vote in the 111th Congress. Additionally, I would like to remind my colleagues that similar language, language that was the basis for the first version of legislation, passed in both the 109th Congress and the 110th Congress.

This language is not controversial, it does not jeopardize consumer privacy, and it does not exempt an institution from having to produce an initial or amended privacy notice. This legislation does eliminate millions of costly, confusing, and often ignored mailings. And, with the passage of this bill, the information included in these mailings would likely become more significant to the consumer because it would come only after a change in the privacy policy.

This legislation is supported by the Independent Community Bankers of America, the Credit Union National Association, the American Bankers Association, the National Association of Federal Credit Unions, and the Consumer Bankers Association, among others.

I'd like to thank the gentleman from California (Mr. SHERMAN) for his work on this bill. I would also like to thank Chairman BACHUS, Ranking Member FRANK, Chairman CAPITO, and Ranking Member MALONEY for their work with us toward swift passage of this legislation.

With that, Mr. Speaker, I ask my colleagues for their support.

Mr. SHERMAN. Mr. Speaker, I yield myself such time as I may consume.

I want to thank the gentleman from Missouri for his work and leadership on this bill. I also want to thank the ranking member, Mr. FRANK, for his support, and, of course, the gentlelady from West Virginia.

If this bill becomes law, a written copy of the privacy policy will still go by postal mail to every customer when he or she becomes a customer of the financial institution. Another copy will go every time that policy is changed, and the policy will be available day and night on the Internet on the Web site of the financial institution. The privacy policy will be known to everyone who has an interest in reading it, whether $100 is paid as a bonus for reading it or not.

Mr. Speaker, I have no further speakers, and I yield back the balance of my time.

Mrs. CAPITO. Mr. Speaker, I also urge passage of this bill.

With that, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from West Virginia (Mrs. CAPITO) that the House suspend the rules and pass the bill, H.R. 5817, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

## ASTHMA INHALERS RELIEF ACT OF 2012

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6190) to direct the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6190

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Asthma Inhalers Relief Act of 2012''.

**SEC. 2. DISTRIBUTION, SALE, AND CONSUMPTION OF REMAINING INVENTORIES OF OVER-THE-COUNTER CFC EPINEPHRINE INHALERS.**

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency—

(1) shall allow for the distribution, sale, and consumption in the United States of remaining inventories of CFC epinephrine inhalers manufactured pursuant to the exception for medical devices under section 604(d)(2) of the Clean Air Act (42 U.S.C. 7671c(d)(2));

(2) shall not take any enforcement action or otherwise seek to restrict the distribution, sale, or consumption of such inhalers on the basis of any Federal law implementing the Montreal Protocol; and

(3) shall, in response to any request of any distributor or seller of such inhalers, including any such request pending on the date of the enactment of this Act, issue a No Action Assurance Letter to the requesting party stating that the Environmental Protection Agency will not initiate an enforcement action relating to the distribution or sale of any such inhaler occurring prior to August 1, 2013.

(b) RULE OF CONSTRUCTION.—Nothing in this Act shall be construed to limit or otherwise affect the authority of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to ensure the safety and effectiveness of CFC epinephrine inhalers to be distributed, sold, or consumed pursuant to this Act.

(c) DEFINITIONS.—In this Act:

(1) The term ''CFC epinephrine inhaler'' means any epinephrine inhaler containing chlorofluorocarbons that was manufactured and classified as over-the-counter before January 1, 2012.

(2) The phrase ''Federal law implementing the Montreal Protocol''—

(A) means any provision of title VI of the Clean Air Act (42 U.S.C. 7671 et seq.) or other Federal law implementing the Montreal Protocol; and

(B) includes the final rule published by the Food and Drug Administration entitled ''Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine)'' published in the Federal Register at 73 Federal Register 69532 (November 19, 2008).

(3) The term ''Montreal Protocol'' has the meaning given such term in section 601 of the Clean Air Act (42 U.S.C. 7671).

(4) The term ''over-the-counter'' means not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) or otherwise required pursuant to Federal law to be dispensed only upon issuance of a prescription.

(d) SUNSET.—This section ceases to be effective August 1, 2013.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Texas (Mr. BURGESS) and the gentleman from California (Mr. WAXMAN) each will control 20 minutes.

The Chair recognizes the gentleman from Texas.

GENERAL LEAVE

Mr. BURGESS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on this bill.

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

There was no objection?

Mr. BURGESS. Mr. Speaker, I yield myself such time as I may consume.

H.R. 6190, this is a bill that I honestly wish we did not have to consider today.

Over the past several years, I have repeatedly asked the Food and Drug Administration, the Environmental Protection Agency, and even the White House, the President himself, for answers to questions that I and other members of the committee have as to why the administration has refused to grant a waiver to sell the existing stock of over-the-counter epinephrine inhalers. Only last summer, and because the committee was moving legislation at the time, did the Food and Drug Administration finally provide at least some sort of response, albeit one that was entirely unsatisfactory.

Under the rules known as the Montreal Protocol, certain chemical propellants used in a number of medical and cosmetic devices were to be phased out over a number of years, the chlorofluorocarbons, CFC, used in the epinephrine inhalers. Here is one of the ones that was one of those propellants. One of the manufacturers of these over-the-counter inhalers has worked on a replacement inhaler only to meet with stonewalling through the Food and Drug Administration and requests for more studies into the device. Although the Food and Drug Administration claims they are awaiting an application from the company, the company counters that the Food and Drug Administration once again continues to move the goalpost. Regardless of the finger-pointing, Mr. Speaker—and there is much of it surrounding this issue—the fact remains that there is no viable alternative for the over-the-counter purchase by an asthmatic suffering from an acute emergency attack.

We've heard that a company is about to market a device, and indeed there is a device available without a prescription, but it's behind the counter. In other words, if the pharmacy is open but the pharmacist is not there, you cannot purchase this device. I know this firsthand because it happened to me one evening while we were home on one of the district work periods. The new product uses a nebulizer rather than a propellant. It's a little more complicated. In my experience, it's a little more difficult to use and less effective. Nevertheless, it is available, but the cost differential is significant

when compared with the old over-the-counter CFC propellant epinephrine inhaler.

The committee and the Congress should be on the side of putting more available products into the hands of patients and allowing them to effectively manage their medical issues. Instead, opponents of this legislation hide behind false claims of the safety and efficacy of epinephrine.

Mr. Speaker, I would point out that I've been an asthmatic my entire life. I have utilized rescue inhalers for a long time. Racemic epinephrine, the active pharmaceutical ingredient in an over-the-counter asthma inhaler, has been around for 60 years. There has not been a question of its safety and efficacy. If so, we know the FDA has the power to remove a drug or device that they think is unsafe or not effective. They have given their stamp of approval to racemic epinephrine again and again over the last 60 years. There continue to be dozens of epinephrine-based treatments for asthma-related issues that are used by doctors and medical professionals. Although opponents of this legislation will claim that they're opposed to the bill because epinephrine is not safe, this claim is simply not true.

There are currently over 1 million units of these inhalers sitting in a warehouse in California not helping patients currently suffering from an asthma attack, not available for a rescue treatment for someone who cannot get their breath. It's unconscionable to allow them to sit and gather dust when they could be used to provide relief to America's asthmatic patients. Moreover, the company is committed to donating any proceeds from the sale to charity to remove any possible profit motive from their request to sell these products.

This is not about allowing a company to continue to sell their product; it's about not allowing a regulatory agency to unreasonably restrict the access of America's asthmatics to a useful product. I wish more companies would come forward with a viable over-the-counter asthma inhaler so that asthmatics could have more and more choices instead of that costly emergency room visit at 2 a.m.

This bill is about allowing asthmatics to continue to get relief during an asthma attack, to continue to have an emergency rescue inhaler available when they deem that they need it, not when the Administrator of the EPA says they need it or not when the Administrator of the FDA says they need it.

Members of Congress spend a lot of time talking about how much they care about the plight of patients—and asthmatics in particular—and decrying the high cost of health care. Even if it is just for a limited time, this bill returns a safe, effective, and inexpensive treatment into the hands of patients suffering from asthma, one that has been in use for decades.

For me, at least, the issue is clear. Let's side with patients on this issue. Let's stop this senseless war on asthmatics the administration has waged for the last 3 years.

With that, I'll reserve the balance of my time.

□ 1400

Mr. WAXMAN. Mr. Speaker, I yield 4 minutes to the ranking member of the Health Subcommittee of Energy and Commerce, the gentleman from New Jersey (Mr. PALLONE).

Mr. PALLONE. I thank my colleague, the ranking member from California (Mr. WAXMAN).

Congress gave the FDA the responsibility of deciding whether specific types of inhalers containing ozone-depleting substances are essential uses and need to remain on the market, and the FDA has established an orderly and open process for making these determinations: 13 types of inhalers containing CFCs were phased out prior to the phase-out of Primatene Mist. The remaining two CFC-propelled inhalers are scheduled for phase-out at the end of 2013.

The FDA determined in 2008 that Primatene Mist was not an essential use. They concluded that there are no substantial technical barriers to developing epinephrine inhalers that do not release ozone-depleting substances. At the request of Armstrong, the manufacturer of Primatene Mist, the FDA set a phase-out date of December 31, 2011, which was 1 year longer than the FDA initially proposed. The FDA took steps to prepare the public for the phase-out. It approved a label for Primatene Mist which indicated to consumers that Primatene Mist would not be available after December 31, 2011, and Primatene Mist was phased out on that date. It has not been available for the past 11 months.

This bill would intervene to put Primatene Mist back on the market. It is a legislative earmark that directly benefits just one company—Armstrong. A long list of public health groups, physician organizations, and patient advocates oppose this bill. They do not believe that returning Primatene Mist to the market is in the best interest of patients with asthma or in the best interest of public health. The following organizations, Mr. Speaker, that oppose this bill wrote to Members of the House: the American Lung Association, the American Thoracic Society, the American Academy of Pediatrics, the Asthma and Allergy Foundation of America, Mothers of Asthmatics.

I could go on. There are eight other public health organizations on this one letter alone, and I am not aware of any public health organization that supports this bill. When FDA officials briefed Members, they expressed many of the same concerns about patient confusion and of Primatene Mist no longer being the standard of care for asthma patients.

Now, let's be clear, Mr. Speaker. Every public health group and patient advocacy group that has looked at this bill has concluded it is a bad idea. Congress shouldn't be overriding FDA's established regulatory process if doing so would pose significant patient confusion and undermine public health. That's just common sense.

Even if we pass this bill, it would not lead to the widespread availability of Primatene Mist that is sought by the proponents of the legislation. According to Armstrong, between 2 million and 3 million people used Primatene Mist before the phase-out, but fewer than 1.5 million Primatene Mist inhalers remain in Armstrong's inventory. That means that as many as half of all previous users of Primatene Mist would not be able to obtain even one inhaler if Armstrong were allowed to sell off its remaining inventory, and it assumes that pharmacies or drug stores would even carry it. Retailers may decide not to sell inventoried units of Primatene Mist because the units will start to expire in January, and that's only a few weeks from now.

So the real effect of this bill would be to provide a regulatory earmark to Armstrong rather than a rescue inhaler that would be available in the middle of the night to someone suffering from an asthma attack.

Mr. Speaker, I don't know what else I can say. This is a bad bill, and I urge my colleagues to oppose it.

Mr. BURGESS. I yield myself 1 minute.

I would point out that the FDA has not retracted the use of racemic epinephrine for the short-term use of a rescue inhaler in the treatment of an acute asthmatic attack. That just simply has not happened. Then to say that Congress is now seeking to overrule the FDA is preposterous because those are not the facts on the table right now.

A regulatory earmark? Come on, give me a break. I would welcome other companies into the marketplace that wanted to create a low-cost, effective, convenient treatment for asthmatics who need acute respiratory relief when their standard meds, when their meds that they take on a chronic basis, either are not working or when, for whatever reason, a flare-up has occurred.

Look, I'm an asthma patient—I'm on asthma medicine—but in the product information provided to patients on the long-term medicine is a statement that this is not intended as a rescue device for an acute attack. For that, you need something that was previously available over the counter. I've got to tell you that I was astounded by the elitism by the EPA at the table in front of us when they told us that they know better than America's asthma patients. Come on. This is the land of liberty. Let's give patients the devices they need to manage their illnesses.

I reserve the balance of my time.

Mr. WAXMAN. Madam Speaker, I yield myself such time as I may consume.

My colleagues, this is a bill that is special for one company in order for it

to sell off the batches of the Primatene Mist that it has on stock. This is a product that's not on the market now—it was taken off the market—and there are substitutes on the market that the public health and medical groups say are far better and are far safer.

There are a large number of organizations that have come to the floor on this bill to oppose it. The Energy and Commerce Committee heard expert medical testimony that Primatene Mist is not safe or recommended for treating asthma, and we have a chart here. These are the groups that oppose this bill and that would urge you to vote ''no'': the American Lung Association, the American Thoracic Society, the American Academy of Pediatrics, the Asthma and Allergy Foundation of America. All of the people involved in health are saying they don't want this drug on the market, that it will only confuse asthma patients, and that it is not the safest drug that they could have.

Now, the gentleman from Texas has said what we ought to do if it's not safe is to take it off the market. It is off the market. It hasn't been taken off because of safety, but it is not recommended by the medical community.

There is another group here called the Alliance for Responsible Atmospheric Policy, and I'd like to indicate some of the organizations that are part of that alliance, which are some of the major corporations in this country.

Lastly, I want to show a chart of those who are in favor of this bill: Armstrong Pharmaceuticals. It is the one company that will benefit from this bill because it will be able to sell off the reserves of its product.

Now, is that in the best interest of the patients? Is that what Congress ought to be doing, passing a special earmarked bill to favor one company in order for it to be able to take the rest of its stock and sell it to people?

We do have a Food and Drug Administration, and we do have an Environmental Protection Agency. We've delegated to them the responsibility to protect the public health, to make sure that drugs are safe and effective. This Primatene Mist was supposed to come off the market, and it was given an additional year. Other companies were also going to have to go off the market. They knew that, and they're not on the market now. So why should we take one company's drug and put it back on the market so that it could sell off the products that it still has in its backlog?

In fact, as you might imagine, those companies are against this bill. They say it would overturn an established regulatory framework to directly benefit just one company—Armstrong. Over the years, more than a dozen types of inhalers containing CFCs have been phased out, but these companies say: Why should we do something special for only one company? We're talking about not just the health groups, but drug companies like AstraZeneca and GlaxoSmithKline. They oppose this bill because it provides one company with the special treatment that none of these other companies receive.

There is no reason for this bill. This is a drug that is already off the market. There are substitutes that are being developed, and there are substitutes that are already on the market. I don't think we ought to be using the Suspension Calendar, of all procedures, to give a special deal to just one company.

I urge Members to oppose the bill, and I reserve the balance of my time.

□ 1410

Mr. BURGESS. I yield myself 1 minute.

The ranking member spoke of a group called the Alliance for Sensible Atmospheric Policy. I wish this were sensible, Madam Speaker. This is the most nonsensical thing I have ever encountered. Look, America's asthma patients are not blowing a hole in the ozone above Antarctica. I get the fact that Mr. WAXMAN and I have to give up our hair spray. I get that. Too much CFCs. You've got it.

I get the fact that our underarm deodorant had too many CFCs and we had to have a different propellant. But we're talking about an effective treatment for a very vulnerable group of patients—2 o'clock in the morning, someone who has asthma who might have run out of their medicine, or maybe they encountered something that caused their airways to react, what choice do they now have? They go to the emergency room, spend $1,500 for a breathing treatment.

This is not something that was held behind the counter by the pharmacist. This was out on the open shelf available to anyone at any hour of the day or night. Asthma patients need access to this type of medication. I would welcome the fact that other companies would want to create a low-cost, available product for asthmatics to use as a rescue inhaler.

I reserve the balance of my time.

Mr. WAXMAN. First of all, I want to address some of these issues myself, and then I will yield to others who want to speak.

There is an environmental problem along with this medical problem. The environmental problem is that there is a deterioration of the upper ozone layer. And the United States, under President George H.W. Bush, negotiated an international treaty called the Montreal Protocol to get those products off the market that add chlorofluorocarbons which cause this environmental damage.

And so my friend from Texas is right: we can't get hair spray or deodorant that has the propellent that has been taken off the market. But no one's arguing we should let them come back on the market to sell off their products. There are substitutes. My hair is in place because I don't need those products any longer. And my friend from Texas is handling his deodorant problem adequately. The fact of the matter is there are other products for asthma that the people in the medical professions say is superior; and they say that Primatene Mist can lead to damage and become a threat to health. So why are we going to take this one drug and put it back on the market?

With those comments, I now yield 3 minutes to my good friend from the State of Michigan (Mr. DINGELL), the dean of the House.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. DINGELL. Madam Speaker, I thank my good friend for yielding me this time. Neither he nor I need hair spray, and so we can approach that matter with some serenity. But I want to say here, I yield to no one in this Chamber over what has been done or what I have done on food and drug safety for the American consuming public. I'm the author of the provisions that require Food and Drug to only market those things which are safe and effective. If Food and Drug doesn't like this, they can take it off the market on that ground. They have not chosen to do so. The only reason it is going off the market is because of the fact that it bothers the folks who want the Montreal Protocol to go into place.

Now, let's take a little bit of a look at it. There are 1.2 million issues of this particular pharmaceutical. A piddling amount of CFCs is going to be released in that these inhalers are very small. They have a few milliliters of propellent. It's not going to make any significant difference. Food and Drug can take it off the market. It is safe. It is efficacious.

Now I want to talk about a couple of other things. The gentleman from Texas has talked about what happens when you have these problem as an asthmatic. My old dad was a former tubercular. He lived through his life with about half a lung, and I listened to him every night, up walking around, gasping like a fish on a rock because he couldn't get air.

There are a lot of people who have used Primatene Mist because they thought it worked. And if that is so, in fact it does work because it gives relief to people who are sick. If it is bad, Food and Drug can take it off the market because it is unsafe. That is not the reason it is off the market; it is the Montreal Protocol.

Let us consider the fact that there are people out there who need this substance. Now, I hear that it is going to benefit one company, the current manufacturer. That manufacturer is not going to make 10 cents on this deal, and the reason is very simple: the profits and the benefits that are going to be generated by these sales of Primatene Mist are going to go—guess where—to charity. That's where they're going.

Who we are helping is the people who have need of this; and if you haven't

had a situation where you couldn't get your breath, you don't know the terrors that exist there. And you don't know the kind of terrors that my old dad had when I listened to him walking up and down at night, every night, gasping to get a breath of air. There was no Primatene Mist in those days, and so there was no relief for him.

Now, they say, well, you can go to the emergency room or somebody's going to develop relief, but there's nothing on the market that matches the price. Some of these things that they have that they are saying are going to be available are possibly going to be available in a little bit—possibly not. And they also are big, so big that they're not going to be readily available to somebody who has need. They might be helpful if they can put them on wheels so that the fellow can tow them around behind him. But the hard fact of the matter is that Primatene Mist is going to be there when it is needed, and it is going to provide the people who want their free choice to have that particular medication. It will be available to them.

I say make it available to the people. There's no rascality. This is a safe substance. If it weren't, Food and Drug wouldn't have taken it off the market because it was either unsafe or inefficacious.

So having said those things, let us support the bill. It's a good bill. The opposition of other manufacturers is to be expected. They simply want to cut a fat hog by making profits by selling their competitive devices.

Mr. BURGESS. I yield myself 1 minute.

The dean of the House described the amount of CFC released into the atmosphere as a ''piddling'' amount. Actually, the Food and Drug Administration has quantitated ''piddling'' for us in the Federal Register of November 19, 2008. They describe that as less than 0.1 percent of the total 1986 global production of CFCs. For the purpose of edification of the body, I did want to provide that information as to a definition of piddling.

I reserve the balance of my time.

Mr. WAXMAN. Madam Speaker, I'm pleased now to yield 5 minutes to the gentlewoman from Florida (Ms. CASTOR), an important member of the Energy and Commerce Committee.

Ms. CASTOR of Florida. I thank the ranking member for yielding me this time.

Madam Speaker, there are a number of reasons why H.R. 6190 is poor public policy, but I'd like to focus on just one, and that is the unfair advantage that this bill will grant to a single business to the detriment of other businesses and manufacturers. And, in fact, the Congress has received a letter from the International Pharmaceutical Aerosol Consortium:

On behalf of the International Pharmaceutical Aerosol Consortium—an association of companies that manufacture medicines for the treatment of respiratory illnesses, such as asthma and chronic obstructive pulmonary disease—I am writing to you today in opposition to H.R. 6190.

IPAC's members include AstraZeneca, GlaxoSmithKline, and a number of other manufacturers. They say that they strongly oppose efforts within the House of Representatives to lift the December 31, 2011, ban on the sale of CFC-based epinephrine Primatene Mist because such drastic reversal in settled law will be, one, unnecessary to protect the public health of asthma patients; and, two, it's contrary to the United States' important and long-standing commitment to international treaties.

They point out that this has been ongoing for two decades. The companies involved in international manufacture, national manufacturers, have known about this for a long time. They say the only possible beneficiary of a reversal of the ban on Primatene Mist would be its manufacturer, which stands to garner a financial windfall if its limited stocks are sold. Granting extraordinary, unwarranted special treatment to a single company would send an extremely negative signal to manufacturers that responded to the U.S. Government's call many years ago to be a partner in meeting our commitment. Similar prior requests for deadline relief have been firmly denied by all of the relevant agencies.

□ 1420

Now, here's the problem: I was contacted by a Florida company some months ago. Part of the early rationale for this bill was there was no alternative. But this Florida manufacturer that played by the rules called me up. They said, We hear about this hearing on Capitol Hill. Do you know that we are manufacturing an alternative to Primatene Mist that will be over-the-counter and that will be affordable?

Nephron Pharmaceuticals has developed such a product, Asthmanefrin, a handheld, battery-operated device that will allow asthma patients to inhale a drug similar to epinephrine in Primatene Mist. It is readily available at Walmart, CVS, Walgreens, Drugstore.com, Walgreens.com, CVS.com. It's also accessible through McKesson Drug, a national wholesaler; Smith Drug, a wholesaler covering the Southeast; and OptiSource. They are doing a national TV campaign now. They have starter kits. This is available. So that rationale, that early rationale that there is no alternative does not exist anymore.

But here's the important point: We can't have the Congress granting an advantage to a single company to the disadvantage of other companies that have played by the rules. This bill would seriously undermine the investment decisions of innovative companies like Nephron that have developed alternatives and solutions to short-term asthma relief. Congress should not pick winners and losers.

Colleagues, we repeatedly heard the rationale for this bill: there was no alternative. That rationale is incorrect. It's inaccurate. Congress should not pull the rug out from under companies that have followed the rules and expect regulatory certainty in order to benefit another single company.

I urge you to vote ''no'' on H.R. 6190.

Mr. BURGESS. Madam Speaker, I reserve the balance of my time.

Mr. WAXMAN. Madam Speaker, may I inquire how much time each side has and which side has the right to close?

The SPEAKER pro tempore (Mrs. EMERSON). The gentleman from California has 4½ minutes remaining. The gentleman from Texas has 12 minutes remaining, and the gentleman from Texas has the right to close.

Mr. WAXMAN. Madam Speaker, I yield the balance of my time to myself.

I just want to point out what the allergy and asthma networks, mothers of asthmatics, the people who are dealing with this problem, they say this act gives unprecedented preferential and exclusive exceptions and financial benefits to Armstrong Pharmaceuticals.

Primatene Mist is specifically not recommended for the treatment of asthma in the National Institutes of Health NHLBI asthma guidelines. They don't see a reason this ought to come back on the market. And the same point of view is expressed by the others that are the professionals that treat asthma patients.

The effect of this bill will be to take the inventory that this company has and allow it to go back on the market, from January to August of 2013, so they can sell it off. It's not going back to the market; it's just going to allow the inventory to be sold off. A lot of that inventory is expiring in terms of its efficacy; so a lot of people, we hope, will not get some Primatene Mist back on the market that's not going to do them any good.

And there are better alternatives. All the medical groups are telling us there are better alternatives.

This is a special interest bill. It's a bad bill. It's bad for public health. It will confuse asthma patients. It provides special treatment to one company at the expense of its competitors. It's opposed by the people involved in health, the people who have asthma, the people who treat asthma, the manufacturers of drugs for asthma.

We don't have to go back to a drug that's been outdated already and put it back on the market so this company can sell off their inventory. They say they're going to give all the money to charity. Well, I don't know what kind of tax breaks they get. I don't see why we should let them sell off their inventory, especially an inventory that's not going to be any good beyond August of next year.

This is a bill that we ought to oppose, and I urge all my colleagues to vote ''no'' on this legislation.

I yield back the balance of my time.

Mr. BURGESS. Madam Speaker, I yield myself the balance of the time.

If advocating for America's asthmatic patients is a special interest group, guilty as charged. But, Madam Speaker, we have heard so much stuff

today that it's almost difficult to refute every point that's been brought up.

Look, we heard from the ranking member of the Energy and Commerce Committee that the FDA had deemed the active pharmaceutical ingredient in Primatene Mist to be dangerous. What is the active ingredient in Primatene Mist? It's racemic epinephrine.

We heard from the gentlelady from Florida that a product manufactured in her district was a good product and was available. What's the active pharmaceutical in Asthmanefrin? Racemic epinephrine. It's exactly the same product. The difference, of course, is the propellant, and that's the object of our discussion here today.

Now, I will tell you, as an asthmatic patient, there are things that I know work better for me than others. I'm willing to go along with a lot of stuff from the EPA, but I will just tell you, the replacement propellant that is available in albuterol inhalers does not work nearly as well as CFC. You don't have to believe me. Go to the Facebook page that has been developed by asthma sufferers who, one after the other, will delineate why CFC worked for them when HFA-containing products do not.

Now, what about Asthmanefrin? There is no propellant. It is delivered because of an ultrasonic nebulizer, a unique approach and one that, quite frankly, I welcome.

But let me stress, Madam Speaker, although this product, Asthmanefrin, is available without a physician's prescription, it's not generally available over the counter, and I know this because of my own experience. Number 1, I had to call several pharmacies back in Texas before I found a Walmart that carried it. After finishing some event late at night in Fort Worth, I stopped by the Walmart near my home that I had already talked to that I knew they had the product there. I went in, but the pharmacy was closed. The pharmacist was gone.

Now, you can buy a vast panoply of almost anything else over the counter in the pharmacy, off the pharmacy shelves at Walmart—in fact, you used to be able to pick up two Primatene Mist inhalers for $30 before January 1 of this year—but no Asthmanefrin was available. When I questioned why, they said that is something that has to be dispensed by the pharmacist. In other words, it's behind the counter, not over the counter.

What does that mean as a functional issue?

If an asthmatic patient woke up at 2 that morning and said, Oh, my golly, I should have never ridden that horse, I should have never petted that cat, I guess the mountain cedar bloomed down by Waco because now I've got a snoutful and I cannot breathe, and they go down to the Walmart, the Walmart's open, the store's lit up, the shelves are full of product, but Asthmanefrin is not available to that patient. They'll have to come back at 9 in the morning when the pharmacist is on duty that can dispense the product to them.

Now, I would also point out that there is a cost differential between Asthmanefrin and Primatene Mist. We've heard a lot about costs and profits and who we're helping and who we're not. The cost for the starter kit for Asthmanefrin is right at $50. At Walmart in my district it was $49.96. A boxful of the packets of the medicine that is necessary to place into the machine to dispense costs $27 for a box of 30. And I'm not that good at math, but that's about 92, 93 cents per packet, one packet per treatment.

How many treatments are in this? I don't know. I've never used one completely. I always lose them before I get to the end. But it's advertised to be between 250 and 275 treatments.

The cost differential, a little bit less than 6 cents for this, 93 cents for this per treatment episode. Not a big deal in days you're talking about medicines that might cost $250, $280 a month for maintenance therapy for asthma. Yeah, the cost is negligible, but for some people it's not. For some people that represents a significant expenditure.

This, I can carry in my pocket. I can bring it to the House floor. If someone's smoking a cigar in one of the anterooms and I get a puff of that, I'll have this available when I get to the House floor.

This is harder to carry in your pocket, not impossible, but much harder to carry in your pocket.

There is a convenience factor. Dean of the House DINGEL mentioned that when he talked about his efforts to preserve products for patients with asthma. A little less user friendly to go through the multiple steps for Asthmanefrin as opposed to squeezing the Primatene Mist bottle and dispensing the medicine where it needs to go into a patient's chest.

The other over-the-counter products are absolutely not equivalent to Primatene. Primatene tablets are, indeed, still available. But what are Primatene tablets? They're ephedrine. That's the active ingredient in some of the diet pills that the FDA pulled off the market a few months ago. Yeah, ephedrine will help you if you're in a tight spot with your breathing, but it's not instantaneous. It's about 30 minutes away after you take the pill.

□ 1430

And you want to talk about something that makes your heart race, it's not Primatene Mist, but the Primatene tablets will do it every time it's tried.

Madam Speaker, here's the real issue: Should we let elites at the Federal agency dictate to our asthma patients in our districts what they can and can't have?

This is one of those instances where I say the Federal agency has gone too far. Ranking Member WAXMAN said that the FDA didn't need to ban Primatene Mist because the EPA had already done it. By what authority does the EPA regulate medicines that I prescribe for my patients? There is no such authority, unless I missed something and we gave them authority where none existed before.

This is about common sense. This is about doing the right thing for the American people. We took away their toilets. We took away their lightbulbs. For heaven's sake, let's not take away their asthma inhalers.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Texas (Mr. BURGESS) that the House suspend the rules and pass the bill, H.R. 6190.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Ms. CASTOR of Florida. Madam Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this question will be postponed.

## NO-HASSLE FLYING ACT OF 2012

Mr. KING of New York. Madam Speaker, I move to suspend the rules and pass the bill (S. 3542) to authorize the Assistant Secretary of Homeland Security (Transportation Security Administration) to modify screening requirements for checked baggage arriving from preclearance airports, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 3542

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''No-Hassle Flying Act of 2012''.

**SEC. 2. PRECLEARANCE AIRPORTS.**

(a) IN GENERAL.—Section 44901(d) of title 49, United States Code, is amended by adding at the end the following new paragraph:

''(4) PRECLEARANCE AIRPORTS.—

''(A) IN GENERAL.—For a flight or flight segment originating at an airport outside the United States and traveling to the United States with respect to which checked baggage has been screened in accordance with an aviation security preclearance agreement between the United States and the country in which such airport is located, the Assistant Secretary (Transportation Security Administration) may, in coordination with U.S. Customs and Border Protection, determine whether such baggage must be rescreened in the United States by an explosives detection system before such baggage continues on any additional flight or flight segment.

''(B) AVIATION SECURITY PRECLEARANCE AGREEMENT DEFINED.—In this paragraph, the term 'aviation security preclearance agreement' means an agreement that delineates and implements security standards and protocols that are determined by the Assistant Secretary, in coordination with U.S. Customs and Border Protection, to be comparable to those of the United States and