

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 serious 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 issues.

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 con-

cern 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

the Nation, but we are not alone in our effort to make our country better. In fact, we are but a small part. There are great events taking place every day in our country that are examples of neighbor helping neighbor, people who do not wait and do not ask for help but take it upon themselves to act. I would like to tell you about one such example that has been going on for years in Wyoming right in the small community I call home.

When people think about my hometown of Gillette, WY, many images come to mind—sagebrush as far as the eye can see, coal trucks, and cattle herds. We have deer, antelope, and some buffalo in the neighboring community of Wright. Our kids are great basketball players, and we work hard to get the methane gas and minerals that power this country. The list goes on. But after living in Gillette for more than three decades, what stands out about home are the people themselves, their character, their sense of community, and how they come together to help each other. And then there is the crawfish. Yes, I said crawfish.

This week, Gillette will be kicking off a 24-year tradition of flying in 10,000 pounds of crawfish for the annual Crawfish Boil. The event raises money for local families with medical hardships and was started in 1983 by the Society of Petroleum Engineers. The event raised \$117,000 last year to help people get medical treatment. This weekend we hope to top that number.

Wyoming may be small in population, but our families know how to help each other out more than any other State in the Nation. Wyomingites do not just rely on government for help—they talk to neighbors, they come up with a good idea, they organize, and they follow through. The crawfish feed is an example for the Nation on how to pull yourself and your neighbor up by the bootstraps and have fun doing it.

Gillette not only raised \$117,000 at last year's Crawfish Boil, the Festival of Trees raised \$51,500 for hospice and lifeline services, the Chili Cook-Off raised \$28,800 for the Council of Community Services, the Black Cat Ball raised \$26,000 for the Hospice Hospitality House, the Chuckles for Charity event raised \$24,000 for the Gillette Area Refuge, and the Rotary Ball raised \$40,000 for education and other programs in Gillette. Mr. President, \$287,000 in 1 year, in one community with roughly 25,000 residents. I could not think of a better place to call home.

ADDITIONAL STATEMENTS

CODY CARITHERS

• Mr. PRYOR. Mr. President, it is with the greatest pleasure that I honor and congratulate Cody Carithers who is a senior at Highland High School in Arkansas and will graduate on May 18, 2007. Cody has accomplished an amazing feat—he has never missed a day of

school. Since kindergarten at Cherokee Elementary School in Highland until now, never missed a day.

This accomplishment has not been easy. Cody was diagnosed with a brain tumor near his optic nerve a little over 2 years ago. This caused frequent headaches and required many trips to Arkansas Children's Hospital in Little Rock. Cody was adamant about maintaining his perfect attendance, and the hospital worked with him to schedule his appointments on school holidays or in the evening so he wouldn't miss a day of school. What a determined young man.

Cody is involved in a number of school activities, clubs and organizations. He is an active member of Future Farmers of America and is president of the Rebels Against Drugs Program at Highland High School. He has also participated in sports.

During the summer, Cody volunteered at the Sharp County Library. He has been employed for the past 2 years at Ivey's Automotive Center in Highland. Cody's plans after graduation are to attend Black River Technical College and pursue a degree in aviation maintenance or automotive technology.

I ask my colleagues to join me in applauding Cody Carithers for his determination, drive and incredible school attendance record. He exemplifies Highland High School's motto, "A tradition of excellence."•

TRIBUTE TO DR. DAVID M. GIPP

• Mr. CONRAD. Mr. President, today I pay tribute to an extraordinary scholar, leader, and friend, Dr. David M. Gipp.

On May 2, Dr. Gipp will celebrate 30 years at the helm of United Tribes Technical College in Bismarck, ND. United Tribes Technical College, UTTC, is the only intertribally owned postsecondary vocational institution in the Nation. Since its founding in 1969, the college has served more than 10,000 students representing 75 federally recognized tribes.

During his tenure as president, Dr. Gipp has spearheaded an incredible transformation of the college and in higher education for American Indians. Dr. Gipp was the first executive director of the American Indian Higher Education Consortium and later he served as its president. He was instrumental in the formulation of the Tribal Colleges or Universities Assistance Act, which started to address the Federal Government's obligation in providing higher education for American Indians.

Under Dr. Gipp's leadership, UTTC has grown from just over 100 students and 12 programs of study to more than 1,018 students for the 2006–2007 school year with 24 different 2-year and certificate programs and bachelor's programs. In this time, Dr. Gipp has led the college's transition from traditional vocational trades to programs geared toward the labor needs of Indian Country. He also propelled UTTC into becoming the first tribal college in the

Nation to be authorized to offer full on-line degree programs. In recent years, Dr. Gipp has led the fight to restore funding for the college that was cut from the Department of Interior's budget.

Dr. Gipp has been an agent of positive change in the lives of thousands of students who have attended United Tribes Technical College. He is a true champion for higher education and a powerful national advocate for the tribal colleges. His passion is infectious, and he has empowered individuals to reach to their goals no matter how small or large.

John Quincy Adams once said "[I]f your actions inspire others to dream more, learn more, do more and become more, you are a leader." Dr. Gipp is a leader in every sense of the word. I want to extend my congratulations to Dr. Gipp on 30 years as president of United Tribes Technical College.●

TRIBUTE TO CECIL E. WILLIAMS, JR.

• Mr. PRYOR. Mr. President, today I wish to honor the life of a man revered as the most influential man in Arkansas agriculture. Cecil E. Williams, Jr., who passed on April 12, was respected by his peers and seen as an unparalleled advocate for farmer's interests, where he tried to save not only their lives, but also their jobs and livelihood.

Undoubtedly, agriculture is the backbone of rural Arkansas and rural America. Today, Arkansas agriculture provides nearly one in every five jobs in my State, and we rank in the top 10 nationally in the production of many commodities, including rice and cotton, where we rank No. 1 and No. 2 respectively. Much of Arkansas' success in agriculture can be directly attributed to Cecil Williams and his hard work. Mr. Williams worked hard during his lifetime to make Arkansas agriculture a force to be reckoned with while establishing workable, sensible, and sound farm policy. For nearly 40 years, Cecil Williams, known as the "Dean of Farm Bills," served as the director of the Agricultural Council of Arkansas, ACA, where he took great pride in serving what he considered a worthwhile cause: farmers and agriculture.

After receiving an agribusiness degree in 1960 from Louisiana State University, Mr. Williams began his career as a fieldworker for the National Cotton Council and gained valuable insight into the production, business, and policy angles of agriculture. After an impressive 5 years with the National Cotton Council, the Agricultural Council of Arkansas recognized his talents and heavily recruited him to join their ranks. Once at the council, he quickly ascended to a leadership role with the organization and went on to fight for farm policy that made sense for Arkansas, improve checkoff programs for