

of children and families through an expanded role advising the J.B. and M.K. Pritzker Family Foundation on its philanthropic endeavors. His approach to this work is made clear by something he said just last year:

My position in the Senate is only one point of entry into public service.

As Jeff moves into his new role, I can only say to him: Thanks for being my friend and my ally in so many good causes. While you may be retiring from the Illinois State Senate, your constituents and I know that you will never retire from working for the public good.

Thanks to Jeff Schoenberg and his family for all they have given to our State.

MAYOR JOHN REDNOUR

Mr. DURBIN. Mr. President, I wish to take a moment to wish Mayor John Rednour of Du Quoin, IL, a happy 78th birthday and to thank him as he prepares to retire after so many great years of public service to his town and Illinois.

John Rednour, known to most people as simply Rednour, has served as mayor of Du Quoin since 1989. Public service was his third career. He started work as an ironworker, a member of the United Ironworkers. He worked on projects in St. Louis and in Chicago and served as site superintendent during construction of the U.S. Federal penitentiary in Marion.

In 1970 John moved to Du Quoin with his wife Wanda and three kids. In the early 1980s John began his second career when he and some local shareholders took control of the Du Quoin State Bank, converting it into a community bank that served downstate Illinois. Today the bank stands as one of the strongest in our State, and John remains the bank's chairman.

But it was John Rednour's work as mayor of Du Quoin that really distinguished his public service. In his 23 years as mayor, he focused on balancing the city's budget and investing in its infrastructure. His legacy to Du Quoin includes construction of the Poplar Street overpass—a major thoroughfare for travel on Highway 51 through southern Illinois—improved water service and the development of an industrial park. He managed to do all of this with a balanced budget, creating new opportunities for his community even in tough times.

He is a member of the five-person Illinois State Police Merit Board and a proud Democrat, I might add, but he knows there are some things that need to be done on a bipartisan basis. He has made it his habit to meet with the Du Quoin city council members and offered to take advice from each and every one of them. He told them to always vote for what is good for Du Quoin.

Loretta and I consider ourselves lucky to count John and Wanda Rednour among our friends. We have

many happy memories of State fair parties at the Rednour home during our trips to the Du Quoin State Fair. Loretta and I have been regular visitors to Rednour's home and have warm memories of staying overnight after the fair party and having Wanda greet us at breakfast with her so-called Texas pancakes—and they could fit in the State of Texas.

As a labor leader, businessman, mayor, husband, and father, John Rednour has contributed enormously to Du Quoin, downstate Illinois, and to our entire State and Nation. While his day-to-day presence in city hall is going to be missed, residents of Du Quoin can take comfort in knowing that John Rednour's leadership is still in their community, with a strong foundation and a bright future.

In addition to three children, John and Wanda are blessed with five grandchildren and five great-grandchildren, who I am sure are going to be glad to have more time with John and Wanda now.

I thank John for his many years of distinguished public service. Loretta and I wish him and his family all the best in retirement. We look forward to many more stories and more pancakes in the years to come.

THE S.S. BADGER

Mr. DURBIN. Mr. President, Chicagoans were asked in a recent poll to identify the one asset in the city of Chicago that meant the most to them. The overwhelming vote was for Lake Michigan—not surprising.

Lake Michigan is the primary source of drinking water for more than 10 million people—not just in my State of Illinois but in Wisconsin, Indiana, and Michigan. It supports a multibillion-dollar fishing industry that is important to local economies. And it is beautiful. It is a recreational asset for swimming, kayaking, boating, or just taking a walk along the beach. It is a gorgeous lake.

I always look forward to getting up to Chicago. We have a condo that overlooks Lake Michigan that I consider to be a great place to sit and just look at this beautiful lake and what happens on it, whether I am drinking a cup of coffee in the morning with my wife or a glass of wine in the evening.

But, unfortunately, the health of our great Lake Michigan is threatened every summer when a coal-burning ferry boat dumps tons of coal ash into the lake every day, all summer long.

Meet the S.S. Badger. Many people have fond memories of this boat, the S.S. Badger, steaming from its homeport of Ludington, MI, to Manitowac, WI, every summer. But they need to be reminded of one thing: The S.S. Badger is the last coal-fired ferry in the United States, and there is a reason it is the last one.

Every year, based on the estimates given to us by the company, this boat dumps 600-plus tons of coal ash into

Lake Michigan—600-plus tons every year since 1953. That is their record. What does that do to Lake Michigan? In the 59 years the S.S. Badger has been in operation, it has discharged a conservative estimate of 35,400 tons of coal ash into Lake Michigan. That is enough to coat the entire floor of Lake Michigan with a layer of ash 2½ inches thick.

A recent article in the Chicago Tribune did a comparison of the amount of coal ash discharged from the Badger to the dry cargo residue discharged by all other vessels operating on Lake Michigan. Here is what they found:

Fifty U.S. ships and 70 Canadian ships on Lake Michigan are responsible for a combined total of 89 tons of solid waste dumped every year. That is 120 ships, 89 tons in a year. The Badger by itself is responsible for almost 6 times more waste than these 120 vessel combined, even when using the most conservative estimate of what the Badger dumps overboard during the course of a summer.

Yesterday the EPA vessel general permit that has enabled the coal-fired car ferry S.S. Badger to discharge coal ash into Lake Michigan expired. The owner of the Badger insists that the coal ash is basically just sand. We know better.

Scientists are concerned about coal ash because it contains such things as arsenic, lead, and mercury. Once in the lake, these chemicals enter the food chain through the water we drink and the fish we eat, and then they accumulate in our bodies and are associated with cancer and reproductive and neurological damage. We know how dangerous mercury contamination in fish is to human health.

Well, it is time for the S.S. Badger to stop adding to the problem and either clean up its operation or close it down. If the Badger's owners had only recently realized that dumping coal ash was a problem, it might be OK to cut them some slack. But the Badger's owners have a long history of avoiding the steps needed to clean up their act.

Most other vessels of the Great Lakes converted from coal to diesel fuel before the Badger made its first voyage. In 2008, when conversion to a new fuel was way overdue, the Bush administration granted the ferry a waiver to continue dumping coal ash through 2012. That was 5 years too many of toxic dumping by this boat, but to make matters worse, the Badger's owners still have not made any reasonable efforts to stop dumping coal ash in the lake.

Now they are attempting to persuade the EPA to give them just 5 more years to take a look at this problem. After I came out in opposition to this 5-year extension, the Badger's owner asked to meet me in my office. I, of course, agreed. He said he was applying for an EPA permit to continue dumping coal ash while he looks for ways to convert the Badger to run on liquefied natural gas. He wanted to make the Badger, he

said, the greenest vessel on the Great Lakes. What a great idea, I thought. But it turns out it isn't even close to being realistic.

Today there are few suppliers of liquefied natural gas in the area. There are no shipyards in the United States that are qualified to convert passenger vessels to run on liquefied natural gas. And it would take close to \$50 million just to develop the infrastructure on the land needed to transport fuel to the dock for the Badger.

One day, all the boats on Great Lakes might be powered by natural gas, but that isn't a realistic plan right now or within the next few years. It is just another delaying tactic from the owners of the S.S. Badger. These owners were given a deadline to convert the ship's fuel or dispose of the ash in a responsible way 5 years ago. The Badger has blatantly avoided complying with these EPA regulations.

There has been an effort in the House of Representatives to provide a special exemption for this filthy boat on Lake Michigan forever. They want them declared some sort of a national historic monument or something and say that it shouldn't be governed by environmental regulations.

These are Congressmen whose districts are on Lake Michigan. I have to ask them, what do you think about the lake and its future, when this boat is responsible for six times the solid waste of all the other ships that use Lake Michigan in commerce on an annual basis? Six times. That to me is a horrible thing to continue.

They have had plenty of time to clean up their act and they failed. Now we have to get serious. I am hoping the EPA decides very quickly that it is time to end the coal-fired ferry tradition of the S.S. Badger. This is a vessel that generates and dumps 5 tons of coal ash laced with mercury, lead, and arsenic into Lake Michigan every single day. This great lake cannot take any more toxic dumping, no matter how historic or quaint the source may be.

LETTERS FROM THE SECRETARY OF HEALTH AND HUMAN SERVICES RE: MEDICAL DEVICE USER FEE PROGRAM

Mr. HARKIN. Mr. President, I ask unanimous consent that, pursuant to Public Law 112-144, the Food and Drug Administration Safety and Innovation Act, the following letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives be printed into the RECORD.

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

MDUFA PERFORMANCE GOALS AND PROCEDURES

The performance goals and procedures agreed to by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Adminis-

tration ("FDA" or "the Agency") for the medical device user fee program in the Medical Device User Fee Amendments of 2012, are summarized below.

FDA and the industry are committed to protecting and promoting public health by providing timely access to safe and effective medical devices. Nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of the safety and effectiveness of medical devices. Both FDA and the industry are committed to the spirit and intent of the goals described in this letter.

I. PROCESS IMPROVEMENTS

A. Pre-Submissions

FDA will institute a structured process for managing Pre-Submissions. Pre-Submissions subject to this process are defined in Section VIII, Definitions and Explanations of Terms. The Agency will continue to improve the Pre-Submission process as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. FDA will issue a draft guidance document and final guidance document on Pre-Submissions.

Upon receipt of a Pre-Submission that requests feedback through a meeting or teleconference, FDA intends to schedule the meeting or teleconference to occur within a timely manner. In the Pre-Submission, the applicant will provide at least three suggested dates and times when the applicant is available to meet.

It is FDA's intent that within 14 calendar days of receipt of a request for a meeting or teleconference, FDA will determine if the request meets the definition of a Pre-Submission, and will inform the applicant if it does not meet the definition. FDA will also determine if the request necessitates more than one meeting or teleconference. A determination that the request does not meet the definition of a Pre-Submission will require the concurrence of the branch chief and the reason for this determination will be provided to the applicant. If the request meets the definition of a Pre-Submission, FDA and the applicant will set a mutually agreeable time and date for the meeting.

At least 3 business days prior to the meeting, FDA will provide initial feedback to the applicant by email, which will include: written responses to the applicant's questions; FDA's suggestions for additional topics for the meeting or teleconference, if applicable; or, a combination of both. If all of the applicant's questions are addressed through written responses, to the applicant's satisfaction, FDA and the applicant can agree that a meeting or teleconference is no longer necessary and the written responses provided by email will be considered the final written feedback to the Pre-Submission.

Meetings and teleconferences related to Pre-Submission will generally be limited to 1 hour. A longer meeting or teleconference time can be scheduled by mutual agreement by the applicant and FDA.

Applicants will be responsible for developing draft minutes for a Pre-Submission meeting or teleconference, and provide the draft minutes via email to FDA within 15 calendar days of the meeting. The minutes will summarize the meeting discussions and include agreements and any action items. FDA will provide any edits to the draft minutes to the applicant via email within a timely manner. These minutes will become final 15 calendar days after the applicant receives FDA's edits, unless the applicant indicates that there is a disagreement with how a significant issue or action item has been documented. In this case, within a timely manner, the applicant and FDA will conduct a teleconference to discuss that issue with FDA. At the conclusion of that teleconference, within a timely manner FDA will final-

ize the minutes either to reflect the resolution of the issue or note that this issue remains a point of disagreement.

FDA intends that feedback the Agency provides in a Pre-Submission will not change, provided that the information submitted in a future investigational device exemption (IDE) or marketing application is consistent with that provided in the Pre-Submission and that the data in the future submission do not raise any important new issues materially affecting safety or effectiveness. Modifications to FDA's feedback will be limited to situations in which FDA concludes that the feedback does not adequately address important new issues materially relevant to a determination of safety or effectiveness. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

B. Submission Acceptance Criteria

To facilitate a more efficient and timely review process, FDA will implement revised submission acceptance criteria. The Agency will publish guidance outlining electronic copy of submissions (e-Copy) and objective criteria for revised "refuse to accept/refuse to file" checklists. FDA will publish draft and final guidance prior to implementation.

C. Interactive Review

The Agency will continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and applicants. As described in the guidance document, *Interactive Review for Medical Device Submissions: 510(k)s, Original [Premarket Approvals] PMAs, PMA Supplements, Original BLAs, and BLA Supplements*, both FDA and industry believe that an interactive review process for these types of premarket medical device submissions should help facilitate timely completion of the review based on accurate and complete information. Interactive review is intended to facilitate the efficient and timely review and evaluation by FDA of premarket submissions. The interactive review process contemplates increased informal interaction between FDA and applicants, including the exchange of scientific and regulatory information.

D. Guidance Document Development

FDA will apply user fee revenues to supplement the improvement of the process of developing, reviewing, tracking, issuing, and updating guidance documents. The Agency will continue to develop guidance documents and improve the Guidance Development process as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.

FDA will update its website in a timely manner to reflect the following:

1. The Agency's review of previously published device guidance documents, including the deletion of guidance documents that no longer represent the Agency's interpretation of, or policy on, a regulatory issue, and notation of guidance documents that are under review by the Agency;

2. A list of prioritized device guidance documents (an "A-list") that the Agency intends to publish within 12 months of the date this list is published each fiscal year; and

3. A list of device guidance documents (a "B-list") that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year.

The Agency will establish a process allowing stakeholders an opportunity to:

1. Provide meaningful comments and/or propose draft language for proposed guidance topics in the "A" and "B" lists.