Merck, or Pfizer, Glaxo, major international companies with the funds able to do this. The device companies are often small organizations—startup venture capital organizations. To tax them at this stage is going to just accelerate driving them offshore, and in many cases they in no way have the wherewithal to provide a tax for that. It is not their responsibility. It is a governmental responsibility.

The President's budget hasn't helped much either. The President's budget proposal for fiscal year 1998 reflects something other than an effort to strengthen the agency. In fact, it proposed a cut of funding for the agency. They wanted to cut the Device Center budget by 27 percent. Clearly that calls for congressional action to address the issue, to ensure that the bureaucracy, and the old ways of doing business give way to some efficiencies and accountability in this era of tight budgets.

So that alone is reason for us to move forward. Here we are now in September on PDUFA and a jeopardy of laying off—expiring and laying off—a whole bunch of people. And we are way behind the timetable that we ought to be on in terms of moving this forward.

Just on another point about the size of device companies. Of roughly 8,000 device companies that exist in United States, 88 percent have fewer than 100 employees and 72 percent have fewer than 50 employees. User fees are clearly not workable in a situation like this. And I am pleased that the bill doesn't impose those.

I have all kinds of statistics here, and all kinds of anecdotes and all kinds of stories. The bottom line is we are attempting to bring the FDA into this century. This century is almost over. We are attempting to try to take a tired, inefficient bureaucratic ideologically driven agency and introduce it to the modern era. We are trying to take advantage of these marvelous technological breakthroughs in drugs and devices and products that are occurring at an ever increasing rate around the world, but particularly in the United States, and make them available to American consumers to improve their health, to ensure their safety, to prolong their lives, to save their lives. That is why we have formed an extraordinary coalition between Republicans and Democrats. This has nothing to do with party lines, liberals, conservatives, and everybody in between. There was an almost unprecedented vote in committee of 14 to 4, and we would have had even a better vote than that if we went back and did it now because we have resolved some of the concerns that those four had. We wouldn't get all four. But we would have even a better vote—probably more like 16 to 2 because we have addressed those concerns that were raised in committee. Those Members thought that they had better reserve their vote and negotiating ability. And we resolved that.

We have done an extraordinary amount of negotiating from the time the committee passed the bill out until this point. We were that far away in July from resolving this. In the negotiations with Senator KENNEDY, we made 30-some concessions on a bill that passed 13 to 4 in order to get the approval of one person because one person could tie this thing up procedurally. We made 30-some concessions—concession after concession after concession by the chairman, this Senator, and other Senators. What is the problem? How can we fix it? Can you work it out? Can you go along with the bill, if we did that? Can you do that?

We finally threw our hands up in total exasperation because every time we thought we were at the goal line, no, move the ball back another 15 yards to another position. Take that up. Will that do it? Yes. Solve that. Then they thought of another one. There was always a reason to delay and delay. And then we went through the August recess. If we were talking about making a widget, if we were talking about something that didn't affect the health and the safety of the American people—I suppose that is just part of the process here—but we are talking about people waiting for steps that would save their lives; waiting for approval from FDA of drugs that can potentially keep them from dying, waiting for products that can make their life a little more tolerable while we play games in the U.S. Senate because one person doesn't think it is a perfect bill in front of him, even though there is a widespread majority in support of it. That is wrong.

So I am glad we are moving forward. I am sorry that we had to invoke a procedure to cut off a filibuster to do it.

I understand people may have some concerns about this bill. It is not a perfect bill. It passed through months of arduous negotiation. There has been give and take. Every Senator is free to come down here and make his point and raise his objection and offer an amendment and take a vote. If it passes, the bill will be modified. If it fails, instead of taking the ball and going home and saying we are not going to play anymore, let's just say apparently I wasn't persuasive enough, or maybe I got my facts wrong, or maybe that is not what the majority wants to do. But let's not deny health improvements and safety improvements for the American people and the American consumer just because we don't get our way. Let's move forward. We will now.

We have invoked cloture. I regret that we had to do that. I regret we had to go through the month of August waiting to reconvene, because there are people out at FDA that are going to be laid off if we do not get this thing moving. All the efforts that we have done to try to hire additional people out there will be undermined in terms of drug approval because we can't get this bill moving.

So let's move forward. Let's raise our objections. Let's have a debate. Let's have a vote and accept the result, and let's move forward with FDA reform.

Mr. President, I will have more to say about this at a later time. I have not gotten into the ''what.'' I was talking about the ''why'' here—why do we need reform. I have not gotten into what the bill includes. It is a broad bill with a lot of depth. It covers a lot of areas. It is significant reform. It is not as much as this Senator would like. It is more than some other Senators would like. But it is a big step in the right direction.

I just note for the RECORD that I don't know what is going on, Mr. President, at the White House. We have been without a commissioner now at FDA for some time. They nominated someone this week, and then withdrew the nomination 24 hours later. I don't know why. But I urge the administration to continue its search. I am going to suggest a couple of names to them of people, if they need people to look at. I don't do it with any hope that they think anybody I would suggest ought to head up FDA—not this administration. But we ought to get somebody in there who is willing to exercise the oversight and the administrative ability to work with the Congress in bringing this agency into the modern era and improving the way things are done there. There are a lot of dedicated, competent, hard-working scientists and researchers and medical personnel at FDA who deserve to have competent leadership, competent management, and deserve to have the support of this Congress in providing the funds and providing the technology and providing the assistance in expediting in an appropriate manner the bringing to market of drugs and devices that can make a difference in people's lives.

Mr. President, there is more to come later. I yield the floor.

Mr. DURBIN addressed the Chair.

The PRESIDING OFFICER (Mr. HAGEL). The Senator from Illinois.

UNANIMOUS-CONSENT AGREEMENT—S. 1061

Mr. DURBIN. Mr. President, I ask unanimous consent that it be in order to offer two amendments to S. 1061, even though the bill is not pending, and that those two amendments be laid aside.

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

AMENDMENT NO. 1078

(Purpose: To repeal the tobacco industry settlement credit contained in the Balanced Budget Act of 1997, as amended)

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself and Ms. COLLINS, proposes an amendment numbered 1078.

The amendment is as follows:

At the appropriate place, insert the following:

SEC. . REPEAL OF TOBACCO INDUSTRY SETTLEMENT CREDIT.—Subsection (k) of section

9302 of the Balanced Budget Act of 1997, as added by section 1604(f)(3) of the Taxpayer Relief Act of 1997, is repealed.

AMENDMENT NO. 1085

(Purpose: To provide for the conduct of a study and a report on efforts to improve organ and tissue donation)

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself, Mr. LEVIN, Mrs. MURRAY, Mr. JOHNSON, and Mr. BREAUX, proposes an amendment numbered 1085.

The amendment is as follows:

On page 49, after line 26, add the following:

SEC. . (a) STUDY.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the General Accounting Office, shall conduct a comprehensive study concerning efforts to improve organ and tissue procurement at hospitals. Under such study, the Secretary shall survey at least 5 percent of the hospitals who have entered into agreements with an organ procurement organization required under the Public Health Service Act and the hospital's designated organ procurement organizations to examine—

(1) the differences in protocols for the identification of potential organ and tissue donors;

(2) whether each hospital, and the designated organ procurement organization of the hospital, have a system in place for such identification of donors; and

(3) protocols for outreach to the relatives of potential organ or tissue donors.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report concerning the study conducted under subsection (a), that shall include recommendations on hospital best practices—

(1) that result in the most efficient and comprehensive identification of organ and tissue donors; and

(2) for communicating with the relatives of potential organ and tissue donors.

Mr. DURBIN. Mr. President, I ask unanimous consent those amendments be laid aside for debate at a later time.

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

AMENDMENT NO. 1086

(Purpose: To express the sense of the Senate that hospitals that have significant donor potential shall take reasonable steps to assure a skilled and sensitive request for organ donation to eligible families)

Mr. DURBIN. Mr. President, on behalf of Senator LEVIN, I would like to, on the same bill, S. 1061, offer an amendment.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself, Mr. LEVIN, Mr. THURMOND, and Mr. INOUYE, proposes an amendment numbered 1086.

The amendment is as follows:

At the appropriate place, insert the following:

SEC. . (a) FINDINGS.—Congress finds that—

(1) over 53,000 Americans are currently awaiting organ transplants;

(2) in 1996, 3,916 people on the transplant waiting list died because no organs became available for such people;

(3) the number of organ donors has grown slowly over the past several years, even though there is significant unrealized donor potential;

(4) a Gallup survey indicated that 85 percent of the American public supports organ donation, and 69 percent describe themselves as likely to donate their organs upon death;

(5) most potential donors are cared for in hospitals with greater than 350 beds, trauma services, and medical school affiliations;

(6) a recent Harvard study showed that hospitals frequently fail to offer donation services to the families of medically eligible potential organ donors;

(7) staff and administration in large hospitals often are not aware of the current level of donor potential in their institution or the current level of donation effectiveness of the institution;

(8) under titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq; 1396 et seq.), hospitals that participate in the medicare or medicaid program are required to have in place policies to offer eligible families the option of organ and tissue donation; and

(9) many hospitals have not yet incorporated systematic protocols for offering donation to eligible families in a skilled and sensitive way.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that hospitals that have organ or tissue donor potential take prompt steps to ensure that a skilled and sensitive request for organ or tissue donation is provided to eligible families by—

(1) working with the designated organ procurement organization or other suitable agency to assess donor potential and performance in their institutions;

(2) establishing protocols for organ donation that incorporate best-demonstrated practices;

(3) providing education to hospital staff to ensure adequate skills related to organ and tissue donation;

(4) establishing teams of skilled hospital staff to respond to potential organ donor situations, ensure optimal communication with the patient's surviving family, and achieve smooth coordination of activities with the designated organ procurement organization; and

(5) monitoring organ donation effectiveness through quality assurance mechanisms.

Mr. DURBIN. Mr. President, I ask unanimous consent that the amendment be laid aside for later debate.

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

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997—MOTION TO PROCEED

The Senate continued with the consideration of motion to proceed.

Mr. DURBIN. Mr. President, I would like to address the motion pending before the Senate at this time on the FDA reform bill.

I have listened very, very closely to the statements by my colleague and friend, the Senator from Indiana. I note that his comments are heartfelt about a very important agency. The Food and Drug Administration is by Federal standards a small agency. The annual appropriations is in the range of $1 billion, and by the standards of Washington, DC, it might be ignored by many. But those of us who are familiar with the important mission of the Food and Drug Administration, those of us who have worked closely with that agency and with its Commissioners over the years, and in my particular case, those of us who have had the opportunity to literally fund this agency through the Appropriations Committee of the House, understand the critical importance of this agency. Though its resources and budget may be small by Washington standards, its responsibilities are immense. There is not an American living who is not touched by the work of the FDA. They regulate things as diverse as the radar guns used by police, microwave ovens used in airplanes, and virtually all of the drugs and medical devices for sale in the United States. We count on them every day. And they are an agency, as you can tell from the previous Senator's remarks, which is not above criticism. This is an agency which has a very difficult mission. On the one hand, a person who is ill seeking a new drug or medical device wants the FDA to issue approval as quickly as possible. That is a natural reaction.

By the same token, a company with a drug or a medical device which they want to see approved is anxious for the FDA to give approval as quickly as possible. The FDA approval on a drug or medical device is better than any Good Housekeeping seal of approval. It is literally a ticket for sales, confident sales, worldwide. Once the Food and Drug Administration of the U.S. Federal Government gives its approval, you know that your medical device or your prescription drug is going to have an opportunity for a worldwide market because that approval means something.

There is another side to this ledger. The Food and Drug Administration, with the pressure to approve drugs and medical devices by not only consumers but also by manufacturers, also has an awesome responsibility to make sure that those approvals are done in the right way, so that the American consumers know that what they purchase is safe and effective.

Those are the two criteria. So the scientists and those working at the FDA put in long hours, days, weeks, months, sometimes years, to make certain that a product, before it goes on the market in the United States, is safe. While they are in the process of evaluating, there are people on the sidelines saying, what is taking so long? Why hasn't this agency moved to approve this drug or this medical device?

I have been frustrated myself when people in my old congressional district or in my State have come forward and said, it has taken months, sometimes years; why don't we have the FDA's final approval? I am sure some of that may be associated with bureaucratic slowdown, and if this bill addresses