Mr. McConnell. The following Senators are necessarily absent: the Senator from Mississippi (Mr. Lott) and the Senator from Arizona (Mr. McCain).

The PRESIDING OFFICER. Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 59, nays 38, as follows:

[Rollcall Vote No. 134 Leg.]

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The motion was agreed to.

Mr. LEAHY. Madam President, I move to reconsider the vote.

Mr. KENNEDY. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

Mrs. MURRAY. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. GRASSLEY. Madam President, I ask unanimous consent the order for the quorum call be rescinded.

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

Mr. GRASSLEY. I ask unanimous consent that I be allowed to speak in morning business.

Mr. REID. Madam President, I ask the distinguished Senator from Iowa, my dear friend, I have to file a cloture motion. It will take me just a minute.

Mr. GRASSLEY. Surely.

CLOTURE MOTION

Mr. REID. Madam President, I send a cloture motion to the desk.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The assistant legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on Calendar No. 107, S. 378, the Court Security Improvement bill.


MORNING BUSINESS

Mr. REID. Madam President, I now ask unanimous consent we be allowed to proceed to a period of morning business with Senators permitted to speak therein. The Senator from Iowa wishes to speak for a half hour. After that, Senators will be recognized for up to 10 minutes each.

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

FINISHING CONSIDERATION OF S. 378

Mr. REID. Madam President, if I could take another minute of the time of the distinguished Senator, we hope we can finish this bill tomorrow. That would be my desire. Tomorrow is Thursday. I am filling this tonight. The time ripens for voting on this Friday morning. But Friday morning occurs at 1 a.m. We have to finish this bill as soon as we can. I am alerting everyone, there could be a vote Friday morning at 1 a.m.

I also suggest that I have been trying for some time now to do a bipartisan bill that has been worked on by many Senators. There are 50 cosponsors of this legislation, dealing with competitiveness. On our side it will be managed by Senator Bingaman. It is my understanding on the other side it will be managed by Senator Alexander. I hope we can have an agreement to move to that. I hope I do not have to file a motion to proceed to that piece of legislation. Remember, next week we need to complete work to send to the President the supplemental appropriations bill.

Having said that, I want to alert everyone I think it is too bad. This bill is that is before the body now, the Court Security bill, has been passed by the Senate on two separate occasions. We have filed cloture; cloture was invoked. I appreciate very much the minority allowing us to move to the bill. But this afternoon I had a meeting with Mr. Clark, head of the U.S. Marshals Service. This year, threats to Federal courts and local justice. We need to be a country that is ruled by the finest judicial system in the world, which we have now, and we cannot have bad people take away our court system—and violence can do that.

I hope we can finish this bill in a reasonable time tomorrow. If not, tomorrow will be a long night.

I appreciate very much my friend from Iowa allowing me to speak for a minute.

The PRESIDING OFFICER. The Senator from Iowa.

DRUG SAFETY

Mr. GRASSLEY. Madam President, today I wanted to speak on an issue I speak on many times, drug safety. Today is a little different approach to it, though, because earlier today the Committee on Health, Education, Labor, and Pensions began marking up S. 1082, the Food and Drug Administration Revitalization Act. For the first time in like a decade, we have an opportunity to reform, to improve, and to reestablish the FDA as an institution committed to making patient safety as important as bringing new drugs to the market.

S. 1082 presents a framework for the future of drug and device safety. I am grateful for some of its current contents and I express some disappointment about others. That is the purpose of my speaking to my colleagues.

First, I am gratified the bill attempts to address some of the overarching issues plaguing the FDA that have been repeatedly revealed by the investigations I conducted of the FDA over the last 3 years. In particular, S. 1082 takes a number of steps to address the issue of transparency, the issue of accountability, and the issue of respect for the scientific process that has been lacking for some time at the FDA. S. 1082, for example, requires that within 30 days of approval, the action package for approval of a new drug must be posted on the FDA's Web site. This requirement, however, only applies to a drug with an active ingredient that has not been previously approved by the FDA. The action package would contain all documents generated by the FDA related to the review of a drug application, including a summary review of all conclusions and, among other things, any disagreements and how these disagreements were resolved. If a supervisor disagreed with the review, then the supervisor's opposing review would be available to the public. And to address the many allegations that the Food and Drug Administration safety reviewers are sometimes coerced into changing their findings, I greatly welcome the provision that states a scientific review of an application is considered the work of the reviewer and must not be changed by FDA managers or the reviewer once that review is final.

The bill also takes steps to bring more resources to the FDA for drug safety, another matter I have been discussing for years. This bill requires the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee to meet...
at least two times a year to address safety questions and to make recommendations regarding post-market studies.

I am also heartened to see that the bill incorporated several elements from the Dodd-Grassley bill entitled the Fair Access to Clinical Trials Act of 2007. S. 1082 ensures that the clinical trial registry includes trials of devices approved by the FDA. The bill requires a drug sponsor to certify at the time of the submission of a drug, biologics, or device application to the agency that the sponsor has met all of the clinical trial registry requirements.

Last but not least, S. 1082 attempts to give the Food and Drug Administration some teeth by requiring specific civil penalties, monetary penalties for submission of false certification, and false or misleading clinical trial information.

These are, in my mind, some of the good things that are proposed in S. 1082. I wish to thank Chairman Grassley and Ranking Member Enzi in this regard.

I hope additions such as these, which strengthen S. 1082, will make it through the HELP Committee’s vote as the committee considers further changes. As I said earlier, I am both gratified and disappointed by the contents of S. 1082.

I turn now to some of what I consider to be lacking in the bill that in my mind fail to address some of the issues that are critical to reestablishing the FDA’s mission and putting John Q. Public and not PhRMA at the helm of the FDA.

I commend the HELP Committee’s attempt to ensure that the office responsible for post-market drug safety is involved in, among other things, decisions made regarding labeling and post-market studies by making specific references to that office throughout S. 1082. However, the bill does not address the outstanding critical problem that the office responsible for post-market drug safety lacks the independence, lacks the authority to promptly identify serious health risks and take necessary steps that will protect the public.

As I think we all agree, the Federal Drug Administration is in desperate need of major overhaul. Over the past 3 years, my investigations have demonstrated the depth and breadth of the problems plaguing the FDA on both the drug and device side.

There are those who believe that we will greatly enhance drug and device safety and improve transparency at the FDA and, most importantly, prevent another Vioxx debacle.

The Federal Drug Administration’s Safety Act and the Fair Access to Clinical Trials Act of 2007 are intended to address some of the problems plaguing the FDA at its very core. Those are the bills that are the Grassley-Dodd bill and the other is a Dodd-Grassley bill.

Let me be clear: Big PhRMA does not like these bills. FDA management does not like these bills. Lobbyists are spending hours upon hours lobbying against the Drug Administration Revitalization Act does not embrace all the critical elements of the Dodd-Grassley and the Grassley-Dodd bill.

Let me ask each and every Member of the Senate the following: What is wrong with establishing a separate center within the FDA—not outside the FDA, within the FDA—with its only job being that of a watchdog for those drugs already on the market? What is wrong with supporting a group of committed FDA scientists who only watch for serious adverse effects that may pop up only occasionally, perhaps only 1 in 10,000 or 1 in 20,000? What is wrong with ensuring that all clinical trial results, regardless of their outcome, are available to the scientific community, health care practitioners, and the public? What is wrong with supporting a clinical trial registry and results database that makes sponsors reveal their negative trials? And what is wrong with giving the FDA strong enforcement tools to combat bad players?

I propose there is nothing wrong with any of these proposals, particularly the proposals that a new, separate, and independent center be created to address post-market surveillance, a proposal supported by Senator Dodd and me, not once but twice.

I have heard the naysayers and the arguments at first blush made me think twice. But, over time, his views have changed. Dr. Nissen probed more, evaluated the facts more, and as he talked more to on-the-ground FDA staff members, Dr. Nissen changed his mind and told the American public so.

Dr. Nissen recently sent me a letter stating that not only does he support the Fair Access to Clinical Trials Act but also the Food and Drug Administration Safety Act. In other words, Dr. Nissen said:

In particular, I support the creation of a new independent center within the FDA called the Center for Post-Market Evaluation and Research for drugs and biologics. Although I had previously expressed some concern about creating this center, I have become convinced that the separation of post-market surveillance from the Office of New Drugs represents the best opportunity to improve the performance of the FDA in handling drug safety issues.

I ask unanimous consent to have that letter printed in the RECORD.

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

Cleveland Clinic, Cleveland, OH, March 29, 2007.

Hon. Charles E. Grassley,
U.S. Senate,
Washington, DC.

Dear Senator Grassley: I share your concern about the need for a significant overhaul of the Food and Drug Administration to improve drug safety. Over the last several years, we have endured a series of disturbing revelations about the lack of vigilance by the FDA in monitoring drugs following approval. I have reviewed the two Bills that you and Senator Dodd have introduced, the Food & Drug Administration Safety Act of 2007 and the Fair Access to Clinical Act of 2007. I strongly support the passage of both of these Acts and believe that they will help protect the public health.

In particular, I support the creation of a new and independent center within the FDA called the Center for Post-Market Evaluation and Research for drugs and biologics (CPER). Although I had previously expressed some concern about creating this center, I have become convinced that the separation of post-market surveillance from the Office of New Drugs represents the best opportunity to improve the performance of the FDA in handling drug safety issues.

Finally, I want to thank you and Senator Dodd for your tireless efforts to promote public health through aggressive oversight of the Food and Drug Administration. Your leadership in this vital area has been invaluable and all of the 300 million Americans who rely upon drugs to protect their health are grateful for your steadfast efforts.

The views expressed in this letter are my own personal opinion and do not necessarily reflect the official views of my employer or the American College of Cardiology.

Sincerely,

Steven E. Nissen, M.D.,
Chairman, Department of Cardiovascular Medicine, Cleveland Clinic, Immediate Past President, American College of Cardiology.

Mr. Grassley. Coupled with Dr. Nissen’s letter of support, I also received a letter from Dr. Curt Furberg, professor of public health science at...
Wake Forest University School of Medicine. Dr. Furberg is not only a professor of medicine, but he is also a member of the Food and Drug Administration Drug Safety and Risk Management Advisory Committee.

Dr. Furberg knows the FDA from the inside-out, and he knows it inside-out, in and out. In fact, even Dr. Furberg has written to me to say he is supportive of creating a new center, and he is particularly supportive of creating a new enforcement tool to be used against bad players in the drug industry.

I also have that letter and would ask unanimous consent to have it printed in the RECORD as well.

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


HON. CHUCK GRASSLEY, U.S. Senate, Washington, DC.

Dear Senator Grassley: I am pleased that members of the U.S. Congress are taking constructive actions to address the major problems with drug safety. Your Bills—FDASA and the FACT Act—are excellent and, if passed, would greatly benefit the U.S. public.

My major concern relates to the FDA’s lack of enforcement tools. Regulations and commitments can have limited value if major and repeated violations involve no consequences. Drugmakers who suppress or delay submission of safety information to the FDA, stall label changes (especially new Black Box warnings) or fail to honor their commitments of any kind have limited value to the U.S. public.

Mr. Grassley. Madam President, if I can be of any assistance in facilitating the passage of this legislation, do not hesitate to call me.

Respectfully,
CURT D. FURBERG, MD, PhD, Professor of Public Health Sciences, Member of the FDA Drug Safety and Risk Management Advisory Committee.

Mr. Grassley. Madam President, if these two thoughtful leaders can come forward and support a new center that is devoted to watching drugs once they are on the market, so that American consumers and their doctors know about a problem promptly, what is wrong with that? That is why I hope the HELP Committee will take a second look at the Dodd-Grassley bill. We have seen time and again that the FDA is not as good at this function as it should be. However, the reality is that the FDA needs to perform this function well because lives of American citizens and maybe around the world depend on it.

I wish to see a bill passed that prevents another Vioxx debacle. This Congress has an opportunity to make meaningful and positive changes. Let’s not allow that opportunity to slip through our fingers. Medicaid

Madam President, I have another set of remarks that I wish to make dealing with the issue that we had before the Senate today, and that we had a closure vote on the other side of the aisle, including the assistant majority leader, said that Republicans do not want this debate. What are they talking about, do not want a debate about anything dealing with Medicare drugs and all those sorts of things?

This body has debated the so-called prohibition on Government negotiation. The Senate had four votes on this issue. What is rather amusing to me about the statement that we do not want the debate is that they did not seem to want the debate when the Senate considered S. 1.

S. 1 was the Senate version of the Medicare drug law. That bill had a non-interference clause in it just like the current law does. It is that clause that the other side has distorted to come up with the absurd claim that no negotiations occur under the Medicare drug benefit. Not once, I repeat, not once during the entire time that S. was on the Senate floor in the year 2003 did anyone on the other side of the aisle bring up this issue.

That is because this is not an issue of merit, it is simply one born out of political pandering. The majority leader also talked about how Medicare should look like the VA because the VA seems to get lower prices.

The VA gets lower prices because the Government passed a law to guarantee itself an automatic discount that no one else can get. By law, that price is automatically 24 percent less than the average price paid by basically all non-Federal purchasers. That is not negotiation, that is a federally mandated price dictation, or you might call it a 21-percent discount, but it is federally mandated.

I agree that the logical question then is: Why not have Medicare get that price? Experts who testified at the Senate Finance Committee, even the VA itself at a 2001 hearing before the Committee on Veterans’ Affairs gave us the answer: They said that giving the Medicare VA prices will increase prices for veterans. Now, why would anybody in this body want to increase prices for veterans?

Now I wish to turn to how the VA uses its own pharmacy benefit manager or PBM as we refer to them. The pharmacy benefit manager for the VA—the VA has one. In 1995, as part of an effort to better manage and monitor drug usage and purchasing and utilization oversight across the entire Veterans’ Administration, the VA established its own benefit manager.

The VA had a choice. It wanted its pharmacy operation work similar to the private sector. They did it because, as stated in the VA news release, they wanted to maximize a developing business strategy in the private sector. That business strategy was getting lower prices on drugs in the private sector.

So here we have people holding out the VA as a model, which uses its own PBM to negotiate, and at the same time, claiming: Using PBMs in Medicare is wrong.

Remember, that process has brought 35-percent lower costs on the 25 most used drugs by seniors under the Medicare drug plans. You heard that right, but let me state it again. The VA system for negotiating is just like the one already used by Medicare through prescription drug plans that seniors join.

If the VA’s PBM looked at itself in the mirror, it would see a Medicare drug plan’s PBM staring right back at it. There is another important difference between the VA and Medicare. The VA prescription drug benefit is just one part of the VA’s health care delivery system. It is a very different system than Medicare.

The VA system requires veterans to use VA hospitals, to use VA physicians, to use the VA formulary, to use their pharmacies, and to use their mail order pharmacy. Now, don’t get me wrong. The VA has a good system that works for veterans. But what it comes down to is choice. So I have a chart I want you to look at. Under the Medicare prescription drug benefit, beneficiaries have choices. They can choose the plan they want, a plan that covers all their medicines. They can choose the doctor and the hospital they want. They can go to their local pharmacy.

Even the VA recognizes this fact. On its own Web site in a “frequently asked questions” page, the VA does not recommend that veterans cancel or disenroll in line coverage in Medicare because a veteran may want to consider the flexibility afforded by enrolling in both the VA plan and the Medicare plan.

For example, veterans enrolled in both programs may obtain prescription drugs that are not on the VA formulary if prescribed by a non-VA physician and filled at a local pharmacy.

Making all Part D programs look like the VA and its formulary then will severely restrict access and will severely restrict choice to the 44 million seniors and disabled who have Part D. There is another important difference between the VA and Medicare.

The VA has no reason to allow the VA formulary to be used by non-VA providers. Why? Because the VA is the single largest buyer of prescribed drugs in the United States. For example, in 2005, the VA spent $10 billion on prescription drugs.

Mr. Grassley. Madam President, the VA is the single largest buyer of prescribed drugs in the country, and there are other reasons.

The VA is a government run health care system. DOD, the Department of Defense’s health care system, is the largest health care system in the world.

Another reason is economic. By using the VA’s PBM, Medicare will have lower prices – lower than it can do on its own.

Here is a chart I wish to show you. As you can see, the VA’s PBM discounts were better than Medicare’s.

So let me state it again. The VA system is a model Medicare should follow. Using the VA’s PBM, Medicare will have lower prices. The VA’s PBM works within the VA’s system and is used by all the veterans who use the VA system.

I have had the privilege of bringing up this very important issue. I hope you will have the opportunity to take up this legislation again, perhaps in a stand-alone bill.
provision banning preferred drug lists. If they do not want to limit bene-
ficiaries’ access to drugs, my amend-
ment should have been easy for them
to support.

But by voting against my amend-
ment, they were voting in favor of the
Government setting a preferred drug
list. Now, the preferred drug list might
sound like a good thing, but in reality
it is not. It is a Government-controlled
list of drugs that you can or cannot
have. If you went to any store and
were not going to pay for what they say
you cannot have.

The preferred drug list then operates
similar to a formulary. In my opinion,
it is not what the courts have found. So
what does that mean for Medicare
beneficiaries? It means that even
though § 3 prohibits the Secretary
from using a formulary, it does not
prohibit the Secretary from using a
preferred drug list. It is clear now then
from all this analysis and their votes
on this amendment that supporters of
this Senate bill want the Government
to set up a preferred drug list. They want
the Government to determine for what
seniors can get coverage.

A number of States have imple-
mented preferred drug lists. Michigan,
for example, has a preferred drug list.
Here is what the Kaiser Family Foun-
dation found in a 2003 case study on
that preferred drug list:

Fearing opposition from the pharma-
ceutical industry, the State sought virtually
no input from providers, pharmacists, bene-
ficiaries and manufacturers.

Continuing the quote:

Ultimately the department [meaning
Michigan] made only a few changes to the
list of drugs on the Michigan preferred drug
list in response to beneficiaries and provider
concerns.

Both the Illinois House and the Illi-
nois Senate resolutions were intro-
duced in 2002 to establish a committee
to oversee that State’s preferred drug
list.

The resolution noted that the cre-
at ion of Illinois’ preferred drug list
“could lead to unintended con-
sequences such as inferior health care,
increased hospitalizations and emer-
gency care, increased admissions into
long-term care, and unnecessary pa-
tient suffering and potentially death.”

In a statement about this bill, S. 345,
the assistant majority leader said that:
The Medicare-administered plan envi-
ronment and to bring attention to
pollution, and to clean up hazardous
waste sites.
Earth Day is celebrated because of
the great work of former Senator Gay-
lord Nelson of Wisconsin. In 1970, he
founded Earth Day to celebrate the en-
vironment and to bring attention to
the legislative challenges facing those
who want to protect the envi-
rnment. Senator Nelson also cospon-
sored the Wilderness Act of 1964, a law
that has been amazingly important to
protecting Nevada’s beauty.

Nevada is one of the many States
that has greatly benefited from the
protected environments that
former Senator Nelson helped to cul-
tivate. Nevada’s dramatic landscapes
from the high alpine lakes of the Ruby
Mountains to the stark open spaces of
the Black Rock Desert to the incred-
ible Joshua tree forests in the Pio-
ute Mountains to the stark open spaces of
the Black Rock Desert to the incred-
ible Joshua tree forests in the Piute
Valley have provided inspiration to
generations of Nevadans. Protecting
Nevada’s wild lands ensured that those
who follow us will have the same op-
portunity to find and experience these
impossible places as we did.

The Wilderness Act of 1964, which
was cosponsored by former Senator
Nelson, has done tremendous things in
Nevada. I have been proud to help des-
ignate nearly 2 million acres of wilder-
ness across Nevada, in addition to cre-
ating the Sloan Canyon, Red Rock Can-
yon, and Black Rock Desert-High Rock
Canyon National Conservation Areas
and Great Basin National Park.

Protecting and serving our environ-
ment has always been one of my pas-
sions, and I have twice had the privi-
lege to chair the Environment and

NATIONAL INFANT IMMUNIZATION
WEEK

Mr. REID. Mr. President, I rise in
recognition of National Infant Immunizi-

National Infant Immunization
Week

Mr. REID. Mr. President, I rise in
recognition of National Infant Immunizi-

Mr. REID. Mr. President, Sunday is
the 37th anniversary of Earth Day. I
have been pleased to read reports that
local health departments, health care
providers, parents, and other partners
will work together to make sure that
all seniors are protected against vaccine-preventable diseases.

This week is also an opportunity for all of
us to spread the message about getting
immunized. Not only do immunizations
give our children a healthy start to
life, they also save lives and protect
the American public’s health.

Immunization against vaccine-pre-
ventable diseases is a tremendous suc-
cess story. Due to the development of
vaccines and immunization campaigns,
infectious diseases that used to dev-
astate entire communities have been
reduced to record lows or eradicated
outright. Thanks to immunizations,
few Americans today have any direct
knowledge of once commonplace
scourges like polio, smallpox, measles,
diphtheria. For most of us, the
deaths, suffering, and disability associ-
ated with these diseases are now
known only through textbooks and old
newspaper accounts.

The National Infant Immunization
Week is a time to reflect on these
achievements. More importantly, this
week is also a reminder that we cannot
lose ground by becoming complacent or
taking the benefits of immunizations
for granted. Approximately 1 million
children in this country are not fully
immunized by age two and many re-
gions of the country have disturbingly
low immunization rates. In my home
State of Nevada, the immunization
rate for infants and young children is
ranked last in the country.

Fortunately, there are Federal and
State programs that work to provide
access to immunizations against seri-
ous but preventable diseases, we can work
to ensure that all Americans will benefit
from this invaluable public health tool
for generations to come.