employee education, and involved in the community. That does not mean that we need to rip down the corporations, but we need to be able to create a job and people need to be able to have a job. Corporate America has got to help with that take-home power. Corporate America has got to be a player in this system, Mr. Speaker. It has got to be sensitive to the working people, as Congress needs to be sensitive to the working people of this country.

We also need legal reform. The country has come into a sense of lawsuit madness and that in itself also has to end.

□ 2030

With all due respect, the trial lawyers are totally out of control in this country. We need to make fundamental changes in Washington, DC, to have a better, brighter, cleaner, safer future for our children.

It is about the wallet, Mr. Speaker, the money that the working people of this country put into the wallet and the money this Government takes out. And under our plan, and we want to join together with the other side of the aisle, working Americans are going to have more of their own hard earned money to spend for their futures.

WASHINGTON'S SPENDING HAS UNDERMINED OUR FUTURE

The SPEAKER pro tempore (Mr. TAYLOR of North Carolina). Under a previous order of the House, the gentleman from Pennsylvania [Mr. FOX] is recognized for 5 minutes.

Mr. FOX of Pennsylvania. Mr. Speaker, the answer for too many people lies in Washington as a solution for all problems. For decades Washington has told America that everything is OK, while it spent our children's and grandchildren's inheritance and undermined their future. For too long Washington has spent more than it takes in, spent your hard earned tax dollars unwisely just to pay for a growing bureaucracy, a bureaucracy that includes 160 different job training programs, 240 educational programs, 300 economic development programs, and 500 urban aid programs.

How has Washington afforded these programs? By raising your taxes through the roof. Just ask Bill Clinton. He was not in office 100 days before attempting to take even more of your hard earned dollars. By comparison, Republicans spent our first 100 days trying to cut taxes.

The fact is virtually every year you send more of your hard earned dollars to Washington and that leaves less for you and your family. Do you ever wonder why the President and the Democrats are asking you to sacrifice a little more so Washington could spend a little more? Should not we demand Washington spend less so that you can keep more? After all, it is your money.

It should not surprise anyone that more and more American families find it difficult to make ends meet; that more and more Americans are forced to live from paycheck to paycheck; that too many Americans want to put something away for the future but cannot; that almost everybody feels the squeeze from rising prices and higher taxes.

The Republican majority is making a difference by making sure we have a line item veto, which passed; a balanced budget. We have regulatory reform and unfunded mandate reform. All of these have led to a stronger economy and less of your tax dollars going out the window.

Against unanimous Republican opposition, the President imposed the largest tax hike in American history in 1993. The cost of the President's policies for a typical family in higher taxes and lower earnings is $2,600, and all of us have felt the crunch. The tax trap costs a lot of money, and higher taxes means less savings and a more uncertain future. The Republican policies that we have put forward and have been adopted by this House, will put our course and our financial security back on track and are making a difference every day.

What we are trying to do here is part of the revolution of change that is positive and good for all Americans. Stay tuned further.

THE TAX TRAP

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Arizona [Mr. HAYWORTH] is recognized for 5 minutes.

Mr. HAYWORTH. Mr. Speaker, this evening we have heard my colleagues talk about the tax trap, the tax trap which has enmeshed so many Americans who fall victim to this simple observation which history and simple mathematics would bear out: The harder you work and the more you succeed, the more Washington and the Washington bureaucracy takes from you.

I realize this is deadly serious business, Mr. Speaker, because we are talking about real people with real concerns and the genuine future of this Nation at stake. And not to make light of this, but to bear it out in one of its forms, I am reminded of the Walt Disney production, ''The Parent Trap,'' because the tax trap for our citizens is all too often a parent trap. This is what I mean.

So often now, across the width and breadth of this country parents, both parents, in a household are working oft-times not because of choice but because of trying to move their family beyond this tax trap. Quite often a spouse goes to work simply to try and satisfy the tax bite; simply to try to lift the family out of this hole created by more and more taxation, and the incessant need of this bureaucracy to ask for more and more money from average Americans.

My colleague from Pennsylvania articulated it, talked about the largest tax increase in American history given to this Nation by people who used to sit in the majority in this very room along with a President who said on the campaign trail that middle-class America needed tax relief, and yet turned around not 100 days into his term and gave us the largest tax increase in American history.

Now, Mr. Speaker, we have heard a lot of playground taunts, we have heard a lot of name calling. The word extreme has been bandied about, and dare I say in extreme fashion. Well, Mr. Speaker, it is fair to ask this question. For those who would throw out the word extreme with such ease, what is so wrong about asking Washington to live within its means? What is so wrong about demanding that Washington not spend so extravagantly as to sacrifice our children's future? And is it fair, Mr. Speaker, to punish working families who are playing by the rules and trying to provide for their family's future?

The good news is that this new majority in Congress, working with a lot of folks, quite candidly, on the other side of the aisle who are willing to own up to these problems, trying to move past partisan bickering, together we have fashioned a constructive way to deal with these problems, to balance our Federal budget, to roll back the tax bite and try to eliminate the tax trap; to try to save health care and Medicare for future generations without bankrupting the generations who must pay for it.

That is the mission we face, and, again, we would ask the President of the United States to join with us in a constructive program for the future.

It is a tragedy, Mr. Speaker, that our President and his term of office thus far has been defined not by accomplishments. Indeed, now, Mr. Speaker, the question is not what can the President accomplish, but, said, Mr. Speaker, the question has become, especially in the wake of recent revelations, how can this President explain it away this time? What rhetorical device, what language can he use, what verbal contortions can be brought to bear to avoid the problem and escape the responsibility?

Mr. Speaker, the American people deserve us to act responsibly, to save this Nation for today's seniors and for our children.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio [Mr. HOKE] is recognized for 5 minutes.

[Mr. HOKE addressed the House. His remarks will appear hereafter in the Extensions of Remarks.]

REFORM OF THE FOOD AND DRUG ADMINISTRATION

The SPEAKER pro tempore. Under the Speaker's announced policy of May

12, 1995, the gentleman from Pennsylvania [Mr. GREENWOOD] is recognized for 60 minutes as the designee of the majority leader.

Mr. GREENWOOD. Mr. Speaker, a number of my colleagues and I this evening have taken it upon ourselves to engage in a 1-hour special order on a very special package of bills we intend to move from the Committee on Commerce, on which we all serve, through the House of Representatives. We expect that the Senate will move its package and that we will put this package on the President's desk and that he will sign it.

The issue is reform of the Federal Food and Drug Administration.

GENERAL LEAVE

Mr. GREENWOOD. Mr. Speaker, before we proceed, I would like to ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on this special order.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

Mr. GREENWOOD. Mr. Speaker, the Food and Drug Administration was created by this Congress at the turn of the century, about 90 years ago, and the Food and Drug Administration has a very important task. Americans from all walks of life, as parents, as sons and daughters, as spouses, rely on the Food and Drug Administration to make sure that the drugs that are prescribed to us, that the food that we consume, that the medical devices that are utilized in our care and hospitals are safe and are effective.

And we are blessed because in this country we have the greatest pharmaceutical industry in the world, we have the greatest medical device industry in the world, and our people enjoy safety and the best health care in the world as a result of the work of the Food and Drug Administration. It does a very good job of making sure that the products that reach us in the marketplace, that our doctors prescribe to us, that we encounter in our hospitals are, in fact, safe and, in fact, are effective; that they do what the makers say they will do for us.

That is the good news. But there is another side of the FDA, and the problem with the FDA is the time it has taken to move these products from the research laboratory through the Federal bureaucracy of the FDA, some 10,000 employees, to those Americans who are waiting for miracle cures, for new drugs, for the latest heart transplant devices, mechanical hearts. That time is too long. It is taking 12 years, on average, to move a product, a pharmaceutical product, through the Food and Drug Administration. It costs about $350 million for a company to do it.

And I think that probably most Americans watching tonight would be surprised to learn that two-thirds of all of the drugs that are actually developed in the Untied States by our pharmaceutical companies are first available to patients overseas, not in our country at all.

So our task has been with this legislation to see if we cannot reengineer the FDA, the Food and Drug Administration; to redesign it, reform it, update it, modernize it, make it better so that as we move into the next century, the FDA can still be the gold standard for safety and efficacy but also will begin to be able to bring these miracle products and miracle cures to our people much more quickly, because patients die in America today waiting for the bureaucracy within the FDA to act.

We appreciate the FDA needs to act with caution, but we think that we can reform the FDA so that it will act much more efficiently and much more in the patient's interest.

Now, as many Americans have noticed, getting things done in this Congress is not easy. It is a partisan place. It is a place of 535 individual Members of Congress. And in a Presidential election year, an election year for most of the Congress, it is difficult to come to an accord, and particularly on an issue as important and critical as reform of the FDA.

So my colleagues who we will hear from tonight, Mr. BARTON from Texas, Mr. KLUG from Wisconsin, Mr. BURR from North Carolina, and Mr. FOX from my own State of Pennsylvania, have done something that is a little unusual lately in the Congress, and that is we have reached out from the beginning in a bipartisan fashion. We have said to our colleagues on the other side of the aisle, this issue is about life and death. This issue is about saving the lives of our children and our parents and our husbands and our wives, and we need to put partisan politics aside.

□ 2045

We need to get the job done. We need to cooperate. We need to work together. And our success to date has been, I think, miraculous. We have gathered 159 cosponsors onto our bills, Republicans and Democrats across the political spectrum.

We have reached out to the patient groups. We have talked to our fellow Americans who suffer from AIDS or who are HIV-positive. We have talked to cancer patients. We have talked to the practitioners treating those patients and talked to patients who suffer from multiple sclerosis and Lou Gehrig's disease, kids who suffer from diabetes, and Americans who suffer from coronary artery diseases and a long, long list of diseases that is extensive.

We asked them what they think we need to do to make sure that these miraculous products being developed in our universities and our laboratories are brought to those who are literally dying, to receive them more quickly; and the result has been legislation that we think is exciting, we think is innovative, and we think actually will be signed into law in 1996.

We would like to share the details of this information with America this evening. To that end, I would first like to recognize my good friend and colleague from Texas, Mr. BARTON, who is the primary sponsor and the lead on the medical devices bill. He will tell us about medical devices and what we hope to do there.

Mr. BARTON of Texas. Mr. Speaker, I thank my friend from Pennsylvania, Mr. GREENWOOD, for organizing this special order. I am pleased to be on the House floor this evening with the gentleman from Pennsylvania [Mr. GREENWOOD], the gentleman from North Carolina [Mr. BURR], the gentleman from Wisconsin [Mr. KLUG], the gentleman from Florida [Mr. BILIRAKIS], and the gentleman from Pennsylvania [Mr. FOX], as we talk about a very important issue.

Mr. Speaker, if you went out to the American people and asked them, what does FDA stand for, I doubt very seriously that very many people could say that it stand for Food and Drug Administration. I joked earlier in the year in a television interview that it stands for ''foot dragging and alibis,'' because it takes about 12 years and $350 million to get a drug and medical device through the entire gauntlet of approval steps at the FDA that are currently in place.

The people that are participating in this special order this evening, colleagues that have cosponsored the bills in a bipartisan effort, we want FDA to stand for fair decisions for all.

We have the best medical devices in the world; we have the best pharmacological drugs in the world; we have the safest food supply in the world. But more and more, our medical device companies, our pharmaceutical, innovative, companies are going overseas because the approvals do not take as long and the regulatory jungle is not as complex as it is here in this country.

To put a personal face on it, Mr. Speaker, my father is in his early 70's. He is a veteran and served his country in World War II. He was a navigator for the B–24 Liberator. Is now a diabetic and has been diagnosed within the last several months to have a slow-growing form of prostate cancer.

There are drugs in the marketplace today and procedures in the marketplace today in other countries that, were he a citizen of Great Britain or France or Germany, he would have access to those drugs and devices. Because he is a citizen of the United States, he does not.

It is very difficult for me to go to Waco, Texas, where my father lives, and say, Dad, I would like to help you, but under the current law we cannot let you use that noninvasive glucose sensor, so you do not have to prick your finger two or three times a day. Or, Dad, there is a new drug that has been approved for prostate cancer overseas, but it has not yet been approved by the FDA. If you live another 10 years, maybe it will be approved.

I cannot say that.

But I can say, Dad, in the next 3 months, I hope to be a part of a coalition of Republicans and Democrats in both the House and the Senate that passes an FDA reform package that makes those drugs and makes those devices accessible to you, not 10 years from now but next year, and maybe even in the next 5 or 6 months.

In the medical device bill that I am the chief sponsor of we have four basic principles. We do want a responsible method for third-party review where a medical device applicant can either go outside the system to an accredited third-party reviewer or can go within the system within the FDA currently to have their application reviewed.

We want a dispute resolution which is obvious in any complex situation. There are going to be disagreements. We think there needs to be some mechanism where if the applicant and the FDA have a disagreement about the application, you can get a fair resolution of that disagreement. We do not want it to be a trivial disagreement; we want it to be a substantive policy disagreement or a time disagreement. But let there be a internal dispute resolution that is actually workable.

Most Americans do not realize, but there is a cutoff date for medical device qualifications in this country. If your device was in existence before 1976, it is reviewed under a certain set of circumstances and if it came into existence after 1976, it has to go through a much more complex set of regulatory findings. We want to do away with this artificial 1976 bright line and we want all devices to be reapproved and, as they are, given an original classification and not automatically put into the most complex classification of Class III.

I think you would be surprised, Mr. Speaker, to realize that a simple piece of plastic called a breast sensor paid, which is two pieces of plastic with a silicone gel between it, about 6 inches in diameter, it took the FDA 10 years to approve the breast sensor device and then only with the use of prescription under the care of a physician, because under current law the breast sensor pad has to be classified as Class III, which would be like a heart implant.

Under our legislation, if approved and put into law, the breast sensor pad would be given a reclassification and almost certainly be put into Class I or Class II, where it would be available over the counter so that millions of American women could obtain it at a nominal fee and would be able to self-examine their breast in the privacy of their home.

The last thing that we want to insist on in the medical device bill is that all new devices be given a fair evaluation within a time certain of when they are presented. And that may again be third-party or may be within the FDA.

Mr. Speaker, I am pleased to participate in this special order. I commend Mr. GREENWOOD and, again, all the other chief sponsors that are here this evening: Mr. KLUG, Mr. BURR, the chairman of our subcommittee, Mr. BILIRAKIS of Florida, and of course Mr. FOX of Pennsylvania.

This is a bipartisan effort. It has got overwhelming support among the American people, 70 to 80 percent approval in the various polls, and we hope that before we adjourn to go home that we can have a bill on the President's desk and we think President Clinton will sign it.

I yield back to the distinguished gentleman from Pennsylvania.

Mr. GREENWOOD. Before the gentleman leaves, I want to recall the gentleman who came to our first press conference who suffered from a coronary problem where he had an artery that was closing down, and he needed a stint. Is that the right term? A stint that could be implanted in this artery to keep it open and keep the blood flowing.

He was told that his time was limited, he did not have long to live. There was a device that had been invented; I have it in my hand. I do not know that the camera can pick it up. It looks like a spring you might take out of a ball point pen. This is implanted in the artery and holds it open.

Mr. BARTON of Texas. I believe that device is available in Italy, but not in the United States.

Mr. GREENWOOD. Finish the story. He did go to Italy.

Mr. BARTON of Texas. It wasn't on the approved list in the United States it was approved in Europe. And so the gentleman went to Italy and his surgeons, I believe, flew to Italy with him, and they had the operation, and it was a success and he went mountain climbing within 6 months after the operation.

Had he stayed in the United States and waited for the FDA for approval, it is arguable that the gentleman would be dead today. He would not only not be mountain climbing, but he would not be breathing today. But because he did go overseas and was fortunate enough to have the money to go overseas, he is alive to tell the story today.

Mr. GREENWOOD. That story tells what needs to be told and what we are trying to accomplish here, and that is save lives. He was fortunate. He could afford to go to Italy and have the surgery and pay for it, but most Americans do not have that luxury.

Let me share one final point with the gentleman. We have something else in common. My dad is a B–24 liberator pilot as well.

Mr. Speaker, I would like to now yield to my colleague, the gentleman from Wisconsin [Mr. KLUG], who is the prime sponsor of the second of our three-bill package and that is the bill that would reform FDA with regard to its responsibilities for approving food products.

Mr. KLUG. Mr. Speaker, I thank the gentleman from Pennsylvania, Mr. GREENWOOD, for the time and also thank him and Chairman BLILEY and Chairman BILIRAKIS for their leadership on this proposal, as well as my colleagues from Texas and North Carolina.

Mr. Speaker, I want to go back, because I do not think we can stress this often enough, to what is at stake in FDA reform, period. Because you managed, Mr. GREENWOOD, at the end of your conversation with Mr. BARTON, I think, to put a very human face on what happens with FDA reform.

I can remember standing about 6 weeks ago in a press conference in Madison with the family of a young boy, Cody Young, who lives in Baraboo about an hour from Madison, the place where the Ringling Brothers Circus was founded. And he has a severe case of epilepsy. And the tragedy of this story, as you will hear over and over tonight, is that the original medication developed for Cody Young's severe case of epilepsy was first conceived at a United States research facility. It was tested in the United States, and it now sits essentially at the FDA's desk, ready to be approved, while the drug is already available in Switzerland. And here is Cody Young's family saying, I do not get it. Developed in the United States, first tested in the United States, ready to be marketed in the United States; and the FDA has it tangled up in bureaucratic redtape while it is available to citizens in Europe.

That is unfortunately not only the story of what happens to individual families, but also the story of individual companies. Frightening statistics say that a majority of United States medical device manufacturing companies, such as Lunar, which makes devices to check bone density, important in diagnosing osteoporosis in elderly women or, for example, a large anesthesia equipment manufacturing operation based in Madison, have considered in their recent past moving some of their operations offshore. Not only is it easier to get pharmaceutical products approved quicker overseas, but also approval of medical devices overseas, in addition, because of the liability problems we have in the United States. And we tried in this Chamber this year to fix the whole tort system and its attendant problems and dramatic costs.

The bottom line is, those companies' items, conceived in the United States, increasingly are being manufactured overseas and United States citizens will not be given access to them.

It is easy to understand why you need to care about pharmaceutical products, when they are available, and medical devices that cannot get approved, such as a child with juvenile diabetes who does not have access to noninvasive glucose testing. I talked to a little girl in Madison, 7 years old, whose fingertips are covered with scars because she has to prick them several times a day to do blood testing, where the testing machinery in Canada measures it in the sweat and you never have to prick your fingers.

Mr. Speaker, I have the middle part which is food. The Food and Drug Administration has grown so dramatically in recent years, it now covers a quarter of the Nation's economy and the first part is food. The second part is drugs, but the first part is food.

Over the years, the FDA has grown so cumbersome it has made it extraordinarily difficult for normal manufacturing operations to go on and normal farming practicing to evolve. What does that mean to you sitting in the Chamber or what does it mean if you are watching this at home? It means that it is more expensive to get food products to your shelves.

And the situation in the droughts affecting the Southwest in particular and the threat we see with wheat crops in Nebraska, it may be more difficult, for example, to help those crops spring back up. If they are hurt in the drought, they are more susceptible to disease and more susceptible to problems with insects and other calamities; and we want to make it more available, make it easier for the American farmer to grow crops and make it easier to get the products to grocery stores at a price that still is reasonable for you as a consumer.

Mr. Speaker, let me tell you a couple of issues. There are four major companies in the United States which sell food gift packages, catalogs that you get at Christmas. Three are based in Wisconsin with two in my districts. No jokes about cheeses tonight.

□ 2100

Wisconsin Cheese is located in Sun Prairie, and another one of them is located in Monroe, WI. Swiss Colony is in fact the largest gift package company in the United States. Now, when you buy something from Swiss Colony, you will notice you get those kinds of little packages of cheese or sausage or crackers, whatever the case may be. Under the Nutritional Labeling and Education Act that was passed several years ago, we have to describe in some detail the ingredients in that packaging.

They were scared to death because imagine if you have a company that manufactures millions of pounds of cheese and sausage and you have got to come up with individual labels that fit on this little 1-by-1-inch square. We worked out an agreement with the FDA at that point that says when you buy a gift box, we will have a loose-leaf sheet in it. We worked that deal out. But now the problem is all across the country.

Suddenly, municipalities and States are developing their own labeling requirements. So now for somebody like Swiss Colony, you look down the road and see that not only do you have to have federal labeling, you now have to have 50 different labels for every State that wants its own set of nutritional information. It may be that municipalities and communities and cities pass their own labeling standards as well, so you have got 50 States and thousands of communities and cities and towns. You cannot do business that way.

Folks say, wait a minute, are not Republicans for shifting power back to States? You want welfare back there, Medicaid back there. Why suddenly are you arguing about nutritional labeling? Because one of the things we are supposed to do in the Committee on Commerce is to take care of interstate commerce. We want to make sure it is easy for things to get shipped across State lines. That is why you do not have toll booths when goods move from Illinois to Wisconsin or from Pennsylvania to New York. It is one of the founding principles in our Constitution.

So, Mr. Speaker, one of the things we are trying to do in this bill is develop national nutritional labeling standards, one size fits all. You can do one label that works in California and in Florida, and one label that works in New York and Wisconsin and Washington State.

Now, a very parallel case several years ago was something called the Town of Casey decision, also involving pesticides. The question in the Town of Casey decision is that the Town of Casey decided they were going to do their own standards for putting pesticide applications on farm fields around the Town of Casey. That was the community's right to do that, until you step back for a minute and try to think of that. What if every community in the United States developed its own standards for pesticide application and pesticide labeling? And some communities said you had to call 24 hours in advance, and some said 48 hours in advance, and some said you had written notice 7 days in advance and 14 days in advance, and 7 days afterwards, and 3 days afterwards with a phone call. It would be crazy. It would make it impossible to farm in the United States.

Mr. Speaker, that was actually a Supreme Court decision, and the Town of Casey went against the town. They said we are going to have one national standard for pesticide application and for labeling and for warning. That is what we are really trying to get at. I think it is a terrific idea that today consumers can pick up any product, whether it is a chunk of cheese or whether it is a piece of chicken or a candy bar and cereal, and look at the back and understand exactly what it is you are eating: what the ingredients are, what the fat content is, what the nutritional value is.

I think we all agree. This Chamber passed that several years ago. The President signed it into law. That is terrific. But one national nutritional labeling standard only is necessary. If you do not like what is listed, then you come here to Congress and you come to the FDA to change it.

Mr. Speaker, the second point I want to make for my colleague in Pennsylvania and other people in the Chamber and folks watching at home tonight is something called the Delaney clause. Now, this is real inside baseball, so stick with me for a minute. But the Delaney clause was passed in the late 1950's to guarantee we would not have cancer in our food chain, or I should say not have products that cause cancer in our food chain.

Now, what has happened over the last 45 years is that our testing equipment has gotten extraordinarily better, and the food chain is safer than it ever was before. But Delaney says you cannot have anything in food products which might even marginally be tied to cancer, one in a billion case. In fact, the testing equipment has now gotten so good. And a story that everybody in my home State of Wisconsin strangely seems to understand is that, if you throw a glass of beer into the Great Lakes, you can detect it with today's testing equipment.

That is the kind of standard you are looking at with an individual piece of food. The food is safer than it ever was before, but the testing equipment is so much better.

Now, what happens from a practical standpoint? The honest answer is nobody enforces Delaney. We make no differentiation whatsoever between a product that causes serious cancer risk or a product that has negligible cancer risk. We simply want to bring this into today's scientific standards.

Now wait a minute; this is not some kind of crazy radical idea. You know who wanted to do this back in 1982? AL GORE. AL GORE, when he was in the U.S. Senate, decided to try to change the Delaney clause to bring it up to today's standards.

In fact, what we do in this piece of legislation is say: Wait a minute, we are not even sure we are smart enough to know how to do it. We are going to ask the Food and Drug Administration to do it. We say to them you bring it up to today's standards. We do not want to do it because it will then be seen as political or be seen as not being tough enough.

The bottom line is everybody knows Delaney does not work, and the Food and Drug Administration has got to fix it. Again, keep in mind the two fundamental points. The idea is to make farming more practicable and safer.

Second, the easier it is to farm, the easier it is to get things to the supermarket, the better selection you will have as a consumer, and the cheaper prices that you will have in front of you.

So the bottom line again in all this FDA reform, what we are really trying to accomplish tonight is to make the Food and Drug Administration more responsible to changes in science and to make the Food and Drug Administration more responsible to changes in the marketplace. It is to tell the Food and Drug Administration your first priority should be to make sure that pharmaceutical products and medical

devices and food manufacturing in the United States is extraordinarily safe. But when it takes 12 years, as my colleague, the gentleman from Pennsylvania [Mr. GREENWOOD] said and $390 million and 400,000 pages of documents in order to get a new prescription drug approved, it has gotten out of control.

Mr. Speaker, that is what this special order is about tonight, which is to take the Food and Drug Administration, which has done a terrific job over the years, and give it the tools and strip away some of the undergrowth and cut back some of the bureaucracy so it can do its job even better and simpler and less costly and less bureaucratic in 1996.

Mr. GREENWOOD. Mr. Speaker, I thank the gentleman. I think it is fair to say that, in both of the central issues of the food bill, what we are really trying to do is leave the authority in the FDA in terms of the uniformity. I represent the State of Pennsylvania, and we have Hershey Foods. As you talked, I tried to imagine a Hershey bar that might have to have one label in Minnesota and a different label in Houston, TX, and yet a third label in some community in New York, et cetera. It would be virtually impossible for the company to comply with all of that crazy patchwork quilt of labels.

All we are saying is the FDA does a good job at this. Let them be the experts. Let them determine what should be on the label, and leave it there because of the interstate commerce.

Mr. KLUG. Mr. Speaker, the gentleman is exactly right. If we think this through rationally, essentially what will happen is, if we end up with this crazy local, State, national patchwork of requirements for labeling standards, eventually companies will say well, we will do that for California, because California has got so many people in it, it is worth the investment. But it might not be in North Dakota, or it might not be in Delaware.

So essentially you will see a situation where companies and consumers will be deprived of the opportunity to buy things off the shelves simply because of labeling standards that add very little value to the amount of information that a consumer already has in front of him or in front of her. Again, we all agree on the committee that you want nutritional labeling standards in place, but one set of labels nationally. And if you are unhappy with an individual provision, get it changed once for California and Delaware and Wisconsin and Pennsylvania and not for every single community.

Mr. GREENWOOD. Mr. Speaker, then on the Delaney clause, all we are saying, again, is we want the FDA to decide what the standard should be for products that might be remotely tested in animals to have some carcinogenic quality.

It is the old story, you hear these stories, well, if you ate 500,000 pounds of grapes every day for the next 500,000 years, you might have a one-in-a-million chance of having cancer. That is sort of an absurd level of micromanagement. What we really want the FDA to do is tell us what is safe for our kids to eat, what is safe for us to eat, what will not increase our chances of cancer. And you tell us, you have got the experts, and we will make it apply nationwide.

Mr. KLUG. Mr. Speaker, it gets back to what I was talking about earlier with medical devices. It is part of that culture of fear. It is a fear within the FDA itself that they cannot say yes. If they say yes, it is that on-in-a-million chance that something will go wrong. But when you look at pharmaceutical products, what you forget is that 999,000 cases where something goes right; and that has really been the problem.

Again on the Delaney clause, what you have to remember is this is a very centrist idea. AL GORE suggested it. Dr. Kessler at the head of the Food and Drug Administration, when he was a staffer in the U.S. Senate, spent years trying to fix the Delaney clause. So this is not any radical idea. If you can get AL GORE and David Kessler and JOE BARTON and SCOTT KLUG and JIM GREENWOOD to all agree on the same issues, I would suggest everybody, including everybody at the FDA, understands Delaney does not work and that it has to get fixed.

Mr. GREENWOOD. Mr. Speaker, I thank the gentleman for his very good work on this legislation and look forward to its passage.

We are very privileged to have with us the gentleman from Florida [Mr. BILIRAKIS], the chairman of the Subcommittee on Health and Environment of the Committee on Commerce, who has provided the leadership for this effort, who has given us the green light to move this important package of legislation through his committee and who will now share his thoughts as our leader on this issue.

I yield such time as the gentleman from Florida may consume.

Mr. BILIRAKIS. Mr. Speaker, I thank the gentleman from Pennsylvania [Mr. GREENWOOD].

Mr. Speaker, tough acts to follow, certainly as we are all here this evening to talk about improving and saving people's lives. That is really what it is all about. We all want to ensure the health and safety of our citizens, and streamlining the approval process at the FDA will help to do just that.

Simply stated, the FDA must be reformed. Simply stated, it has to be reformed. Consumers must have quicker access to safe and effective new drugs, medical devices, and foods. Countless numbers of individuals and groups have contacted Congress to ask for help, and many of us have received this message loud and clear. The message is that FDA approvals, as so many of us have already said, of drugs, medical devices, and foods take too long.

Mr. Speaker, I would like everyone here today to know that this message has not fallen on deaf ears. I will not say that the message which we all have received time and again over these many past years has fallen on deaf ears prior to this Congress, but the fact of the matter is nothing was done by the Congress. Since this effort was started this year, some approvals all of a sudden, I might add, have been expedited. I am sure that is just a coincidence. Anyhow, Mr. Speaker, as chairman of the Health and Environment Subcommittee, I am really proud to be part of the FDA reform team created by the gentleman from Virginia, Chairman BLILEY, and spearheaded by the gentleman from Pennsylvania, Mr. GREENWOOD.

The team has come forward with several bipartisan proposals for reform that will speed up the approval process for drugs, medical devices, and foods so that consumers will have increased access to these products while still being assured of their health and safety. I want to underline that, as others have, while still being assured of their health and safety. This goal has guided our team in this effort.

As we have heard, the approval process takes much too long. Today, it takes something like 12 years and $350 million to get the average new drug from the laboratory to American patients who need it. To make things even worse, as others have said, the majority of the new drugs approved by the FDA in the last 5 years were already approved and in use in other countries.

The FDA approval process actually interferes with the essential need to approve vital research in products that fight serious illness. This legislation changes that. In the medical device area, I know it has been very thoroughly discussed. The average time it takes for the FDA to approve a medical device has increased from 415 days in 1990 to 773 days in 1995, all while the FDA is required by law to take no longer than 180 days to approve new medical devices. The legislation introduced in the House addresses these concerns.

Mr. Speaker, let me stress that streamlining and improving the FDA does not weaken our resolve for the safety or effectiveness of products. Once again, I would like to thank Chairman BLILEY for his leadership on this issue and especially JIM GREENWOOD, who has directed our FDA reform effort. Together with JOE BARTON, RICHARD BURR, and SCOTT KLUG, we have developed a balanced, bipartisan approach to approving the FDA's approval process. I am proud of you guys. You have done good, as we say in the South.

As I have said before, in closing, Mr. Speaker, the safety and health of our Nation's citizens is my and our concern. This FDA reform legislation is a balanced, bipartisan approach that will streamline the approval process to allow safe and effective drugs, devices and foods to reach patients, consumers

more quickly and efficiently without sacrificing safety. So I urge my colleagues to carefully consider this legislation which would streamline and improve the approval process to allow our Nation's citizens better access to safe and effective drugs, medical devices, and foods.

Mr. Speaker, I thank the gentleman from Pennsylvania for his wonderful work.

Mr. GREENWOOD. Mr. Speaker, I thank the chairman very much. Let me say that the gentleman from Florida [Mr. BILIRAKIS] has served long and with great distinction on the Health and Environment Subcommittee, and this is his first term as the chairman of that committee. I think that working together in bipartisan fashion, we will be able to accomplish something that we will be able to say that on your watch, we passed legislation, the President signed it, and we talked about life and death issues. This will save lives. Children will survive rare diseases. Cures for horrible plagues, like AIDS and cancer will come to patients, relieve their suffering much more quickly for years and years to come. That will be just a part of your legacy as chairman of this subcommittee, and we are very pleased for your leadership.

Mr. Speaker, I would now like to yield time to my colleague, the gentleman from North Carolina [Mr. BURR]. Mr. BURR is the prime sponsor of the pharmaceutical bill, deals with pharmaceutical products and biologic products, all that new science that deals with fighting disease at the molecular level. It is where we are, I think, on the dawn of a new age in medicine where we will have cures for diseases that we cannot even image right now.

Mr. Speaker, Mr. BURR is a new Member. He is a freshman, but he has done just an extraordinary job on this project. He has, I would say, far more than anyone else in the House been responsible for the large number of cosponsors on this bill. He has been working with Members from around the country, from both sides of the aisle, preaching the good word of FDA reform and has converted a lot of folks to this cause.

With that, I would like to yield such time as he may consume to the gentleman from North Carolina [Mr. BURR].

□ 2115

Mr. BURR. Mr. Speaker, I thank the gentleman from Pennsylvania [Mr. GREENWOOD] and thank him for his leadership, as I do the gentleman from Florida [Mr. BILIRAKIS] and the gentleman from Virginia [Mr. BLILEY], and I think the gentleman raises a good question.

It is 9:15 at night. Why are we here? We are here tonight, and we have put months of work into hearings and into meetings with patient coalitions and with hospitals and with doctors about the horror stories at FDA, and I am here tonight to say that we also heard some successes with FDA.

We have an agency in the Food and Drug Administration that needs to be here. It has a purpose. But we have also seen the instances where the Food and Drug Administration has no human face, and what we have seen is, in fact, the human faces.

I never will forget, JIM, when I got to Washington just a year and a half ago; it seems like eternity now. In one of the first hearings I ran into a product called the censor pad, and I am sorry JOE BARTON is not here because JOE usually talks about it; I am the one that carries it around. And the reason I carry it around with me:

It probably was the best example since I have been here about the failure of bureaucracy, the fact that bureaucracy cannot make decisions that apply common sense to something. This product was designed to aid women with the examination of a breast for possible cancer. It increases the sensitivity over soap and water because it is plastic with some silicon in the middle, and it allows a woman at any time of the day to apply this pad and to begin an exam.

If this pad were to find breast cancer in 1 woman, then I feel that it is our responsibility to have it on the market because it is nonintrusive, it cannot hurt a person, it is not there to replace a mammogram or any other exam that is done in a medical office. It is there to encourage a woman any time of the day or night to check herself. This is the type of common sense thing that I think we ought to make sure is approved by the FDA.

Now this was classified as a medical device under the same category as a pacemaker because there was no prior product like it, and the reality is that this has been at the Food and Drug Administration now for 11 years. The person who invented this product won the inventor of the year award in medical devices, and the year after that the FDA sued him. It is an incredible story about the abuses that happen in bureaucracy.

But we are here to talk about positives tonight, we are here to talk about what we can do by this Congress taking a responsible look at the problems that we have at the Food and Drug Administration using the talents and creativity of people there that are the best in the country, and then, looking at the private sector in America where we have more talented people and saying how can we plug them into this process. How can we do it while assuring safety and efficacy to all the American people for the drugs and pharmaceuticals and medical devices that they have become so accustomed to that safety?

The gentleman from Texas [Mr. BARTON] talked about tonight third party review. Think of the teaching hospitals that we have in this country who do clinical trials today, who do drug research, who come up with new compounds that might be the breakthrough for cancer or for diabetes; they are at our disposal to try to use them not only in the clinical process, but in the overall overseeing of the clinical trial and maybe with the applications. There is an option that we look at. It is not that we have to do it. It is that we have a responsibility to explore any option that exists that might make it better because in fact what we hope is that we can reach new efficiencies while maintaining safety and efficacy.

As a matter of fact, the first thing, JIM, we changed, I think, was the mission statement. The mission statement was changed to say that the FDA should promote and protect, to promote, to move forward, to advance and to protect the integrity of the safety system that Americans had come to know. In fact, what we want to do is we want to open up the communication of what has been a very closed agency, one that communicates freely with the applicants of pharmaceuticals and devices, one that shares with the companies where they are in the process, one that solicits information from companies that companies are willing to supply because it is their intent to speed up the process.

I think we alluded to the fact earlier tonight that right now it takes 14.8 years to approve a new pharmaceutical in this country. In fact, in the 1960's, in 1963, it was 8.1 years. Today it is $350 million. Then it was about $70 million. If Americans wonder why drugs that hit the marketplace that are new are so expensive, all they have to do is look at the investment that pharmaceutical companies have to make in research and development and the approval time to realize why a new prescription is a hundred dollars. Well, nobody wants to make it $30 worse than we do, and if we can reach that through new efficiencies, we have a responsibility, as Members of Congress, to try to explore how in fact we can do that with the help of the FDA.

In fact, one of the single most important things of the FDA reform legislation is that we require the Food and Drug Administration to do an annual report to Congress, tell us how many drugs have we had applications for, how many have we approved. Is it unreasonable to believe that the American people deserve some type of accountability for the approval process? I think it is very much within the responsibility of Congress, as we represent people all across this country, to say to every agency in the Federal Government you have accountability to the people through us.

In fact, one of the most contentious parts of the bill deals with the dissemination of information. 70 percent of all the cancer treatment today is the off-label use of an approved drug. Doctors find that there is a drug that is already on the marketplace that works well for a certain disease, and they choose to use that drug to treat that particular problem. But in fact pharmaceutical companies cannot take their experience, their successes where they might

write about them in professional medical journals and duplicate those and send them to other doctors. They can only make a copy and send it to a doctor when a doctor requests that information.

Well, 70 percent of my district is rural. My doctors are doing everything they can to provide primary care to their population. They do not have time to read medical journals. This would be such a tremendous aid to them, to have the ability for peer review articles to be replicated and sent to them. Think of the valuable information that one can find in peer review articles.

Mr. GREENWOOD. Mr. Speaker, if the gentleman will yield on that point, just to make this crystal clear to everyone because I think Americans will be surprised to understand this.

In your district, rural North Carolina; in my district in Bucks and Montgomery Counties of Pennsylvania, we can have a physician treating a child for a disease and frustrated because he cannot cure that disease, and somewhere in another part of the country a physician may have treated a thousand children with this disease with a pharmaceutical product that was not originally designed for that purpose, but it works, and it is saving these children. And today under the law, if the maker of that drug wanted to send an article that the doctor who treated the thousand kids wrote in a medical journal, wanted to mail it to the doctor, your physician in your district or my district, and say, ''You might want to see what this doctor over here has done; he's curing these kids,'' it is against the law.

Mr. BURR. It is not only against the law, but to do it he would have to rely, we would have to rely, on our doctor who might not have read it to request it. What an insane way to go through the process.

And I think the thing that is scary and should be scary for the American people is that as this off-label use is tried more frequently, a doctor might determine that the dosage is very crucial, and if other doctors are going to use that off-label use or that pharmaceutical for an off-label use, should they not have the latest information about the dosage to use and the frequency of usage, where today again that is information that pharmaceutical companies can only disseminate when a physician requests it, not when there is a peer review article that states this new information that might have been found.

So in fact there are many areas, many parts of this legislation, that are crucial to the health of the American people. America has the best health care system in the world. It is unconscionable for Americans to have anything less than superior access to lifesaving drugs. I believe that by safely streamlining the drug approval process it will not only help families by lowering drug prices and keeping high paying jobs here in America, but give terminally ill patients access to lifesaving treatments.

FDA reform is not radical, it is responsible. It is not senseless, it is safe. America's health industry and patients are chained to an FDA process that provides no flexibility, has no common sense and has no human face. The FDA reform legislation will remove these chains and ensure safety in a process structured to more effectively and efficiently approve drugs.

In fact, as people have told stories tonight, JIM, about patients in their own districts, I have got several, too, several patients who are now being treated by alternative methods. Why are they doing that? Because it is their choice. They have determined that that choice that exists is the best choice for them, and right now we are slowly moving to a situation, if we are not there already, where the Government will tell us no, you cannot do that.

Well, when these people have a choice between nothing and nothing, do we not have a moral responsibility as Members of Congress to present them with an option? I think we do, and that is why I am proud to be here tonight. I am proud to be a sponsor of 3199, I am proud to say that this is a bill JON FOX started legislation long before I did, and this has incorporated much of JON's it has incorporated the thoughts of hundreds of people around this country and in this town, but more importantly, it is a bill that we can all stand here tonight and say that we are proud that it has bipartisan support, that Democrats and Republicans believe very strongly in the changes that we propose to make.

Why? Because we have put politics aside and we tried to put human health in the forefront. Well, we will succeed to do that. We will succeed by marking up this legislation in a bipartisan way, coming to this very House floor and debating with our critics the importance of it, and we will win because we are right.

☐ 2130

Mr. GREENWOOD. Mr. Speaker, I thank the gentleman for his remarks, and also for his stellar work throughout this process. Just to follow up, on a bipartisan note, I spend 2½ to 3 hours today in my office, and I am a Republican, with a Republican staff member, an attorney, a Democratic staff member, and we worked through the bills line by line, Republicans and Democrats, just using our common sense, just using the knowledge that each of us brings to the subject.

It has been a joy for me, in contrast to so much of what the House of Representatives has done since I have been in Congress that has been so partisan and had such a biting edge to it, to do it together, Democrats and Republicans, because we know that lives hand in the balance.

Mr. Speaker, I yield to my colleague, the gentleman from Pennsylvania [Mr. FOX], who represents the district immediately to the west of mine. Mr. FOX and I served in the Pennsylvania legislature, and he has been a leader in FDA reform and introduced his own legislation. I would like him to share his thoughts with us.

Mr. FOX of Pennsylvania. Mr. Speaker, I thank the gentleman from Pennsylvania and the gentleman from North Carolina [Mr. BURR] for his leadership in this movement. I know that he in the Pennsylvania legislature and the Pennsylvania Senate was particularly a leader into his own right when it came to health care reform and to making sure medical devices and pharmaceuticals were covered in the legislature, to the extent they could get them to those patients.

So I am very happy that the gentleman from Virginia, Mr. BLILEY, chairman of the Committee on Commerce, appointed you as the point person, the task force chairman for FDA reform, to bring together people like the gentleman from North Carolina, Mr. BURR, who has fashioned legislation which, I appreciate the acknowledgement of our initial efforts, but your bill, working with Mr. GREENWOOD and the gentleman from Virginia, Mr. BLILEY, and the gentleman from Florida, Mr. BILIRAKIS, the gentleman from Texas, Mr. BARTON, and the gentleman from Wisconsin, Mr. KLUG, together you have the package here that I think is the most important legislation in the second session of the 104th Congress.

We may have set the tone on reforming Congress in the first session and getting our fiscal house in order, but what could be more important for our constituents than making sure that health care opportunities to live longer and better can in fact be a reality?

What you two gentlemen, the gentleman from Pennsylvania [Mr. GREENWOOD] and the gentleman from North Carolina [Mr. BURR] have done here tonight I think is to bring out to our colleagues and to others exactly what can be done by the passage of this reform legislation. So I am very appreciative of your leadership and looking forward to having the bill passed.

I did want to mention that from my perspective and that of the American public, this legislation will speed up the lifesaving life-extending drugs and medical devices while people are awaiting a cure or a vaccine. Very important. What is amazing to me is that American patients have been denied, even though they have already been approved overseas, many important drugs. If the FDA had approved the drug Interleukin 2 in the United States as soon as it was approved in Europe, the lives of 3,500 kidney cancer patients might have been saved. On Alzheimer's disease, the drug THA was delayed for 7 years after it was available in Europe. I had a hearing in my country seat of Montgomery County in Norristown just last year with patients who had cancer, ALS, AIDS, epilepsy. One

individual with epilepsy explained that they had to go to England to get a drug which really was not as good as the American drug, but the American drug was not approved by FDA yet.

So the fact is this legislation that Mr. GREENWOOD Mr. BURR are here tonight talking about will streamline product approval, allow for third party review, establish a fast track standard for filings and applications, have a collaborative approach to clinical research, promote harmonization; and by that we mean the discoveries overseas and in other countries which are clinically correct, we will allow their studies to be used and implemented here in the United States without the delay of further time.

Those annual reports by the FDA to Congress will certainly let us know how we are doing on speeding up the process. If we do not pass this legislation, but I am sure we will, the discoveries and jobs that they bring will go overseas. We just have to look to a 1995 study by the American Electronics Association that found 40 percent of medical device firms reduced their number of U.S. employees because of FDA delays. Twenty-nine percent boosted investment in foreign operations. Twenty-two percent moved U.S. jobs out of the country.

With the legislation that the gentleman from Pennsylvania [Mr. GREENWOOD] and the gentleman from North Carolina [Mr. BURR] are discussing tonight with their colleagues from the Committee on Commerce, we will stop that. The jobs will return, the discoveries will be made earlier, and our patients will be the beneficiaries.

So by working together with Commissioner Kessler, Republicans and Democrats together, House and Senate Members together, working with the White House, we will have FDA reform this year in the 104th Congress, and then we will be able to go back to our districts and say that we really passed important, bipartisan legislation that will improve the health care of every American.

I thank the gentlemen for their leadership, and for allowing me to join them in this important special order.

Mr. GREENWOOD. Mr. Speaker, I thank the gentleman. What I would like those Americans who are listening to us and watching us on C-Span tonight to think about is to imagine that their mother or father, their elderly parent, lies in a bed in a hospital, with a condition that is fatal, and the doctor takes you outside the room and says, ''It does not look good for your mom or your dad. It does not look like he or she is going to make it,'' and why.

And you say, ''Isn't there anything that you can do?'' And the doctor says, ''Well, there is a device that has been developed in our country, it has been tested in Europe, and it seems to be working in cases just like this, in France and in England and in Italy. And if I had that, if it was legal for me to use that, I would take your mom or your dad to surgery right away, we would implant that device, and I think the prognosis would be excellent. But it has not been approved by the Food and Drug Administration, it has been sitting there for years, and until I can get it, there is nothing I can do.''

Or imagine your little child, boy or girl, the same situation, in a hospital, suffering, and as a parent you want to relieve that suffering. And the doctor tells you that there is a drug, there is a medicine, it is a wonderful medicine that has fixed these kids up elsewhere in the world, but we cannot get it through the FDA. It is still bogged down there. ''If I could only get that, I could relieve your child's suffering or save his life.''

I think if Americans picture themselves in that situation as sons and daughters of their elderly parents, or thinking about their husband or their wife in that situation, or in the worst case of all, a small child, they would say, somebody has to take care of this.

That is what we are doing. That is what we are trying to do. We are trying to say that the U.S. Congress needs to take an agency that has been around for 90 years, doing some very good work, and bring it into the next century, so that the spectacular and wonderful drugs that are being developed by the brightest and most dedicated people in our country, who want nothing other than to save those lives, to relieve that suffering, to get that product through the Food and Drug Administration, make sure that it is safe, make sure that it works, and get it to those patients as quickly as possible.

If we do that, and we do that because we put politics aside and say that Republicans and Democrats will work together, we will hold hands on this, we will get it done and we will all go over to the White House, Republicans and Democrats, for the bill signing ceremony, that will have made my stay in this Congress worthwhile.

Mr. BURR. Mr. Speaker, if the gentleman will continue to yield, I think the interesting thing here is that we are convicted to make sure that this legislation passes and gets a Presidential signature. Why? It is because we have seen the human face that we need to apply to the problem. Bureaucracy never tends to see the human face. I think for many people who listen tonight, they may wonder, you are Members of Congress. What do you know about reforming the FDA?

The number of hearings in oversight and investigation, and I would say to my colleague, JIM you were there, the number of hours that we spent once we had the first draft of this legislation, I believe 17 hours in 2 days, where we brought people in from all over the country who could lend their expertise to the language and to the intent, and to assure the efficacy and the safety, it all exists in this one package. For once, we have seen the process work exactly like it is supposed to.

But to an agency that I continue to hear the same remarks that I hear from other agencies, ''We are making changes. Let it work. Let it happen. It will fix itself,'' it only reminds me of a statement that a gentleman made several years ago, that a fool is one that believes you can continue to do the same thing and expect a different result. In fact, we have to change culturally and fundamentally what we do if we want to expect a different result.

I carry in my voting card wallet a statement that I think is very appropriate, that is printed at the Jefferson Memorial. I will read it just very briefly. It is Jefferson's words: ''I am not an advocate of frequent change in laws and constitutions, but laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths discovered and manners and opinions change, with the change of circumstances, institutions must advance also to keep pace with the times.''

Mr. Speaker, tonight we are keeping pace with the times.

Mr. GREENWOOD. Mr. Speaker, I thank the gentlemen who have participated in the special order. I think we are going to make this a textbook example of how the Congress of the United States can put politics aside completely and utterly, work with Democrats and Republicans evenhandedly, put a bill into law that will save thousands of lives, and I look forward to the bill signing ceremony.

Mr. TOWNS. Mr. Speaker, I am pleased to participate in this evening's special order on FDA reform. On March 29, three ''FDA reform'' bills were introduced to amend the Food, Drug and Cosmetics Act with respect to the regulation of drugs and biological products, foods and animal drugs and medical devices.

I believe that three bills offer an earnest and responsible approach to the reform of FDA regulations and procedures which govern a variety of very different and distinct products and industries. These legislative reforms recognize the need to streamline the operations of the Food and Drug Administration while giving the agency ultimate authority to protect the public's health.

Under the reform approach now before the Commerce Committee, the FDA would also be responsible for getting new products on the market through a prompt, efficient review and approval process. This effort responds to the agency's critics who argue that the current product approval process slows down the availability of safe and effective products. It is an approach which I believe will still protect the public health but it will also enhance American companies' ability to be more competitive in the internatonal marketplace.

That is why I am supporting these legislative reforms and also why I am the principal cosponsor of H.R. 3200, introduced by the gentleman from Wisconsin [Mr.KLUG], to address needed changes in the food and animal drug areas.

H.R. 3200 proposed changes to the labeling of Foods and the approval process for animal

drugs. The current standard which subjects health claims to the same scrutiny that is applied to drugs is simply not warranted. In addition, the food additive petition process, which has allowed 200 petitions to languish, is in dire need of revision. Last year, an investigative report by the Subcommittee on Human Resources and Intergovernmental Relations found that reviewers requested too much data that was not even used to determine the safety of a food additive. Irrelevant data only adds unnecessary cost and depresses investments in new food ingredients and technologies. This ''zero risk'' management approach could be directly attributed to the influence of the Delaney clause which almost everyone agrees is no longer reflective to today's best scientific measurements. The findings, in this report, support the proposed change in H.R. 3200 from zero risk to a ''negligible risk'' standard.

H.R. 3200 also incorporates the provisions of H.R. 2508, to modernize the requirements for the regulation of animal drugs. The time frame for approval is shortened from 180 days to 90 days. In addition to these provisions, the bill provides for the regulation of certain drugs through a ''veterinary feed directive'' regulation for medicated feeds to be issued by a veterinarian.

Mr. Speaker, it is my hope that the three reform bills currently under consideration will retain FDA as a strong and viable agency that has the necessary resources to ensure product quality. It is also my expectation, however, that these reforms will make FDA a strong partner, rather than an impediment, in making useful technology and products to market.

WHAT MAKES AMERICA GREAT?

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from California [Mr. ROHRABACHER] is recognized for 60 minutes.

Mr. ROHRABACHER. Mr. Speaker, today I would like to begin my talk here with a question of why do we think that America is a great country. I would like people who are listening and the people who are perhaps reading this in the CONGRESSIONAL RECORD to ask themselves why they think that America is such a great country.

Is it because we have a powerful military? No, that could not be the answer, could it, because there are a lot of great countries? There are a lot of countries in the world that have strong militaries, powerful militaries. Yet, they are not great countries. They are not countries that we would wish to identify with.

Is it because we have a lot of big companies, a lot of industrial companies in the United States? No. They have a lot of big firms and big companies in other parts of the world that are pretty despicable parts of the world. In fact, there are big companies at different places in the world that no American would want to live?

Perhaps it is because we have a beautiful flag, and we have the red, white, and blue, that is sitting behind the podium there. A beautiful flag does not make a great country, nor does a big military or a powerful military make a great country.

Certainly one of the factors that make a society a great country is the fact that people have a certain degree of freedom, and that was one of the guiding principles that led to the formation of the United States 200 years ago, when our Founding Fathers struggled for liberty and for independence.

But America is not just a free country. America is a prosperous country as well, but it is not just a prosperous country for a few people. It has a prosperity that has impacted on the lives of the common man and woman. Yes, in this country we have freedom. Everyone, every individual, has the right to vote, to speak, to pray; basically, to control his or her own destiny. These things are important to what is great about America.

Even our poor people, however, which is another factor, live a decent life. In America, a working person, an average working person, if he or she is willing to work and to try and to live an honest life, they can live a decent life economically. This, too, is part of the American dream, because what we have in America, what essentially makes America great, is our freedom and the opportunity of our people, the opportunity to live in a certain degree of prosperity. And our people have, indeed, lived more abundant lives than anyone else in the history of the world. Here, wealth is abundant enough so that the average person lives a good life.

Home ownership in this country is more widespread than in almost any society in the world. People own their own cars. Some of these things are considered miraculous in other parts of the world, where only a chosen elite, a very few people, get to participate in this, the blessings of America. In this country, our people select their own job, even. That is not the case in many other countries.

□ 2145

In our country, what we see is even the most arduous physical labor is assisted by machines, and this is part of the history of our country. Many people say, well, the reason America has done so well is because our people work so hard and they have always been hardworking people. Well, that is not really true. There are hardworking people all over the world. Yet very few societies have prospered and have enjoyed the freedom that we have here in the United States.

No, what we have done in the United States is ensure that our working people are assisted by machines and that the work that they do is multiplied, the product of their labor is multiplied by technology. Basically ours is a history of technology being brought to play to help save the backbreaking pain of our working people.

I recently came across a story of one of the early patents in the United States. It is not really all that early of a patent. It was issued March 20 of 1883. It was a patent that was issued to Jan Matzeliger and two investors who had invested in his project.

What was his project? What was his patent all about? It was a machine that revolutionized the manufacturing of shoes. Most people just take shoes for granted, but before this machine was invented, many people of the United States never wore shoes. In fact, the price of shoes was out of reach. Most people owned shoes, maybe one pair of shoes for their entire life.

But within a few years of Mr. Matzeliger's invention being brought to play, the price of shoes in our country dropped by 50 percent. Ordinary people were able to afford shoes for their feet. We just take this for granted today.

We also take for granted machines like Eli Whitney's reaper or the electric light bulb, or how about Robert Fulton's steam engine? By the way, Robert Fulton never invented the steam engine. If you look back at Robert Fulton, not only did he not invent the steam engine, he also was not the first one to ever put a steam engine onto a ship.

Robert Fulton put a steam engine on a ship and they called him a great inventor. Well, the fact is that the Germans had put a steam engine on a ship long before, but it had never been brought to play in their economy because special interest groups in the German economy refused to permit that steam engine on that ship from being used because it would displace people from work.

In the United States we saw it as a means of ending the terrible labor, the painful labor of pushing ships with sticks through the water. Our society welcomed technology and the German society did not.

In fact, even the Germans were not the first ones to invent the steam engine. The steam engine was invented by the Greeks in ancient times. Maybe you will remember seeing a picture of a steam engine, an early steam engine which revolved like this over a fire. That was invented by the Greeks, but in the Greek marketplace, relieving the pressure of work and the burden of work on so many people like the steam engine would have done was not something that was thought to be a worthy goal.

So the steam engines were passed up by the Greeks and by the German boatmen. But it was Robert Fulton that revolutionized the world and created steamboats which changed the world.

Thomas Jefferson, Ben Franklin, so many of our Founding Fathers were technologists because they believed in freedom and technology, they believed that technology would change the world just as democracy would change the world. In fact, creating a patent office was written into our Constitution. Can you imagine that? Over 200 years ago, our Founding Fathers wrote that there would be an office to patent new technologies and that was mandated in the basic law of the land, the Constitution.