report reiterated recommendations in an article published last week in the Journal of the American Medical Association. In particular, they stated:

The Institute of Medicine identified the imbalance in authority between the Office of New Drugs and the Office of Surveillance and Epidemiology as a major weakness in the drug safety system. In an effort to facilitate a collaborative and constructive team approach, the Institute of Medicine recommended joint authority for the Office of New Drugs and Office of Surveillance and Epidemiology in the postapproval setting.

These experts noted that the FDA's response to the Institute of Medicine's recommendations ''represent incremental progress'' but suggest that the FDA failed to embrace, among other things, ''the equality between the preapproval and postapproval activity of the agency.''

Having equality between the preapproval and postapproval activities at the FDA is fundamental to real reform. It is common sense. This is especially true when we think about what we have learned from the operation of the FDA over the past few years and those shortcomings.

As we debate this bill, we are going to hear a lot about the impressive Institute of Medicine study and its recommendations to improve the FDA. We have and will continue to hear Members talk about how S. 1082 addresses many of the Institute of Medicine's recommendations. However, this is one important and sweeping recommendation that is not addressed in the bill before us.

Amendment No. 1039 is intended to address that shortcoming. I have seen time and again in my investigations that serious adverse effects that emerge after a drug is on the market do not necessarily get the prompt attention they deserve. They are certainly not getting the attention from the Office of New Drugs.

Even the Government Accountability Office report entitled, ''Improvement Needed in FDA's Postmarket Decisionmaking and Oversight Process,'' stated:

FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues.

I, for one, have seen too many people suffer from the results of the Vioxx mess. I also have heard from parents whose children committed suicide on antidepressants.

This amendment is about making postmarketing safety in S. 1082 a reality, not just another byline. Identifying a safety issue after a drug is on the market is the beginning of the process of protecting the American consumer.

Once the safety questions are identified, FDA needs to be empowered and willing to take action to address those questions and to ensure timely notice to doctors and consumers of new safety risks for drugs that they are already taking.

Senator ENZI stated last Monday that with Vioxx, the Food and Drug Administration did not have enough tools to deal with the new risks that became evident only after Vioxx had been on the market for some time.

But the problem with the Vioxx mess and the antidepressant mess wasn't only about having enough tools, it was about FDA managers disregarding the concerns raised by its own scientists in the Office of Surveillance and Epidemiology and not taking action in a timely manner.

Amendment No. 1039, which is in the Institute of Medicine recommendations, is intended to curb delays when it comes to safety.

I have also been told by scientists and epidemiologists working in the FDA, as well as independent thought leaders, that S. 1082 as it stands will not prevent another Vioxx debacle.

They have told me that the Office of Surveillance and Epidemiology needs, at the minimum, joint postmarketing decisionmaking authority with the Office of New Drugs to ensure prompt postmarketing action.

I also am afraid to say, that right now, I am at the beginning of another review that will likely lead to concerns similar to those we have seen in the past—a situation where the postmarketing adverse events are severe and the public knows nothing.

The other amendment I want to talk about, amendment No. 998, is just plain common sense.

For FDA's new authorities to be meaningful, there has to be strong civil monetary penalties.

I hear that there is a lot of opposition to having stronger civil monetary penalties than those currently in S. 1082. But that just does not make sense to me.

Over the last week I have heard members talk about giving FDA some bite. Well, let's add some teeth.

Civil monetary penalties need to be more than the cost of doing business.

If civil monetary penalties are nothing more that the cost of doing business, you can't change behavior and, more importantly, you can't deter intentional bad behavior.

Amendment No. 998 would increase the penalties that can be imposed if companies fail to comply with the requirements of the ''risk evaluation and management strategies,'' such as labeling changes and requirements for postapproval studies or risk communication plans.

These requirements are at the core of S. 1082. But, FDA cannot be an effective regulator if it's all bark and no bite.

The last thing we need to do with this bill is to provide the FDA with new authorities but little enforcement capacity. That's not accountability and that won't help FDA do its job better for the American people, and it won't punish bad players.

That is why amendment Nos. 1039 and 998 make sense.

They fit into S. 1082 and its stated goal of promoting postmarketing safety.

I again thank Senators KENNEDY and ENZI for the tremendous efforts that went into bringing this bill to the floor, and I again thank them for incorporating a number of the provisions set forth in the two bills filed by Senator DODD and me.

Mr. President, I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, I understand there is a time allocation; am I correct?

The PRESIDING OFFICER. That is correct.

Mr. KENNEDY. Could the President tell us the time allocation remaining?

The PRESIDING OFFICER. The Republicans have 9 minutes remaining and the majority has 35 minutes.

Mr. KENNEDY. I note that the Senator from Maine was on the floor before I came down, and I know there are other Senators, Senator ROBERTS being one, who wanted to speak, and I think Senator BURR. We also have a number on our side.

My ranking member is here, and I imagine he will allocate the time on his side. I am glad to have the good Senator from Maine go ahead. I understand there are 9 minutes in total on her side.

Mr. President, I ask unanimous consent that I be allowed to follow her.

The PRESIDING OFFICER. Without objection, it is so ordered.

IMPORTATION OF PRESCRIPTION DRUGS

Ms. SNOWE. Mr. President, I thank the Senator from Massachusetts for his courtesy and for his cosponsorship of this initiative. I, obviously, want to also thank the sponsor of this legislation, with whom I am privileged to join, the Senator from North Dakota, who has demonstrated leadership for the last decade on this initiative which is so crucial to the American consumer.

I rise to speak today on behalf of the Dorgan-Snowe amendment regarding drug importation. I know the Senator from Mississippi, Mr. COCHRAN, has offered a second-degree amendment to require the Secretary of Health and Human Services certify both the savings and safety of drug importation. Obviously, there is concern for the safety of the American people. It is one that I appreciate strongly. It must be our highest priority. But we have been at this juncture before with respect to drug importation.

As I mentioned earlier, twice before we have seen the Congress adopt a requirement for the Secretary to certify safety and savings before implementing a program of prescription drug importation, and not a single prescription drug was imported under either the MEDS Act of 2000 or the Medicare Modernization Act of 2003. Americans deserve access to affordable medications, and that access must be safe, but

it is not made so by simply certifying with respect to drug importation. As I said, twice before we have been through this—in 2000, and of course in the Medicare Modernization Act of 2003 under the prescription drug benefit for the Part D Program.

Many who are in the Senate today supported a certification requirement in good faith, recognizing that the Secretary of Health and Human Services would certify the safety upon reviewing and evaluating circumstances, but that has not occurred. Most would not think such a certification would block Americans from legally importing medications. That is because for years we have seen our constituents—and certainly those from my State of Maine—using Canadian pharmacies, and both the safety and savings were indisputable. Yet certification did not arrive.

As a result, the former Secretary of Health and Human Services, Secretary Shalala, declined to make the certification with respect to the MEDS Act, and we know she did so because of three specific flaws in the law, each of which this legislation addresses.

After the passage of the Medicare Modernization Act, which included the prescription drug program, we saw that former Secretary Thompson could not certify importation. The fact is, it is patently unfair to ask the Secretary to make such a certification, especially as to safety. That is because you must give the Secretary the resources and the authority to implement measures to make prescription drugs and their distribution as safe as possible.

So it comes as no surprise that given no standards, no authority, and no resources, we have failed to see a Secretary provide certification over the last 7 years. Secretary Thompson understood this well. He said it simply:

> The law is this: In order to import drugs from any country, and especially Canada, I have to certify that all those drugs are safe. That is an impossible thing. If Congress wants to import drugs, they should take that provision out.

The certification of savings is no less of a red herring. In fact, it has become a persistent roadblock every time we have passed certification to allow drug importation by the Secretary of Health and Human Services. Without a doubt, Americans would not purchase imported medications if substantial savings were not being realized. Indeed, the Congressional Budget Office has told us the countries from which we would import under this bill pay 35 to 55 percent less for brand prescription drugs and that we can realize a drug savings alone of $50 billion over 10 years. It should be patently obvious the savings part of certifying importation is a nonissue.

In fact, the Congressional Budget Office has confirmed those savings again, estimating that in addition to consumer savings, the Federal Government would save $10.6 billion—including the Medicare and Medicaid Programs that would achieve indisputable savings. Every cent of that savings, the CBO estimates, will be lost if the Cochran amendment is adopted because, as we all know, there would be no legal importation.

The savings are clear. Yet the advocates of certification continue to insist certification is critical—particularly regarding safety. Yet what is needed is not a certification requirement, which simply is a stamp on the status quo, but real action to assure the safety of prescription drugs.

By way of analogy, I would like to know where we would be if we applied this simple certification approach to other areas. Consider air travel. Americans embark on thousands of flights every day, but the travel of millions is not dependent on certifying the status quo. We rely on regulation and oversight of the aircraft that fly and their maintenance—of the individuals who crew, service, and direct those aircraft—of every critical aspect of aviation. If we were waiting for the FAA and its international partners to simply say flying is safe rather than acting to make it safe, we simply wouldn't have commercial air travel.

I note that last week, as the Senate discussed problems with both the drug and food safety, I did not hear my colleagues suggest FDA certify that imported food is safe. We, instead, spoke about measures to make it so. That points to what this amendment is about—not ensuring safety but blocking fair access to imports for Americans.

The fact is, Americans simply cannot see why it is that they cannot be provided a safe and effective system, which is exactly what the Dorgan-Snowe amendment does and what this legislation has been drafted to accomplish year in and year out. We have taken every conceivable concern regarding safety and incorporated it in this legislation.

As you can see on this chart, we incorporate 31 provisions. Compare that to the Medicare Modernization Act, which included the Part D prescription drug program for seniors, that included only six safety-related provisions. We included 31 different provisions. That is crucial to understanding that this sets up a system that will allow FDA inspectors to approve registered prescription drugs imported from other countries—in fact, countries that meet or exceed our standards. Compare that, for example, to the fact that the FDA approves manufacturing facilities in other countries that actually have lower standards than our country does. We allow medications to be manufactured in other countries with lower standards than what we have. Yet we are now saying we will not allow importations of medications from countries that meet or exceed our standards.

At a time in which American consumers are paying 35 to 55 percent more for drugs than foreign consumers—in fact, paying the highest prices in the world—this amounts to $99 billion more than the foreign consumers. That is what Americans pay today. Some would say: Oh, that affects research and development. Well, no, not exactly. In fact, the pharmaceutical industry spends about 10 percent of that $99 billion. So about $10 billion in research and development more than they do in Europe. So we are not seeing the increase in prices that Americans pay being channeled into more research and development. It simply is not the case.

What this does say is that American consumers are paying more than anyone else in the world. Not only are they paying more for their drugs, but American taxpayers are underwriting the research and development, as we have seen obviously with the National Institutes of Health. The taxpayer understands how important it is that the Federal Government remain on the vanguard of research and development of life-threatening medications, and not only are they paying for the research and development that benefits foreign consumers, who are paying 35 to 55 percent less, but they are also paying the highest prices in the world.

That is why this legislation allowing for drug importation is so essential. We have addressed every safety concern. We create a regime for tracking the shipments, creating a pedigree, creating a history with FDA approval—inspected and registered. So I would urge the Members of the Senate to defeat this certification amendment and to support the Dorgan-Snowe amendment. I think we have achieved a milestone moment in the Senate, where we have finally recognized and acknowledged that the day has come to allow Americans to take advantage of more competitive prices than have been available to them before.

I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, we will speak as in morning business for 10 minutes and if the Chair would let me know when I have a minute left.

Mr. DORGAN. Mr. President, reserving the right to object, and I certainly would not object, but I want to understand the time. We have a vote at 4 o'clock, I believe, which is already ordered. Would the President tell me what the time is between the two parties, how it is divided and who controls time at this point?

The PRESIDING OFFICER. The time for morning business has been equally divided until 4 o'clock. The Republicans have no time remaining, and the majority has 33 minutes.

Mr. DORGAN. Senator KENNEDY is asking for 10 minutes in morning business?

The PRESIDING OFFICER. Senators are permitted to speak for 10 minutes.

Mr. DORGAN. Might I ask to follow Senator KENNEDY in morning business for 10 minutes?