of approximately $1,235,374,000.00 in taxable wagers were had and received. That is over $3.5 billion in three years, and Internet betting has increased significantly in the last two years.

I would like to point out that significant income taxes and excise taxes appear to be owed by numerous persons. Collecting these amounts would be an important component of the Administration's efforts to address the ''tax gap.''

Further, with such large sums at issue, the IRS and the Department of Justice should see if money laundering is involved.

The State Department has expressed strong concern that Internet gambling operations could be used not only for tax evasion, but also for other criminal activities such as money laundering and terrorist financing:

Internet gambling is particularly well-suited for the laying and integration stages of money laundering, in which launderers attempt to disguise the nature or ownership of the proceeds by concealing or blending transactions within the mass of apparently legitimate transactions. Due in large measure to the volume and speed of transactions, as well as the virtual anonymity offered by the Internet, offshore gambling websites are an area of considerable money laundering concern. The Internet gambling operations are, in essence, the functional equivalent of wholly unregulated offshore banks with the bettor accounts serving as bank accounts for account holders who are, in the virtual world, virtually anonymous. For these reasons, Internet gambling operations are vulnerable to be used, not only for money laundering, but also for criminal activities ranging from terrorist financing to tax evasion. (State Department, International Narcotics Control Strategy Report, released March 2004.)

The Department of Justice has echoed these concerns. At a hearing before the Senate Banking Committee, John G. Malcolm, Deputy Assistant Attorney General, Criminal Division, testified:

Another major concern that the Department of Justice has about on-line gambling is that Internet gambling businesses provide criminals with an easy and excellent vehicle for money laundering, due in large part to the volume, speed, and international reach of Internet transactions and the offshore locations of most Internet gambling sites, as well as the fact that the industry itself is already cash-intensive.

It is a fact that money launderers have to go to financial institutions either to conceal their illegal funds or recycle those funds back into the economy for their use. Because criminals are aware that banks have been subjected to greater scrutiny and regulation, they have—not surprisingly—turned to other non-bank financial institutions, such as casinos, to launder their money. On-line casinos are a particularly inviting target because, in addition to using the gambling that casinos offer as a way to hide or transfer money, casinos offer a broad array of financial services to their customers, such as providing credit accounts, fund transmittal services, check cashing services, and currency exchange services.

Individuals wanting to launder ill-gotten gains through an on-line casino can do so in a variety of ways. For example, a customer could establish an account with a casino using illegally-derived proceeds, conduct a minimal amount of betting or engage in offsetting bets with an overseas confederate, and then request repayment from the casino, thereby providing a new ''source'' of the funds. If a gambler wants to transfer money to an inside source in the casino, who may be located in another country, he can just play until he loses the requisite amount. Similarly, if an insider wants to transfer money to the gambler, perhaps as payment for some illicit activity, he can rig the game so the bettor wins.

The anonymous nature of the Internet and the use of encryption make it difficult to trace the transactions. The gambling business may also not maintain the transaction records, in which case tracing may be impossible. While regulators in the United States can visit physical casinos, observe their operations, and examine their books and records to ensure compliance with regulations, this is far more difficult, if not impossible, with virtual casinos. (John G. Malcolm, Deputy Assistant Attorney General, Criminal Division, Department of Justice, March 18, 2003.)

Again, there should be strong enforcement efforts to ensure that Internet gambling entities are not violating the law.

AMERICA COMPETES ACT

Mr. OBAMA. Mr. President, I congratulate Senator BINGAMAN and Senator ALEXANDER for the passage of America COMPETES, legislation which they crafted carefully to enhance American innovation and competitiveness. I also thank them for accepting three amendments which I offered, which will help expand the range of innovative possibilities by which America faces its competitive challenges.

Let me explain this. The president of the National Academy of Engineering once said that innovation is a profoundly creative process, and that like other creative processes, it depends on the life experiences of the people involved. If we include a more diverse sample of our population, we will derive more varied and more innovative design options. We become more competitive by embracing our diversity, by involving a more representative cross-section of our populace in science, technology, and engineering endeavors.

To increase participation, I have offered three amendments that have been accepted into America COMPETES. The first establishes a mentoring program to support women and underrepresented groups as they progress through science and technology education programs, increasing the likelihood of their success. I also propose that groups representing women and minority scientists and engineers be involved as strategies are developed to increase America's competitiveness.

Also accepted was an amendment to increase the math and problem solving skills of young learners, by providing summer learning opportunities for students in elementary grades. This amendment springs from legislation I introduced earlier, with Senator MIKULSKI, the STEP UP Act, S. 116. This legislation responds to evidence showing that students may lose several months equivalent of math skills during the summer, if not provided learning opportunities when not in school. This is particularly important for children of poverty, for whom summer learning losses are greatest. Summer programs combat this loss in knowledge and skills, and well-designed programs can fuel the curiosity of children, helping them become active problem solvers and learners when they return to school in the fall.

I thank my colleagues for their support of these amendments.

FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT

Mr. GREGG. Mr. President, the Food and Drug Administration, FDA, plays a major role in ensuring that the American people have access to the safe and effective medicines that they need. In fact, FDA-regulated products account for about 25 cents of every consumer dollar spent. At the heart of all FDA's regulatory activities is a judgment about whether a product's benefits to users will outweigh its risks. These judgments must be science-based to allow the agency to provide the most health promotion and protection at the least cost to the public. As we work on FDA legislation this year, we need to keep that science-based mission at the forefront of our decision making.

Last week, the HELP Committee reported S. 1082, the Food and Drug Administration Act, FDARA. The bill couples must-pass reauthorizations of the Prescription Drug User Fee Act, PDUFA, and the Medical Device User Fee and Modernization Act, MDUFMA, with tour additional pieces of legislation that I am unable to support at this time. It is my hope that we can continue to work in a bipartisan way to improve this bill as it moves to the floor.

The Prescription Drug User Fee Act, PDUFA, first enacted in 1992, gives the FDA the authority to collect user fees from pharmaceutical manufacturers in order to enhance their ability to ensure timely access to safe and effective medicines. By reducing the length of review time required to approve a drug, PDUFA has clearly been a success.

Following the success of PDUFA, Congress enacted the Medical Device User Fee and Modernization Act; MDUFMA in 2002. Like with prescription drugs, MDUFMA funds have been essential to reducing the length of time of the approval process and other improvements critical to the success of the device review process.

This year, both the PDUFA and MDUFMA reauthorizations have been negotiated between the FDA and industry and are worthy of support. In fact, I believe these agreements improve both programs and will improve the safety of these products in the marketplace. If we do not renew these programs by September 30, we risk losing this essential source of funding and patients will face longer review times and

diminished access to much needed medicines and devices.

However, the Kennedy-Enzi language also includes provisions on drug safety and pediatric medicines and devices. All are important issues, but each title of the bill includes provisions that I believe could do more harm than good.

Originally, drug safety legislation was intended to address legitimate concerns many had about how long it took FDA to identify unexpected complications after a drug was approved and to provide FDA with additional authorities to act in those instances.

The Kennedy-Enzi language attempts to address the length of time it can take to identify problems by including language that directs the FDA to establish an active surveillance system. This is essential to addressing any potential problems with postmarket drug safety. I strongly support this in concept but feel the language needs to be strengthened to ensure that the FDA has the direction it needs to implement a robust system in an expedited timeframe. Information collected must be standardized, and the overall system should be validated. Without these and other important benchmarks included in my Safer DATA bill, we are essentially setting the FDA up for failure.

While not going far enough on drug surveillance, the bill goes too far on providing FDA with new authorities. The Kennedy-Enzi language imposes new requirements on manufacturers to develop Risk Evaluation and Mitigation Strategies, REMS, and gives the FDA the authority to require them in both the preapproval and postmarket settings. Importantly, the standards by which FDA can impose REMS are very broad and lack specific requirements through which this standard is triggered. This gives the FDA excessive discretion on imposing REMS on manufacturers even when a drug has a low risk profile.

While clearly the FDA needs new authorities, it is critical to strike a balance, and I fear the Kennedy-Enzi language has gone too far and will slow the approval of new medicines and thereby reduce access.

Instead, the language should be modified so that REMS only applies when the Secretary determines that the new active surveillance system has signaled a risk. At that point, FDA should have the authority to require manufacturers to judiciously minimize risks without encumbering drug availability or interfering with drug research, development, and delivery. Any expansion of FDA authority should respect this approach.

The Kennedy-Enzi language also gives the FDA the authority to require prereview of direct-to-consumer advertising, specific drug advertising disclosures, and a 2-year moratorium on direct-to-consumer advertising. As drafted, these provisions raise a variety of first amendment issues, specifically the 2-year ban on advertising. Much can be done to ensure that consumers receive information that is not false or misleading without banning patient access to health care information.

The Kennedy-Enzi language also includes three separate pediatrics bills: the reauthorization of the Best Pharmaceuticals for Children Act, BPCA, the reauthorization of the Pediatric Research Equity Act, PREA, and the Pediatric Medical Device Safety and Improvement Act.

To encourage the study of more drugs in the pediatric population, BPCA as originally enacted as part of the Food and Drug Administration Modernization Act in 1997, and reauthorized in 2002, grants an additional 6 months of patent life to a product or pediatric exclusivity in exchange for the voluntary studies of prescription drugs conducted on children. Since its enactment, BPCA has been viewed as a highly successful program and has produced at least 132 completed studies, leading to at least 115 pediatric label changes.

Under the Kennedy-Enzi language, the pediatric exclusivity would be capped at 3 months if annual sales for all drugs with the same active ingredient are over $1 billion in any year. This cap for ''blockbuster'' drugs unfairly segments patent protection regimes by making more successful drugs subject to reduced incentives. Our health care system needs to enhance research into children's drugs, not reduce the incentives for manufacturers that produce them. Simply put, the current program is working, and imposing a ''cap'' on the pediatric exclusivity award will reduce the incentive to conduct pediatric studies and, however formulated, would significantly complicate the administration of the program.

Enacted in 2003, PREA gives the FDA authority to require pediatric studies on the same approved indication of a certain drug in adults. BPCA and PREA work hand in hand to encourage the further study of prescription drugs in pediatric populations. It is because of the great success of these two programs that I am pleased that the bill requires both programs to be reauthorized together in 2012. This joint sunset date allows for further reauthorizations to continue to balance the incentives and authorities that drive pediatric study.

One troubling aspect of the BPCA and PREA reauthorizations is the creation of an internal review committee. Nobody would argue that pediatric populations should not get special consideration within the inner workings of the agency; however, as drafted, the internal review committee conflicts with the current staff functions of the FDA.

The Pediatric Medical Device Safety and Improvement Act aims to improve the process for approving pediatric medical devices and encourages research, development, and manufacture of pediatric devices through demonstration grants and incentives. It modifies the human device exemption for medical devices to allow manufacturers to earn a profit for HDE-approved pediatric devices but maintains the requirement that a humanitarian use device is limited to one that treats and diagnoses diseases or conditions that affect fewer than 4,000 individuals in the United States. This is a good policy, which will help foster the development of pediatric devices. Unfortunately, the bill also expands FDA's authority to require companies to conduct postmarket studies of adult devices, even in circumstances in which the manufacturer has no intent to market the device to pediatric populations. Forcing companies to conduct studies on their products for unintended and unapproved use diverts resources that could be used for further innovation, research, and development.

Of additional concern is that at this time, many provisions of the bill have never been scored by CBO. The provisions in this bill have a significant impact on the FDA and require a number of changes at the agency that will require significant dollars. Because PDUFA and MDUFMA are based on negotiations between industry and the administration, any changes that impact that careful compromise need to be fully vetted and understood. Unfortunately, at this time we do not have that information.

It is clear to all that there are numerous complicated issues involved. Some provisions provide a great benefit, while others may have graver consequences than even the bill's sponsors would intend. It is my hope that as we deal with these issues, we can do so in a manner that is science based and favors patient access over regulatory burden.

I ask that the following statement of HHS Secretary Leavitt be printed in the RECORD.

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

SECRETARY OF HEALTH AND HUMAN SERVICES,
Washington, DC, April 17, 2007.

Hon. EDWARD M. KENNEDY,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR CHAIRMAN KENNEDY: I am pleased to share the Department's views on the Chairman's mark to S. 1082, the Food and Drug Administration Revitalization Act. We appreciate the commitment of you and the Committee in addressing many of the critical issues facing the Food and Drug Administration. We support many of the provisions of the bill and note the many changes made in response to HHS comments. However, we continue to have significant concerns with a number of provisions and hope to work with you to address these before the measure is considered on the floor.

OVERVIEW

The Administration strongly supports the reauthorization of the prescription drug user fee and medical device user fee programs. These user fee programs expire at the end of the current fiscal year and their timely reauthorization is critical to the ability of FDA to continue to speed new drugs, biologics and devices to market to benefit the health of the American people.

We are pleased that the bill is consistent with our PDUFA IV proposal by providing the sound financial footing for FDA, enhancing premarket review, creating a new program for review of television advertisements, and significantly strengthening the post-market drug safety system. However, we are troubled by the proposal to fund drug safety activities in Title II with user fees. In our view, the amount that could be raised through user fees may be inadequate, but we are concerned with reopening the PDUFA IV proposal.

We also thank the Committee for including language that reflects the draft MDUFMA II proposal. However, we want to work with you to address any concerns once the public comment process has been completed and we are able to transmit the final package to Congress.

There are other provisions in the bill that raise serious concerns. In particular, both BPCA and PREA have been very successful in providing the necessary incentives for drug companies to conduct pediatric clinical trials to improve drug labeling for children, thus enhancing the quality of their medical care.

We support the extension of the Best Pharmaceutical for Children's Act. However, the provisions in the substitute bill would reduce the incentive to conduct clinical trials for children, thus reducing the effectiveness of the program and changes are made that make the program virtually unworkable. For these reasons, we favor a straight extension of current law over the enactment of the BPCA provisions in this bill.

In addition, the PRIA, as drafted, would make this program burdensome for FDA to the point that we would instead propose a straight extension of current law.

Finally, as demonstrated by proposed increases for drug safety in the President's FY 2008 Budget Request and the drug safety enhancements in our PDUFA IV proposal, we have a strong commitment to improving the FDA drug safety system. In our view, the core issues of drug safety are better tools for surveillance of drug events, improved scientific tools for evaluating drug safety problems, and better means of communicating drug safety problems to providers and patients. However, the bill as drafted is overly onerous in terms of process and structural changes and could actually have the unintended effect of slowing down drug approvals—while doing little to address the core issues of drug safety. In addition, this would be extremely resource intensive.

Now, I would like to turn to more detailed comments on the substitute bill.

TITLE I—PRESCRIPTION DRUG USER FEES

FDA's review of new drug applications (NDAs) and biologics license applications (BLAs) is central to FDA's mission to protect and promote the public health. In 1992 Congress enacted PDUFA, intending to reduce the time necessary for new drug application review, and subsequently has reauthorized it twice. As you know, the current user fee program is scheduled to expire on September 30, 2007.

PDUFA has produced significant benefits for public health, including providing the public access to 1,220 new drugs and biologics. During the PDUFA era, FDA reviewers have approved: 76 new medicines for cancer; 178 anti-infective medications (including 56 for treatment of HIV or Hepatitis); 111 medicines for metabolic and endocrine disorders; 115 medicines for neurological and psychiatric disorders; and 80 medicines for cardiovascular and renal disease.

In addition, PDUFA implementation efforts have dramatically reduced product review times. While maintaining our rigorous review standards, we now review drugs as fast as or faster than anywhere in the world. The median approval time for priority new drug and biologic applications has dropped from 14 months in fiscal year (FY) 1993 to only six months in FY 2006.

The most recent reauthorization of PDUFA directed FDA to consult with the House Committee on Energy and Commerce, the Senate Committee on Health, Education, Labor, and Pensions, appropriate scientific and academic experts, health care professionals, patient representatives, consumer advocacy groups, and the regulated industry in developing recommendations for PDUFA reauthorization. We have complied with these requirements in preparing our PDUFA IV proposal, and we are pleased that the draft bill reflects the Administration's PDUFA IV proposal. We believe that the proposal places PDUFA on a sound financial footing, enhance premarket review, and create a modern post-market drug safety system that follows products across their life cycle. Importantly, the proposal also supports new user fees to support the review of direct-to-consumer television advertisements voluntarily submitted to FDA for review prior to airing.

TITLE II—DRUG SAFETY

SUBTITLE A—RISK EVALUATION AND MITIGATION STRATEGIES [REMS]

New drugs, biologics, devices, and diagnostics present the greatest opportunities currently available to improve health care and the way medicine is practiced. The number of lives saved are prolonged by new therapies outweighs the risks that the treatments themselves pose. It is also true that all such products pose potential risks. Thus, a drug safety system of the highest possible quality should not be confused with a system in which drugs are risk free. Because there are risks whenever anyone uses a medication, safety considerations involve complex judgments by the healthcare provider community, patients, and consumers, who must constantly weigh the benefits and assess the risks before deciding to use a medical product.

Attempts to address these risks must balance access and innovation with regulatory steps to improve the approach to safety issues. We need to make sure that such steps do not impede access to new medical products that can be used safely and effectively by patients suffering from unmet medical needs today. Many of these bill provisions seem fixed on process changes and structural changes in government programs, and not on making fundamental improvements in the science of drug safety. Some changes prescribe specific Agency action when the science of drug safety may not require such intervention, such as the requirement to present all new molecular entities to advisory committees for discussion. Such changes could limit access to needed medicines and slow down new innovations while doing little to address the core issues of drug safety.

Improved drug safety is not simply a matter of extending new legal authorities to FDA or requiring the Agency to engage in certain detailed activity. Indeed, extending these interventions or expanding the use of REMS is unlikely to result in improvements in drug safety as desired by the bill's sponsors.

The better overall strategy is to ensure that FDA has appropriate resources and the capacity to develop better scientific tools and approaches to drug review, including (1) improving information available to the Agency; (2) improving its ability to evaluate this information; and (3) improving how that evaluation is communicated to the public.

Accordingly, the Administration's proposed PDUFA IV recommendations support improvements with respect to: the information that the Agency receives, and with which it makes drug-safety related decisions, including the spontaneous reports we get from sponsors and providers as well as our ability to tap into epidemiological data sets to probe more routine questions; our analytical tools and approaches for evaluating this information and turning raw data about drug-safety related questions into practical medical facts that can be communicated to providers and patients to help them better inform their decision making; and the way in which we can effectively communicate these findings, as well as communicate the Agency's response once we draw a conclusion about the data we have, or we are made aware of a potential drug safety problem or an emerging safety issue.

We support the addition of provisions for an active drug safety surveillance system that would be established through a public-private partnership and we want to work with you on this provision to ensure the most effective implementation.

We continue to oppose the breadth of the proposed requirements for risk evaluation and mitigation strategies outlined in the bill. We believe it is unnecessarily burdensome on FDA and industry to require routine active surveillance and periodic reassessments for all drugs, as the legislation now does.

Even as modified in the substitute bill, the REMS approach would duplicate and overlap elements of the extensive adverse event reporting system already required by FDA (which includes incident-specific, quarterly, and annual reporting). It would also duplicate existing FDC Act labeling requirements, which provide for MedGuides, package inserts, and other materials which convey information to physicians and pharmacists (as well as patients) to address and minimize risk. Moreover, FDA and industry already engage in efforts with respect to implementation of risk minimization action plans (''RiskMAPs'') for those products that warrant such additional risk minimization protocols. In addition, FDA already has authority to require post-approval studies in select circumstances. Codifying new authority to these same ends is unnecessary and redundant.

We are also concerned about the adequacy of resources proposed for the significant increase in work that the legislation would entail (e.g., active surveillance, REMS-related activities, the Drug Safety Oversight Board activities, compliance work, and public meetings). Moreover, we are particularly concerned that the proposal would support all of these activities by PDUFA user fees, although this was not part of the industry agreement. Reopening negotiations at this time would risk the timely reauthorization of PDUFA.

Finally, the Drug Safety Oversight Board [DSOB] would be used to review disputes between the sponsor and the FDA concerning REMS. Not only does the DSOB not have the necessary expertise to handle dispute resolutions, the bill proposes the disputes be raised directly to the DSOB bypassing the existing dispute resolution process specified in current law [Section 562 of the Act] thus eliminating the possibility of resolving disputes at a lower level. Since the DSB would be the primary source of dispute resolution, this requirement would so overburden the DSB that they will be unable to conduct their other important functions.

SUBTITLE B—REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

This subtitle would amend chapter VII of the Federal Food, Drug and Cosmetic Act to

establish the Reagan-Udall Foundation for the Food and Drug Administration, for purposes of advancing the FDA's mission to modernize the medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety. We believe that the proposed Foundation may accelerate the national effort to modernize product-related sciences with some additional changes. Another se10us concern is the creation in statute of the Office of the Chief Scientist. This is redundant and the functions would duplicate and conflict with the functions of the current Chief Medical Office position. We look forward to working with you to continue to refine this section.

SUBTITLE C—CLINICAL TRIALS

Subtitle C would establish a publicly available database to improve opportunities for enrollment in clinical trials and to enhance access to clinical trials results for the benefit of patients, health care providers and researchers.

We support the goal and concept of enhancing access to information on clinical trials and providing a mechanism to enable health care professionals and the public to obtain information about trial results. We believe that such efforts should: emphasize transparency; minimize costs and administrative burdens and build on current efforts; utilize available technology to streamline and minimize the need for new funding; ensure that such activities improve the public health; and recognize legal or funding limitations of the affected federal agencies.

In addition, we have concerns with the mandated negotiated rule making process which is time consuming and resource intensive.

The draft language takes important steps to addressing concerns previously raised by the department, and we look forward to continuing to work with the Committee on these issue.

SUBTITLE D—CONFLICTS OF INTEREST

FDA's advisory committees play an essential role in FDA's activities to protect and promote public health through the regulation of human and animal drugs, biological products, medical devices, and. foods: It is important that any legislation concerning review of conflicts of interest for advisory committee members and criteria for eligibility for participation in meetings afford FDA the flexibility to obtain needed external expertise while minimizing the potential for a conflict of interest. We appreciate the improvements to the draft legislation to address these important issues. We note that some concerns remain regarding the scope and applicability of the waiver provision, the limitation on waivers if a member's own scientific work is under consideration, prescreening requirements and the scope of financial disclosures by advisory Committee candidates and members. We hope to work further with the Committee to address these remaining issues.

TITLE III—MEDICAL DEVICE USER FEES

FDA's review of medical device applications is essential to FDA's mission to protect and promote the public health. In 2002 Congress enacted MDUFMA, intending to reduce the time necessary for new medical device application review. As you know, the current user fee program is scheduled to expire on September 30, 2007.

Similar to PDUFA, FDA was directed to consult with stakeholders in developing recommendations for MDUFMA reauthorization. We have complied with these requirements in preparing our MDUFMA II proposal, and we are pleased that the draft bill is consistent with the Administration's draft MDUFMA II recommendations as laid out in the Federal Register notice.

As we announced on April 16, FDA is holding a public meeting on April 30 and providing the public with a 30-day period in which to comment on the Administration's legislative recommendations in accordance with Section 105 of MDUFMA. We look forward to sending you the Administration's final recommendations shortly after the public comment period closes.

TITLE IV—PEDIATRIC MEDICAL PRODUCTS

SUBTITLE A—BEST PHARMACEUTICALS FOR CHILDREN

The Administration supports reauthorization of the Best Pharmaceuticals for Children Act. The incentive for pediatric studies provided in this legislation has had a powerful impact on providing important safety, efficacy, and dosing information for drugs used in children. It has created an environment that promotes the study of drugs in children, fostered an infrastructure for pediatric clinical trials that was previously non-existent, and enabled FDA to obtain important pediatric information and numerous labeling changes.

However, the substitute bill contains several provisions that we believe will have a severe negative impact on this successful program. The incentive to conduct clinical trials for children will be compromised and the creation of an internal review committee and other program changes will make the BPCA virtually unworkable. For this reason, the Administration would favor a straight reauthorization over the enactment of these provisions. I will now review some of our specific concerns.

First, as mentioned above, the current incentive of the 6 month period of exclusivity has worked well and should be maintained. Through this legislation, FDA has been able to effect important labeling changes on 122 different products. Any weakening of this incentive can only have the effect of reducing its effectiveness. Accordingly, the proposal to shorten this incentive or to only provide exclusivity to drugs with one or more year left of patents and exclusivity life are of significant concern.

FDA supports greater internal cooperation; however, the draft bill's creation of an internal review committee is of concern for a number of reasons. First, a legislative requirement for what are primarily staff functions is in direct conflict with the expertise, flexibility and efficiency needed to ensure rapid review of pediatric product development. We have concerns about the structure and composition of the committee. Second, the proposal assigns the dual function of approving written requests and granting exclusivity, which may result in conflicts between the subjective intent of the written request and the objective evaluation as to whether the studies fairly respond to the actual terms of written request. We recommend keeping the two functions separate. Third, we believe that tracking pediatric studies are responsibilities more appropriately assigned to agency staff, since they are routine functions that do not require a decision-making body.

There are a number of critical technical provisions which affect the submission of reports, labeling changes, and disclosure of information which needs to be modified to ensure the process works as intended.

SUBTITLE B—PEDIATRIC RESEARCH IMPROVEMENT ACT

As noted above, we support the efforts to improve internal consistency and efficiency. However, the bill's creation of an internal review committee for Pediatric Research Equity Act [PREA] assessments is also of concern similar to the reasons stated above. A legislative requirement for what are primarily staff functions is in direct conflict with the expertise, flexibility and efficiency needed to ensure rapid review of pediatric product development. We do have serious concerns about the structure and composition of the committee as well as the potential impact on the current process given the number and extent of assessments.

There are technical provisions which affect the submission of reports, labeling changes, and disclosure of information which needs to be modified to ensure the process works as intended. As stated above with regard to BPCA, we feel that the changes in the substitute bill will make the Pediatric Research Equity Act program unworkable and the Administration would rather have a straight reauthorization of PREA than enactment of the substitute bill.

SUBTITLE C—PEDIATRIC MEDICAL DEVICES

With regard to Subtitle C-Pediatric Medical Devices, while we support measures to stimulate the increase availability of pediatric devices, we have major concerns with these provisions.

In the area of pediatric device research, NIH has a number of research efforts underway in this area and we believe it would be more efficient and effective to utilize current research initiatives at NIH rather than embark on a new private sector initiative. The funding of a private consortia would siphon off dollars for administrative expenses [that could otherwise go for pediatric device research. In addition, we oppose having a private entity making the decisions on research priorities.

The amendment to the Humanitarian Device Exemption would remove the profit-making restriction for HDEs approved for pediatric indications on the theory that allowing profit will stimulate the production of more pediatric devices for limited populations. Allowing profits up to a sales cap is an impractical policy tool. Our view is that this amendment to the HDE exemption would be administratively burdensome and costly for industry and the FDA, and would have a questionable impact on the incentive to develop new pediatric devices.

CONCLUSION

In conclusion, this letter has cited many problems with provisions included in this bill—some we believe will not achieve their policy objectives; some are unduly burdensome on the industry and the FDA. Still others appear to be unworkable or potentially costly. In addition to these concerns, the Administration may have additional concerns in connection with this legislation.

We have raised many serious objections in our comments above and it is our hope that we can work with you and others to resolve these before the bill is considered on the floor. Our support of this legislation is contingent on the satisfactory resolution of these concerns.

OMB advises that from the standpoint of the Administration's program there is no objection to the transmittal of this letter. We look forward to our collaboration with you on this legislation.

Sincerely,

MICHAEL O. LEAVITT.

ANNUAL CRAWFISH BOIL IN GILLETTE, WYOMING

Mr. ENZI. Mr. President, I would like to speak about community spirit. In the Senate, we work day in and day out to pass good policy that will provide for the safety, security, and health of