The clerk will call the roll.

The legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN), the Senator from Connecticut, (Mr. DODD), the Senator from California (Mrs. FEINSTEIN), the Senator from South Dakota (Mr. JOHNSON), and the Senator from Massachusetts (Mr. KENNEDY) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Utah (Mr. BENNETT), the Senator from Arizona (Mr. MCCAIN), the Senator from New Hampshire (Mr. SUNUNU), and the Senator from Louisiana (Mr. VITTER).

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

The result was announced—yeas 91, nays 0, as follows:

[Rollcall Vote No. 153 Ex.]

YEAS—91

Akaka	Dorgan	Mikulski
Alexander	Durbin	Murkowski
Allard	Ensign	Murray
Baucus	Enzi	Nelson (FL)
Bayh	Feingold	Nelson (NE)
Bingaman	Graham	Obama
Bond	Grassley	Pryor
Boxer	Gregg	Reed
Brown	Hagel	Reid
Brownback	Harkin	Roberts
Bunning	Hatch	Rockefeller
Burr	Hutchison	Salazar
Byrd	Inhofe	Sanders
Cantwell	Inouye	Schumer
Cardin	Isakson	Sessions
Carper	Kerry	Shelby
Casey	Klobuchar	Smith
Chambliss	Kohl	Snowe
Clinton	Kyl	Specter
Coburn	Landrieu	Stabenow
Cochran	Lautenberg	Stevens
Coleman	Leahy	Tester
Collins	Levin	Thomas
Conrad	Lieberman	Thune
Corker	Lincoln	Voinovich
Cornyn	Lott	Warner
Craig	Lugar	Webb
Crapo	Martinez	Whitehouse
DeMint	McCaskill	Wyden
Dole	McConnell	
Domenici	Menendez	

NOT VOTING—9

Bennett	Feinstein	McCain
Biden	Johnson	Sununu
Dodd	Kennedy	Vitter

The nomination was confirmed.

The PRESIDING OFFICER. Under the previous order, the President shall be immediately notified of the Senate's action.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will now return to legislative session.

RECESS

The PRESIDING OFFICER. Under the previous order, the Senate will stand in recess until the hour of 2:15 p.m.

Thereupon, the Senate, at 12:36 p.m., recessed until 2:15 p.m. and reassembled when called to order by the Presiding Officer (Mr. CARPER).

PRESCRIPTION DRUG USER FEE AMENDMENTS ACT OF 2007—Continued

The PRESIDING OFFICER. The Senator from Maine is recognized.

Ms. COLLINS. Mr. President, I ask unanimous consent that I be permitted to speak as in morning business for not to exceed 10 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered. The Senator from Maine is recognized.

Ms. COLLINS. I thank the Chair.

(The remarks of Ms. COLLINS pertaining to the introduction of S. 1329 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

The PRESIDING OFFICER. The Senator from New York is recognized.

IRAQ

Mr. SCHUMER. Mr. President, this week we in Congress are continuing to work toward a solution in Iraq that both supports our troops and changes our mission away from policing a civil war to more narrowly focusing on what should be our first and foremost goal—fighting terrorism, counterterrorism, to make sure al-Qaida cannot set up a camp and strike at us.

I rise today because we are beginning. We have said all along that this is going to be a long battle. Because we do not have 61 votes in the Senate, because the President has the veto power and we certainly do not have 68 votes to override a veto in the Senate, we are going to have to continue to bring up resolution and amendment after resolution and amendment until we persuade our colleagues on the other side of the aisle to do what the American people want, to do what the American people asked for in November of 2006; that is, dramatically change the course in Iraq, the mission—greatly reduce the number of troops so we can keep some troops there who can fight terrorism, but that will be many fewer. Most will be out of harm's way.

We are getting good signs. First, 6 months ago President Bush said he wouldn't accept any benchmarks or any limitation. Now the word from the White House seems to be that they will accept some types of benchmarks or other types of language that would not just be a simple funding the troops without our other goal, changing the mission. But second and more significant, what I and my colleague from Washington—and I believe my colleague from Illinois will be speaking about—are seeing is our Republican colleagues begin to set their own timetables, their own deadlines. This weekend, House minority leader JOHN BOEHNER signaled that, as this debate wears on, the President will continue to lose support among the members of his own party.

> By the time we get to September or October, members are going to want to know how well this is working and, if it isn't, what is plan B?

That sure seems similar to what we are trying to do, although we want to do it now.

Mr. BOEHNER's comments are echoed by a number of other Republicans who are hearing back in their States and districts that we must change the mission in Iraq. There are many comments.

TRENT LOTT:

> I do think this fall we have to see some significant changes on the ground in Baghdad and other surrounding areas.

There are many more. One of those is JIM WALSH, from my home State of New York. Today, the New York Times reports that Mr. WALSH is replying to his constituents that he could soon be prepared to reassess our policy and begin withdrawing our troops.

Republican Congressman RAY LAHOOD is indicating he expects Republican members will grow increasingly ''nervous'' about the President's strategy.

Asked about the President's demand for a funding bill with no benchmarks, no conditions, and no reports, says Senator COLLINS, who just spoke here:

> Many of us on both sides of the aisle don't see that as viable.

We are going to try to come up with a very strong resolution that both supports our troops and changes the mission. But we know we are making progress because our Republican colleagues themselves have been setting timetables, benchmarks, and other types of goals—limitations that are not terribly dissimilar from ours.

We will continue this battle, this struggle to require the President to change course in Iraq. We eagerly await our Republican colleagues joining us.

I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, I thank my colleague from New York. I know my colleague from Illinois, Senator DURBIN, will be here shortly as well to talk about a critical juncture at which we are now in terms of the war in Iraq.

Last week, both the House and Senate sent a very strongly worded bill to the President of the United States supporting our troops, saying we are there for them when they need us, but we also said it is time for a change of course in Iraq, that we can no longer leave our troops in the middle of a civil war. It is disappointing to all of us that the President chose to veto that bill and sent it back to us. But I think it is very important for us to set the context of where we are now as we look at what we are going to send back to the President.

These are the facts. There is increased violence in Baghdad as we speak. There is increased violence outside Baghdad today. In fact, over 100 American soldiers died last month alone, and at least 27 more American troops have been killed this month. In my home State of Washington, we got the sad news yesterday morning that six of our Fort Lewis soldiers were killed over the weekend. These are

families—husbands, children, grandchildren—who will be impacted forever and who will not forget.

Months ago, the President said to the American people that he was going to change his course by having a surge of American troops—25,000, 30,000, 40,000 new troops. They are now on the ground in Iraq. What we are seeing is increased violence inside and outside of Baghdad, more American soldiers losing their lives. And what are we looking at? An Iraqi Government that has not changed, has not stood up to the mark to care for their own country and make the tough decisions they need to make. The bill we sent to the President was designed to give him the tools to turn to Iraq and say: You need to take on your own battles and make these tough decisions. It is time for Iraqis to stand up. Four years after removing Saddam from Iraq, the Iraqis have still not made the political compromises necessary to bring peace to their own country. In fact, they are on pretty shaky ground today, even as we speak, as we hear of factions that may pull out.

Most important, what is happening here in our country? Mr. President, 64 percent of Americans and 65 percent of independents support setting a timetable for redeployment.

That is the ground we are now on, as the President vetoed that very important piece of legislation which funded our troops. We had funding for our veterans as they came home and important, critical funding for Katrina and other important causes.

Despite all the facts I just laid out—the increased violence, the soldiers being killed, the Iraqis not standing up for their own Government—we have seen Republicans on the other side of this aisle stubbornly stand with President Bush and refuse to set a timetable for our troops to come home, refuse to set a timeline to force Iraqis to take responsibility for their own future, and refuse to set a timetable to let Iraqis know we are not going to be there endlessly, month after month, year after year, for decades.

Mr. President, what is heartening to me today, after the President's veto, is we now are hearing from many of our Republican colleagues that they, too, believe we cannot continue to send a message that we will continue to be there forever.

Senator SCHUMER was just here on the Senate floor and spoke of some of our Republican colleagues who have been speaking out. House Minority Leader BOEHNER said:

> Over the course of the next 3 to 4 months, we'll have some idea how well the plan is working. Early signs are indicating there is clearly some success on a number of fronts. But, by the time we get to September or October, Members are going to want to know how well this is working, and if it isn't, what's Plan B.

We are now hearing, thankfully, our Republican colleagues set forth time tables of their own. I think it is important we listen to what they are saying because despite the fact they said no time tables in the bill, we are hearing them say there is a timeline; that this country cannot continue to send our troops to Iraq without Iraqis standing up.

Importantly, as well, we are hearing our Republican colleagues talk about benchmarks. We know benchmarks without consequences are pointless. But unlike the President, our Republican colleagues are starting to realize this and are breaking with the White House.

Senator SUSAN COLLINS said:

> Obviously, the President would prefer a straight funding bill with no benchmarks, no conditions, no reports . . . Many of us, on both sides of the aisle, don't see that as viable.

I hear that as very promising language from our colleagues on the other side. We are hearing from many others—Senator VOINOVICH, who spoke out this weekend. We are hearing from House minority whip ROY BLUNT, who says he ''can support binding benchmarks on the Iraqi Government tied to a 'consequences package,' so long as it would not put restrictions on the military.''

Mr. President, we support our troops. The bill we sent to the President last week supports our troops. Our troops have done everything we have asked them to do and more, and they have done it courageously. It is time now for us to give them the tools they need so the Iraqis will stand up and take control of their own government.

We can no longer simply say: We will stand down when you stand up to the Iraqi people. I hope our Republican colleagues will join with us in standing up as well, now, to send a strong message to the Iraqi people that it is time for our troops to get the support they need and to know that they will be brought home in a timely manner.

It is encouraging to hear the comments we are hearing. I hope they are met by the courage of our colleagues on the other side to stand with us, find some language we can agree on, and send the supplemental to the President. I hope that is what we can do over the next several days. I encourage our colleagues to work with us to do so.

I yield the floor.

The PRESIDING OFFICER. The Senator from Illinois is recognized.

Mr. DURBIN. Mr. President, I ask unanimous consent that I be recognized to speak as in morning business.

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

IRAQ SUPPLEMENTAL

Mr. DURBIN. Mr. President, for a long time in Washington, if you talked about a deadline or a timetable, the response from the President, from the administration, even from the Republican side of the aisle, was the same. When you talked about a specific end to this war, they argued: It endangers our troops.

I did not agree with that premise. In fact, I believed this was the only way to convince the Iraqis we were not going to stay forever. If they think the very best military in the world, the American military forces, will stay there indefinitely, there is no incentive for them to make the right decisions, the hard decisions to govern their own country.

Well, time has passed at great cost to our Nation. As of this morning, we have lost 3,361 of our best and brightest soldiers—3,361. The month of April was the deadliest month this year in Iraq: 104 American soldiers lost their lives. I think we all understand now that as each day passes, more American soldiers are in danger and, sadly, more will give their lives. So to wait for a month, two or three or four, is, sadly, to extend that period of time of danger.

Now we find from Republican leaders a new approach. No longer are they rejecting the idea of deadlines or timetables. In fact, they are starting to speak in more specific terms.

This is a quote from the Republican leader of the House, JOHN BOEHNER, who said:

> By the time we get to September or October, members are going to want to know how well this is working, and if it isn't, what's Plan B?

That, to me, sounds like a deadline of September or October.

Then, of course, our colleague from Mississippi, Senator LOTT, said:

> I do think this fall we have to see some significant changes on the ground, in Baghdad and other surrounding areas.

I think it is an indication that our colleagues on the other side of the aisle are hearing the same thing we hear when we go home: First, an immense pride in our men and women in uniform, pride as well in their families who have stood by them through this long struggle; an understanding of the sacrifices that are being made by our soldiers as well as those who love them so very much but, secondly, an understanding that this is a failed policy that the President is pursuing in Iraq.

This is the fifth year of this war. This war has lasted longer than World War II. It is now only exceeded in cost by the cost of World War II in today's dollars. It is an extremely expensive undertaking, first, in human life, with over 3,000 Americans dying, and then with thousands coming home injured, some very seriously injured, with traumatic brain injury and amputations.

Senator MURRAY of Washington has been a leader when it comes to the care for our returning soldiers and veterans. We know our system is breaking down and falling behind, increasing the sense of urgency I feel and many feel in Illinois, as I see them on the streets of Chicago and Springfield and all around my State. They understand this is a heavy cost we are paying.

When our friends on the Republican side of the aisle say all we need is maybe 4 or 5 more months, I hope they understand that time they are asking

for is time that will have a heavy price. They want us to buy some time for political purposes but at a heavy price.

We think, and I hope they will come to understand, we need to tell the Iraqis now they have the responsibility to govern and lead. If they fail, then American troops are not going to stay there indefinitely. Some worry when American troops leave, there may be an unstable situation in Iraq. That is entirely possible. That can happen if we leave in 10 months, 10 years, or 15 years.

They have to understand the responsibility of the future of Iraq lies in the hands of the Iraqis. We cannot put that burden on American soldiers and their families any longer. I am heartened by these statements from the Republican side that finally they understand we cannot stay there forever, that the policy of this administration has not succeeded, that we owe it to soldiers and their families to treat them humanely, to let them know they will be coming home to a hero's welcome soon.

Our colleagues, Senator JIM WEBB and CARL LEVIN, as well as JACK REED, have spoken out about the readiness of our troops, too. I worry about that. As the President has extended this war, far beyond what anyone ever dreamed of, those who voted for that authorization of force, as he has extended this war, have put pressure on our soldiers beyond anything we could have imagined.

We have extended the tours of duty for National Guard members to the longest period of time since World War II. We now know many of our soldiers are asked to stay on an additional 3 months after they have served 12. We know when they come home, they do not receive the rest they were promised, the time with their family. They are quickly reactivated and sent into battle.

This has to have an impact on morale. It certainly has a negative impact on their families. So I believe as we talk about how this war is to be waged and what the next stage will be, regardless of what our plan may be, it has to include readiness and a commitment to these troops. I think it is important that we say to the President: Don't send a single soldier into harm's way or into combat unless they have had the time to rest, unless they have been retrained and equipped, unless they are prepared to go to battle with all of the forces they need to come home safely.

Shortchanging our soldiers is not a strategy that we should follow in Iraq. Let's come up with a plan to start bringing these troops home. We sent one to the President last week. He, in a press conference, told the American people he was going to reject it. We haven't heard anything back from him since then. But, in the meantime, many members of his own party have decided it is time for them to finally speak up. We welcome them. We need them. We need them particularly on this supplemental bill.

Mr. President, if a handful of Republican Senators will now cross the aisle and join us, we can have a positive impact on changing this failed policy in Iraq. We can finally stand as one in a bipartisan way and say there is a better way; that the Iraqis cannot take long vacations while the members of their parliament relax as our soldiers risk their lives. We have to tell the Iraqis we are not going to stay indefinitely.

When leaders such as Mr. BOEHNER of Ohio speak of plan B, just remember what the B stands for. The B stands for bring our soldiers home. That is what we need to start doing in an orderly, sensible way as soon as possible.

Mr. President, I yield the floor, and 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. SESSIONS. I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mrs. MCCASKILL). Without objection, it is so ordered.

Mr. SESSIONS. I ask unanimous consent to speak as in morning business.

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

IMMIGRATION

Mr. SESSIONS. Madam President, I want to take a few moments this afternoon to follow up on my remarks of last evening about concerns I have involving the immigration process that is ongoing in the Senate and what Senator REID, the Democratic leader, has indicated he plans to do.

I absolutely believe a framework exists for us to develop comprehensive immigration reform that can be worthy of the American people, to create a lawful system of immigration that will work. It will be difficult in a number of areas, but we can do that. A framework is being discussed, I know, because I have seen the PowerPoint presentations and some of the other discussions about it. A framework exists that could lead to effective immigration reform. There is no doubt that this Nation needs comprehensive immigration reform. The whole system is broken. Nothing about it works. The legal system is an embarrassment to us as a nation and a source of frustration to the American people. They rightly are concerned about it, and politicians don't seem to be. That is why we have had a problem for so long, and frustration and anger gets built up. People sometimes call in to radio stations and say things they shouldn't say that are unkind. A lot of it is a direct response to a failure of the Congress and the executive branch to do what is required to create a lawful system of immigration. For Heaven's sake, don't we all agree with that concept, a lawful system of immigration?

What interests should it serve? It should serve the national interest, the American interest. I asked Secretary Chertoff of Homeland Security and Secretary Gutierrez of Commerce at a hearing of the Judiciary Committee not long ago, what should a lawful system of immigration do? Should it not serve the national interest? They said: Yes, sir.

Professor Borjas, a Cuban refugee, at Harvard has written a book on immigration. He said: If you tell me what interest you wish to serve, I can help you draft an immigration policy that will work. For example, if you say it should be the national interest, I can help you achieve that. If you want to serve the interest of poor people around the world, I can help achieve that. He basically said in his book ''Heaven's Door,'' we could serve poor people around the world by just letting them all in. That would be in their interest. We know that. In 2000, we had 11 million people apply for 50,000 lottery slots. The names are drawn out of a hat randomly. Only 50,000 are drawn out a year. We had 11 million apply for those slots.

We have to look at the basics. More people want to come to this country than we can accept, and those whom we accept should be based on what is in our interest. How much more simple can it be than that? I submit that is a moral and legitimate basis.

We always have a humanitarian component to immigration. I would not reduce that. About 16 percent of those who come, thereabouts, are for humanitarian reasons. I think we will always want to have that available for people who are persecuted or otherwise need humanitarian relief. Fundamentally, the rest of our program ought to serve the national interest.

This is what has happened. There are supposedly bipartisan discussions going on—and I know they are going on—to try to take the framework that has been agreed on by the President, Cabinet members, and some Members and to flesh that out and develop an immigration policy. That hasn't reached fruition. I understand some of the leaders on the Democratic side have walked away. They are not prepared to follow through on the overall agenda item for a given area, this framework. When you start writing down the words that will actually effectuate what you promise to do, then people start backing off.

I have said a number of times on the floor that we have a great deal of interest in immigration reform, except that we need a lawful system which will work. If it is a system that will actually work, we find immediately people start objecting.

Senator REID has said these negotiators—I sometimes want to call them masters of the universe; I don't know who selected them—are meeting here and they are deciding the fate of American immigration. I want to say, well, let's see what they produce. I have told my constituents I hope they will discuss it, and maybe some agreement can be reached, one I could support. But I

promised my constituents—and every Senator ought to make this commitment—that I am going to read that bill. Just because people have great sounding words, if you don't read the words carefully and what they will actually mean in the effort to enforce immigration law, then you don't know what you are going to get. You are going to end up as we did in 1986, with a program that was an utter failure. The one we had last year would never have worked. It would have been a disastrous failure. It had no chance of being successful or ever achieving the ideas it purported.

Senator REID apparently is unhappy. He has the power, as the Democratic leader, to call up any piece of legislation he wants to call up. He has said: I am not happy with the speed of this. He has said he is going to call up, under the power of the majority leader under rule XIV, last year's bill, and that this will be on the floor. Then he will want the negotiators to continue to negotiate, and maybe they will figure out what would be better. Then he might substitute this newly negotiated bill that hasn't been written yet—nobody has seen a word of it—and then we will vote. That will make everybody happy.

Let me say this, with all sincerity: The American people know immigration is a big issue. It is an important issue; it really is. It says a lot about the nature of this country. Are we going to be a country that the world knows has laws that are never enforced, that our immigration policies make a mockery of the law, as they do today? Will we continue to see people all over the world get the idea in their heads—correct today, basically—that if they can just get into America, sooner or later we will make them citizens and give them everything, even if they came illegally? Is that the kind of message we want to send?

Senator REID has said he is going to bring up last year's bill. He also indicated that after last year's bill is introduced and maybe a compromise would be reached. Maybe they would substitute this compromise as a new bill which we have never seen before, nor the words in it.

Let me tell my colleagues, an immigration bill is not an itty-bitty thing. An immigration bill consists of a lot of pages. A group of us, about 15 of us, wrote to the majority leader and asked that we have 7 days—I thought that was way too short—to read the bill. Isn't that pathetic? The immigration bill last year was 700-plus pages. Seven hundred pages. This never before seen compromise version may be longer. At least last year's bill came out of the Judiciary Committee, and we had a chance to argue over it in there, although the train ran right through the Judiciary Committee and it ran through—basically through the floor of the Senate. But we began to read it before it was over, and I remember making a speech down here, several speeches, pointing out 17 loopholes in that bill, fatal flaws in the legislation. But anyway, it passed, but the House refused to even consider it.

Based on what was in the New York Times and Rollcall or The Hill or one of the publications, the plan would then presumably be for Senator REID to bring up last year's bill, which is unthinkable, in my view. It was fatally flawed. We will stay on that bill for some time, and then perhaps they will plop on it a substitute and take out all or parts of last year's bill and substitute an entirely new bill, 600, 700 or 800 pages, and then we will vote on it. That will be good for the masters of the universe, you see, because when you do that, there would not be time for the American people or for Lou Dobbs or Rush Limbaugh to find out what is in it and to tell the American people what is in it so they can get mad about it. That is basically what it is about. They want to slide it through with the least possible time to discuss it. I think that is irresponsible. It is wrong.

We should spend plenty of time on this legislation. We should go to the American people with honesty and integrity and tell them: Some of the things you want to do, Mr. and Mrs. America, we can't do. We are not going to be able to make immigration come out exactly like you would want it or exactly like I would want it. We are going to have to reach a compromise, but we understand we have a commitment to you, and that commitment is to create a system that will work in the future.

But I am worried about it because from what I am hearing, the system seems to be moving in a way that is going to create an opportunity to vote on a completely unseen immigration bill—nobody has read it except a little group—and move it through this Senate. Now, remember, the bill that passed last year was a bad piece of legislation, but it did pass this Senate. People thought it would die in the House, and sure enough, it did die in the House and it was never considered. They wouldn't even look at it. But I am not sure that is going to happen this time.

So we may have this plan in the works, and it will work something akin to this: Well, we spend 2 or 3 days talking about immigration, burning time and filibustering, filing cloture on a motion to proceed, and we get on the bill for a day or two and then all of a sudden a new bill comes on and in a day or two, it is passed. Hardly anybody knows what is in it or has had a chance to read it. Then it goes to the House of Representatives, where the Democratic majority now has a 15 seat, 16 seat or so majority over there; some of the Republicans would clearly be in favor of whatever passed out of the Senate. They don't have any way to delay votes over there, so the bill could be brought up and passed, the same bill, without any amendment. That could happen. Then it goes to the President and he signs it and then we will find out 2, 3 or 4 years from now whether it works.

I don't think it is going to work. I am worried about it. I am worried about it. I am worried there is not a commitment among the executive branch to enforce the immigration laws.

Anybody who would like to be elected President—the new executive branch leader has a commitment to ensuring a lawful system of immigration. That is all the American people want. They are not saying they don't want any immigrants in America.

So I am saying this because I am concerned this is where we are headed. I think it is unhealthy for the Senate. If we do that, we would have failed in an august responsibility. This is the body that is supposed to let the passions cool, where Senators look over important issues, think them through, and then make a decision on them. Also, the delay and the slowdown that goes on in the Senate is helpful so the American people can be advised on what their representatives are actually doing. So I am worried about it, and Senator REID's strategy is frightening to me.

So let me repeat: I believe the framework that has been mentioned for the drafting of a comprehensive immigration reform bill actually has the potential to be successful. But based on my experience in the 10 years I have been in the Senate and the debate we have seen on immigration, I am inclined to believe they will have positive-sounding words on the headlines in big print, but the real language will not effectuate the promises they make or the goals they set. We could end up with no progress whatsoever. We could end up with amnesty and no enforcement in the future.

That is what happened in 1986. If you remember, in 1986, they said there are probably a million people in the country illegally. The system was not working. We had to do something, so we should grant amnesty to the people who came illegally, contrary to law, and then we would develop a new system in the future so that this would be the amnesty to end all amnesties. There would be no more amnesties. Well, 3 million people showed up to take advantage of it rather than 1 million people, and in the 20-plus years—21 years—since, we now have found in our country an estimated 12 million to 20 million people here illegally. So now we want to, I guess, give amnesty again on a promise that we will have a system that will work in the future. But the American people, you see, are cynical about it. They are not comfortable with us anymore on this subject, and frankly they are right to be cynical. Because there are a lot of special interests out there who are asking for what is in their interests but not what is in the national interests. It is time for us to consider what is in the national interests and do the right

thing on immigration. I firmly believe we will do a better job of writing a bill that will work, a bill that will serve our national interests, that will create a lawful immigration system, if the American people know what is going on, because that is what they want.

The American people have been consistently right on this issue. Their instincts have been right consistently. Oh, there are some nutty folks out here who are mean spirited, there is no doubt about that, but they represent a very small number. The basic feeling of the American people is sound on immigration and has been. It is the Congress and the executive branches that have failed them for 50 years. We don't have to continue to fail the American people. We have a responsibility to make it work, and I am hopeful that in the discussions for the first time with Secretary Chertoff and Secretary Gutierrez helping behind the scenes to develop some plans that would actually work, we might even get this thing done. There is some possibility. I wouldn't have believed it, but now I am beginning to think it is possible.

But if at the last minute the special interest groups who seem to have dominated last year get their way, we would not be able to pass the bill we can be proud of. We would not pass a bill that will work, and we will be back in 10 years, 15 years, 20 years from now, dealing with another crisis.

So I will not go on anymore about it. I will mention what the framework, as I understood it, contained, that these PowerPoint presentations that were shown around and got leaked to the press, it has real improvement in border enforcement. We need that. That is essential. If you are serious about immigration, you want border enforcement. It set up as a goal a very effective job workplace enforcement, something that could actually work, using biometric identifying cards, helping the businesses and telling them exactly what they need to do so they can't be prosecuted or sued for doing something wrong. They are told exactly what to do and what will work. We can make the workplace cease to be the magnet for illegal jobs. That is very important, and it can be done. We need to deal compassionately and realistically with the people who are here illegally, but I don't believe that someone who broke the law in our country should be given every single benefit that we give to those who come lawfully. We will have to wrestle with that, and nobody is going to be happy, I am sure, with the way that comes out. That is the way it is with any big piece of legislation.

We need a genuine temporary seasonal worker program that is separate and apart from the program that would allow people to come into the country on a citizenship track. On the basic entry, citizenship entry into the United States, we need to be far more similar to Canada, which has a merit-based, skill-based system that evaluates applicants on what they bring to Canada: Do you speak English? Do you have an education? Do you have skills that Canada needs? It is a skill-based point system. It is objective and fair, and it serves the Canadian interests, and they are very happy with it. So is Australia, so is New Zealand, and I think the United Kingdom is also moving forward in this direction. A merit-based point system can actually be a framework for success. I understand that is being discussed. We do not need to promote such a framework, and then vote on a bill that doesn't create the merit-based point system when you read the fine print. That would be a failure.

So those are my concerns, and I will object with every ability I have, I will utilize every tool I have to ensure that whatever bill hits this floor, that Senators and the American people have time to evaluate it and an opportunity to know what is in it. But there are ways that this time and opportunity can be denied if the leadership is determined and can get the support. We could deny the American people that right, and it would be wrong to do so.

I thank the Chair, and I yield the floor.

The PRESIDING OFFICER. The Senator from Kansas is recognized.

Mr. BROWNBACK. I ask unanimous consent to speak as in morning business for up to 15 minutes.

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

TORNADO IN GREENSBURG, KANSAS

Mr. BROWNBACK. Madam President, I just returned from Greensburg, KS, yesterday, where we had a horrific tornado hit late Friday evening. I want to share with my colleagues some of the damage assessments, some of the pictures of what has taken place, and some of the needs we have for this community. It is a community I have been to a number of times while serving in different positions in Kansas. It is a wonderful community, full of community spirit, with people who have been there for a number of years. They have a celebration around a hand-dug well that is kind of an unusual event. It is the world's largest hand-dug well. You can go to the bottom of it, and I have done that.

Greensburg is a community with a lot of spirit in the middle of the State and in the middle of our country. Now it is experiencing this tremendous devastation. The tornado covered 40 miles in 90 minutes. It was first spotted at 8:24 p.m. last Friday 3 miles south of Sitka, KS, in Clark County.

The tornado tracked through six counties: Comanche, Kiowa, Edwards, Stafford, Pratt, and Barton. At 9:45 p.m., the tornado demolished Greensburg before wrapping north and dissipating before 10 p.m. Fortunately, the National Weather Service and a weather man out of Dodge City spotted it and warned the community, and the community had about a 20-minute warning that a tornado was coming and that it was a big one.

When Greensburg was struck, the tornado's wind forces exceeded 205 miles per hour, falling into the highest category on the Enhanced Fujita Scale, EF–5. The size of the tornado was 1.7 miles in diameter, which, if you know anything about tornadoes, is enormous. Twelve people have died as a result of this storm cell. They found another two individuals yesterday.

When a tornado hits—and you will see pictures here—often the houses will blow up in the process because of the air pressure outside of the house that is much reduced from the air pressure in the house, and there will be a blowing up of the house, or the wind comes in and hits it. It can be destroyed by the wind.

Thirteen people are still in the hospital, with four of them in critical condition today. There was some good news on Sunday. We found a person still alive underneath the rubble.

Ninety percent of the town has been destroyed, from Greensburg to the Northeast, which was hit by multiple tornadoes that were spawned by the same supercell thunderstorm. It is an older community. More than 50 percent of the population is 45 years of age or older, and 25 percent of the population is 65 years of age or older. Primarily, the economic drivers of the community are farming and oil and gas production.

We will need substantial assistance. I want to show pictures from the wreckage I toured yesterday. I am pleased to note that the President is coming tomorrow. I was there yesterday with the Governor and several members of the congressional delegation. Senator ROBERTS was there on Saturday. It is devastating to see.

Here you see a structure left standing there, which is a grain elevator. That is really the only structure left standing in the town. The courthouse is standing, but its roof has been ripped off. It is amazing people can actually survive something like this. Most people have storm shelters or basements they can go into, and they did with the warning, and some called other people in the community. All of these trees were denuded in the area, and the whole place was ripped and torn into shreds in the county and in this particular community.

This is one of the main structures in the downtown area of Greensburg. All of the brick around it is damaged.

They were able to keep the Greensburg sign still posted in this picture. These were taken when the storm system was still in the area. There was a tornado the next day within a mile of Greensburg, from the same supercell system. It dumped 10, 12 inches of rain in northeast Kansas.

You can still see ominous-looking clouds in this photo. It was very dicey over the entire weekend.

This was one of the more stable houses that remains standing in the area. I went into a house that was somewhat like this, which was built almost 100 years ago. I talked with the

owner. They were going to celebrate the 100-year anniversary for the house, which was built in 1908. He said, ''We didn't quite make it.'' The house is going to be demolished now. It will not survive.

This is a view of some of the damage to vehicles. This is a blank landscape in the backdrop. I wanted to give some views of what has taken place in the community. It has been completely and utterly destroyed.

I would like to note that FEMA has been questioned by me and by a number of my colleagues. Prior to Katrina, it had done a lot of good work that people had respected and appreciated. They felt there was a good group on the job. But then Katrina happened and you looked and said: Where is the FEMA that I knew that would go in and respond in these situations? We are watching carefully to see how FEMA responds to our situation, to our devastation.

I am pleased to state—and I talked with a number of individuals in the community—they are meeting the needs. The needs of the community are being met. They are there on the grounds, being aggressive in dealing with it. The people appreciate they are there. We are going to watch and make sure all of their needs are met.

I will ask my colleagues for assistance as well. This is a small, older community. It lacks much in the way of resources. We need help in this particular situation. We are going to be pushing—Senator ROBERTS and I—for 100-percent coverage on public assistance and on matters such as debris removal and repair and rebuilding public facilities: city hall, fire stations, hospitals, water/wastewater, city powerplant, and gas and diesel generators. The community lacks the resources to meet these needs. We will look to remove the 25-percent local match for FEMA funds. The entire town and their economy was destroyed. There is no way Greensburg can come up with the match of funds that is necessary in this community.

I also want to try something innovative. This is a community in the High Plains. The New Homestead Act is a bill that Senator DORGAN from North Dakota and I have been pushing for some time. I have been a lead cosponsor. As I said, it is a bill called the New Homestead Act. We have had many communities drained in the High Plains, particularly in the Midwest, because of a consolidation in agriculture primarily, but also other features, to where we have had out-migration in huge areas. This is a county that has experienced a lot of out-migration. I would like to see us use Kiowa County—Greensburg is the county seat—as a pilot project for the New Homestead Act.

The biggest concern, once we complete cleanup, is getting the people and their businesses back up and going. Here is a chance for us, given the level of public commitment in place and the desire to rebuild this community, to try this New Homestead Act that can work as a magnet to attract people back into these communities that have had difficulty transitioning from an agricultural economy to something else. This bill is to encourage people to move to rural areas that have depopulated. This bill will help repay college tuition loans for people who move back into the community, help folks buy their first home and set up individual homestead accounts to help people save for the future. Also, this bill will help pump capital to Main Street America through a rural venture capital fund.

I think these are things we can look at and say let's try this here and let's see it work. Let's see what we can model off of to help many places in the High Plains that have experienced this depopulation. We will be pushing also for an enhanced USDA rural development package.

There has been a controversy coming up that I think is unfortunate. That has been the question about whether there has been enough equipment from the National Guard—the Kansas National Guard, on the ground in Greensburg to take care of this atrocity, this disaster, or has too much been diverted to the war on terrorism and in Iraq. Yesterday, I asked specifically the Kansas adjutant general—the head of the Kansas National Guard: Do you have enough equipment on the ground to take care of Greensburg? He said: Yes, we have enough equipment.

I made the point: If you don't, we are going to push Fort Riley and other places to come up with this equipment.

He said: No, we have enough equipment.

Unfortunately, this has grown into a bit of a controversy as to whether there is sufficient equipment or if too much has been diverted to Iraq. The specific statement by Kansas' head of the National Guard—the adjutant general—says there is sufficient equipment on the ground to meet this need. I think it is important that be stated and that be clear because these needs are existing, but they are being met and the equipment is there.

I want to make sure that we can respond. I want to note, finally, to anybody who is interested, fortunately, because of the nature of the country and generous people in the United States, they want to help. They want to know what they can do for the people of Greensburg.

There are three places that I suggest they look to contribute: the American Red Cross, Salvation Army, and the United Way of the Plains in Wichita, KS. Those three groups are ones that are receiving and funneling funds into Greensburg. Being a small community, it didn't have these sorts of organizations there. But these groups do work. Cash donations are being accepted. There is no current need for donations in-kind, but I hope people will look back and come back in the future and consider that on in-kind items. Those groups would be helpful. The United Way of the Plains established a Greensburg disaster fund to which people can contribute. I hope people will consider contributing to those three entities.

We have a number of different groups that are stepping up, including Pizza Huts through Kansas, which are donating 20 percent of their profits on Thursday, May 10, to go to this United Way of the Plains—the Greensburg disaster fund. I hope other groups will also do that so Greensburg can rebuild and renew itself and grow into the future. These are tough times for this community, but it is a resilient community.

It impresses me when you see horrific disasters such as this, just a complete devastation, and you talk to the people and they want to rebuild and dig out and they want to go on. That is the resilience of the human spirit in the face of a horrendous disaster, loss of life and property, and a loss of almost an entire community. The people there were talking about how to rebuild. It is beautiful to see that.

We mourn their losses. The people of Greensburg and Kansas are thankful for all the prayers people have given for that community, in all of their tragedy and difficulty. They will be back and they will rebuild and they will go forward and raise the next generation of families in Greensburg and Kiowa County.

The country is going to help out, and I think the country will help in a powerful, positive way, and we will celebrate as Greensburg comes back.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

IRAQ

Mr. REID. Madam President, today is a somber day in Nevada. Last night, a helicopter crashed in Austin, NV, killing all five crew members on board. It is believed the flight was from Fallon Naval Air Station.

Also yesterday, Nevada lost another soldier in Iraq—25-year-old SGT Coby Schwab—to an improvised explosive device.

Our State and our Nation mourn the loss of all six servicemembers who served with honor and courage. Our hearts and our prayers are with the families.

No one wants success in Iraq more than we in the Senate. I can think of no greater tribute we can pay to those six servicemembers and the more than 3,300 others who have lost their lives in Iraq than to reach a responsible and successful end to the war which has cost so much in so many different ways.

The Washington Post this morning ran an article entitled ''The Cost of

War, Unnoticed.'' It tells us that the war in Iraq is about to become the most expensive conflict in United States history, after World War II. But unlike World War II, which was fought all over the world—in faraway Japan, Africa, all the islands in the South Seas, all over Europe—the Iraq conflict is taking place in a country the size of the State of California.

Also unlike past wars, President Bush is putting the costs squarely on the shoulders of our children and grandchildren by financing it entirely through borrowing and raising the national debt.

Robert Hormats, a former Republican administration official, says:

> They tried to do this on the cheap and without a candid conversation with the American people about the cost. But the irony is the great wartime leaders have seen it in the opposite way.

From the beginning, President Bush has called this war a great challenge of our time. Yet his actions don't match his rhetoric. He has expected sacrifice from our troops now, but has pushed the sacrifice of American taxpayers years and years into the future and long past his term in office.

In 18 months, there will be a new election—18 months—to select a President. All Americans will continue to bear the financial burden of this war in the future, long past a new President assuming office. But right now, we are seeing the toll it is taking on our security at home.

In the wake of the tragic tornadoes that ripped through Kansas this past weekend, our National Guard did the best job it could there, a fantastic job, and we are grateful for their work, of course, but the toll of the war in Iraq crippled the ability of our National Guard to do the dangerous and heroic jobs they are charged with doing.

According to the Governor of Kansas, Kathleen Sebelius:

> Fifty percent of our trucks are gone. Our front loaders are gone. We are missing humvees that move people. We can't borrow them from other States because their equipment is gone. It's a huge issue for States across the country to respond to a disaster like this.

We can't expect our first responders to keep America safe if they don't have the supplies and the equipment to get the job done.

Our men and women in uniform, both active and in the Guard and Reserve, are bearing the bulk of the burden of this war. But we all pay a price, whether in death and injury to troops, or whether tremendous financial burden not yet fully realized, or whether in the inability of the Kansas National Guard to rescue and recover more quickly. That is why it is crucial and well past time to change course toward a successful and responsible end to the war.

We continue to negotiate with the White House and our Republican colleagues in Congress. We continue to stand firm in our belief that the time for a new direction has come. Even some of our Republican colleagues who have long supported the President on the war now seem to agree it can no longer be open-ended.

Yesterday my colleague Senator LOTT said:

> This fall we have to see some significant changes on the ground.

Over the weekend, House Minority Leader BOEHNER said:

> By the time we get to September or October, members are going to want to know how well this is working, and if it isn't, what's Plan B.

Just yesterday, my colleague Republican Leader MCCONNELL echoed Leader BOEHNER's sentiments.

> I am glad to hear them move to our view, to set their own timeline. But we can't wait until fall. We have to have a responsible plan B right now.

Plan B gradually reduces combat operations and refocuses our troops on protecting America's security throughout the world.

Our plan B begins to bring troops and equipment home, where they can protect American lives in Kansas and across the country.

Our plan B begins to reduce the financial burden that this war is weighing on our shoulders and the shoulders of future generations.

And our plan B puts the pressure on the Iraqi Government that will ultimately lead them to take responsibility for their own future.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

Mr. REID. Madam President, there will be no more votes today. The managers are working to try to come up with a package that can be accepted. As I have indicated, the time on postcloture will run out sometime tonight about 10 or 11 o'clock. We hope it is not necessary to run the clock that long, but we are going to finish this bill in the morning, and we will see how many votes we have. We will try to be aware of people's schedules, but the Senate itself has a schedule we have to deal with. So we are going to do our best to finish this bill tomorrow and move on to other business.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. INHOFE. I ask unanimous consent that the order for the quorum call be rescinded.

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

(The remarks of Mr. INHOFE pertaining to the introduction of S. 1335 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

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

The PRESIDING OFFICER (Mr. SALAZAR). Without objection, it is so ordered.

TRIBUTE TO SUSAN GORDON

Mr. ISAKSON. Mr. President, I will address the Senate as in morning business for a few minutes on two points of great personal privilege for me.

The first is, I read last week of the retirement of Susan Gordon, executive secretary and office manager of the Office of Legislative Counsel in the Georgia General Assembly. That might seem an odd thing for me to come to the Senate floor and talk about, but for me Susan is emblematic of all of the people who make us look good in this job of public service.

For 31 years, she served the people of Georgia and the Office of Legislative Counsel for the Georgia General Assembly. In my 17 years in that assembly, I can think of hundreds of times where Susan stayed late or went the extra mile to see to it that legislation was drafted, perfected, and got to the floor within the constraints of the general assembly. She never played Republicans over Democrats or Democrats over Republicans, and she loves the State of Georgia.

When I learned of Susan's retirement, it only seemed appropriate for me to memorialize on the Senate floor to her my appreciation for all she has done for me, and countless other legislators who have gone before me in Georgia would say precisely the same thing.

I say for all those others who work in our offices, in legislative counsel, and in the departments of government, the unsung heroes of this great thing we call democracy and public service, to all the ''Susan Gordons,'' thank you very much.

In particular, I thank the Susan Gordon I know in Atlanta, GA. I memorialize my thanks and appreciation for her 31 great years of service to me and the people of Georgia.

BIRTH OF CECILIA GAY MITCHELL

Mr. President, on a second point of personal privilege, at 4:33 p.m. on Sunday afternoon, my daughter, Julie, gave birth to Cecilia Gay Mitchell, my seventh grandchild.

With Mother's Day coming up on Sunday, I was struck while on the plane flying here on Monday by the generations of people before us, what they have done and the importance of family and the importance of motherhood.

You see, Gay is a family name on my wife's side: My wife's great-grandmother Gay Deam, my wife's mother Gay Davison, my wife Dianne Gay, my daughter Julie Gay, and now Cecilia

Gay—a fifth generation of Gays, all ladies, all but one a mother, all close and treasured by me.

I will never claim to be the equal of ROBERT BYRD in terms of his great Mother's Day speech, which I think we will all hear on Friday, but for me on the celebratory day where I celebrate the birth of a seventh grandchild and the fifth-generation Gay in our family and the Davison family and the Isakson family, I pay tribute to my daughter Julie, her husband Jay, and my expression of thanks to them on behalf of Dianne and me for the greatest present that could ever be given to a parent—that is the gift of a grandchild, especially a fifth-generation Gay.

I yield the floor. Mr. President, 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. DURBIN. I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. MENENDEZ). Without objection, it is so ordered.

Mr. DURBIN. I ask unanimous consent to speak in morning business.

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

IMMIGRATION REFORM

Mr. DURBIN. Mr. President, in the coming weeks the Senate will again consider legislation to reform our broken immigration system. The Presiding Officer has been personally and deeply involved in this issue since coming to the Senate. I thank him for his leadership.

I think we all understand the challenge is substantial. If we want to solve the problem, we need a comprehensive approach that is tough but fair. We should improve border security by increasing manpower and deploying new technology. We should enforce the law against employers who are hiring millions of undocumented workers. And we need a realistic, honest approach to the 12 million undocumented immigrants who live and work in our country illegally.

Most importantly, we must ensure that immigration reform legislation protects the American economy and American workers as well.

I am concerned about the H–1B visa program as it is currently structured. I am afraid it is being abused by foreign companies to deprive qualified Americans of good jobs.

To address this problem, Senator GRASSLEY and I have introduced S. 1035, the H–1B and L–1 Visa Fraud Abuse Prevention Act of 2007. This is a bipartisan bill. It would overhaul the H–1B and L–1 visa programs to protect American workers and crack down on unscrupulous employers.

The H–1B visa program was designed to allow employers to attract and hire high-skilled foreign workers with specialized knowledge. H–1B visas are probably best known for their use in technology to import computer engineers and programmers.

I can't tell you how many leaders in industry, including one this afternoon, come into my office and say: We absolutely need H–1B visas. We can't find enough people with specialized education for our businesses. If you won't allow us to bring these workers in from overseas, we are going to be facing the possibility of taking our production facilities overseas where they live.

It is a compelling argument. I understand it on its face. But let me explain some of the problems with the current system and why Senator GRASSLEY and I believe the system needs to be changed.

Supporters claim the goal of the H–1B program is to help the American economy by allowing U.S. companies to hire needed foreign workers. The reality is that H–1B visas are being used to facilitate the outsourcing of American jobs to other countries. It seems counterintuitive that a visa that allows people to come into the United States could lead to jobs being outsourced overseas, but when you hear my illustrations, you will understand the conclusion.

A recent expose in the International Herald Tribune disclosed that 8 of the top 10 H–1B visa applicants last year were outsourcing firms with major operations in one country—India. So in many cases it wasn't the American high tech company using the H–1B visa that was given this opportunity but, rather, a firm, more likely in India than any other country, that was given the authority to use H–1B visas to send workers into the United States. The Herald Tribune concluded:

> As Indian outsourcing companies have become the leading consumers of the [H–1B] visa, they have used to it further their primary mission, which is to gain the expertise necessary to take on critical tasks performed by companies in the United States and perform them in India at a fraction of the cost.

According to this report, the Indian Government has been lobbying hard for the United States Government to increase the number of H–1B visas. Kamal Nath, the Indian Commerce Minister, was very blunt when he said recently that the H–1B visa ''has become the outsourcing visa.'' He concluded:

> If at one point you had X amount of outsourcing and now you have a much higher quantum of outsourcing, you need that many more visas.

That is a very candid statement by this commerce minister in India. It should give us pause as we think about this program, what it was designed to do and what it is actually doing.

In other words, the Indian Government wants more H–1B visas so Indian companies can outsource more American jobs to India.

Let me be clear. India is a valuable American partner in commerce, diplomacy, and many other endeavors. Indians who have come to the United States have made immeasurable contributions to the benefit of our country in so many ways. I trust them as great friends. But some in India today understand that we have a weakness in our visa system and are using it for their own economic advantage.

It is not surprising the Indian Government is advocating on behalf of Indian companies. The American Government should advocate on behalf of American companies. I don't criticize the Indian Government for doing that. But we should expect the same from our Government for our workers. We need to stand up to make sure American workers don't lose their jobs to outsourcing because of H–1B visas.

H–1B supporters claim we need more H–1B visas to stop American jobs from being outsourced. That was the logic behind H–1B visas. It appears the opposite is true. Under the current system, more H–1B visas will mean more outsourcing.

Let me give an example. Indian outsourcing company Wipro was No. 2 on the list of top applicants for H–1B visas in the year 2006. Wipro has more than 4,000 employees in the United States, and approximately 2,500 of them are here on H–1B visas. It is pretty clear that when it comes to Wipro's American operation, the majority of the workers are here on H–1B visas. Every year Wipro brings 1,000 new temporary workers here from India, while they send another 1,000 U.S. trained workers back to India. This is essentially an outsourcing factory.

Here is what the Herald Tribune concluded:

> Rather than building a thriving community of experts and innovators in the United States, the Indian firms seek to funnel work—and expertise—away from the country.

It is hard to believe, but it is perfectly legal to use the H–1B visa program for outsourcing. A foreign outsourcing company with a U.S. office can use H–1B visas to import workers from their home country, train the workers in the United States, and then outsource them back to their home country to populate businesses competing with the United States. They are not required to make any efforts to recruit American workers for these jobs. In fact, they can explicitly discriminate against American workers who apply for the same jobs by recruiting and hiring only workers from their home country.

Here is what the Labor Department says about the current law:

> H–1B workers may be hired even when a qualified U.S. worker wants the job, and a U.S. worker can be displaced from the job in favor of a foreign worker.

Is that what we had in mind with H–1B visas? That certainly wasn't the way it was explained to me. In fact, under current law, only employers who employ H–1B visa holders as a large percentage of their U.S. workforce are required to attempt to recruit American workers before bringing in foreign workers.

Senator GRASSLEY and I have taken a look at this system. We both reject the notion that what is wrong with the H–1B program is that we need more visas. We have to look at the system that generates these visas and the way they are used. The legislation we have introduced would overhaul the H–1B program, protecting American workers first, and stopping H–1Bs from being exploited as outsourcing visas.

Here are the highlights. First and foremost, we would require all employers who want to hire an H–1B worker to attempt to hire an American worker first. Employers would also be prohibited from using H–1B visas to displace American workers. You can't fire an American and turn around and appeal to our Government for an H–1B visa to bring someone in from overseas to replace that worker.

This is an important principle. We have to make it clear that companies doing business in the United States have to give first priority to American workers.

Our bill would require that before an employer may hire an H–1B worker, the employer must first advertise the job opening to American workers for 30 days on the Department of Labor Web site.

Some companies that abuse the H–1B visa program are so brazen, they say ''no Americans need apply'' in their job advertisements. Hundreds of such ads have been posted on line. They say things such as ''H–1B visa holders only'' or ''we require candidates for H–1B from India.''

Is that what we have in mind, to create this perverse discrimination against American workers? That isn't the way it was explained to me. Our H–1B reform bill would prohibit this blatant discriminatory practice.

There is another serious problem with the H–1B visa program. Federal oversight is virtually nonexistent. Under current law there are many roadblocks to effective Government enforcement. For example, the Department of Labor does not have the authority to open an investigation of an employer suspected of abusing the H–1B program unless the Department receives a formal complaint, even if the employer's application is clearly fraudulent. Even if there is a complaint, the Labor Secretary—and this is something that is almost unique in our law—must personally authorize the opening of an investigation.

These restrictions in the law are aggravated by lax Government enforcement. According to the Department of Homeland Security's own Inspector General, Homeland Security has violated the law by approving thousands of H–1B applications in excess of the annual cap of 65,000. The Government Accountability Office found that the Labor Department approves over 99.5 percent of H–1B petitions it receives, including those that on their face clearly violate the law.

There is virtually no Government oversight of potential abuse in this system. The Labor Department's inspector general has concluded that the H–1B program is ''highly susceptible to fraud.'' Remember, this program was designed to help the American economy, to help create jobs and prosperity in our country. Our Government is not even watching it closely to make sure that fraud isn't being perpetrated.

The bill Senator GRASSLEY and I are proposing would give the Government more authority to conduct employer investigations and streamline the investigative process. Currently, the Labor Department is only authorized to review applications for ''completeness and obvious inaccuracies.'' Our bill would give the Labor Department more authority to review employers' H–1B applications for ''clear indicators of fraud or misrepresentation of material fact.''

Our bill would authorize the Labor Department to conduct random audits of any company that uses the H–1B program and require the Department of Labor to conduct annual audits of companies that employ large numbers of H–1B workers. We would also increase the penalties for companies that violate H–1B visa rules and authorize the hiring of 200 additional Government investigators to oversee and enforce the H–1B program.

Last month, the government began accepting H–1B visa petitions for Fiscal Year 2008. In the first 24 hours, the government received 150,000 petitions for 65,000 slots, supposedly for the whole year. Based on last year's statistics, it is likely that the top petitioners for visas were companies from India. They understand the system. They understand how to make this profitable. But this is not the way it has been described to most Members of Congress. It certainly isn't consistent with our intent.

There is another program I wish to mention, the L–1 visa. The L–1 visa allows companies to transfer certain employees from foreign facilities to the United States for up to 7 years.

Experts have concluded that some employers use the L–1 program to evade restrictions on the H–1B program, because the L–1 program doesn't have an annual cap and doesn't include even minimal protections for American workers. As a result, efforts to reform the H–1B program are unlikely to succeed if the L–1 program is not overhauled at the same time.

The bill Senator GRASSLEY and I have prepared would reform the L–1 program. We would establish for the first time whistleblower protections for those who call attention to employer abuses of L–1 programs, and for the first time we would authorize the Government to investigate and audit L–1 employers suspected of violating the law.

Before we are persuaded to increase the number of H–1B visas, we have to reform the program to protect American workers first and to stop H–1Bs from being used as outsourcing visas that send jobs and business away from America. That is what our bill would do, and that is what Senator GRASSLEY and I will be pushing for as the Senate considers comprehensive immigration reform legislation.

I know this immigration debate is contentious, controversial, and some think it is politically dangerous, but it is long overdue. The current immigration system in America has failed us.

We now have upwards of 800,000 undocumented immigrants who come across the borders each year. That has to change. We have to reach a point where we have control of our borders. Some of the measures that have been suggested during the course of the debate I think are extreme. We don't have to move in that direction.

I recently met with Senators from Mexico who were visiting the Capital last week and encouraged them to join with us in a joint effort between the United States and Mexico to police the border, to try to make sure there is less exploitation of people who are coming across for jobs or for moving drugs or contraband—whatever the reason may be. I think more cooperation would go a long way between our two countries.

We also need to be sensitive and cognizant of the burden facing many employers in this country. If someone presents themselves, in downstate Illinois in a meat-packing plant, with a name and a Social Security number and a local address, what is the responsibility of the employer today? It certainly isn't to launch a full-scale investigation. If the papers presented to that employer appear to be legal on their face, most employers will hire the person. They may learn later on that the documents were fraudulent.

How can we change that system? I think we need to move toward some form of identification that is reliable so the person carrying the card who is here in a legal and temporary employment status can prove their identity to the employer, so that the system is able to police itself more.

We also need to deal with the reality of 12 million undocumented people currently here. I know all about these folks because almost 90 percent of our casework in our Senate office deals with immigration. I have met many of them and their families. We need to find a fair way to hold them accountable, to make certain that over a period of time they can earn their way into legal status. They have to have a job and no criminal record; they have to pay a fine, pay their taxes, learn English, whatever it takes, to make sure that over a period of time, it is clear they have every intention to be a citizen of this country, and a good one. In that way, they can earn their way, over many years, into a position of citizenship or permanent legal status.

This country is great because of the immigrants who came here. My mother was one of them. I am very proud of that fact and happy to serve in a State

that would elect me and in a State that has so many immigrants who can tell the same story I have to tell.

I think the immigrant spirit is something that has made America a unique country. I think of people who, in their foreign lands, get up one day and say: We are not going to take it anymore. We are coming to America. We have a better chance. That is the kind of get-up-and-go we like to see that has made this a much better country.

I think we can capture that spirit in real, comprehensive immigration reform and avoid abuses such as those I have just described with the H–1B program and at the end of the day have a program and a law supported by both political parties that will really move us forward as a Nation.

Mr. DURBIN. Mr. President, I yield the floor, and 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. NELSON of Florida. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

AUTOMOBILE SENSOR DEVICE

Mr. NELSON of Florida. Mr. President, in the month of April, 16 children in this country have been backed over and killed by an automobile backing out of the driveway. Each of us can visualize what I am saying right now because we have a car in the garage or in our home driveway, we walk around to make sure there are no obstructions and then get into our car, and we really don't know that a small child may, in fact, have gotten in the way.

Last year, over 200 children in this country—in the United States alone—over 200 children were killed by these kinds of accidents. Last month, of the 16 who were killed nationwide, 3 of them were in Florida. I have had come to me moms and dads who have agonized and who have gone through the grieving of losing a child. A couple from Boca Raton, FL, who have spurred a national effort, came to me. Their child was only 5 feet in front of the mom, and out backs a car as they are walking down the sidewalk and it was too late; that child is gone.

It is so easily fixable with our technology. If you rent an Avis rent-a-car and it is a high-end car, it already has a built-in device that has a sensor in the back. Higher end automobiles such as the Lexus have a television screen with a little camera mounted in the rear. The sensor emits a beep, and the frequency of the beep increases as you get closer and closer to an object. It is estimated that such a device may cost in the range of $50.

So the question is, Are we going to encourage the automobile manufacturers to include this to stop these kinds of needless deaths? Increasingly, the Members of the Senate are going to hear from moms and dads who have gone through the grief of losing a child that could have been prevented. So it is my hope we will get some action.

I now bring to the attention of the Senate that it is my understanding this is getting ready to be put on the consent calendar in the House of Representatives, and it is my understanding we would consider this under unanimous consent here in the Senate, and we could then save some children's lives; otherwise, their parents will grieve forever.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. BROWN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

TRADE

Mr. BROWN. Mr. President, our trade policy is fundamentally flawed. Years of wrongheaded trade pacts have sent millions of jobs overseas and have devastated far too many of our communities and have opened our Nation to new and serious homeland security concerns.

When we open our borders to trade, as we should, we open them to national security threats. Congress must assure the American people that we have done everything within our power to protect their safety, health, and welfare while promoting trade.

It is estimated that less than 10 percent of foreign cargo is inspected before entering our country—only 10 percent.

We must both ensure our ports are operating securely and with clear lines of accountability—unlike the deal to transfer ownership of six U.S. ports to a State-owned company controlled by the United Arab Emirates that this administration approved about a year ago.

The decision to allow a UAE-controlled company had significant national security implications, including warnings that the UAE was a financial and travel outlet for known terrorists. It took leaders of both political parties, here and in the House of Representatives, to call attention to this enormous blunder.

Something else may be happening. This administration has recently signed a free-trade deal with South Korea and will soon ask this Congress to approve it under fast track, or trade promotion authority. One of the major goals South Korea sought in these negotiations was securing special treatment for products made in the Kaesong Industrial Complex, located in North Korea.

In Kaesong, South Korea, companies employ more than 11,000 North Korean workers. South Korea intends to expand the complex over the next few years and will employ close to 70,000—70,000—North Koreans by the end of this year, according to a Congressional Research Service report. U.S. negotiators had vehemently opposed including the Kaesong complex in the trade deal. But then, in a rush to sign a deal, our trade negotiators backed off—as they too often do when it comes to representing our national interests—and allowed room for future negotiations on the Kaesong complex.

This is a dangerous precedent, and it opens this agreement to a series of national security questions:

How much income, for example, does this Kaesong complex currently provide the North Korean Government? How much income can we anticipate it providing North Korea under its expansion plans? How are these North Korean workers treated? Under a fair trade agreement, would our government's actions be no different than the repressive North Korean Government?

Free-trade agreements, as currently written, live well beyond political administrations. We can't predict the future decisions and intentions of the South Korean Government, nor any other trading partners. As national security concerns continue to accompany efforts to promote trade, Congress must take proactive steps to ensure our homeland security needs are secured every bit as much as our economic well-being.

Last week, Senator DORGAN of North Dakota and I introduced the Trade-Related American National Security Enhancement and Accountability—TRANSEA—Act. This act requires the Office of U.S. Trade Representative, in collaboration with the Department of State, the Department of Justice, the Department of Homeland Security, and the Department of Agriculture to submit a report to Congress detailing the national security considerations of proposed trade agreements prior to commencing negotiations and the trade agreement again after concluding the trade negotiations.

The bill also requires future trade agreements negotiated by the administration to include a national security waiver that allows the President to suspend any terms of the agreement should it be required in the interests of United States national security.

Lastly, as a final safeguard, the legislation creates a new Congressional Executive Commission on Trade Security, which requires the appointment of Commissioners by both political parties in both Chambers of this Congress. The Commissioners will be charged with annually certifying that the terms of the free-trade agreement do not pose a threat to U.S. national security interests.

Should the Commission find that compliance with the agreement would pose a threat, the President would be obligated to exercise his or her waiver to the extent necessary to ensure the safety and security of the United States.

In a post-9/11 world, U.S. economic policy can no longer be simply viewed

in a vacuum of bottom lines and profit margins. Homeland Security Secretary Michael Chertoff said in 2006:

We have to balance the paramount urgency of security against the fact that we still want to have a robust global trading system.

It is the responsibility of our Government to ensure that while opening markets for our exporters—again, as we should—our first priority remains the safety and the security of the American people.

Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. BROWN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

Mr. BROWN. Mr. President, I, first, thank Senator ENZI, the distinguished Senator from Wyoming, for his terrific work, both as the ranking member of the Health, Education, Labor and Pension Committee, but more precisely today and yesterday for the work he has done on this legislation in working out agreements on a set of very complicated issues.

His staff has been terrific in explaining some of the more archaic parts of this legislation, and I am very appreciative. I know Senator KENNEDY is very appreciative, and I know Members on both sides of the aisle are as well. So I thank him for his leadership and his reasonableness in helping us to move forward in a particularly important way on this very important bill.

UNANIMOUS-CONSENT AGREEMENT

Mr. President, I ask unanimous consent that it be in order for the Senate to consider, en bloc, the following list of amendments that has been cleared by both managers; that the amendments, as modified, if modified, be considered and agreed to, the motions to reconsider be laid upon the table:

Amendments Nos. 985, 1011, 1009, 1026, 987, 1006, 1005, 1004, 1041, 1019, 1053, 1050, 1049, 1047 and 1056; and that amendments Nos. 983 and 988 be withdrawn; that a colloquy between Senators GREGG and KENNEDY be entered into the CONGRESSIONAL RECORD and then amendment No. 993 be withdrawn; further that any statements relating to amendments in this agreement be inserted in the RECORD; that when the Senate resumes consideration of S. 1082 tomorrow, Wednesday, May 9, the only amendments remaining in order be the following:

Grassley amendment No. 1039, a Grassley amendment No. 998, and a Durbin amendment No. 1034; that at the close of morning business, the Senate resume S. 1082, and there be a total of 60 minutes of debate remaining, to run concurrently on the bill and remaining amendments; with 10 minutes under the control of Senator GRASSLEY or his designee; 5 minutes under the control of Senator DURBIN or his designee; and the remaining time equally divided and controlled between the chairman and ranking member or their designees; that upon the use or yielding back of that time, there be 2 minutes of debate equally divided and controlled prior to a vote in relation to the Grassley amendment No. 1039; that upon disposition of that amendment, there be 2 minutes of debate prior to a vote in relation to the Grassley amendment No. 998; that upon disposition of that amendment, there be 2 minutes of debate prior to a vote in relation to the Durbin amendment No. 1034; that upon disposition of that amendment, the committee substitute, as modified and amended, be agreed to, and the motion to reconsider be laid upon the table; the bill be read for a third time; the Senate proceed to vote on passage of the bill; with the above occurring without further intervening action or debate; that upon passage the motion to reconsider be laid upon the table, and the title amendment, which is at the desk, be agreed to and the motion to reconsider be laid upon the table; further, that the cloture motion on the bill be withdrawn.

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

The amendments were agreed to, as follows:

AMENDMENT NO. 985, AS MODIFIED

At the appropriate place, insert the following:

SEC. ___. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) AIDS.—The term 'AIDS' means the acquired immune deficiency syndrome.

''(2) AIDS DRUG.—The term 'AIDS drug' means a drug indicated for treating HIV.

''(3) HIV.—The term 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS.

''(4) NEGLECTED OR TROPICAL DISEASE.—The term 'neglected or tropical disease' means—

''(A) HIV, malaria, tuberculosis, and related diseases; or

''(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

''(5) PRIORITY REVIEW.—The term 'priority review', with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

''(6) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

''(7) TROPICAL DISEASE PRODUCT.—The term 'tropical disease product' means a product that—

''(A) is a new drug, antibiotic drug, biological product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

''(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such tropical disease product.

''(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a new drug for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

''(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection is not included in such application.

''(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.''.

AMENDMENT NO. 1011, AS MODIFIED

At the appropriate place, insert the following:

SEC. ___. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

''(s) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the

Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION OR APPROVAL.—Except as provided in clause (iii), the receipt and consideration of a petition described in clause (i) shall not delay consideration or approval of an application submitted under subsection (b)(2) or (j).

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 25 business days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request for an action described in paragraph (1)(A)(i) to the Secretary, without regard to whether the request is characterized as a petition.''.

AMENDMENT NO. 1009, AS MODIFIED

At the end of title II, insert the following:

Subtitle ____—Antibiotic Access and Innovation

SEC. 2____. INCENTIVES FOR THE DEVELOPMENT OF, AND ACCESS TO, CERTAIN ANTIBIOTICS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

''(s) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

''(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

''(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

''(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

''(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

''(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

''(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

''(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

''(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

''(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

''(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

''(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

''(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

''(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

''(3) LIMITATIONS.—

''(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of

an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

''(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of enactment of this subsection.

''(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).''.

(b) TRANSITION RULE.—With respect to a patent issued on or before the date of enactment of this Act, any patent information required to be filed with the Secretary under subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to be listed on a drug to which subsection (s)(1) of such section 505 (as added by this section) applies shall be filed with such Secretary not later than 60 days after the date of enactment of this Act.

SEC. 2___. ANTIBIOTICS AS ORPHAN PRODUCTS.

(a) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting and, if appropriate, issue guidance, regarding which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(b) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a) there are authorized to be appropriated—

''(1) such sums as already have been appropriated for fiscal year 2007; and

''(2) $35,000,000 for each of fiscal years 2008 through 2012.''.

SEC. 2___. IDENTIFICATION OF CLINICALLY SUSCEPTIBLE CONCENTRATIONS OF ANTIMICROBIALS.

(a) DEFINITION.—In this section, the term ''clinically susceptible concentrations'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested.

(b) IDENTIFICATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), through the Commissioner of Food and Drugs, shall identify and periodically update clinically susceptible concentrations.

(c) PUBLIC AVAILABILITY.—The Secretary, through the Commissioner of Food and Drugs, shall make such clinically susceptible concentrations publicly available within 30 days of the date of identification and any update under this section.

(d) EFFECT.—Nothing in this section shall be construed to restrict, in any manner, the prescribing of antibiotics by physicians, or to limit the practice of medicine, including for diseases such as Lyme and tick-borne diseases.

SEC. 2___. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 355), as amended by this subtitle, is amended by adding at the end the following:

''(t) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

''(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

''(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

''(ii) the application submitted under subsection (b) for such non-racemic drug—

''(I) includes full reports of new clinical investigations (other than bioavailability studies)—

''(aa) necessary for the approval of the application under subsections (c) and (d); and

''(bb) conducted or sponsored by the applicant; and

''(II) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

''(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

''(i) in a therapeutic category in which the approved racemic drug has been approved; or

''(ii) for which any other enantiomer of the racemic drug has been approved.

''(2) LIMITATION.—

''(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

''(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

''(3) DEFINITION.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'therapeutic category' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of enactment of this subsection.

''(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

''(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of enactment of this subsection and before October 1, 2012.''.

SEC. 2___. REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this subtitle has—

(1) encouraged the development of new antibiotics and other drugs; and

(2) prevented or delayed timely generic drug entry into the market.

AMENDMENT NO. 1026, AS MODIFIED

At the appropriate place, insert the following:

SEC. ___. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study based on a comparison with equivalent products manufactured, distributed, or sold in the U.S. (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, the Department of Commerce, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

AMENDMENT NO. 987, AS MODIFIED

At the appropriate place, insert the following:

SEC. ___. HEAD START ACT AMENDMENT IMPOSING PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

The Head Start Act (42 U.S.C. 9831 et seq.) is amended by adding at the end the following:

''SEC. 657A. PARENTAL CONSENT REQUIREMENT FOR NONEMERGENCY INTRUSIVE PHYSICAL EXAMINATIONS.

''(a) IN GENERAL.—A Head Start agency shall obtain written parental consent before administration of any nonemergency intrusive physical examination of a child in connection with participation in a program under this subchapter.

''(b) DEFINITION.—The term 'nonemergency intrusive physical examination' means, with respect to a child, a physical examination that—

''(1) is not immediately necessary to protect the health or safety of the child involved or the health or safety of another individual; and

''(2) requires incision or is otherwise invasive, or involves exposure of private body parts.''.

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit agencies from using established methods, for handling cases of suspected or known child abuse and neglect, that are in compliance with applicable Federal, State, or tribal law.

AMENDMENT NO. 1006, AS MODIFIED

Strike section 505(o)(6)(C)(i) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and insert the following:

''(i) health care providers who prescribe the drug have particular training or experience, or are specially certified (which training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at minimal cost to the provider);''.

Add at the end of section 505(o)(6)(F) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, the following: ''The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 561.''.

AMENDMENT NO. 1005, AS MODIFIED

At the appropriate place, insert the following:

SEC. ___. SAFETY OF FOOD ADDITIVES.

Not later than 90 days after the date of enactment of this Act, the Food and Drug Administration shall issue a report on the question of whether substances used to preserve the appearance of fresh meat may create any health risks, or mislead consumers.

AMENDMENT NO. 1004, AS MODIFIED

At the end of the bill, add the following:

TITLE ____—DOMESTIC PET TURTLE MARKET ACCESS

SEC. ___. SHORT TITLE.

This title may be cited as the ''Domestic Pet Turtle Market Access Act of 2007''.

SEC. ___. FINDINGS.

Congress makes the following findings:

(1) Pet turtles less than 10.2 centimeters in diameter have been banned for sale in the United States by the Food and Drug Administration since 1975 due to health concerns.

(2) The Food and Drug Administration does not ban the sale of iguanas or other lizards, snakes, frogs, or other amphibians or reptiles that are sold as pets in the United States that also carry salmonella bacteria. The Food and Drug Administration also does not require that these animals be treated for salmonella bacteria before being sold as pets.

(3) The technology to treat turtles for salmonella, and make them safe for sale, has greatly advanced since 1975. Treatments exist that can nearly eradicate salmonella from turtles, and individuals are more aware of the causes of salmonella, how to treat salmonella poisoning, and the seriousness associated with salmonella poisoning.

(4) University research has shown that these turtles can be treated in such a way that they can be raised, shipped, and distributed without having a recolonization of salmonella.

(5) University research has also shown that pet owners can be equipped with a treatment regimen that allows the turtle to be maintained safe from salmonella.

(6) The Food and Drug Administration should allow the sale of turtles less than 10.2 centimeters in diameter as pets as long as the sellers are required to use proven methods to treat these turtles for salmonella.

SEC. ___. SALE OF BABY TURTLES.

Notwithstanding any other provision of law, the Food and Drug Administration shall not restrict the sale by a turtle farmer, wholesaler, or commercial retail seller of a turtle that is less than 10.2 centimeters in diameter as a pet if—

(1) the State or territory in which such farmer is located has developed a regulatory process by which pet turtle farmers are required to have a State license to breed, hatch, propagate, raise, grow, receive, ship, transport, export, or sell pet turtles or pet turtle eggs;

(2) such State or territory requires certification of sanitization that is signed by a veterinarian who is licensed in the State or territory, and approved by the State or territory agency in charge of regulating the sale of pet turtles;

(3) the certification of sanitization requires each turtle to be sanitized or treated for diseases, including salmonella, and is dependant upon using the Siebeling method, or other such proven non-antibiotic method, to make the turtle salmonella-free; and

(4) the turtle farmer or commercial retail seller includes, with the sale of such a turtle, a disclosure to the buyer that includes—

(A) information regarding—

(i) the possibility that salmonella can recolonize in turtles;

(ii) the dangers, including possible severe illness or death, especially for at-risk people who may be susceptible to salmonella poisoning, such as children, pregnant women, and others who may have weak immune systems, that could result if the turtle is not properly handled and safely maintained;

(iii) the proper handling of the turtle, including an explanation of proper hygiene such as handwashing after handling a turtle; and

(iv) the proven methods of treatment that, if properly applied, keep the turtle safe from salmonella;

(B) a detailed explanation of how to properly treat the turtle to keep it safe from salmonella, using the proven methods of treatment referred to under subparagraph (A), and how the buyer can continue to purchase the tools, treatments, or any other required item to continually treat the turtle; and

(C) a statement that buyers of pet turtles should not abandon the turtle or abandon it outside, as the turtle may become an invasive species to the local community, but should instead return them to a commercial retail pet seller or other organization that would accept turtles no longer wanted as pets.

SEC. ___. FDA REVIEW OF STATE PROTECTIONS.

The Commissioner of Food and Drugs may, after providing an opportunity for the affected State to respond, restrict the sale of a turtle only if the Secretary of Health and Human Services determines that the actual implementation of State health protections described in this title are insufficient to protect consumers against infectious diseases acquired from such turtle at the time of sale.

AMENDMENT NO. 1041, AS MODIFIED

At the appropriate place, insert the following:

SEC. ___. IMPROVING GENETIC TEST SAFETY AND QUALITY.

Not later than 30 days after the date of enactment of this Act, the Secretary shall enter into a contract with the Institute of Medicine to conduct a study to assess the overall safety and quality of genetic tests and prepare a report that includes recommendations to improve Federal oversight and regulation of genetic tests. Such study shall take into consideration relevant reports by the Secretary's Advisory Committee on Genetic Testing and other groups and shall be completed not later than 1 year after the date on which the Secretary entered into such contract.

AMENDMENT NO. 1019

(Purpose: To express the sense of the Senate concerning orphan disease treatment in children)

At the appropriate place, insert the following:

SEC. ___. ORPHAN DISEASE TREATMENT IN CHILDREN.

(a) FINDING.—The Senate finds that parents of children suffering from rare genetic diseases known as orphan diseases face multiple obstacles in obtaining safe and effective treatment for their children due mainly to the fact that many Food and Drug Administration-approved drugs used in the treatment of orphan diseases in children may not be approved for pediatric indications.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Food and Drug Administration should enter into a contract with the Institute of Medicine for the conduct of a study concerning measures that may be taken to improve the likelihood that Food and Drug Administration-approved drugs that are safe and effective in treating children with orphan diseases are made available and affordable for pediatric indications.

AMENDMENT NO. 1053

(Purpose: To modify provisions related to pediatric testing and medical products)

On page 226, line 4, strike ''later'' and insert ''if the determination made under subsection (d)(3) is made less''.

On page 228, line 3, strike ''later'' and insert ''if the determination made under subsection (d)(3) is made less''.

On page 233, line 12, insert '', such as expertise in child and adolescent psychiatry,'' after ''expertise''.

On page 233, line 15, strike ''including'' and insert ''which may include''.

On page 233, between lines 18 and 19, insert the following:

''(C) ACTION BY COMMITTEE.—The committee established under this paragraph may perform a function under this section using appropriate members of the committee under subparagraph (B) and need not convene all members of the committee under subparagraph (B) in order to perform a function under this section.

''(D) DOCUMENTATION OF COMMITTEE ACTION.—The committee established under this paragraph shall document for each function under paragraphs (2) and (3), which members of the committee participated in such function.

On page 234, line 1, strike ''determine'' and insert ''make a recommendation to the Secretary''.

On page 235, line 2, strike ''and''.

On page 235, line 6, strike ''.'';'' and insert ''; and''

On page 235, between lines 6 and 7, insert the following:

''(H) the number of times the committee established under paragraph (1) made a recommendation to the Secretary under paragraph (3), the number of times the Secretary did not follow such a recommendation to accept reports under subsection (d)(3), and the number of times the Secretary did not follow such a recommendation to reject such reports under section (d)(3).

''(5) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505B(f)(1).'';

On page 260, lines 17 through 19, strike ''of a letter, or a written request under section 505A that was declined by the sponsor or holder'' and insert ''of a written request under section 505A that was declined by the sponsor or holder, or a letter referencing such declined written request,''.

On page 261, line 3, strike ''appropriate'' and insert ''appropriate, for the labeled indication or indications,''.

On page 263, line 14, insert '', such as expertise in child and adolescent psychiatry,'' after ''expertise''

On page 263, between lines 19 and 20, insert the following and redesignate the remaining paragraphs accordingly:

''(2) ACTION BY THE COMMITTEE.—The committee established under paragraph (1) may perform a function under this section using appropriate members of the committee under paragraph (1) and need not convene all members of the committee under paragraph (1) in order to perform a function under this section.

''(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee established under this paragraph shall document for each function under paragraph (4) or (5), which members of the committee participated in such function.

On page 265, between lines 18 and 19, insert the following:

''(7) COMMITTEE.—The committee established under paragraph (1) is the committee established under section 505A(f)(1).

On page 289, line 16, strike ''**SURVEILLANCES**'' and insert ''**POSTMARKET SURVEILLANCE**''.

On page 289, line 17, strike ''SURVEILLANCES'' and insert ''SURVEILLANCE''.

On page 290, strike lines 9 through 12 and insert the following:

''(iii) that is intended to be—

''(I) implanted in the human body for more than 1 year; or

''(II) a life-sustaining or life-supporting device used outside a device user facility.

On page 290, line 15, strike ''of an'' and all that follows through ''section 510(k) only for'' on line 19, and insert ''or clearance of''.

AMENDMENT NO. 1050

(Purpose: To provide for color certification reports)

At the end of the bill, add the following:

SEC. ___. COLOR CERTIFICATION REPORTS.

Section 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e) is amended by adding at the end the following:

''(g) COLOR CERTIFICATION REPORTS.—Not later than—

''(1) 90 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a performance report for such fiscal year on the number of batches of color additives approved, the average turn around time for approval, and quantifiable goals for improving laboratory efficiencies; and

''(2) 120 days after the close of a fiscal year in which color certification fees are collected, the Secretary shall submit to Congress a financial report for such fiscal year that includes all fees and expenses of the color certification program, the balance remaining in the fund at the end of the fiscal year, and anticipated costs during the next fiscal year for equipment needs and laboratory improvements of such program.''.

AMENDMENT NO. 1049, AS MODIFIED

Beginning on page 104, strike line 23 and all that follows through line 14 on page 105 and insert the following:

''(II) the amount equal to one-fifth of the excess amount in item (bb), provided that—

''(aa) the amount of the total appropriation for the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of the total appropriation for the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1); and

''(bb) the amount of the total appropriations for the process of human drug review at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) exceeds the amount of appropriations for the process of human drug review at the Food and Drug Administration for fiscal year 2007 (excluding the amount of fees appropriated for such fiscal year), adjusted as provided under subsection (c)(1).

In making the adjustment under subclause (II) for any fiscal year 2008 through 2012, subsection (c)(1) shall be applied by substituting '2007' for '2008.'''.

At the appropriate place, insert the following:

SEC. ___. PROHIBITION ON IMPORTATION FROM A FOREIGN FOOD FACILITY THAT DENIES ACCESS TO FOOD INSPECTORS.

Notwithstanding any other provision of law, no food product may be imported into the United States that is the product of a foreign facility registered under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) that refuses to permit United States inspectors, upon request, to inspect such facility or that unduly delays access to United States inspectors.

At the appropriate place, insert the following:

SEC. ___. COUNTERFEIT-RESISTANT TECHNOLOGIES.

Notwithstanding any other provision of this Act, the requirement that the Secretary of Health and Human Services certify that the implementation of the title of this Act relating to the Importation of Prescription Drugs will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer shall not apply to the requirement that the Secretary require that the packaging of any prescription drug incorporates—

(1) not later than 18 months after the date of enactment of this Act, a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) unique to each package of such drug, applied at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing); and

(2) not later than 24 months after the date of enactment of this Act for the 50 prescription drugs with the highest dollar volume of sales in the United States, based on the calendar year that ends of December 31, 2007, and, not later than 30 months after the date of enactment of this Act for all other prescription drugs—

(A) overt optically variable counterfeit-resistant technologies that—

(i) are visible to the naked eye, providing for visual identification of product authenticity without the need for readers, microscopes, lighting devices, or scanners;

(ii) are similar to that used by the Bureau of Engraving and Printing to secure United States currency;

(iii) are manufactured and distributed in a highly secure, tightly controlled environment; and

(iv) incorporate additional layers of nonvisible convert security features up to and including forensic capability; or

(B) technologies that have a function of security comparable to that described in subparagraph (A), as determined by the Secretary.

At the appropriate place, insert the following:

SEC. ___. ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary of Health and Human Services to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') is authorized to, by regulation, enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(c) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit to Congress a report that—

(1) describes the specifics of the aquaculture and seafood inspection program;

(2) describes the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported, for the purpose of identifying the processing plant of origin of such products; and

(3) provides for an assessment of the risks associated with particular contaminants and banned substances.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

At the appropriate place, insert the following:

SEC. ___. SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.

(a) FINDINGS.—The Senate makes the following findings:

(1) Innovation in developing life-saving prescription drugs saves millions of lives around the world each year.

(2) The responsible protection of intellectual property is vital to the continued development of new and life-saving drugs and future growth of the United States economy.

(3) In order to maintain the global competitiveness of the United States, the United States Trade Representative's Office of Intellectual Property and Innovation develops and implements trade policy in support of vital American innovations, including innovation in the pharmaceutical and medical technology industries.

(4) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.

(5) Strong and fair intellectual property protection, including patent, copyright, trademark, and data protection plays an integral role in fostering economic growth and development and ensuring patient access to the most effective medicines around the world.

(6) There are concerns that certain countries have engaged in unfair price manipulation and abuse of compulsory licensing. Americans bear the majority of research and development costs for the world, which could undermine the value of existing United States pharmaceutical patents and could impede access to important therapies.

(7) There is a growing global threat of counterfeit medicines and increased need for the United States Trade Representative and other United States agencies to use available trade policy measures to strengthen laws and enforcement abroad to prevent harm to United States patients and patients around the world.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the United States Trade Representative should use all the tools at the disposal of the Trade Representative to address violations and other concerns with intellectual property, including through—

(A) bilateral engagement with United States trading partners;

(B) transparency and balance of the annual ''Special 301'' review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants trade preferences;

(C) negotiation of responsible and fair intellectual property provisions as part of bilateral and regional trade agreements; and

(D) multilateral engagement through the World Trade Organization (WTO); and

(2) the United States Trade Representative should develop and submit to Congress a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

At the appropriate place, insert the following:

SEC. ___. CONSULTATION REGARDING GENETICALLY ENGINEERED SEAFOOD PRODUCTS.

The Commissioner of Food and Drugs shall consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

At the appropriate place, insert the following:

SEC. ___. REPORT ON THE MARKETING OF CERTAIN CRUSTACEANS.

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Secretary of Commerce, shall submit to the Health, Education, Labor, and Pensions Committee and the Committee on Commerce, Science, and Transportation of the Senate, a report on the differences between taxonomy of species of lobster in the subfamily *Nephropinae*, and species of langostino, specifically from the infraorder *Caridea* or *Anomura*. This report shall also describe the differences in consumer perception of such species, including such factors as taste, quality, and value of the species.

AMENDMENT NO. 1047

(Purpose: To modify provisions relating to direct-to-consumer advertisements)

Strike subparagraphs (E) and (F) of section 505(o)(5) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and insert the following:

''(E) SPECIFIC DISCLOSURES.—

''(i) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(ii) DATE OF APPROVAL.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and disclosure of a serious risk would be false or misleading, the risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

''(iii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may specify the advertisements required to include a specific disclosure under clause (i) or (ii).

''(iv) REQUIRED SAFETY SURVEILLANCE.—If the approved risk evaluation and mitigation strategy for a drug requires the specific disclosure under clause (ii), the Secretary shall—

''(I) consider identifying and assessing all serious risks of using the drug to be a priority safety question under subsection (k)(3)(B);

''(II) not less frequently than every 3 months, evaluate the reports under subsection (k)(1) and the routine active surveillance as available under subsection (k)(3) with respect to such priority drug safety question to determine whether serious risks that might occur among patients expected to be treated with the drug have been adequately identified and assessed;

''(III) remove such specific disclosure requirement as an element of such strategy if such serious risks have been adequately identified and assessed; and

''(IV) consider whether a specific disclosure under clause (i) should be required.

On page 101, strike lines 7 through 9.

At the end of the bill, add the following:

SEC. ___. CIVIL PENALTIES; DIRECT-TO-CONSUMER ADVERTISEMENT.

(a) CIVIL PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g)(1) Any applicant (as such term is used in section 505(o)) who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading and a violation of section 502(n) shall be liable to the United States for a civil penalty in an amount not to exceed $150,000 for the first such violation in any 3-year period, and not to exceed $300,000 for each subsequent violation committed after the applicant has been penalized under this paragraph any time in the preceding 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as 1 violation.

''(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the applicant to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the applicant to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

''(3) Upon the request of the applicant to be assessed a civil penalty, the Secretary, in determining the amount of a civil penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the applicant submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the applicant submitted the advertisement for prereview if required under section 505(o)(5)(D).

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the applicant disseminated the advertisement before the end of the 45-day comment period.

''(D) Whether the applicant failed to incorporate any comments made by the Secretary with regard to the advertisement or a similar advertisement into the advertisement prior to its dissemination.

''(E) Whether the applicant ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the applicant had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the applicant who created the advertisement acted in good faith.

''(I) Whether the applicant who created the advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

''(J) The scope and extent of any voluntary, subsequent remedial action by the applicant.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no applicant shall be required to pay a civil penalty under paragraph (1) if the applicant submitted the advertisement to the Secretary and disseminated such advertisement after incorporating any comment received from the Secretary.

''(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the applicant of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

''(5) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owned by the United States to the applicant charged.

''(6) Any applicant who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such applicant resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

''(7) If any applicant fails to pay an assessment of a civil penalty—

''(A) after the order making the assessment becomes final, and if such applicant does not file a petition for judicial review of the order in accordance with paragraph (6); or

''(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.''.

(b) DIRECT-TO-CONSUMER ADVERTISEMENT.—

(1) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by inserting after the first sentence the following: ''In the case of an advertisement for a prescription drug presented directly to consumers in television or radio format that states the name of the drug and its conditions of use, the major statement relating to side effects, contraindications, and effectiveness referred to in the previous sentence shall be stated in a clear and conspicuous (neutral) manner.''.

(2) REGULATIONS TO DETERMINE NEUTRAL MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement, relating to side effects, contraindications, and effectiveness of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by paragraph (1)) is presented in the manner required under such section.

AMENDMENT NO. 1056

(Purpose: To require the FDA to conduct consumer testing to determine the appropriateness of the labeling requirements for indoor tanning devices)

At the appropriate place, insert the following:

SEC. ___. REPORT BY THE FOOD AND DRUG ADMINISTRATION REGARDING LABELING INFORMATION ON THE RELATIONSHIP BETWEEN THE USE OF INDOOR TANNING DEVICES AND DEVELOPMENT OF SKIN CANCER OR OTHER SKIN DAMAGE.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall determine—

(1) whether the labeling requirements for indoor tanning devices, including the positioning requirements, provide sufficient information to consumers regarding the risks that the use of such devices pose for the development of irreversible damage to the eyes and skin, including skin cancer; and

(2)(A) whether modifying the warning label required on tanning beds to read, ''Ultraviolet radiation can cause skin cancer'', or any other additional warning, would communicate the risks of indoor tanning more effectively; or

(B) whether there is no warning that would be capable of adequately communicating such risks.

(b) CONSUMER TESTING.—In making the determinations under subsection (a), the Secretary shall conduct appropriate consumer testing, using the best available methods for determining consumer understanding of label warnings.

(c) PUBLIC HEARINGS; PUBLIC COMMENT.—The Secretary shall hold public hearings and solicit comments from the public in making the determinations under subsection (a).

(d) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to the Congress a report that provides the determinations under subsection (a). In addition, the Secretary shall include in the report the measures being implemented by the Secretary to significantly reduce the risks associated with indoor tanning devices.

AMENDMENTS NOS. 1039, 998, AND 1034, EN BLOC

Mr. BROWN. I now call up amendments Nos. 1039, 998 and 1034, en bloc, and ask that once they are reported by number they be set aside.

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

The legislative clerk read as follows:

The Senator from Ohio [Mr. BROWN], for Mr. GRASSLEY and for Mr. DURBIN, proposes amendments Nos. 1039, 998, 1034, en bloc.

The amendments are as follows:

AMENDMENT NO. 1039

(Purpose: To clarify the authority of the Office of Surveillance and Epidemiology with respect to postmarket drug safety pursuant to recommendations by the Institute of Medicine).

At the end of subtitle E of title II, insert the following:

SEC. 2__. AUTHORITY OF THE OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY.

With respect to all actions of the Food and Drug Administration related to postmarketing drug safety, including labeling changes, postapproval studies, and restrictions on distribution or use of drugs with serious risks, the Office of Surveillance and Epidemiology (or successor office) of such Administration and the Office of New Drugs (or successor office) of such Administration shall make decisions jointly. In the event of a disagreement with respect to an action related to postmarketing drug safety, including labeling changes, postapproval studies, and restrictions on distribution or use of drugs with serious risks, between such 2 offices, the Commissioner of Food and Drugs shall make the decision with respect to such action.

AMENDMENT NO. 998

(Purpose: To provide for the application of stronger civil penalties for violations of approved risk evaluation and mitigation strategies)

At the appropriate place in section 505(o) of the Federal, Food, Drug, and Cosmetic, as added by section 202, insert the following:

''(9) CIVIL MONETARY PENALTY.—Notwithstanding any other provision of this Act, an applicant (as such term is defined for purposes of this section) that knowingly fails to comply with a requirement of an approved risk evaluation and mitigation strategy under this subsection shall be subject to a civil money penalty of $250,000 for the first 30-day period that the applicant is in noncompliance, and such amount shall double for every 30-day period thereafter that the requirement is not complied with, not to exceed $2,000,000.''.

AMENDMENT NO. 1034

(Purpose: To reduce financial conflict of interest in FDA Advisory Panels)

In title II, strike subtitle D and insert the following:

Subtitle D—Conflicts of Interest

SEC. 241. CONFLICTS OF INTEREST.

(a) IN GENERAL.—Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by inserting at the end the following:

''SEC. 712. CONFLICTS OF INTEREST.

''(a) DEFINITIONS.—For purposes of this section:

''(1) ADVISORY COMMITTEE.—The term 'advisory committee' means an advisory committee under the Federal Advisory Committee Act that provides advice or recommendations to the Secretary regarding activities of the Food and Drug Administration.

''(2) FINANCIAL INTEREST.—The term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

''(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

''(1) RECRUITMENT.—

''(A) IN GENERAL.—Given the importance of advisory committees to the review process at the Food and Drug Administration, the Secretary, through the Office of Women's Health, the Office of Orphan Product Development, the Office of Pediatric Therapeutics, and other offices within the Food and Drug Administration with relevant expertise, shall develop and implement strategies on effective outreach to potential members of advisory committees at universities, colleges, other academic research centers, professional and medical societies, and patient and consumer groups. The Secretary shall seek input from professional medical and scientific societies to determine the most effective informational and recruitment activities. The Secretary shall also take into account the advisory committees with the greatest number of vacancies.

''(B) RECRUITMENT ACTIVITIES.—The recruitment activities under subparagraph (A) may include—

''(i) advertising the process for becoming an advisory committee member at medical and scientific society conferences;

''(ii) making widely available, including by using existing electronic communications channels, the contact information for the Food and Drug Administration point of contact regarding advisory committee nominations; and

''(iii) developing a method through which an entity receiving funding from the National Institutes of Health, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, or the Veterans Health Administration can identify a person who the Food and Drug Administration can contact regarding the nomination of individuals to serve on advisory committees.

''(2) EVALUATION AND CRITERIA.—When considering a term appointment to an advisory committee, the Secretary shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subsection (c)(3) of this section for service on the committee at a meeting of the committee.

''(3) PARTICIPATION OF GUEST EXPERT WITH FINANCIAL INTEREST.—Notwithstanding any other provision of this section, an individual with a financial interest with respect to any matter considered by an advisory committee may be allowed to participate in a meeting of an advisory committee as a guest expert if the Secretary determines that the individual has particular expertise required for the meeting. An individual participating as a guest expert may provide information and expert opinion, but shall not participate in the discussion or voting by the members of the advisory committee.

''(c) GRANTING AND DISCLOSURE OF WAIVERS.—

''(1) IN GENERAL.—Prior to a meeting of an advisory committee regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of

the committee who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

''(2) FINANCIAL INTEREST OF ADVISORY COMMITTEE MEMBER OR FAMILY MEMBER.—No member of an advisory committee may vote with respect to any matter considered by the advisory committee if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

''(3) WAIVER.—The Secretary may grant a waiver of the prohibition in paragraph (2) if such waiver is necessary to afford the advisory committee essential expertise.

''(4) LIMITATIONS.—

''(A) ONE WAIVER PER COMMITTEE MEETING.—Notwithstanding any other provision of this section, with respect to each advisory committee, the Secretary shall not grant more than 1 waiver under paragraph (3) per committee meeting.

''(B) SCIENTIFIC WORK.—The Secretary may not grant a waiver under paragraph (3) for a member of an advisory committee when the member's own scientific work is involved.

''(5) DISCLOSURE OF WAIVER.—Notwithstanding section 107(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

''(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but in no case later than 15 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet website of the Food and Drug Administration—

''(i) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

''(ii) the reasons of the Secretary for such determination, certification, or waiver.

''(B) LESS THAN 30 DAYS IN ADVANCE.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code) on the Internet website of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

''(d) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(5) (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 552a of title 5, United States Code).

''(e) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(1) with respect to the fiscal year that ended on September 30 of the previous year, the number of vacancies on each advisory committee, the number of nominees received for each committee, and the number of such nominees willing to serve;

''(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(5) for each meeting of each advisory committee and the percentage of individuals to whom such disclosures did not apply who served on such committee for each such meeting;

''(3) with respect to such year, the number of times the disclosures required under subsection (c)(5) occurred under subparagraph (B) of such subsection; and

''(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

''(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review guidance of the Food and Drug Administration regarding conflict of interest waiver determinations with respect to advisory committees and update such guidance as necessary.''.

(b) CONFORMING AMENDMENT.—Section 505(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(n)) is amended by—

(1) striking paragraph (4); and

(2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (4), (5), (6), and (7), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on October 1, 2007.

The PRESIDING OFFICER. The amendments are set aside.

The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I congratulate everybody on reaching the point we just reached with the unanimous consent agreement that was done. I thank the Senator from Ohio for his tremendous work on the committee and then on the floor, and on working through some of these amendments.

I particularly thank Senator KENNEDY for his efforts. He is having a spectacular day. I am sure actually he is probably on a plane again now. He represented the United States at the unification treaty signing in Ireland today. He left as soon as we finished voting last night, traveled through the night, attended that ceremony, and will travel virtually through the night tonight to get back again so he will be here for tomorrow morning's votes.

That is just the kind of tireless dedication that he puts in on international issues, as well as the issues that come before our committee. I am very impressed with the stamina he has and the capability he has to do all these things.

This has been a long road and it has had a few lumps in it, but there has been cooperation on both sides. The staff people who have worked on this have gone into excruciating detail on every amendment to make sure it would do what people said it would do and that it would work, both in a United States context and in an international context.

I think we have progressed to a point where we can do three votes and then final passage tomorrow and have this on the way to having the Food and Drug Administration reformed so they have more tools in the toolbox and can get the job done that we have always been expecting, and have more confidence that our food and drug supply in the United States will be safe.

Everybody has been tremendously cooperative. We look forward to finishing in the morning.

I yield the floor.

Mr. KOHL. Mr. President, I rise to elaborate on a food safety amendment that has been accepted on both sides.

Under current law, the FDA's most decisive legal recourse for dealing with suspect food imports is to stop them at our boarder. My amendment strengthens the FDA's hand by providing explicit authority under section 415 of the Federal Food, Drug and Cosmetics Act, to proactively deny entry of all food products from questionable suppliers if they fail to cooperate and allow timely inspection of their facilities.

Events of recent weeks have made clear that the FDA's ability to inspect foreign food is inadequate. In the case of melamine tainted wheat gluten from China, FDA inspectors were forced to wait more than 2 weeks before the Chinese Government would grant them access. Two weeks is unacceptable. There is simply no excuse for such delays if you want to ship food into this country. FDA must be able to respond quickly to identify threats and protect public health and safety.

My amendment provides a succinct and direct legal basis for the FDA to seek access and inspect foreign food facilities on demand. If a foreign exporter to the United States delays access for FDA inspectors unnecessarily, the FDA can stop all food imports from that firm immediately thereby denying them access to our markets. If an exporter does not want to let the FDA inspect its firm—on FDA's schedule—that exporter can't ship to this country. It is that simple. For the vast majority of firms and countries, this is not a problem. But for those times it is needed, it will be an important tool.

This amendment will not fix all of the problems that are out there. This Congress needs to do some thorough oversight and develop a comprehensive plan to improve food safety and security. I intend to participate in that process and will exercise my prerogatives as chairman of the Agriculture Appropriations Subcommittee to see that the FDA follows through.

Again, I appreciate the help of Senators KENNEDY and ENZI and their talented staff in getting this amendment included in this bill. They have been very helpful, and I look forward to providing them any assistance they need in order to keep this in conference.

AMENDMENT NO. 993

Mr. GREGG. Mr. President, last week, the FDA just sent out a warning to American consumers regarding purchasing medications from certain Internet sites because the FDA cannot verify that the drugs purchased over those sites are going to be safe or that they won't be counterfeit. We need to give the FDA the authority and the resources to address the issue of unsafe Internet pharmacies and the Gregg Internet pharmacy amendment does just that. It creates a comprehensive framework to assure consumers that they can shop with confidence, knowing that the drugs they purchase online will be safe and effective. Hopefully, we will address this important and timely drug safety issue, if not now, at least before this bill completes the whole process and comes back from the conference committee

Mr. KENNEDY. I thank the Senator from New Hampshire for his interest and work on this important issue. Ensuring that people have access to safe and effective medications when purchasing prescription drugs online is an important part of our efforts in the area of drug safety. The Dorgan legislation in this bill includes some provisions on the issue of Internet pharmacies, but I am willing to work with my colleague and our colleagues in the Senate to enhance these provisions to address the important issues he has raised over the course of this debate.

Mr. ENZI. I would also like to take the opportunity to express my support for the need to address the issue of unsafe Internet pharmacies. We have worked very hard in other portions of this bill to ensure the safety of prescription drugs on the market, and as this bill advances, I look forward to working with you both to enhance the provisions in this bill relating to the safety of Internet pharmacies.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

MORNING BUSINESS

Mr. BROWN. I ask unanimous consent that there now be a period of morning business with Senators permitted to speak therein for up to 10 minutes.

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

IN RECOGNITION OF TOM CLEWELL

Mr. REID. Mr. President, I rise today to recognize the contributions of Tom Clewell to Sparks, NV. After serving the city of Sparks for more than 36 years, Tom retired from his 3-year post as fire chief on May 4, 2007.

Tom is a native Nevadan, attending school in Reno and raising a family in Sparks. He joined the Sparks Fire Department as a temporary firefighter in April 1971, and eventually climbed the ranks to become the city's 10th fire chief in its history. He served in many roles throughout his time with the Sparks Fire Department including operator, captain, battalion chief, and division chief.

Throughout his 36 years, Tom led the fire department through many changes in Sparks. For example, Tom reorganized the department creating four division chiefs. Tom also encouraged greater training of firefighters in Sparks. He also managed the rapid growth surrounding Sparks and introduced fire prevention measures as housing developments began heading toward the foothills.

Upon his retirement, the city manager of Sparks said, ''Tom has been one of the greatest leaders I have ever been associated with.'' That quote speaks volumes about Tom's leadership. I have known Tom for many years. His professional accomplishments are numerous, but I think Tom would likely describe his family as his greatest honor. He is the proud father to Angela and Lindsey. He shares in this joy with his wife Francine.

I am privileged to have the opportunity to honor Tom Clewell before the United States Senate today. I am certain that in his retirement Tom will continue to serve the citizens of Sparks with the dedication he has shown over the past 36 years and I wish him well on his future endeavors.

GENOCIDE ACCOUNTABILITY ACT

Mr. DURBIN. Mr. President, S. 888, the Genocide Accountability Act, is the first legislation produced by the Senate Judiciary Committee's new Subcommittee on Human Rights and the Law, which I chair. It is bipartisan legislation that I introduced with Senator TOM COBURN, ranking member of the Human Rights and the Law Subcommittee, Senator PATRICK LEAHY, chairman of the Judiciary Committee, and Senator JOHN CORNYN.

The Genocide Accountability Act would close a legal loophole that prevents the U.S. Justice Department from prosecuting individuals who have committed genocide. Under current law, genocide is only a crime if it is committed within the United States or by a U.S. national outside the United States. The Genocide Accountability Act would amend 18 U.S.C. 1091, the Genocide Convention Implementation Act, to allow prosecution of non-U.S. nationals who are brought into or found in the United States for genocide committed outside the United States.

I recently received a letter from David Scheffer, U.S. Ambassador at Large for War Crimes from 1997 to 2001, which makes clear the impact that the Genocide Accountability Act could have. Ambassador Scheffer's letter explains that the loophole in our genocide law hindered the U.S. Government's efforts to secure the apprehension and prosecution of former Cambodian dictator Pol Pot, one of the worst war criminals of the 20th century. If the Genocide Accountability Act had been law when Pol Pot was alive and at large, maybe the United States would have been able to bring him to justice.

The Genocide Accountability Act recently passed the Senate unanimously. I am hopeful that in short order the House of Representatives will pass it and the President will sign it into law.

The United States should have the ability to bring to justice individuals who commit genocide, regardless of where their crime takes place and regardless of whether they are a U.S. national. The Genocide Accountability Act would end this immunity gap in U.S. law.

Mr. President, I ask unanimous consent to have Ambassador Scheffer's letter to which I referred printed in the RECORD.

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

CENTER FOR INTERNATIONAL
HUMAN RIGHTS,
April 6, 2007.

Re lost opportunities to achieve international justice.

Senator RICHARD DURBIN,
Chairman, Subcommittee on Human Rights and the Law, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR SENATOR DURBIN: you have asked me to recount how limitations in U.S. federal law during the 1990's prevented the Clinton Administration, in which I served as U.S. Ambassador at Large for War Crimes Issues (1997–2001), from ensuring the speedy apprehension and prosecution of the former Cambodian leader, Pol Pot, on charges of genocide, crimes against humanity, or war crimes (''atrocity crimes'') prior to his death in March 1998. Because such limitations in U.S. law remain, particularly with respect to the crime of genocide, it may be useful for Members of Congress to consider how historically devastating was this lost opportunity to achieve some measure of justice for the deaths of an estimated 1.7 million Cambodians under Pol Pot's rule from 1975 to 1979.

In June 1997 the then two co-prime ministers of Cambodia, Hun Sen and Norodom Ranariddh, sent a letter to the Secretary-General of the United Nations seeking assistance to establish an international criminal tribunal that would render justice to the senior Khmer Rouge leaders, none of whom had been prosecuted with the sole exception of a highly dubious in absentia trial of Pol Pot and his foreign minister, Ieng Sary, in a Cambodia in 1979 shortly after the fall of the Khmer Rouge regime. The jointly-signed letter in June 1997 opened two pathways of action by the Clinton Administration: the first continues to this day, namely how to investigate and prosecute surviving senior Khmer Rouge leaders and bring them to justice before a credible court of proper jurisdiction; the second interrelated issue dealt with effective measures to apprehend and hold suspects in custody until they could be brought to trial.

Since no international criminal tribunal existed in 1997 that was specially designed to