials to be used for that construction, which would be in the hands of the CPSC.

H.R. 727 also specifies a 20 mph limit on speed, on a flat surface, for these electric assisted bikes. The bikes covered by this bill look similar to ''regular'' low-weight bicycles and will have similar speeds but require less human leg power and stamina.

It is important to note that this bill does not relate to other devices such as the Segway human transporter which does not meet any of the detailed requirements for a bicycle set forth in the CPSC rules.

I am aware of companies researching such electric bicycle product advancements, such as Wavecrest right here in Northern Virginia, and am excited about the prospects for the future.

I appreciate the strong efforts in the other body of Mr. CLIFF STEARNS, Mr. BILLY TAUZIN, Mr. HOWARD BERMAN, Mr. EARL BLUMENAUER, Mrs. LOIS CAPPS, Mr. DENNIS MOORE, Mr. MICHAEL OXLEY, Mr. CHARLES PICKERING, Mr. JAMES OBERSTAR and many others. In the Senate, I appreciate efforts of Chairman HOLLINGS, ranking member Senator MCCAIN and Senator BURNS, all of the Commerce Committee, in getting this bill to the Senate floor where it passed without opposition.

As I work on the massive reauthorization of our surface transportation