

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 supplemental 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, 2001 in 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

program next year, I intend to work to fund additional bicycle paths and enhance existing paths as use of these paths increases over time.

#### THE FAILURE TO PASS AN ENERGY BILL

Mr. ROCKEFELLER. Mr. President, it is with a tremendous amount of frustration and disappointment that I come before the Senate to discuss the failure of efforts in the 107th Congress to craft an energy bill. I have been a long-time advocate of a comprehensive national policy that would address the national and economic security aspects of this country's growing demand for energy, as well as the importance of protecting our environment.

I was very proud of the work the Senate had done this year to produce this legislation. Under the leadership of Majority Leader TOM DASCHLE and Senate Energy and Natural Resources Chairman JEFF BINGAMAN, the Senate did what many in Washington thought impossible—we produced balanced and responsible energy legislation combining increased domestic production of conventional fuels, expanded use of alternative and renewable energy sources, and energy conservation and efficiency programs. Unfortunately, in our rush to complete work on a number of pending matters, many Senators chose to not proceed with Conference negotiations, acquiescing in what I would characterize as a strategy to scuttle this worthwhile bill.

Perhaps the thought was that a better bill—or at least one that better met a different set of priorities—could be crafted next year. Candidly, I doubt it. I believe the demise of the Energy bill this year is unfortunate for West Virginia, and for the entire nation. During a nearly year-long debate on the complex components of the energy bill, my position as a senior Majority member of the Senate Finance Committee allowed me to influence the legislation so that its end results would be good for consumers, workers, and industries in my state of West Virginia. I am concerned that a new set of circumstances confronting the 108th Congress will result in a bill that does not serve my state nearly as well.

While the need to grapple with energy issues will not go away, no matter what other factors are to be considered, Congress will be forced to act in a vastly changed budgetary climate. The growing deficit, additional proposed tax cuts, and the need to fund both a war on terrorism and a possible war with Iraq, will inhibit the ability of Congress to make any significant outlays to improve our energy situation.

The 2002 energy bill was a bipartisan effort. Perhaps most significantly for West Virginia, there was general agreement among Senate conferees that the final bill should include meaningful Clean Coal incentives. I worked very hard to see that the Senate-passed bill

included incentives for the installation of Clean Coal technologies on smaller existing coal-burning facilities, such as we have in West Virginia. The version passed by the House would have bypassed existing facilities altogether—putting thousands of West Virginia jobs at risk and jeopardizing the health of all West Virginians downwind of these plants. As a member of the House-Senate Conference Committee reconciling the two versions of the energy bill, I was able to ensure that the final legislation included incentives for existing facilities. If the energy bill is considered again in the 108th Congress, I will likely again be a conferee, but my ability to apply pressure to benefit the people and environment of our state will be lessened.

I also worked closely with a number of colleagues from both parties to see that the bill included incentives to capture coal mine methane, a deadly hazard in coal mines, and a potent greenhouse gas when vented to protect the lives of miners. I was proud to join with members from both sides of the aisle to extend credits for the production of oil and natural gas from non-conventional sources. Without this credit, the natural gas industry in the entire Appalachian Basin would likely cease to exist. Likewise, I was pleased to join in a bipartisan effort to promote the use of alternative fuels and alternative fuel vehicles. Similarly, I joined colleagues from across the political spectrum to further research and development and create tax incentives for the production of electricity from renewable sources, and to increase energy efficiency in homes, commercial buildings, and appliances.

In fact, what most frustrates me is that this product of so much bipartisan cooperation is dead because of what may have been a cynical calculation to reconsider later a few issues with which there will never be truly bipartisan agreement.

If the next Congress does revisit the issue of a national energy policy, I am certain that those in charge will put much-needed emphasis on domestic production. At the same time, I have serious doubts that the incoming congressional majorities will toil quite as hard to balance that priority with the equally necessary issue of protecting the environment. In the same vein, while I suspect that there will be new efforts to exploit the Arctic National Wildlife Refuge and on our other public lands, regardless of the minimal amounts of mineral resources that may be recoverable, I am not confident that a new bill's authors will show the same zeal to expand our domestic energy production from clean and abundant renewable resources.

This has been a hard fight, and while not perfect, the legislation we were so close to producing would have been the truly comprehensive and balanced energy policy that I have been calling for since I came to Congress eighteen years ago. Since then, I have continu-

ously urged my colleagues in the Congress, as well as both Republican and Democratic presidential administrations, to work together on a responsible energy policy for this country. The 107th Congress was prepared to deliver a balanced, comprehensive energy plan for the President's signature. Now, for a number of reasons the energy bill is dead, putting the American economy and the American environment at risk. I find this frustrating, short-sighted, and extremely unfortunate.

#### U.S. LEADERSHIP IN AEROSPACE—TODAY AND TOMORROW

Mr. AKAKA. Mr. President, I rise to discuss a core factor in America's leadership and strength in the new century: aerospace. The aerospace industry dominates the telecommunication and transportation world, while military aerospace expertise has defended the Nation and served as the eyes and ears of our forces overseas.

Congress established an Aerospace Commission last year to study the state of the American aerospace industry in the global economy and national security and to assess the importance of the domestic aerospace industry for the future security of the Nation. It is appropriate that the Aerospace Commission released its report on the future of the aerospace industry this Monday during the final debate on homeland security, an area only beginning to appreciate what aerospace can offer.

The Aerospace Commission reviewed the range of military, civil, and commercial aspects of aviation and space and studied the key components of the aerospace community—government, industry, labor, and academia. The Commission benefited from the broad range of expertise and experience among its Commissioners, including former Astronaut Buzz Aldrin, former Defense Under Secretary John Hamre, and Director of the Hayden Planetarium Dr. Neil Tyson.

The Commission offered several recommendations to correct the weakening of the aerospace sector. Each recommendation addressed a different critical factor that is showing signs of fatigue. I would like to discuss the Commission's recommendations relating to the aerospace workforce and education.

The aerospace industry, like many of our high-tech sectors, has a workforce crisis. According to the Commission report, our Nation has lost over 600,000 scientific and technical aerospace jobs in the past 13 years. These job losses, first due to reduced spending in defense, then due to acquisitions and mergers of aerospace companies, and later to foreign competition in the commercial aerospace market, represent a significant loss of skill and expertise. Many of the talented people