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``HEARING ON H.R.___, THE U.S. AGRICULTURAL SECTOR RELIEF ACT OF 2012, AND H.R.___, THE ASTHMA INHALERS RELIEF ACT OF 2012''

WEDNESDAY, JULY 18, 2012

House of Representatives,

Subcommittee on Energy and Power

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:20 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Ed Whitfield [Chairman of the Subcommittee] presiding.

Members present: Representatives Whitfield, Shimkus, Walden, Terry, Burgess, Bilbray, Scalise, Olson, McKinley, Gardner, Griffith, Barton, Upton (ex officio), Rush, Sarbanes, Dingell, Engel, Green, Capps, and Waxman (ex

officio).

Staff present: Anita Bradley, Senior Policy Advisor to Chairman Emeritus; Allison Busbee, Legislative Clerk; Cory Hicks, Policy Coordinator, Energy and Power; Heidi King, Chief Economist; Ben Lieberman, Counsel, Energy and Power; Mary Neumayr, Senior Energy Counsel; Jeff Baran, Democratic Senior Counsel; Phil Barnett, Democratic Staff Director; and Caitlin Haberman, Democratic Policy Analyst.

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Mr. {Whitfield.} I would like to call this hearing to order this morning. This morning, we will be focused on two pieces of legislation, the U.S. Agricultural Sector Relief Act of 2012 and the Asthma Inhalers Relief Act of 2012. Our friends on the other side of the aisle are not here yet. They have been delayed except for Mrs. Capps of California, so the way we will proceed is that I will give my 5-minute opening statement. Then, I will call on the chairman of the full committee, Mr. Upton, to give his 5 minutes. And by then, we believe Mr. Waxman will be here and then if Mr. Rush is not here, I think Mrs. Capps is going to give an opening statement. So you all have to listen to the Republicans for about 10 minutes first before we hear the other side.

As I said, we are holding a legislative hearing on the U.S. Agricultural Sector Relief Act of 2012 and the Asthma Inhalers Relief Act of 2012. Both bills relate to Title VI of the Clean Air Act, specifically, the Montreal Protocol. This international environmental treaty seeks to phase out the use of ozone-depleting substances. One of the substances to be phased out is the fumigant methyl bromide. And basically, it has been phased out except for certain critical use exemptions.

Now, this substance is used by many agricultural groups

around the country, those who grow eggplant, flowers, peppers, strawberries, used in milling companies and so forth. And while many of these farmers have been able to switch to substitutes for certain purposes--for example, sulfuryl fluoride--we now discover that EPA wants to ban sulfuryl fluoride, the substitute. So we think that that does provide a problem.

And I might also add that this methyl bromide is very important--I think I indicated this earlier--in milling operations. So it is also critical uses that the U.S. Agricultural Sector Relief Act sets out a process to allow limited but continued availability of methyl bromide. And we want to set that out clearly in the statute.

I would also like to just say brief word about the Asthma Inhalers Relief Act. This bill simply allows the CFC inhalers already manufactured before the ban to be sold or distributed providing a temporary supply for those asthmatics who would like the option to purchase this. So it is a limited amount. It has already been manufactured. It is just sitting on the shelves and there are many people out there who have requested the ability to continue to use this over-the-counter medicine for their asthma condition. So that is the purpose of this legislation.

At this time I would like recognize the gentleman from

Texas, Mr. Burgess, for 2 minutes and 35 seconds.

[The prepared statement of Mr. Whitfield follows:]

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Dr. {Burgess.} I thank the chairman for the recognition.

You know, this past January 1, a common over-the-counter emergency asthma inhaler was taken off the pharmacy shelves due to an international treaty agreement known as the Montreal Protocol. Now, asthma sufferers who find themselves awakened at 2:00 a.m. with an unexpected attack and who don't have other medicines in the home don't have immediate access to an inhaler and they are forced to undergo a time-consuming and expensive emergency room visit, or worse yet, stay up the rest of the night using the accessory muscles of breathing, wondering if they are going to live through the experience.

A replacement inhaler has been before the Food and Drug Administration's Approval Board for some time, but the FDA has taken no action to allow for another over-the-counter inhaler to be available for consumers. When the January 1, 2012, ban went into effect, people expected that its replacement would be available. They did not expect disruption to health services for asthma patients. But this is not the case. Because of the Food and Drug Administration's intransigence, asthmatics currently do not have an over-the-counter remedy when they have an unexpected attack, especially if that attack happens when they are

traveling and they don't have access to their regular medicines.

However, there is a fairly simple solution. The Environmental Protection Agency has within its authority to ability to waive the ban on the over-the-counter epinephrine multi-dose inhaler to allow the existing stock to be sold, at least until a replacement can be approved. Yet, despite multiple letters to the EPA and in fact to the President of the United States and questions during committee hearings, the EPA remains unresponsive to the plight of millions of asthmatics.

Why does EPA refuse to grant a waiver? I simply cannot tell you because they will not tell me. It is because of their refusal, EPA's refusal to account for the health and safety of asthma patients that we are in the predicament that we are in today. We have got a straightforward piece of legislation--require the EPA to grant a waiver to allow for the sale of remaining stock, which otherwise would be wasted on the shelves of storage facilities where it sits, allowing perfectly good inhalers to sit unused when patients need them really cries out for remedy. The miniscule amount, I mean miniscule amount of chlorofluorocarbons that exist in the over-the-counter inhalers will have a negligible effect on the hole in the ozone, especially considering the limited

supply left.

The Environmental Protection Agency should be on the side of patients and consumers. In this case, it is not. Administrator Lisa Jackson and President Obama need to stop this senseless war on asthmatics.

And I will yield back my time.

Oh, Mr. Chairman, I would ask for unanimous consent to provide for the record a copy of the letter I sent to the President of the United States on February 29 of this year asking for this waiver.

[The prepared statement of Dr. Burgess follows:]

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Mr. {Whitfield.} At this time, I would recognize the gentleman from California, Mr. Waxman, for his 5-minute opening statement.

Mr. {Waxman.} Thank you, Mr. Chairman.

In the 1970s, scientists warned that manmade chemicals were depleting the stratospheric ozone, which protects our planet from harmful ultraviolet rays from the sun. In response, governments around the world acted to address the threat. At first, we acted unilaterally taking steps such as banning CFCs from hairspray. Then, we entered into the Montreal Protocol to ensure that all the nations of the world were working together to solve the problem. The Montreal Protocol is widely recognized as a tremendously successful international environmental agreement. As a result of the protocol, global emissions of the gases are a small fraction of their 1990 levels. And if we continue to comply with the protocol and enforce the Clean Air Act, the ozone layer is expected to recover later this century.

But this progress cannot be taken for granted. Legislation like we are considering today would undermine the effectiveness of the Montreal Protocol. The first bill we are considering would increase the use of methyl bromide, a pesticide that is a powerful ozone-depleting chemical.

Methyl bromide has been banned since 2005, but there is a mechanism in the law for critical use exemptions.

Each year, growers apply for exemptions. EPA analyzes those applications with the help of USDA and the U.S. Government requests critical use exemptions under the Montreal Protocol. This process is working. Since 2005, the level of critical use exemptions requested by the United States and granted through the Montreal Protocol has decreased dramatically. That is exactly what is supposed to happen.

California's strawberry growers are the largest remaining user of methyl bromide. They have been predicting for years that these reductions in methyl bromide would ruin their crops, but according to a recent study, ``the years of declining methyl bromide use have been years of rising yields, acreage, exports, revenues, and market share for California growers.''

This bill reverses the progress that has been made on methyl bromide. Instead of requiring growers to justify continued use of methyl bromide, the bill reverses the presumption. It would require EPA to accept growers' requests unless EPA can prove they are unnecessary. The bill also freezes into law an outdated list of approved critical uses. As a result, sectors that have completely phased out

the use of methyl bromide during the last 7 years would be permitted to use methyl bromide again. Incredibly, even golf courses would once again be allowed to seek critical use exemptions. And the bill creates a gaping emergency event loophole.

I also have concerns about the Primatene Mist bill. Primatene Mist is an over-the-counter epinephrine inhaler from the 1960s. It was phased out at the end of 2011 and has been off the shelves for over 6 months. The bill would put Primatene Mist back on the shelves to its manufacturer could sell off its remaining inventory. A long list of physician, patient, public health, and industry groups strongly oppose the bill. Medical and public health organizations don't want Primatene Mist back on the market because they say it is not safe or recommend it for treating asthma. Physician groups are concerned that the bill will result in patient confusion and companies that made the necessary investments to develop CFC-free inhalers argue that the bill would unfairly provide special treatments to a single company.

Mr. Chairman, we should be looking at these issues very carefully. We should be celebrating and strengthening the Montreal Protocol, not considering legislation to weaken it. And I hope we will reject the methyl bromide bill and rethink the Primatene Mist bill as well.

In the last 30 seconds I just want to point out some history. I was here in 1977 when the first time the issue was raised. We were considering Clean Air Act amendments. One of my colleagues was able to dissuade the Committee from doing anything on CFCs because he said it had not been proved beyond a reasonable doubt that CFCs were harmful, and therefore, Congress didn't act. We finally did act and we acted first and then went to complete and international agreement. It is exactly the kind of thing we ought to do with carbon emissions. We ought to be looking at that issue and dealing with it, not denying the science, which is where we are now today in the Congress of the United States.

I thank the chairman for allowing me to exceed my time by 22 seconds.

[The prepared statement of Mr. Waxman follows:]

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Mr. {Whitfield.} Thank you.

At this time, I recognize the chairman of the full committee, Mr. Upton, for 5 minutes.

The {Chairman.} Well, thank you, Mr. Chairman.

Over the last several decades, environmental quality has improved significantly, and our goal is to maintain that progress without imposing unnecessary burdens on our economy or the American people. And that is why we have consistently advocated for regulatory common sense and balance. And that is what we are going to talk about today--two sensible proposals, I believe, that ensure environmental rules do not impose unnecessary hardships.

Congress examined and addressed ozone depletion through the 1990 Clean Air Act amendments, which provide the framework of the U.S. participation in the Montreal Protocol treaty. As a result, the use of CFCs as refrigerants in air-conditioners and refrigerators has been sharply curtailed. And other ozone-depleting substances have also been restricted.

For the most part, the transition to the substitutes has gone well, but there are two exceptions that we hope to address through targeted legislation. One deals with the crop fumigant methyl bromide, which was widely used in

agricultural applications until it was included on the list of ozone-depleting compounds. For many crops and uses there are adequate substitutes, and as a result, methyl bromide use is down by 90 percent. But for some crops, methyl bromide is still needed because viable alternatives are not yet available.

And to address that issue, I am pleased that Michigan farmer Russ Costanza has joined us today. Russ grows peppers, eggplant, squash, tomatoes, cucumbers back on his farm in Sodus, Michigan, and he employs 125 folks. And we need to hear him out because his message is that of many farmers throughout the country who doubt whether they can remain in business without continued access to methyl bromide. The Agricultural Sector Relief Act would allow farmers like Russ to keep using methyl bromide on a limited basis.

While one bill provides relief to farmers, the other provides relief to patients with asthma. The over-the-counter asthma inhalers containing CFCs, most commonly marketed as Primatene Mist, have been banned because they use very small amounts of CFCs as propellants. But no non-CFC over-the-counter inhalers are available at this time, leaving asthmatics without an over-the-counter option. The Asthma Inhalers Relief Act would allow for the remaining inventories

of this inhaler, which were available in the U.S. for more than 40 years, to be temporarily sold or distributed without penalty.

So on behalf of the American people, we are working to ensure reasonable environmental protections and we are doing so while avoiding unnecessary harm. The two bills at issue today satisfy those obligations.

And I yield to the chairman emeritus, Mr. Barton, the balance of my time.

[The prepared statement of Mr. Upton follows:]

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Mr. {Barton.} Thank you, Chairman Upton. And thank you, Chairman Whitfield and Mr. Rush, for holding this hearing. We may have already done it, but I would like to welcome back former Congressman Bart Stupak, who is in the audience and a distinguished former member of the committee. We are glad to have you, Bart.

I support the U.S. Agricultural Sector Relief Act of 2012 and I tend to support the Asthma Inhaler Relief Act of 2012 also, although I have got some concerns about that piece of legislation.

Methyl bromide is essential as an agricultural fumigant. There are some alternatives for agricultural uses, but methyl bromide is still needed for others where there doesn't appear to be a viable alternative. Under the Montreal Protocol, we have seen a considerable decrease in the critical use exemptions since 2005. This bill is important not only for American jobs but as a matter of national security as well.

In terms of the Asthma Inhaler Relief Act, Dr. Burgess has got a well intended piece of legislation. I am going to put into the record, Mr. Chairman, by unanimous consent, a letter from the Allergy and Asthma Caucus and the Mothers of Asthmatics. Their president and founding member is in the audience today, Nancy Sander, and we are glad to have you,

too, Nancy, here.

Their group has got very legitimate concerns about Dr. Burgess' bill, and I have worked with them and put them in touch with Dr. Burgess to try to alleviate some of those concerns. I think it is important that Americans have an over-the-counter alternative to a prescription inhaler. And that is basically what Dr. Burgess' bill intends to do. The letter that I will ask unanimous consent to put in the record at the end of my statement, Mr. Chairman, does say that there is an alternative. There is a handheld bulb nebulizer that is available over-the-counter, and that is one reason I have some concerns about Dr. Burgess' bill.

With that, I would ask unanimous consent to put a letter dated July 17, 2012, from the Allergy and Asthma Network Mothers of Asthmatics, into the record and then yield back the balance of my time.

[The prepared statement of Mr. Barton follows:]

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Mr. {Whitfield.} Without objection, it will be entered.

[The information follows:]

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Mr. {Whitfield.} At this time, I would like to recognize the gentleman from Illinois, ranking member of the subcommittee, Mr. Rush, for a 5-minute opening statement.

Mr. {Rush.} Well, thank you, Mr. Chairman.

Mr. Chairman, in keeping in line with the majority party's overall agenda of bypassing, overriding, and curtailing the Clean Air Act, as well as any and all regulations that may hamper industry profits regardless of the health or environmental benefits that those rules were designed to protect, we are here yet again holding this hearing on the Agricultural Sector Relief Act and the Asthma Inhalers Relief Act of 2012.

My Republican colleagues, Mr. Chairman, continue to ignore the fact that the U.S. has set more than 40,000 high temperature records this year and that the last 12 months have been the hottest ever recorded in U.S. history. And the fact that more than 113 million Americans are living under extreme health advisories, while the USDA has declared a federal disaster area in more than 1,000 countries covering 26 States also does not seem to concern the majority party.

Mr. Chairman, while the country literally burns around us, I can't believe that we are here today holding yet another hearing on two issues of far less importance to most

Americans other than a few industry lobbyists.

Today, fully 2/3 of the country is experiencing extreme drought and 30 percent of the Nation's corn crop is in poor or very poor condition. While at the same time, water levels of four of the five Great Lakes have plummeted due to high evaporation rates and insufficient rainfall. We are still here having hearings on two not very important bills to the majority of the American people.

Mr. Chairman, I ask this committee to not to deal with these two bills but to deal with a different kind of drought, the drought of laws that come from the inaction of this subcommittee. While even all the heat-related and fire-related and the atrocities that are occurring to farmers of our Nation, to the consumers of our Nation, the two bills before us would only serve the interests of select industries by rolling back gain we have made under the Montreal Protocol.

The Montreal Protocol is widely recognized as a tremendously successful international environmental agreement, and in 2009 became the first of its kind to achieve universal ratification by every country in the world. Mr. Chairman, let us get on to some real business.

And with that, I yield a minute, the balance of my time, to Mrs. Capps of California.

[The prepared statement of Mr. Rush follows:]

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Mrs. {Capps.} I thank my colleague for yielding to me. And I want to focus a few comments on the methyl bromide bill, a very important issue to my constituents.

I represent some of the very best strawberry and cut flower growers in the country, and just a couple of weeks ago, I was invited by the Strawberry Commission of California to meet with them in Santa Maria to discuss this exact issue. We met in the midst of the strawberry fields. While I have seen firsthand the tremendous progress in finding alternatives to methyl bromide, I have also seen firsthand why methyl bromide is still a necessity to many if not most strawberry growers.

I am proud to say that many of the flower farmers in my district like June and Rene Van Wingerden of Ocean Breeze Farms and Lane Devries of Sun Valley Floral no longer use methyl bromide because they have pioneered innovative new methods that are effective. But let us be clear. These alternatives don't work for everyone and they don't work in every situation. And the cost of the disease our growers face are very real, very threatening. During my recent visit, I saw firsthand the impacts of charcoal rot in some fields in Santa Maria, as well as other diseases. They can literally shut down an operation hurting not only the growers

but also their workers and the local economy.

I must add that agriculture is a growing force of my congressional district, strawberries are the number one crop, and these local economies stretch far and wide in central and southern California, including the local economies of my colleague, Mr. Bilbray, I know.

So it is very important that this issue be addressed but I am, I must say, Mr. Chairman, disappointed that we are going to be back here in just a very few hours to markup this legislation without hearing from the Administration or really adequate time to fully consider the testimony of our witnesses. I am pleased to say that one is from the Strawberry Commission in California. It is a very important issue that should not be rushed through the legislative process.

That being said, I do look forward to hearing the witness testimony and working toward a solution on this matter. And I yield back. Thank you, Mr. Rush.

[The prepared statement of Mrs. Capps follows:]

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Mr. {Whitfield.} Thank you, Mrs. Capps.

And I will say that while we did invite EPA to testify, they were unable to be here, but they have submitted a pretty detailed statement for the record relating to these two bills. And this will be part of the record, so thank you.

We have two panels of witnesses this morning and I would like at this time to call up the first panel of witnesses. And on that panel we have five people. First, we have Mr. Russell Costanza, who is the owner of Russell Costanza Farms. Number two, we have Mr. Scott Dimare, who is vice president and director of farm operations, Dimare Ruskin, Inc. We have Mr. David Doniger, who is no stranger to our committee, and he is the policy director of Climate & Clean Air Program at the Natural Resources Defense Council. And I would like to call on Mr. Bilbray to introduce our next witness, please.

Mr. {Bilbray.} Thank you, Mr. Chairman.

Chairman Whitfield, thank you for holding this hearing on this very important issue, especially to certain segments of our society and economy.

Methyl bromide is a critical application, as my colleague from California said, in certain situations, limited but critical in those limited. And I wish to ask for unanimous consent to enter into the record a letter

supporting the U.S. Agricultural Sector Relief Act.

Mr. {Whitfield.} Without objection.

[The information follows:]

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Mr. {Bilbray.} It is my honor to introduce Michelle Keeler. She is one of our panelists today. Ms. Keeler, I apologize for the un-San Diego weather that you have to endure at this time. I hope you understand what a sacrifice those of us in California who serve in Congress do every day, okay, at least during the summer.

Mr. Chairman, Ms. Keeler is vice president of Mellano & Company. It is a prestigious family-owned business that specializes in cut flower growing in the sunny San Diego/Carlsbad area and right along the coast. As you are driving up Highway 5, you can see the hillsides filled with her products and the beauty that has been appreciated by the community.

The company prides itself in progressive ideas of cut flowers. Many of them have been developed as an industry-wide standard as improved logistics in growing techniques. These achievements have utilized pre-cooling allowing flowers to be shipped with optimum freshness.

Mr. Chairman, let me point out that when Mrs. Keeler speaks, she is not just speaking about her endeavor to keep a family business alive, to keep American jobs in America, but as a former California Coastal Commissioner, I want to remind everybody, too, that the California Coastal Commission has

determined that Mrs. Keeler's operation is a cultural heritage that needs to be preserved. It is actually mandated in the Coastal Act's enforcement that she keep her production of flowers in this area.

And Ms. Keeler, I want to welcome you to California and welcome your ability to enlighten those of us in Washington of the challenges you face on the West Coast.

Mr. {Whitfield.} Thank you. And welcome, Ms. Keeler.

And the final witness in the first panel will be Mr. Mark Murai, who is the president of the California Strawberry Commission. And we appreciate your being here.

I will be calling on each one of you to give a 5-minute opening statement and on the table there are a couple of little small boxes that have colors red, yellow, and green. And when you get to red, we hope you will be finished, but if not, we will let you go over for a brief period of time.

So Mr. Costanza, we will recognize you first and you are recognized for 5 minutes to give an opening statement. And make sure your microphone is turned on as well. Thank you.

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^STATEMENTS OF RUSSELL COSTANZA, OWNER, RUSSELL COSTANZA FARMS; SCOTT M. DIMARE, VICE PRESIDENT AND DIRECTOR OF FARM OPERATIONS, DIMARE RUSKIN, INC.; DAVID DONIGER, POLICY DIRECTOR, CLIMATE & CLEAN AIR PROGRAM, NATURAL RESOURCES DEFENSE COUNCIL; MICHELLE CASTELLANO KEELER, VICE PRESIDENT, MELLANO & COMPANY; AND MARK MURAI, PRESIDENT, CALIFORNIA STRAWBERRY COMMISSION

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^STATEMENT OF RUSSELL COSTANZA

} Mr. {Costanza.} Well, thank you. And thank you for the warning because it takes me about 6-1/2 minutes to read this and I am going to skip over some of this keeping this in mind. Okay.

First of all, I want to thank each and every one of the members for allowing me this opportunity to speak before you today and represent my farm, my workers in the State of Michigan.

My name is Russ Costanza. I grew up on our family farm. I am the owner of Russell Costanza Farms. My wife and I established our farm in 1976 with 10 acres. Today, we have grown that farm with our two kids and their families to over 500 acres of peppers, eggplant, squash, tomatoes, and

cucumbers. Our farm is labor-intensive. Over the years, we have grown from my wife and I doing all the work on the farm to 125 farm workers. Sadly, the inability to use methyl bromide and the lack of a truly viable alternative is threatening our family and our remaining workers' livelihood.

Mr. {Whitfield.} Would you mind just moving the microphone a little closer?

Mr. {Costanza.} I am usually a little loud anyway.

Methyl bromide is a fumigant that controls insects, nematodes, pathogens, and weeds, and we use the fumigant on our farm to treat the soil prior to planting. Fumigation with methyl bromide allows us to grow a higher quality crop with increased yields and provides more onetime effective pest control than any other alternative product.

Methyl bromide has allowed us to treat our fields and cultivate abundant, high quality, high demand produce. This year, however, we were not granted any critical use exemptions for methyl bromide. Without any CUEs, the only way to use methyl bromide is to purchase dwindling stocks of the chemical that were produced prior to 2005. Such stocks are not readily available and are cost prohibitive. I currently have enough methyl bromide to last through one or perhaps two growing seasons for eggplant only, but after that, I do not know how I will be able to continue to produce

adequate crops.

I used to be able to purchase methyl bromide for about $1 a pound. Today, the cost averages $9 a pound. It costs over $800 an acre to use methyl bromide. Between the scarcity and high cost, it is impossible to compete with inexpensive, quality produce from other countries whose growers are able to legally use methyl bromide. Further, the quality of our produce will deteriorate due to the lack of methyl bromide use, further eroding our ability to compete with foreign growers in our own markets.

While we have a limited supply of methyl bromide available for eggplant, we cannot use methyl bromide for our other crops. Due to the loss of quality and yields associated with these crops, we have experienced decreased profits for our remaining workers and our farm. Our dwindling profits also mean a loss of tax revenue for local, state, and federal governments.

Our family and our workers pride ourselves on providing high quality and affordable food to U.S. consumers and to making a meaningful contribution to our country's economy. Unfortunately, our ability to do this is diminishing due to the lack of methyl bromide and an effective, affordable alternative.

Our farm has spent a great deal of money and effort

seeking viable alternatives to methyl bromide. In 2005, staff from the EPA Chicago office was invited to tour our farm. They came, observed our operation, how we worked, and how methyl bromide was used. We demonstrated how methyl bromide increased our yield of our eggplant and pepper crops. These increased yields and lack of effective alternatives were documented through the research conducted on our farm with Michigan State University on all methyl bromide alternatives. We donated the land, the manpower, and the resources to research the efficiency of alternatives on eggplant. Sadly, we did not find any affordable, usable replacement.

Due to the weather in Michigan, we have a narrow window of time before planting in which we can apply a fumigant. We cannot wait an additional 2 or 3 weeks to reenter the field prior to planting, as was required by iodomethane, Midas, and some other alternatives, or we would lose our market window. Further, Midas is no longer being sold in the United States.

For my Michigan operation, methyl bromide is truly the only treatment option available. And then we will go on with a study from Michigan State University. Our circumstances are dire, which I am very appreciative of the Committee. I and other Michigan growers are facing an emergency situation on our farms, and for that reason, I am grateful that the

legislation includes the provisions related to the emergency use of methyl bromide under certain circumstances.

The law must allow for flexibility when a planned, affordable alternative is no longer an option or another unanticipated event occurs. While I understand that EPA is the lead organization in making CUE recommendations to the parties, I appreciate that the legislation includes consultation with the U.S. Department of Agriculture. Because of its close working relationship with growers, the USDA and extension agents are best equipped to determine when an emergency situation exists. The Department's role in this process is critical.

I cannot overstate the importance of access to methyl bromide for my farm operation and my fellow Michigan growers. We are facing a crisis and need relief. I am hopeful that Congress will pass the Act of 2012 and the EPA and USDA will quickly implement a process to allow for limited emergency exemptions when circumstances exist.

Thank you very much for your leadership in addressing this critical issue for myself and other Michigan growers.

[The prepared statement of Mr. Costanza follows:]

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Mr. {Whitfield.} Well, thank you, Mr. Costanza.

And Mr. Dimare, you are recognized for 5 minutes.

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^STATEMENT OF SCOTT M. DIMARE

} Mr. {Dimare.} Thank you, Mr. Chairman.

Mr. {Whitfield.} Be sure and turn your microphone on and move it up close.

Mr. {Dimare.} Thank you, Mr. Chairman. Ranking Member, the rest of the Committee, I want to thank you for having me here today. My name is Scott Dimare. I am a director of farm operations for a family business that is over 80 years old. I am a third-generation farmer. We are based in Ruskin, Florida. We farm tomatoes. I employ about 5 to 600 people. And we are here to talk about methyl bromide for emergency use.

With rising costs, we have a cost of about 2,500 to 3,000 an acre to lay our plastic mulch and do our fumigation process before we ever put a plant in the ground. Methyl bromide is the foundation for our operation. It allows for uniformity and consistency, which is key in our industry. It kills soil-borne diseases, pests, and weeds. The idea is to sterilize the ground before you plant it. We used to call methyl bromide idiot-proof. And basically, it is not a reckless term; it is how we view under all conditions--and the key being all conditions, okay, because the rest of the

alternatives that we will talk about are very sensitive to soil, moisture, temperature, and so forth, whereas methyl bromide worked uniformly across the board under all conditions.

Furthermore, with the tools that we have available today, I feel pretty confident that we have reduced any if not all emissions. And among those tools we use are a Raven computer, which is on the tractor, which precisely turned on and off the system, allows for no leakage. We are also using the VIF or high barrier films, which reduce the emissions down to virtually nothing.

And let us just talk about the alternatives for a minute. We have made numerous capital investments over the years. We have known the phase-out was coming. For many years, we have tried to be ahead of the curve by being proactive in trying the number of different alternatives that are available. As Mr. Costanza mentioned earlier, one of the tools that we had has been taken away--Midas--which I felt was one of the most comparable or efficacious products out there but still had its limitations.

But be that as it may, we have the alternatives that are there, and among them, we cannot use them in certain areas because of groundwater issues. In the other areas we can use them, we still have many unresolved issues and most of them

are attributed to weather. Soil conditions, soil temperature mainly being wet or cold does not allow for the dispersion of the product, which again brings us to the point where we have an unpredictable situation. As a farmer, we can control only so many things. And what we do before we lay our plastic mulch is crucial. And once we do that, we are at the hands of Mother Nature. And we can't control the weather. In Florida we live in a subtropical climate. With these alternatives, the plant-back periods are up to 2 months that I have to have this plastic sitting out there with nothing being grown because of the fact that it is damaging to the crop because we don't know what the result is going to be, whereas methyl bromide in the past we had a maximum of a 2-week leeway time. That is a huge risk that we have created. Okay?

We have got, as I told you, $3,000 in the ground before we ever put a plant in the ground. You got leeching of fertilizer, you got more weed control issues, herbicides, weeding by hand, which is very labor-intensive for that extra month-and-a-half period. We got tropic storms. We have laid hundreds of acres before and been wiped out by storms. The longer time you have between your planting periods, the more risk you have, the higher your cost is going to be. And with methyl bromide we didn't have that.

I guess, you know, when all is said and done, you know, this comes down to a need of a product that we I feel need, must have, in order to clean up some of these situations that we have. Since the phase-out of methyl bromide, we have an increasing incidence of soil-borne diseases. You can see it getting worse every year behind methyl bromide and it is going to continue to get worse. We have, you know, Fusarium, Fusarium crown rot, southern blight, which we never had. Fusarium I have in fields this year that I have never had before ever. Weeds, nutsedge is getting out of control and, you know, again these are things that we never had issues with when we had methyl bromide.

I just again appeal to you to use some good foresight and--it is a tool that we need. Thank you.

[The prepared statement of Mr. Dimare follows:]

********** INSERT 2 **********

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Mr. {Whitfield.} Thank you very much.

And Mr. Doniger, you are recognized for a 5-minute opening statement.

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^STATEMENT OF DAVID DONIGER

} Mr. {Doniger.} Thank you very much, Mr. Chairman and Mr. Rush.

Protecting the ozone layer is a huge bipartisan public health success story. The treaty was signed under Ronald Reagan and it has had the support of four Presidents since then. The phase-out of ozone-destroying chemicals, including methyl bromide, is saving literally millions of Americans and tens of millions of people around the world from death and disease, from skin cancer, cataracts, and immune diseases. And it is also savings farmers billions of dollars in avoided ultraviolet light, ultraviolet radiation crop damage.

Now isn't the time to tamper with the Protocol or the Clean Air Act. I won't mince words. By slowing or actually reversing the transition from methyl bromide, this bill will lead to more skin cancers, more cataracts, more immunological disease. It will benefit a number of growers who have profited by abusing the critical use exemption for more than a decade. Some of the people now seeking relief now haven't even asked for critical use exemptions for years. Thousands of other farmers growing other crops will suffer more crop losses as a result.

Now, the treaty and the Clean Air Act already allow for well supported exemptions and no one is suggesting that the pursuit of exemptions under existing law isn't possible. This has been done for 7 years and well supported exemptions have been forwarded by the U.S. and granted by the parties. But this industry has dragged its feet on replacing this dangerous compound. No other industry has had more time or more leeway to transition away from dangerous ozone-destroying chemicals.

The U.S. is responsible for more than 90 percent of all methyl bromide exemptions. Every other strawberry- and tomato-growing country with California-like growing conditions or Florida-like growing conditions--including Italy, Spain, Greece, and Australia--has ended use of methyl bromide. There is a lot of concern expressed over the years about competition from Mexico. Mexican growers use less methyl bromide per acre than their California counterparts, and Mexico will end the use of methyl bromide entirely this year.

California strawberry growers have done very well during this whole experience. Strawberry acreage is up despite ground rules that countries would not use methyl bromide on expanded acreage. Yields are up, grower prices are up, crop values are up.

U.S. critical use exemptions have been coming down. California strawberries are now the only field use for which the U.S. still seeks exemptions. And there are several other structural and commodity uses. Together they amount to about a little more than 400 tons. That is significantly down from 10,000 tons 7 years ago. And as I said, there is an opportunity to keep asking for well supported exemptions. There is also a stockpile of 1,200 tons, three times the requests now being made.

This bill would do reckless damage in three ways. First, it would permanently define as critical uses all of the uses that were deemed critical in 2005 even though the vast majority of those uses don't use methyl bromide anymore. Why would we make golf course turf grass a critical use again? It makes no sense to freeze into law the utterly out-of-date list from 2005.

Second, the bill relieves the applicants of the need to show why they need exemptions. Doesn't it make sense that if you are asking for an exemption for a banned product, you should explain why and you should produce the data that shows that you need it? Some people do that and some people make the case. Some people's case is convincing and the U.S. makes the application and the other parties agree to it. Other people don't even ask. Some people make exemption

requests that can't even get past first base.

So EPA under this bill would bear the burden of saying why any wish list shouldn't be forwarded to the parties. And this is actually going to backfire for the applicants because it actually helps the U.S. to win approval for the exemptions to show that it has exercised judgment and discipline in framing its requests and hasn't mechanically asked for everything that domestic applicants may have wanted.

Lastly, the bill would blast an enormous loophole into the Clean Air Act and our pesticide safety laws by allowing any individual user to write his own ticket for up to 20 tons of methyl bromide per farm simply by asserting the existence of an ``emergency.'' There could be a hundreds of emergency exemptions per year, totaling up to 2,000 tons, the 2011 critical use amount.

The testimony today illustrates the abuse that this emergency exemption would provide where some witnesses are saying, well, we just needed to go in and ``clean up'' problems for which we didn't get critical use exemptions. So it is just an alternate route to write your own critical use exemption.

This is a bad bill. It is an unneeded bill. It would harm public health, harm other farmers, and indeed it would even harm the farmers it is intended to help because it would

make it even more difficult to get critical use exemptions through the current process. The current process is working and this committee should leave well enough alone. Thank you.

[The prepared statement of Mr. Doniger follows:]

********** INSERT 3 **********

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Mr. {Whitfield.} Thank you, Mr. Doniger.

At this time, Ms. Keeler, you are recognized for a 5-minute opening statement.

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^STATEMENT OF MICHELLE CASTELLANO KEELER

} Ms. {Keeler.} Thank you.

As Congressman Bilbray stated, my family grows cut flowers in the San Diego area of California where we employ over 200 employees. We farm approximately 400 acres at any given time, have over 50 varieties of flowers growing on our farm. Unlike other farms, you have to picture our farm sort of like a patchwork quilt because we just don't have one product; we have several products. So you might have 2 acres of tulips next to 10 acres of lilies next to 20 acres of myrtle, so there is all kinds of things taking place. And each of those squares is constantly changing in terms of the crops, cultivating times, diseases, pests, irrigation needs, and the market demands.

We are very concerned by EPA's arbitrary cuts of our allocations with no real burden of evidence showing a feasible or technical alternative exists for certain crops. We are also concerned about situations that are emerging on our farms requiring emergency cleanup applications of methyl bromide.

As a grower, we have a limited number of tools in our toolbox, and when you take a tool away from us, it puts

pressure on the remaining tools. And when you leave us with only weak tools, we become as weak as the tools are. As soon as these tools become useless, we have to walk away, and sadly, many growers are starting to walk away from growing their crops.

Please understand, we are using alternatives whenever possible, and in some instances, they work for a short time. But then issues start to pop up. A good example is nut grass. We have been using alternatives such as Telone, chloropicrin, and Vapam, and while they did a decent job for a little while of knocking down the nut grass, it never eliminated it and after a few years these popped back up and take over our crop. We then find ourselves applying excessive amounts of these so-called alternatives. So not only are we compounding the use of alternative chemicals, we are also finding now later on that there is a detrimental effect to our crops, which forces us to prematurely disk under our flowers and we are disking under our investment as well. A periodic application of methyl bromide is more effective and we believe it is safer.

We also have difficulty in the cut flower industry because we can't fit our growing practices into one neat formula due to this ever-changing patchwork quilt that I described earlier. In these squares we have perennials,

annuals, bulb crops, seed crops, and shrubs. Our crops at Mellano & Company can have a planting value of $60,000 an acre, and some of these perennial crops will be in the ground from anywhere from 5 to 25 years. We can't afford to put plants like this that are this expensive into dirty soil. We also can't predict when in that 5 to 25 years we will be replanting this crop based on issues that pop up. So periodic applications--it is difficult for us to fit into an application process because it is not every year. It might be in 5 years; it might be in 8 years.

The cut flower industry has converted many, many crops over to alternatives, but in a few instances, alternatives do not exist. This year, the cut flower industry submitted a similar application to EPA as in the previous few years. However, EPA determined we had no need and submitted nothing to the international body. We understand EPA assumed methyl iodide would be a drop-in replacement for our entire industry despite the fact that we provided scientific information showing that methyl iodide was not useful to California growers. We can't afford for EPA to make assumptions in our dynamic industry about our growing practices without understanding our industry first. Not only is methyl iodide not a replacement in California, the manufacturer withdrew sales of that compound in the U.S., so now, what does our

industry do?

The United States agricultural community has complied with the CUE requirements where no alternatives exist, despite the fact that this process is cumbersome, time-consuming, and costly. We are willing to do so because in a few instances, we still need this strong tool in our toolbox, yet our applications continue to be arbitrarily reduced without any or inadequate scientific explanation. So now we are left with weak tools or with nothing at all.

I personally cannot understand why EPA can so easily make these cuts. Every miniscule cut that they make means so much to our survival and so little in the grand scheme to the other parties. Why is our government hurting us? And we are being hurt. In the floral industry, many growers, including my family, is cutting back on our crop mix to a very limited number of varieties to ensure that we have access to the proper growing tools. This means fewer varieties available and certainly nothing new in the marketplace. Thus, other developing countries are taking on these varieties and providing them to the consumer, which begins the decline of our business.

People are in pain. Our family farm is in pain. And it is something that Congress can do something about. Please reaffirm the CUE process beyond 2014, ensure that EPA

protects its American growers with scientifically sound reasoning, and make available the tools we need to grow our crop, especially in emergency rescue and cleanup situations. Thank you.

[The prepared statement of Ms. Keeler follows:]

********** INSERT 4 **********

Mr. {Whitfield.} Thank you, Ms. Keeler.

And Mr. Murai, you are recognized for 5 minutes.

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^STATEMENT OF MARK MURAI

} Mr. {Murai.} Good morning, Mr. Chairman. Chairman Whitfield, Ranking Member Rush, and members, thank you for holding a hearing on this very important issue. My name is Mark Murai and I am a third-generation strawberry farmer and president of the California Strawberry Commission, representing all of California's strawberry growers, shippers, and processors.

Farmers lead the way in the world to find alternatives. The United States has eliminated over 90 percent of ozone-depleting products and the ozone layer is healing faster than predicted. As we all know, legacy fluorocarbons, CFCs, from a variety of consumer products such as plastics, foam, solvents, and fire extinguishers--

Mr. {Whitfield.} Sorry. You can continue.

Mr. {Murai.} --are the largest impact on the ozone layer. Because these legacy fluorocarbons have a long life, the scientists forecast it will be another 39 years before the ozone layer is fully restored. But methyl bromide can also impact the ozone layer, and I am proud to say the strawberry farmers have taken this seriously. We have innovative new farming techniques such as drip fumigation and

employed new technologies such as emission reduction measures to reduce our methyl bromide imprint.

California strawberry farmers are also leaders in organic production methods. These farmers grow more organic strawberries than all other 49 States combined. In fact, nearly 1 out of 5 California strawberry farmers grows both organic and conventional.

By combining all of these approaches, California strawberry farmers transition to non-methyl bromide alternatives faster than any other strawberry farmers in the world. And unfortunately, we have learned that there are still some diseases that can only be treated by methyl bromide.

In the late '90s, I made the decision to phase down my farm's use in methyl bromide ahead of the official 2005 deadline. I was past chairman of our Research Committee and an officer of the Commission, so I believed my family's farm should demonstrate that using alternatives were feasible. I was confident; I was cavalier. The first year, the yields looked comparable. The second year, my new plants didn't look so good, a little peaked. And by the third year, my field was dying before I picked my first berries. Calling your banker is a difficult call to make having to explain your field is dying, and notwithstanding a miracle, I would

not be able to pay back my crop loan that year. And by the way, I need to borrow more money for next year's planting in a few months. That is a tough call to make.

But the worst part was telling my family that we are deep in the hole and our soil is now contaminated with disease. That is a tough thing for a farmer to swallow. So farmers need clean soil.

As you can see in my written testimony, I am not alone in my experience. After multiple years of repeated use of alternatives, we learned that alternatives do not work on all the soil-borne diseases. In 2008, we saw the emergence of new diseases that resulted in widespread crop failure.

The CUE process needs to be improved. In 2011, a new fumigant called methyl iodide was approved for use in California. Everyone thought the fumigant would be an effective treatment for these tough soil-borne diseases. EPA immediately rushed to try and force farmers to use methyl iodide. EPA stated, ``our 2013 critical use nomination assumes an aggressive transition rate to methyl iodide of 7 percent per year between now and 2013 and resulting in a reduction of 21 percent.'' When I heard this, I could hardly believe my ears. Doesn't EPA know about the community concerns in California? We specifically made a trip to EPA to show news clips and newspaper articles to give them a

flavor of what we were going through back in California and how our communities and State and legislators were in an uproar around this compound. There was an obvious disconnect between D.C. and our farming communities. And we believed at best our transition, if this product was registered, would be at a rate of maybe 1 to 2 percent and that was aggressive.

Well, 4 months ago, the manufacturer decided that this controversy was too big and they cancelled methyl iodide in California. We immediately advised EPA and asked that they restore the 21 percent but they did not take any action to request a supplemental CUE for 2013. I wanted to believe our government would work to ensure that our critical needs were met within the rules of the treaty, but this has not happened. At every turn, there is always another arbitrary reason our application should be cut. This is just not right. Our farmers have followed all the rules, but now EPA doesn't want to follow the rules. They should substantiate their new reasons with data standards that we are held to. I should be able to go back and tell our growers that the system is fair, the interpretations are correct, and we should all just live with it, but I can't.

The new science report on methyl bromide CUEs, perhaps what is most frustrating is that nobody seems to be following the science. Scientists have always described methyl bromide

as quickly dissipating in about 1 year and having a relatively smaller impact compared to other ozone-depleting products. The newest scientific assessment by NOAA, NASA, UNEF, WMO, and the EU concludes the ozone layer is improving faster than predicted due to legacy products that were required by 39 years to fully restore the ozone layer and continued use of methyl bromide will add less than 73 days to the 39 years. More specifically, the report stated, ``the scientific assessment of ozone depletion 2010 is the product of 312 scientists from 39 countries of the developed and developing world who have contributed to its preparation and review, 191 scientists prepared the report, and 196 scientists participated in the peer-review process''--196. They said methyl bromide ``continuing critical use exemptions at the approved 2011 level indefinitely would delay the return of the equivalent effective stratospheric chlorine 1980 levels by .2 percent of a year.

Mr. {Whitfield.} Mr. Murai, your testimony is very interesting and you have gone over considerably, so if you would try to summarize it here, we would appreciate it.

Mr. {Murai.} Sorry about that.

So what is the benefit to the economy of allowing continued use of methyl bromide while the California Department of Food and Agriculture commissioned an economic

study and they said if there is no methyl bromide and no methyl iodide, the California communities will lose over 1.5 billion annually and more than 23,000 jobs annually.

So if all the scientists and economists are accurate and the environmental impact of continued use of methyl bromide CUEs would just add no more than 73 days to a 39-year schedule while the economic downside for not allowing this would be $58 billion and 897,000 jobs over those same 39 years, I just ask please bring some common sense to this issue and restore our CUE. Thank you for your time.

[The prepared statement of Mr. Murai follows:]

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Mr. {Whitfield.} Thank you.

And I thank all of you for your testimony.

At this time, we will have some questions for you and I will recognize myself for 5 minutes of questions.

Mr. Murai, Mr. Doniger in his testimony said that California strawberry growers have led the pack in coming to Congress playing the hardship violin. And he said that your growers have done very well, you have increased your yields, you have increased the strawberry acreage, and that you all are doing very well. But from what you said, that doesn't sound like that is the case. Now, have you increased your yields? Have you increased your acreage or--

Mr. {Murai.} Yields have increased and it has barely kept us floating. The margins are razor thin. I think the economic studies only show one side of the story, and I don't think I would even really be here if we were doing well, right?

Mr. {Whitfield.} Yeah.

Mr. {Murai.} I think this is a priority and an important issue because the growers are in a risky situation, very difficult to plant. The bankers are even asking about what are you doing to ensure--

Mr. {Whitfield.} How much do you borrow to put out a

crop?

Mr. {Murai.} It is about 20 to $22,000 per acre per year.

Mr. {Whitfield.} And what about you, Ms. Keeler?

Ms. {Keeler.} At the high end, we are at $60,000, so between 20 and 60,000 depending on the varieties. I--

Mr. {Whitfield.} Per acre.

Ms. {Keeler.} Per acre.

Mr. {Whitfield.} And Mr. Dimare?

Mr. {Dimare.} The operating costs alone are around $10,000 an acre. That doesn't include harvesting or land cost or anything like that.

Mr. {Whitfield.} Mr. Costanza?

Mr. {Costanza.} Our operating cost per acre is between 10 and $12,000 an acre per year.

Mr. {Whitfield.} Yeah. Now, from my understanding, it is very difficult to obtain a critical use exemption for methyl bromide, is that correct, Mr. Costanza?

Mr. {Costanza.} Yes. In our case, we were told we were going to have Midas to use this year.

Mr. {Whitfield.} Okay. What about you, Mr. Dimare? Have you tried to get a critical use exemption?

Mr. {Dimare.} Yes, it is an exhausting process.

Mr. {Whitfield.} Ms. Keeler?

Ms. {Keeler.} Yeah, we have been part of the process from the beginning. And like I said earlier, it is a very time-consuming process, and private sector, we are doing a tremendous amount of research looking for these alternatives. There seems to be this idea that we are not doing this research looking--

Mr. {Whitfield.} Right.

Ms. {Keeler.} --for alternatives and we just want this simple free ticket for methyl--

Mr. {Whitfield.} Right.

Ms. {Keeler.} --bromide. It is not an easy process.

Mr. {Whitfield.} Yeah. Mr. Murai?

Mr. {Murai.} Yes, Mr. Chairman, every year.

Mr. {Whitfield.} Yeah. Mr. Doniger mentioned that in other countries, Mexico, Italy, so forth, that they are using less methyl bromide and being quite successful. What would be your reaction or statement or comment about that? Or do you have any information about it, any of you?

Ms. {Keeler.} In our industry, I can comment to that. Mexico produces some pretty unsophisticated flowers, so they have no need for it. And my family immigrated from Italy and we still have some connections there, and in the EU, the same thing is happening there. The EU is off-shoring a lot of their flowers over to Africa. And so like we are seeing

flowers going down to the South American countries. The Italian growers are getting rid of the same products we are getting rid of for the same problem--

Mr. {Whitfield.} Yeah.

Ms. {Keeler.} --and they are being grown in Africa for some of those countries.

Mr. {Whitfield.} You know, one of the common things that seems to be coming through a lot of hearings that we have is that we are hearing a lot of concerns about EPA that many people in various businesses dealing with EPA view them almost as an adversary. And I would just like to ask you, do you view EPA as a partner trying to help solve a problem or do you view them as an adversary?

Mr. {Murai.} Well, the actions result in an adversarial result. I would say we work closely and try to collaborate and really flesh the data out. You know, like Mr. Doniger said, we want to put up a nomination that is credible and we are using the best data.

Mr. {Whitfield.} Yeah.

Mr. {Murai.} And so I think we try to have a collaborative effort but there is nobody listening over there.

Mr. {Whitfield.} So you feel it is an adversarial relationship, is that correct?

Mr. {Murai.} Yes, at times--

Mr. {Whitfield.} Ms. Keeler, what about you?

Ms. {Keeler.} Yeah, like Mr. Murai, I hate to use that word because we have been trying to work with them and so we are all going to this international body together--

Mr. {Whitfield.} Yeah.

Ms. {Keeler.} --but at the end when our application just gets denied and we don't really get the scientific research of why our crops were denied, it is--

Mr. {Whitfield.} Okay. Mr. Dimare--

Ms. {Keeler.} --hard to say we work together.

Mr. {Whitfield.} --what about you?

Mr. {Dimare.} I feel basically the same way they do. We try to work in concert with them--

Mr. {Whitfield.} Mr. Costanza, how do you feel?

Mr. {Costanza.} I invited EPA out to our farm--

Mr. {Whitfield.} Yeah.

Mr. {Costanza.} --and their minds were made up before they got there.

Mr. {Whitfield.} Okay.

Mr. {Costanza.} They didn't want to hear what we had to say.

Mr. {Whitfield.} Okay.

Mr. {Costanza.} They didn't want to see what we had to

show them.

Mr. {Whitfield.} Now, without methyl bromide and this methyl iodide, is there something else you can use?

Mr. {Dimare.} Well, it depends on where you are at in the country. Even in the State of Florida we have from one end to the other Telone cannot be used in south Florida because of the groundwater issue--

Mr. {Whitfield.} Yeah.

Mr. {Dimare.} --but we do use that as one of the alternatives in other places--

Mr. {Whitfield.} Yeah.

Mr. {Dimare.} --as well as others. Methyl iodide that they are talking about is gone in the U.S. It is off the shelf. They have taken it away so that is not an alternative anymore.

Ms. {Keeler.} And some of those alternatives have different buffer requirements, so for us in San Diego you can't really picture a farm like out in the middle of Iowa.

Mr. {Whitfield.} Yeah.

Ms. {Keeler.} We have houses and industry coming right up to us. So buffer zones, township caps put a lot of limitations on--

Mr. {Whitfield.} Well, my time is expired but I mean it is pretty clear that all four of you feel like methyl bromide

is essential and that is my impression.

Mr. Rush, I recognize you for 5 minutes.

Mr. {Rush.} Well, and thank you, Mr. Chairman.

Mr. Doniger, somehow I am feeling like I am a registration clerk at heartbreak hotel when I listen to the testimony of some of the witnesses here. And, first of all, you raised your finger up because you wanted to react or respond to something that I think Ms. Keeler said. Is there something that you wanted to respond to?

Mr. {Doniger.} Well, I wanted to make one point in connection with the issue of whether the relationship with EPA is adversarial. If anything from the environmental perspective I see the EPA bending over backwards to service these applications, to consider these applications. I thought they were grossly too large in the beginning. The numbers have come down. That is true. But I would offer you one factoid to think about. To my knowledge, there has not been one lawsuit filed against EPA for denying these applications. There has not been one agricultural association or individual grower who has taken EPA to court over these supposedly too-small allocations. What other industry hasn't sued EPA? It is very hard to take the matter that seriously if that is the situation we have. I mean I don't want to encourage these guys to sue EPA but everybody

does.

Mr. {Rush.} This industry is one of EPA's favorite industries, then, whether they are being adversarial.

Let me just move on. What are some of your biggest concerns with the definition of critical use in the discussion draft that is before us today?

Mr. {Doniger.} Well, the most serious problem is the-- the two problems are, one, putting into law a list of critical uses. The idea is supposed to be dynamic, that some uses would start out being critical, and then as alternatives were found, they would no longer be critical and they would drop off the list. And that in fact is what has happened. Now, some of the growers can have concerns about individual decisions but that is the way it is supposed to work. You work your way to alternatives and then that use is no longer a critical use exemption. So why would we go back to the original list?

The second thing is how is it going to work now? A grower can write on a piece of paper I need x tons. I don't have to tell you why. I don't have to give you any information or evidence about what I tried and whether it works and so on. It is now up to you, EPA, to tell me why I don't need that many tons and you would have the obligation, EPA, to go abroad to the other countries and say this is what

my guys say they need. So where is the support for it? The reason that the exemptions have been granted--and more than 88 percent, I think, nominations have been granted--is that the U.S. comes in frankly with a bulldozer of a case for each one. And that starts with the growers being challenged frankly to come up with a very convincing case, that they have tried all the alternatives, that they don't work in these particular situations and thus the methyl bromide is still needed. When you get a case that is sound, the nominations are forwarded and the nominations are granted.

Mr. {Rush.} Do you share my concerns with the provision of the bill that would shift the burden of proof to the EPA and that a requested use of the exemption is unwarranted?

Mr. {Doniger.} Yeah, I mean that is what I am say leads to the counterproductive result because if the U.S. goes to the other parties and says this is the piece of paper I got. I don't have any scientific backup or I don't have the full backup I used to have, but my guys say they need it so I say I need it. It is not a very persuasive case. And it is more likely to lead to the nominations being turned down than the current situation.

Mr. {Rush.} How would this bill impact the Clean Air Act in your opinion?

Mr. {Doniger.} Well, right now, the Clean Air Act

allows for the critical use exemptions and that is the process under which the nominations have been made for the last seven years and the requests have been made by the government to the treaty parties and that is the process that is working. The folks here are concerned, some of them, that, gosh, there is some expense involved, there is some work involved in making the applications. And even the best applications you only get, you know, roughly 90 percent of them approved by the parties.

Remember that all the other strawberry-growing and tomato-growing countries in the western world have stopped using methyl bromide. So they look at these applications and say what is going on? Why can't the U.S. do what we do in Australia, Greece, Italy, Spain with respect to strawberries and tomatoes? And it is a tough sell. So if EPA doesn't get the full dossier of data from the growers, they are not going to be able to make that sale and I don't think they should make that sale.

Mr. {Whitfield.} Gentleman's time is expired.

At this time, I recognize the gentleman from Oregon, Mr. Walden, for 5 minutes.

Mr. {Walden.} Mr. Chairman, thank you. And I want to thank our panel of witnesses, appreciate your testimony and the answers to the questions the Subcommittee has posed.

Mr. Murai, do you want to take what the gentleman just said, so when it comes to dealing with strawberries and all, what is your take on what he just said about the international situation and be able to explain why every other country doesn't use methyl bromide and we need to?

Mr. {Murai.} I think those growers need a process that they can come to a hearing like this and voice their opinions, because I visited those growers and they are under extreme pressure of disease. They are exporting strawberry-growing to Morocco. They are exporting the problem rather than dealing with it in their own community and that is what our California strawberry growers are trying to do. We are trying to deal with it in our own community but the rules keep changing every page we turn. And that is what we want. We need transparency, we need accountability, we need data coming back that shows the argument coming back, not just arbitrary. The process is broken. I don't want to say we are adversaries but it is broken and it needs to be fixed. I want to go back to my growers and say this is the way it is, guys, or ladies. This is the way it is. But I can't say that with conviction because I know how broken it is.

Mr. {Walden.} I appreciate that. You know, methyl bromide has obviously been used in nursery crops in Oregon. It is a nursery business, of course, one of our biggest in

Oregon. I know they had a big outbreak of potato cyst nematode in Idaho recently. And while they don't usually use methyl bromide for potatoes, it has been successfully used against potato cyst nematode, which, as you know, can just wreak havoc on potatoes if it gets away from them. And I know the industry is conducting research to find alternatives but none have been found to date. Can any of you speak to the potato side of the world and what happens in that respect?

Mr. {Murai.} I can't speak to the potato crop but I would only add that the strawberry industry went through the same types of mass destruction. And what we are trying to do is provide food for the world with a consistent supply of healthy nutritious food, and I think we go to school and we learn the newest techniques and we try to innovate--

Mr. {Walden.} Um-hum.

Mr. {Murai.} --to try to avoid mass destruction of crops. We don't need to go back to the potato famine days. Why do we have to revisit that where people are suffering? That is not what our intent is, and as farmers, we want to feel good about what we do and provide that food and we will work within the rules. But the rules and the structure and the process must be corrected.

Mr. {Walden.} And can you elaborate on the efforts that

have been undertaken by the strawberry sector to identify potential alternatives?

Mr. {Murai.} We have invested over $10 million over the last 15 years to look at steaming the soil using anaerobic soil disinfestations. We are looking at growing strawberries in substrate, peat moss, coconut coir, but there are other issues around that. How sustainable is that when our strawberry industry would use up the North American supply of peat moss in 1 year? Or steaming takes 21 hours to steam an acre of strawberries right now. How much fossil fuel is needed, how much emissions are needed to steam one acre? You know, 20 hours.

Mr. {Walden.} How many acres do you have in production, strawberries in California?

Mr. {Murai.} Thirty-eight thousand acres in California.

Mr. {Walden.} That is a lot of steaming.

Mr. {Murai.} And the--

Mr. {Walden.} Or you could just try and grow them here where we have steam all the time, or at least today, or a lot of hot air.

Mr. {Murai.} The funny part is you have to soften the water before you put it through the steamer. So we have to have a water softener on the road with the long hose that takes it to the big steaming machine, and the steaming

machine creeps along, inches, and covers 1 acre in 21 hours.

Mr. {Walden.} So what does that mean to your cost, your ability to compete?

Mr. {Murai.} There is not enough time in the year to put your crop in.

Mr. {Walden.} So I guess the question is how do these other countries grow strawberries without using methyl bromide? Do they just have different pests and different issues?

Mr. {Murai.} They are trying to grow in substrate. If you go into like northern European areas, they are growing in a lot of the coconut coir --

Mr. {Walden.} I see.

Mr. {Murai.} --but even that is becoming controversial there. So, you know, you move to one solution but it creates other problems.

Mr. {Walden.} Got it.

Mr. {Murai.} And I think that is where we need a comprehensive look and a realistic look, right?

Mr. {Walden.} Yeah, I appreciate that. I know my time is expired. I grew up on a cherry orchard and represented a lot of ag interests in Oregon, farmers and ranchers that just feel like there is a whole onslaught out of the Federal Government that is going to shut down our way of life in the

West and especially on the farms.

Mr. {Murai.} We are California farmers and we want to stay in California.

Mr. {Walden.} Yeah. Well, we Oregonians want you to stay in California. It has been an issue dating back--no, I am just kidding. Yeah, but--

Mr. {Murai.} That is a good one.

Mr. {Walden.} --we want you to come up and spend your money in Oregon, then go back. Thank you. Thanks for your testimony.

Mr. {Whitfield.} Mrs. Capps, you are recognized for 5 minutes for questions.

Mrs. {Capps.} Well, thank you, Mr. Chairman.

As my colleague knows, I was trained as a nurse in Oregon and I moved to California so, you know, I guess it can go both ways, just an aside. And actually, I want to thank you because I know this is not the same as standing in the fields, but we are getting close to getting the feeling of what the various challenges are to complying with regulations that I believe in with all my heart but that are complicated and need to have a discussion. If you can't be there to smell the strawberries and see for ourselves what the peppers are like in the fields, we need this kind of discussion. We need this back-and-forth and this give-and-take.

And I was going to continue the same line with you, Mr. Murai. I have got two Californians here I am going to pick on for my time. I know growers have put millions of dollars into developing alternatives to methyl bromide. Could you continue this explanation of why your growers are putting so many valuable resources into finding these alternatives? And you are not doing it just because of the Montreal Protocol. It is not just that.

Mr. {Murai.} I think we are trying to improve and innovate our practices to be an example for the world. And the regulatory environment and the environmental laws are very strict in California. It is a whole other layer, and I believe that is what the world bodies don't understand is the sovereign power within California to have those laws, but the California growers will meet that challenge. We have invested our resources, we have put in a lot of time, we have lost a lot of crop--

Mrs. {Capps.} Um-hum.

Mr. {Murai.} --in this time frame and we have had a lot of hurt. And I think that is why we believe in what the Montreal Protocol is doing and we want to be part of the solution, but we also have to understand if there are exemptions due to critical use, they should be recognized and held to a standard as the applicant is doing. So if there is

a change in the nomination put forth to the United Nations unbeknownst to the California strawberry growers and in our application, we should understand why they are doing that and what data backs that up.

Mrs. {Capps.} Okay. Ms. Keeler, would you agree that the flower growers are similarly committed to phasing our methyl bromide and finding alternatives?

Ms. {Keeler.} Absolutely. I can only repeat what Mr. Murai just said. Our industry is absolutely committed. We have a much more dynamic industry with so many different crops and varieties, so there has been a tremendous amount of research that maybe something works in one crop, we try it in a different crop. We have actually teamed up with the strawberry growers. We share our information--

Mrs. {Capps.} Yeah.

Ms. {Keeler.} --university, private sector, we put in so much research into this. And like Mr. Murai said, we want to cooperate. We believe in the Montreal Protocol.

Mrs. {Capps.} Well, as Mr. Murai told me before, you are there, you breathe the air, your families are suffering whatever health consequences there are to whatever you put into the soil.

I wanted to move on if I could--I didn't mean to interrupt you--but Mr. Murai, you mentioned the CUE process,

which I am going to expand on just briefly. When the critical use exemption process is working, growers get the methyl bromide they need while you also phase out its use and incentivize the development of viable alternatives. No matter how well designed, however, no complex international system can fully anticipate every issue that may come up down the road, and that is why we always need to be looking at ways to improve and adapt the system to the current needs of its stakeholders while still moving forward, ultimately achieving its original goals.

Mr. Murai, I am aware of several fields in Ventura County, California, which is in my district, that have had some issues transitioning to Telone. And I know that California has banned certain alternative chemicals like methyl bromide for its cancer-causing and water-polluting qualities, yet EPA has not responded accordingly. Perhaps, Mr. Murai, you could expand on that just a little, touch on the types of flexibility and coordination that could be built into the current system to help prevent these problems in the future.

Mr. {Murai.} Well, we are very intentional on maximizing the alternatives that are available within the law and we explain that in our application every year. And what changes, though, sometimes when you are using some of these

alternatives, they don't do a thorough enough job. And so in order for a family farm not to abandon their land, they need to be able to have a way to clean that soil up and make it healthy again. And, you know, in this global economy, we are moving products back and forth and think new pests are coming in, new diseases, and there has got to be a mechanism. The authors of the protocol were very smart and that is why they wrote it in the critical use exemption because they anticipated there might be critical needs.

Mrs. {Capps.} Could I ask for time to ask one further question? I know I have used my time.

Mr. {Whitfield.} Yeah, your time has expired.

Mrs. {Capps.} All right.

Mr. {Whitfield.} Thank you.

Mrs. {Capps.} Thank you.

Mr. {Whitfield.} At this time, I would like to recognize the gentleman from Texas, Mr. Barton.

Mr. {Barton.} Mr. Chairman, my questions are for the second panel, so I am--

Mr. {Whitfield.} Okay.

Mr. {Barton.} --going to defer or yield back.

Mr. {Whitfield.} Then I recognize the gentleman from California, Mr. Bilbray.

Mr. {Bilbray.} David, would you upgrade me on the

latest status? We are talking strawberries and I know we have had a conflict and have consistently had a conflict between EPA and ag on importation of certain issues. What alternative to methyl bromide has the ag people put on importation of strawberries, the fumigation of those fruits? Do you know--

Mr. {Doniger.} I think you are asking, Congressman, about quarantine of pre-shipment?

Mr. {Bilbray.} Yes.

Mr. {Doniger.} And I am not sure I precisely understand your question--

Mr. {Bilbray.} We have run into--

Mr. {Doniger.} --and I am not sure I know the answer.

Mr. {Bilbray.} You know, when I was working the Air Resources Board when I got over here we had this big conflict because the accord we were trying to follow but then we had the Federal Government mandating the use of methyl bromide as a condition of importing certain fruits--

Mr. {Doniger.} Right.

Mr. {Bilbray.} --and vegetables.

Mr. {Doniger.} So one of the problems in that field, which is outside the scope of this bill, is double-dosing where the importing country requires the treatment even though it may have been treated on the way out of the

exporting country. So I think there has been some progress made in reducing that kind of double-dosing.

Mr. {Bilbray.} But they are still looking at methyl bromide as being their--

Mr. {Doniger.} Well, this is an area where sulfuryl fluoride may be quite promising and--

Mr. {Bilbray.} Maybe, but, you know, I--

Mr. {Doniger.} No, I mean more than that. It is almost ready to be approved as a substitute for methyl bromide in certain quarantine uses. And sulfuryl fluoride was mentioned in the beginning if I may--

Mr. {Bilbray.} No, no, no, no, wait, wait a minute.

Mr. {Doniger.} I just want to make sure people--

Mr. {Bilbray.} Let me double back--

Mr. {Doniger.} --understand that NRDC is opposed to the withdrawal of the tolerances for sulfuryl fluoride.

Mr. {Bilbray.} Okay. My biggest concern is that we have known since the early '90s there was a conflict between our mandated procedures in one department and a treaty that we were agreeing to in another. And it has been at least 15 years, not 20 years, we still haven't kind of put that together.

Mr. {Doniger.} The treaty doesn't cover quarantine and pre-shipment.

Mr. {Bilbray.} Okay.

Mr. {Doniger.} I believe it should but it doesn't. So there are no restrictions on quarantine and pre-shipment use of methyl bromide under the treaty.

Mr. {Bilbray.} Okay. I appreciate you clarifying that. It is frustrating to me to see the government that says this is so essential that we reduce the use and everything else.

And Mr. Chairman, you know, my family has been personally affected by diseases directly related to the ozone issue. So I really believe, you know, this is a concern. But it is a reasonable application of the concept. I think any law, no matter how good intentioned, if there isn't a reasonable application, there is going to be major problems of not only unforeseen adverse impact but also unforeseen inefficiency in acquiring the original goal. And that is one of the things I want to address.

And Dave, why I asked you about that is that we talk about priorities in the Federal Government but it isn't reflected by our actions at getting to go. We always love to say no. It is easier to say. But getting to go, getting to an alternative answer, we know what is bad but getting to what we are willing to say is good takes 20 years at a time that we are saying the ozone is being depleted as we speak, people are going to be dying, but don't ask me to rush to

finding a viable alternative. And I think there is an obligation that those of us in the system, if we want to claim the moral high ground like some members on this committee love to do, that we are saving lives and we are avoiding this and that, we have more of a responsibility than just saying no. We have a real obligation to find a yes and doing it quicker than 20 years down the pike.

Mr. {Doniger.} Well, the one thing I think we can all agree on is that there has been--all of the witnesses here can agree on--is there has been a lot of progress in phasing down methyl bromide. If you had this hearing 5 years ago--actually, you did have this hearing 5 years ago--the crisis of impossibility of terrible impact was at the then current level where we are now down some 80 or 90 percent below that. And that is why the critical use exemption process is there. If the case can be made, the exemption should be granted.

Mr. {Bilbray.} I just worry we are quick here to put regulations on to outlaw stuff and we are not quick here at creating the vehicles to create an opportunity to make that product obsolete. In other words, just outlawing something is not answering the problem. The problem is identifying the problem and then finding an alternative answer to be able to move things forward without the social economic impacts and the health impacts that may be related.

Mr. {Doniger.} There has been a fair amount of USDA research and we would have supported there being more to help the growers find these alternatives.

Mr. {Bilbray.} Well, I would just say 20 years is pretty slow.

Mr. {Whitfield.} The gentleman's time is expired.

At this time, I recognize the gentleman from Louisiana, Mr. Scalise, for 5 minutes.

Mr. {Scalise.} Thank you, Mr. Chairman, appreciate you having this hearing on these two bills that--

Mr. {Whitfield.} Mr. Scalise, I am sorry. I didn't see Mr.--

Mr. {Scalise.} Oh, I will yield to the gentleman from Michigan.

Mr. {Whitfield.} Okay, you go ahead and then I will come back to Mr. Dingell. Thank you.

Mr. {Scalise.} All right. Thank you, Mr. Chairman. I thank the former chairman, the gentleman from Michigan.

As we are talking about strawberries, I, you know, represent a city called Ponchatoula, and the Ponchatoula strawberries I would argue are the plumpest, juiciest, most bright red. We could probably have a taste test and we would both enjoy it. But, you know, I look at these new regulations and, you know, really have concern about what it

is going to mean to those strawberry farmers in Ponchatoula just as it is a concern to those of you in whether it is California, Michigan, all across the country. Do you all have any estimates on how many jobs are at risk if this industry is threatened with the inability to use methyl bromide? I will just start with you, Mr. Costanza, and we can go down. Any kind of estimates on job losses that may be in play?

Mr. {Costanza.} On our farm presently we have about 125 employees. I am 30 employees short for harvest. We are leaving product in the field. In the local economy in the state and federal level, there is about four jobs for every farm worker I have on the farm. So the economic impact across the country if we are out of business is dramatic.

And I would like to mention that I have been to your district and I have visited some of your growers, Anthony Liuzza being one of them--

Mr. {Scalise.} I know him well.

Mr. {Costanza.} --looking for an alternative to use other than methyl bromide.

Mr. {Scalise.} And what have you all been able to come up with?

Mr. {Costanza.} Nothing. We need a product that is affordable and that will produce--

Mr. {Scalise.} And effective.

Mr. {Costanza.} --a crop that the public demands. Now, these European countries, they will accept a lower quality berry. Americans won't accept that quality. So--

Mr. {Scalise.} And it is my understanding that under the protocol, developing nations are exempt from this. They don't even have to comply what is being imposed on you, but a developing country that competes against you would not have to comply, is that correct?

Mr. {Costanza.} My understanding that is correct but the other thing is accountability. How are you going to account for what goes into Mexico from China? How are you going to account for what goes into some of the European countries from China? How are you going to account for what goes into Morocco? Because they produce a lot of methyl bromide in China because we pay for the plant to be built.

Mr. {Scalise.} Yeah. And then that would be just more jobs outsourced, exported that we lose that go to foreign countries.

I want to ask Mr. Murai, because you represent the California growers, if you can give me any kind of estimates on jobs as well, kind of similar questions as I was asking Mr. Costanza. I am not sure if you have met Mr. Liuzza as well but he is a good man.

Mr. {Murai.} Our California Department of Food and Agriculture commissioned an economic study with the University of California Davis, and their latest numbers show that without methyl bromide and without methyl iodide now, they are anticipating California communities would lose over $1.5 billion annually and more than 23,000 jobs annually.

Mr. {Scalise.} How many jobs?

Mr. {Murai.} Twenty-three thousand.

Mr. {Scalise.} Just in California that would be lost?

Mr. {Murai.} Just California coastal communities.

Mr. {Scalise.} Okay, thank you.

Mr. Dimare, if you can answer the same question?

Mr. {Dimare.} I can't speak from a study standpoint on the data or statistics but just from our own perspective, on the one farm location that we have where I am at in central Florida is about 5 to 600 people, but for the whole company we are in the thousands. We employ thousands of people.

Mr. {Scalise.} Okay. And then Ms. Keeler.

Ms. {Keeler.} I don't have specifically those numbers. I could get them to you. The California cut flower industry is a $10 billion industry from farm to florist, so it is a pretty big industry. Our farm alone employs over 200 people for 400 acres. But I could get the stats to you afterwards.

Mr. {Scalise.} Okay. And then we don't have any kind

of indirect jobs. You know, we are looking at this regulation. Unfortunately, if this was the only one, you could kind of isolate it and deal with it, but we have seen time and time again it is far from this one. We have already seen job losses in other industries due to EPA coming out with regulations that do nothing to address the problems they are concerned about. I mean if you are concerned about carbon emissions, jobs that are being sent overseas from greenhouse gas regulations, those countries where we lose our jobs to, they emit even more carbon.

You know, you look at this, you know, the farms, it is going to go to developing countries. These jobs will go to developing countries that under definition can still use the product. And so you just cost American jobs. You do nothing to reduce usage of the product. And again, it is one more regulation that makes no sense. I know we have got legislation that we passed called the REINS Act that tries to rein in some of these radical regulations.

But I know I am out of time. I appreciate the discretion, Mr. Chairman, and I yield back.

Mr. {Whitfield.} The gentleman's time is expired.

Mr. Doniger, you want to make a comment.

Mr. {Doniger.} I would just like to correct the record on a couple of points. 1) Mexico is ending its use of methyl

bromide this year, 3 years before the obligation. They have an obligation under the protocol to end it in 2015. They are ending it in 2012.

Mr. {Scalise.} I don't know if you are correcting the record because other witnesses are shaking their head no.

Mr. {Doniger.} Well, I am sorry. That is fact. The second fact I want to correct is that the United States didn't pay for or contribute in any way to the production capacity of China from methyl bromide, and it is because of this treaty that their production and use is also coming down. The treaty protects Americans because it controls the dangerous chemicals and the impact on the stratosphere around the world. We cannot protect our people by ourselves. That is why we need--

Mr. {Scalise.} Can Mr. Dimare respond? Because it looks like he disagrees--

Mr. {Whitfield.} Well, now, the time is up but I am just going to make one other comment. You had asked the question about jobs and Mr. Murai in his testimony pointed out I believe that the California Department of Agriculture said without methyl bromide, that there would be a loss of 23,000 jobs annually, is that correct?

Mr. {Murai.} Yes.

Mr. {Whitfield.} Okay. At this time I recognize the

gentleman from California, Mr. Waxman, for 5 minutes.

Mr. {Waxman.} Thank you, Mr. Chairman, and thank you, Mr. Dingell, for allowing me to ask my questions.

Mr. Doniger, the whole idea of the protocol international agreement is that we are not going to give an advantage to other countries. We are going to require everybody to reduce what is a threat to all of us in this planet. And in the case of CFCs, U.S. acted unilaterally and then moved forward. I sometimes think if we had that problem today, we would probably treat it the way we are treating greenhouse gases. They are not doing anything, we are not going to do anything. Cost us jobs? Well, we are not going to allow that to happen. And of course the result is every day we hear about another drought destroying the crops and I am sure more crops are being destroyed by the drought which I think has to do with global warming and climate change than the issue that we are discussing today, which is an important one but a very narrow one.

The bill freezes an outdated list of approved critical uses. As a result, sectors that have completely phased out the use of methyl bromide during the last 7 years would be allowed to use methyl bromide again. Incredibly, as I understand it, even gold courses would once again be allowed to seek critical use exemptions.

Let me ask, does anyone on the panel think that we should amend the Clean Air Act to allow sectors that have completely eliminated the use of methyl bromide to start using it again? No one? Do you think that we ought to allow sectors of our economy that have completely eliminated the use of methyl bromide to start using it again?

Mr. {Murai.} Yes, because they were eliminated under false pretenses of an alternative being available and that alternative has been now taken off the market.

Mr. {Waxman.} I see. What alternative has been taken--

Mr. {Murai.} Methyl iodide.

Mr. {Waxman.} I see. So you would let them--we would go back and allow methyl bromide--

Mr. {Murai.} For critical use exemption--

Mr. {Waxman.} For critical use exemption.

Mr. {Murai.} --under the critical use exemption process.

Mr. {Waxman.} Well, do you think it makes sense to have a critical use exemption to allow golf courses--to allow the turf grass to be preserved with methyl bromide?

Mr. {Murai.} I think if it is under the law, if it is within the law, it is within the law.

Ms. {Keeler.} And I think that is what Congresswoman Capps was asking earlier when she was talking about the

flexibility and her time ran out. I can't speak to golf courses. That is not my area. But in some areas we thought we found an alternative in a certain crop and we tried it, and this is our commitment to the protocol. But sometimes you try something new and after 3, 4, 5 years, you find out there is a problem. A new disease develops. Something you thought was taking place didn't. So I think what Mr. Murai is saying if there is adequate information for a critical use exemption, whether it is golf courses, strawberries, flowers, that is how the protocol was written.

Mr. {Waxman.} Mr. Murai, the California strawberry growers are by far the largest remaining users of methyl bromide in the United States. I know you have concerns with the amount of methyl bromide available to your industry, but do you really think that this legislation is the most constructive way to go about addressing these concerns?

Mr. {Murai.} I think there could be several approaches and I think this has probably gotten to a point where we were so frustrated that we needed people to listen. We tried to collaborate with EPA. We tried to introduce what we best thought best information, put forth a package of application for the critical use exemption. If they could tell us otherwise based on data, then, you know what, that is how it is. But they weren't providing that data back, Congressman,

and that is what bothered me about the system is when you can make a cut based off methyl iodide and now methyl iodide is gone, so what happens now with all the CUEs that have gone by the wayside because of this alternative? There needs to be some resolution to that.

Mr. {Waxman.} But I am concerned--

Mr. {Murai.} There are no alternatives coming off the shelf ready for the field.

Mr. {Waxman.} I am concerned about the provision of the bill that would allow growers to obtain methyl bromide without a critical use exemption for so-called emergency events. This could create a big loophole that would allow for the use of large quantities of additional methyl bromide. Mr. Doniger, my understanding is that a Montreal Protocol decision allows for the use of methyl bromide in true emergencies. Do you know how many times this emergency event provision has been invoked?

Mr. {Doniger.} Yes, it has been invoked twice and they were true emergencies, once by Canada and once by Australia. It was not a routine thing and that is what this bill would allow. Emergencies would become routine. It would be like every time you don't have enough money in your bank account, you just declare an emergency and write another check.

Mr. {Waxman.} Well, Ms. Keeler, in your testimony you

argue that growers should be allowed to develop an emergency cleanup process that will allow you to go into your fields every few years and use methyl bromide to clean up any pests or diseases that have developed, is that right?

Ms. {Keeler.} What I was referring to in our industry we have perennials we have to take out of the fields when certain diseases pop up. So we don't have situations in many of our crops where it is an every-year process. So the way that the protocol is set up in the application process, it is very difficult for us to fit in because we aren't scheduled.

Mr. {Waxman.} So it is not an emergency. It is the opposite of emergency. They are planned, routine use of methyl bromide without a critical use exemption.

Ms. {Keeler.} Well, I am referring to a cleanup process that would allow us to go in and clean those fields up when--

Mr. {Waxman.} Mr. Doniger, what do you think of that idea?

Mr. {Doniger.} Well, I think if this problem of not needing it every year, you figure that out, you build that into the critical use exemptions. If the case can be made for it, that is what the critical use exemption process is for. The Committee is approaching this as though there is no exemption and we need to create one. Actually, there is one already and it is working. We don't need to enlarge it.

Mr. {Waxman.} Well, Mr. Murai doesn't think it is working.

Mr. {Murai.} I think it has worked well for a while and I think lately in the last 2, 3 years it has gotten very tenuous because there hasn't been a real listening to what is really happening in the field. And so when we come to EPA with our package to demonstrate the need, it is very easily put forth, here is what you can do. In this case, methyl iodide was put forth and you are going to transition 21 percent in 3 years. I don't think so but okay. That went away. Now, there is no restoration for any of the crops that were dependent on methyl iodide based on EPA's aggressive nature with that product.

Mr. {Waxman.} So you think EPA is not being reasonable in deciding when emergency event should take place and this exemption should be allowed?

Mr. {Murai.} Yes, I believe they are not being reasonable and I believe the rules change at every corner. And that is where I want to be able to go back to our growers and say, hey, the process is the process and it is correct, it is transparent, their interpretations are right on the science, and it is fair and we have to live with it. But I can't honestly go back to my growers and speak with conviction that that is the process right now. And that is

what I am talking about today is that this process needs to be corrected.

Mr. {Waxman.} Okay, thank you.

Thank you, Mr. Chairman.

Mr. {Whitfield.} At this time, I recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. {Dingell.} Mr. Chairman, I thank you for your courtesy. I am sorry.

Mr. {Whitfield.} Go ahead, Mr. Griffith.

Mr. {Griffith.} Thank you, Mr. Chairman. I do appreciate that.

Mr. Dimare, a couple times Mr. Doniger has said that Mexico is outlawing the use this year or ending the use this year of methyl bromide, and each time you have indicated at least with your body language that you didn't agree with that, so I am giving you an opportunity now to explain what disagreement is with that or other statement regarding the use in other countries of methyl bromide you might have disagreed with Mr. Doniger on.

Mr. {Dimare.} Well, you know, I don't know that that is written into law there, but I will believe that when I see it.

Mr. {Griffith.} Trust but verify, is that what you are saying?

Mr. {Dimare.} I am sorry?

Mr. {Griffith.} Are you saying trust but verify?

Mr. {Dimare.} That is correct.

Mr. {Doniger.} It is a commitment that Mexico has made under the Multilateral Fund, which is part of the Montreal Protocol and it is in writing. It is referenced in my testimony.

Mr. {Griffith.} I understand.

Mr. {Doniger.} And it is firm.

Mr. {Griffith.} I think what Mr. Dimare is saying, though, that illegal drug trafficking takes place, you know, on both sides of the border. It is written into law but he will believe that they stop using methyl bromide when he sees it because he is not sure they are going to follow the law. I understand what you are saying but I understand what he is saying, too.

Mr. {Doniger.} It is harder to get methyl bromide than it is to get illegal drugs.

Mr. {Griffith.} And that is what, apparently, even the people who want to use it legally are saying and it is one of the reasons we need the bill is that it is harder to get methyl bromide than it is to get the illegal drugs. And they have got a concern and they are hoping that maybe it can be a little easier so they can use this substance legally and

appropriately.

Along those lines, Mr. Doniger, is there anything in this bill that would force the EPA or the State Department out of compliance with the protocol?

Mr. {Doniger.} I think what would happen, Congressman, is that if the United States went forward with unsupported applications, they would be turned down. And that would be the normal operation of the protocol but it wouldn't be a good result for my colleagues here on this panel. They want the nominations to succeed, not to fail because they weren't supported.

Mr. {Griffith.} But inherently there is nothing in this bill that would put us out of--

Mr. {Doniger.} Yeah, actually, I believe the emergency exemptions provision would be grossly out of line with the protocol and freezing the critical use list, you know, permanently at the 2005 list would be contrary to the protocol.

Mr. {Griffith.} All right. And if I might ask Ms. Keeler and others who have talked about this, and feel free to jump in, because I am not as familiar with methyl bromide, I don't know what happened that made methyl iodide--what were the negative effects that we decided as a country to take methyl iodide out of the mix--either one of you--as a

potential fix for using methyl bromide?

Mr. {Murai.} I think methyl iodide was identified as an effective fumigant but the science on health effects was debated and there were two sides of the science. And it was deemed a cancer-causing agent and so it caused definite uproar in the communities. And as growers, we were just as sensitive to that and we believed that the process of science and examination should go forth. And so we weren't resting on that product as being the replacement for methyl bromide and that is what we tried to articulate back to EPA is that we aren't convinced this will be the tool for California or the Nation.

Mr. {Griffith.} And then am I also hearing the testimony correctly when I was listening to your opening statements, the four of you that are in production of various types of vegetables or fruits that to replace the methyl bromide you are using a lot more pesticides and things that would get into the water supply? Is that accurate? And Mr. Costanza, you want to comment on that?

Mr. {Costanza.} When using methyl bromide eliminates a lot of sprays across the field that we are going to have to do with methyl bromide. As far as Midas is concerned, I am concerned about my workers because it is not worker-friendly, whereas methyl bromide is easier to work with and it is less

risky to my employees. But one of the biggest worries I had about Midas was the fact that it could affect my workers more than anything else. But this was the replacement the EPA gave us, said we were going to have, and then that is gone. So they promised us that we would have a drop-in replacement. And the reason I am here is because we don't. If somebody has got a magic wand here that I could use, I don't want methyl bromide. But you don't have a replacement.

You know, if I need a blood transfusion today and I am A positive and you don't have A positive and you give me something else, you are going to kill me. But with methyl bromide it worked. And my customers demand the product that it produced. My employees liked the product because it yielded more fruit. And they get paid an incentive on volume. They made more money. So why don't produce it? The chain stores are going to go to where it is if they have to import it. It doesn't matter if it comes from--you know, you could fly anything anywhere from the world today. You know, I have got Chinese product in the stores in my hometown. My grandson was eating Chinese-produced diced pears, not American, Chinese. We don't need that. We can do it here. But all you are doing is eliminating jobs and exporting the production to other countries. Give me a break.

Mr. {Whitfield.} The gentleman's time is expired.

At this time I recognize the gentleman from Michigan, Mr. Dingell, for 5 minutes.

Mr. {Dingell.} Thank you.

I am very sympathetic with the witnesses here. I am very much concerned about their views and their need for a pesticide, but I have a feeling that we are like the surgeon who conducted a superb operation in which the patient died. I don't see here, Mr. Chairman, EPA. They have a story to tell. Where are they? I don't see here the Department of Agriculture. I don't see here others who could tell us whether there are substitutes or why those substitutes are available or not available.

I note here as I am looking at it the annual critical use exemption summary. I don't know whether the panel has seen this or not but it shows a continuing decline in the exemption that has been given by the folks up at the Montreal Protocol. It started out they were getting about 10,000 tons and it is down now to less than 2,000 tons. My concern here is that every time we have seen this, it has gone down and down and down but I don't see any real prospect of getting relief through the Montreal Protocol. If I look, they have consistently been below what the farmers have requested and they have not given the amount that the farmers say they need.

And we are going to take this legislation to the Floor after virtually no hearings. We have had a panel and I am sure the panel are most respectable of folks in their fields, but we haven't heard a word from the government agencies. Frankly, I am in the view we ought to have EPA up here and let us find out what the facts are from EPA's view. I am in the view we ought to hear from Department of Agriculture. Let them tell us what is the need but I don't see that. So we are going to take this bill to the Floor, probably pass, and then when it passes it goes to Senate. And it is going to sink out of sight.

And if it doesn't sink out of sight in the Senate, it is probably not going to be signed by the President and it is going to be opposed with utmost diligence by the environmentalists, and I don't think this committee is going to afford the relief that quite frankly our agriculture community needs. I don't think that we are going to see them get the opportunity to have new pesticides that will address the concerns of our farmers. And I see us lining up if the dire predictions I hear today are to be realized, I see just nothing but trouble coming from this legislation. And I see under the legislation the farmers tell EPA what they go to the Montreal Protocol with and the Montreal Protocol takes a look at it and says, well, we are just not going to do that.

So the farmers walk away and the farmers got nothing and there is no methyl bromide or anything else that is available to help our farmers with their problem.

So we are giving our farmers the most successful operation, but when we are done, the patient is going to fall off the table and he is going to die. And we are going to have a huge fight on the Floor and everybody is going to get all torn up, but the farmers aren't going to get the relief that they need or they want. And to me that is not only bad policy but it is very bad legislating and it is going to leave this committee quite frankly looking kind of whoosh because we really didn't do the job that we should have done in terms of having an intelligent bunch of hearings where we heard the witnesses.

And, you know, I warned about this in earlier times. I remember one morning Chairman Staggers brought in the swine flu bill and we had a great big hearing on swine flu and my friend John Moss, who was a member of the committee, and I, we said this is a hell of a way to do business. We don't have the vaguest idea what this is going to do. So we had a magnificent program for the production of vaccine. We produced a hell of a lot of vaccine. We absorbed liability for everything from the building burning down while the patient was in it to being raped or assaulted in the parking

lot. And lawyers said oh, my, isn't this wonderful? So they rushed out and had swine flu seminars at which they told everybody how to sue the government. We wound up with about $7 billion of liability. They developed this wonderful inoculant but they never found the damn disease and they never found the virus. And the government got about a $7 billion liability and the trial lawyers had a wonderful time and made lots and lots of money.

I am not going to say that that is what is going to happen here but I think we are working most diligently to create red faces on the members of this committee, and I just hope, Mr. Chairman, that you will slow down and you will bring in the witnesses from the Department of Agriculture, witnesses from EPA, and maybe somebody else and let us find out why they are not producing what our agriculture needs and exposing them to what looks like is the work product of a snake oil salesman.

I yield back the balance of my time.

Mr. {Whitfield.} Thank you very much. I might add, Mr. Dingell, that we do have a document from the EPA making comments on this particular legislation, even though they are not here today. But we do have comments from them.

At this time--

Mr. {Dingell.} If you want EPA up here, they will come

and the Committee will support you. And if you want the Department of Agriculture up here, they will come and the Committee will support you. And that is the way to do the business. Let us find out--

Mr. {Whitfield.} We don't want to sit around and subpoena them every time we ask them. We try to work with them and--

Mr. {Dingell.} Did you invite them, Mr. Chairman?

Mr. {Whitfield.} We did invite them, absolutely.

Mr. {Dingell.} And did you get on the phone and say we want to have you up here? I have run committees for about 20 years and I am somewhat knowledgeable--

Mr. {Whitfield.} We contacted them one month ago about this hearing.

Mr. {Dingell.} I never had any trouble getting anybody in here. I have watched my Republican colleagues waiving subpoenas and throwing them around here like confetti and they don't get anything done. But it is fairly simple, let them know, By the Great Horn Spoon, you are coming and we are going to have you up here.

Mr. {Whitfield.} See, our goal is to accumulate the esteem and respect that you have so that when we ask them, next time, they will show up immediately.

Mr. {Rush.} Mr. Chairman, with all due respect I have

to join in here with Mr. Dingell. You know, here we have this hearing and we are going to finish maybe these hearings by 1:30, maybe 2:00. And then at 4:00 the markup starts. You know, that is not enough time. I think that if we delay this pending markup, I will certainly join in with you and I am sure Mr. Waxman would and the chairman of the full committee would. We would join with you if you want to do a telephone call, request that the EPA appears before a hearing we could schedule tomorrow morning, I am sure we would be able to do that--or the following day. But just to rush pell-mell into a markup less than probably 2 hours after a hearing on this obviously very important matter in your opinion, I think that is ludicrous on its face.

And so I would strongly suggest and recommend that you consider postponing your markup until we are able to get EPA and USDA here so they could have some testimony from the departments.

Mr. {Whitfield.} Mr. Rush, you and I both know that whether Democrats are in control or Republicans are in control, there are times when the other party does not agree with the procedure. There were a lot of things, for example, about the healthcare procedure bill we didn't agree with, and I have a number of letters. I have farmers talking to me all the time, milling companies all the time about methyl

bromide, the importance of methyl bromide. And we have this panel of witnesses that reflects the agriculture community, reflects the environmental groups, and we are going to intend to have opening statements today at 4:00. And I guess the markup is scheduled for tomorrow at 10:00.

Mr. {Rush.} But Mr. Chairman, why the hurry? Why do we have to hurry up and get this done? Why--

Mr. {Whitfield.} We are trying to be responsive to the agriculture community--

Mr. {Rush.} I would like to have the opportunity to invite, along with yourself, along with Mr. Waxman, along with Mr. Upton, to request that the EPA appear before the markup. I would like to have that opportunity and I would respectfully request that we be given an opportunity. Mostly Democrats and the Republicans send invitation over the phone, however you want to send it, email it, asking them to show up for a hearing before we go into a markup.

Mr. {Whitfield.} Now, have you had the opportunity to read their comments on this bill?

Mr. {Rush.} Mr. Chairman, I want to ask them questions. I want them sitting right there at that table so that we can have a vigorous debate or discussion and ask questions and ask them some important questions that I and other members of the committee want to get some answers to. The departments

need to be here.

Mr. {Whitfield.} Well, we invited them and you know what, I would be happy to join with you, Mr. Waxman, and we can sit down with EPA between the subcommittee markup and the full committee markup and we can ask them all the questions you would like to ask them.

Mr. {Rush.} It should be public and every member of this committee should have that opportunity.

Mr. {Whitfield.} We will invite the public in.

Mr. {Rush.} And in fact, Mr. Chairman, I don't know why we can't delay the markup for 24 hours if necessary so that we can be responsible and have some real deliberative discussions with the Administration, with the EPA, and Department of Agriculture. I don't see what--

Mr. {Whitfield.} So you prefer to do it on Friday instead of tomorrow?

Mr. {Rush.} Yeah, and we can do it on Friday. I don't have any reason why that isn't okay, but we need to get the EPA and the Department of Agriculture at the witness table.

Mr. {Whitfield.} Well, listen, I really do thank you and Mr. Dingell for your comments. And like I said, we will make sure that you get a copy of this. And like I said, I would be happy to join you all in having EPA come up and talk to us, but we do believe that this is an important issue. A

lot of jobs are at stake.

And at this time I think, Mr. Olson, you are the only one who hasn't asked questions, so I recognize Mr. Olson from Texas for 5 minutes.

Mr. {Olson.} And I thank the chair. And welcome to our witnesses. I appreciate your time and your expertise this afternoon.

One of the largest annual festivals back home in Texas 22 is the Strawberry Festival in Pasadena, Texas. It just was completed this past May and so because of those strawberries, American strawberries, strawberry production in America is important to me. Beyond strawberries, I am concerned about some of the comments you made, Mr. Doniger. You essentially said that citizens who are impacted by the loss of methyl bromide have an avenue to have their objections heard, and that is a lawsuit suing the EPA. That apparently is how the NRDC sees a remedy for people who are impacted by loss of methyl bromide. But I am curious if the people working on the farms think a lawsuit is a viable alternative.

So my first question is for you, Mr. Costanza, and I will work down to the other three. Do you have the money, the time, and the resources to sue the EPA?

Mr. {Costanza.} No. When I was using methyl bromide on

the other crops, I was paying a lot higher income tax. My employees were paying a lot higher income tax than they are now. So both my employees and myself, our incomes have been reduced because we are not using methyl bromide. And to sue the EPA, where am I going to get this kind of money from? You know, we are a family farm. Our margins are 2, 3 percent.

Mr. {Olson.} So a lawsuit is not a viable alternative for yourself?

Mr. {Costanza.} Not unless you got some money.

Mr. {Olson.} We got a spending problem here in Washington, see. We don't have the money, sir.

Same question to you, Mr. Murai. Do you have the time, money, and resources to sue the EPA?

Mr. {Murai.} We are in the business of farming. We are not in the business of suing people. We are just looking for an alternative that is viable. If methyl bromide is the only product, this will not be disputed. The only product out there that did kill all the pathogens that it killed, all the weeds that it killed, all the alternatives that are out there are lesser, okay, which increases our cost, decreases our yield, which is not a productive way to do business.

Mr. {Olson.} And probably lose jobs as well, just like--

Mr. {Murai.} Well, the jobs will follow, yes. As we know it, the type of farming we do will go under.

Mr. {Olson.} Ms. Keeler, same question for you, ma'am. Do you have the time, money, resources to sue EPA?

Ms. {Keeler.} No, we barely have profit margins. I have to repeat what Mr. Murai said earlier and we appreciate the opportunity to be here to tell you our story. It should be not an adversarial situation with EPA. We in our government should have a conversation about what is going on on our farms. We don't expect you all to know how to run a flower farm. That is what we do. But we can come here and tell you and tell EPA how that is taking place and the struggles that we have.

And Mr. Murai made a wonderful comment earlier. Italy, Greece, they don't have the opportunity to come and talk to their governments. At the very first international meetings that I attended, I actually went and talked to the Italians and the French because we know what they are growing. And we basically said how are you guys going to grow these cut flower products without methyl bromide? And they said we are not. The EU came to us and told us this is what the EU is agreeing to. There was no discussion. The Italians were on a vacation and all these international locations at the meetings because there was nothing for them to talk about.

So, no, we don't have the money, no, we don't want to sue EPA. We want to be here, discuss with you, discuss with EPA and follow the CUE process the way it is laid out and get our allocations when necessary.

Mr. {Olson.} Thank you. And finally, for you, Mr. Murai, being a strawberry man, very special to my heart with the passing of the Strawberry Festival, so I mean again, same question. Do you have the time, resources, money to sue EPA?

Mr. {Murai.} Our time and resources should be invested in researching alternatives to methyl bromide. That is where our efforts should be. And the process just broke down. It needs to get fixed. People need to listen, get their boots dirty, and clean their ears out because it is just not computing. And we are not making things up. It is based on real data, real science, and I think the EPA really needs to prove to all of us that they have legitimate reasons for reducing our nominations or eliminating them.

Mr. {Doniger.} So instead what these folks are doing is coming to you at no small expense and asking you to change the law, not to get EPA to carry out the law but to change the law, to tilt the playing field in their direction. All I am saying is there is an existing law and an existing process. Let us make it work. It does work in my opinion. And use all the tools that people have under existing law.

If we change it--

Mr. {Olson.} Mr. Doniger, with all due respect, sir, the four panelists sitting next to you disagree completely with that statement there. I mean EPA is hurting their business, is killing their jobs, and again that is not EPA's role. I mean again we need to get the Federal Government off the peoples' backs and let the American people grow their products, create jobs in this country. That is the biggest challenge we have right now.

I guess one more question for you, last one, Mr. Costanza.

Mr. {Costanza.} I don't want the EPA to change their rules. I just want them to do what they told me they were going to do. They were going to get me a viable, affordable alternative and they have not. So until they give me a viable, affordable alternative, give me the CUEs.

Mr. {Doniger.} Mr. Costanza hasn't even requested one--

Mr. {Costanza.} That is not correct.

Mr. {Doniger.} --since 2007.

Mr. {Costanza.} No, that is not correct.

Mr. {Olson.} Well, we will settle that later, gentlemen.

Again, one commonsense thing from Mr. Murai--

Mr. {Costanza.} We are in the process of doing it now.

Mr. {Olson.} Dirt on the boots, wax out of the ears, that is how we get through this problem. Thank you. I yield the balance of my time.

Mr. {Whitfield.} Okay. Time is expired.

That concludes questions for the first panel. We appreciate all of you being here and talking to us about--

Mr. {Rush.} Chairman, I ask unanimous consent to insert three items related to methyl bromide into the record. And one is a recent article from the Journal of Environmental Medicine citing that the California strawberry industry is experiencing rising crop yields while methyl bromide use declines. And there are also two letters from the California growers describing their success with alternatives to methyl bromide.

Mr. {Whitfield.} Well, without objection.

[The information follows:]

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Mr. {Whitfield.} And then we have some additional letters from millers and Agricultural Trade Services, Almond Processing Association, the American Farm Bureau, California Date Commission, California Walnut Commission, Florida Farm Bureau, Florida Tomato Exchange, Georgia Fruit and Vegetable Growers, Holsinger Flowers, Inc., Knappan Milling Company, Lassen Nursery, Maritime Exchange for the Delaware River and Bay, Ledbetter Fruits and Vegetables, Star of the West Milling Company, Sunkist, Sunshine, Sunsweet, and Western Industries. Without objection, so ordered.

[The information follows:]

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Mr. {Whitfield.} At this time I would like to call up the second panel of witnesses for testimony on the Asthma Inhalers Relief Act of 2012. On that panel we have Mr. Jason Shandell, who is general counsel and secretary, Amphastar Pharmaceuticals. We have Dr. Monica Kraft, who is the professor of medicine at Duke University, president of the American Thoracic Society, and director of the Duke Asthma, Allergy, and Airway Center. We have Dr. Edward Kerwin, who is senior medical director, Allergy & Asthma Center of Southern Oregon. And we have Mr. Chris Ward, who is the former chairman of the Board of Directors of the Asthma and Allergy Foundation of America.

And I would like at this time call on Mr. Walden for the purpose of introducing Dr. Kerwin.

Mr. {Walden.} Thank you very much, Mr. Chairman. It is my honor to introduce Dr. Edward Kerwin, an allergy, asthma, and clinical research physician who traveled from Oregon out here today. We appreciate your being here. Dr. Kerwin founded the Allergy & Asthma Center of Southern Oregon in 1997, and prior to that, practiced in the area since '93.

Today, he is going to provide the Committee with insight on his years of experience as a physician serving patients in and around Medford, Grants Pass, Klamath Falls, and Ashland.

In addition to his role as health provider, Dr. Kerwin is a leading clinical trial investigator on issues that we will discuss today. He authored over 25 medical publications on allergy and asthma, and even previously worked for NASA on solar energy technology and space antenna projects in the '80s. So maybe Mr. Olson will be back and we can talk NASA antennas.

He is active in multiple professional trade associations, even finds time to participate in the Medford Rotary Club. And after this hearing he will be able to testify before Congress to his long and impressive résumé. And with that, Mr. Chairman, we thank you for having Dr. Kerwin invited to testify today.

Mr. {Whitfield.} We have got a meeting in here for just a minute, but Dr. Burgess is going to go on and get the opening statements started and then we will be right back.

Dr. {Burgess.} [Presiding] So again, welcome to our witnesses. We will first hear from Mr. Jason Shandell, 5 minutes for opening statement, please.

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^STATEMENTS OF JASON SHANDELL, VICE PRESIDENT AND GENERAL COUNSEL, AMPHASTAR PHARMACEUTICALS, INC.; DR. MONICA KRAFT, PROFESSOR OF MEDICINE, DUKE UNIVERSITY, PRESIDENT, AMERICAN THORACIC SOCIETY, AND DIRECTOR, DUKE ASTHMA, ALLERGY AND AIRWAY CENTER; CHRIS WARD, FORMER CHAIRMAN OF THE BOARD OF DIRECTORS, ASTHMA AND ALLERGY FOUNDATION OF AMERICA; AND DR. EDWARD M. KERWIN, SENIOR MEDICAL DIRECTOR, ALLERGY & ASTHMA CENTER OF SOUTHERN OREGON

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^STATEMENT OF JASON SHANDELL

} Mr. {Shandell.} Thank you. Good afternoon and thank you for this opportunity to testify. I am Jason Shandell, Vice President and General Counsel for Amphastar Pharmaceuticals, which is the parent company of Armstrong Pharmaceuticals. We are grateful to the Members and professional staff of the Energy and Commerce Committee for their assistance in helping us to hopefully distribute the remaining units of Primatene Mist. We strongly believe that allowing Americans to have access to Primatene Mist is better than leaving it to expire in a warehouse in California.

Primatene Mist, an epinephrine inhaler with CFC as propellant was developed by Wyeth Labs in July 2008.

Primatene Mist is approved for temporary relief of occasional symptoms of mild asthma. There are at least 2 to 3 million loyal Primatene Mist users in the U.S.

When our company purchased Primatene Mist brand in 2008, we knew it would be going off the market and that there were technical challenges in creating an epinephrine inhaler without CFCs. This is referred to as Primatene HFA. We accepted the challenge, and in fact, we have developed Primatene HFA and we are targeting to file a new drug application with the FDA in the fourth quarter of this year.

Because Primatene Mist was removed from the market on January 1, 2012, there is currently no over-the-counter inhaler for asthmatic patients on the U.S. market. An individual who previously used Primatene Mist must now pay to see a doctor and then buy a prescription inhaler that costs four to five times more than Primatene Mist.

We have received thousands of inquiries from users of Primatene Mist who are desperate for availability of an over-the-counter inhaler. Unfortunately, these inquiries have also cited two possible deaths because of the lack of such an over-the-counter inhaler, and I have these emails here.

Last December, we submitted a request to the EPA to allow for the sale of the remaining units of Primatene Mist based on public health and economic interests. The public

health interest is growing since the untreated and undertreated asthma patient population is largely comprised of uninsured, economically disadvantaged black and Hispanic communities. This includes a large number of women and children. Without Primatene Mist, those asthmatics who have no insurance, they may have to seek care in emergency rooms, which can take many hours and cost thousands of dollars.

The company's request for enforcement discretion was denied by the EPA on December 30, 2011, citing that it would not be in the public interest to allow for the sale of the remaining units of Primatene Mist. Since the EPA did not address the economic factors raised in our original request, we again requested enforcement discretion from the EPA on January 4, 2012. The 2008 Final Rule stated that removing Primatene Mist from the market will cost consumers between $300 million to $1.1 billion. That is based on 2007 estimates. The cost to the Federal Government and taxpayers for Medicare and Medicaid could run as high as $75 million in each program, not to mention the severe financial burden that an emergency room bill can place on a family.

We have not received a response from the EPA on this subsequent request based on economic concerns.

Amphastar understands that Members of Congress have also written to the EPA expressing their concerns, and they have

not received any response from the EPA as far as I can tell. The company has repeatedly asked why Primatene Mist was pulled from the market when actually there are two prescription drug inhalers that also use CFC as their propellants and they have been allowed to stay on the market through December of 2013. No one from EPA has ever explained why these two inhalers, with CFC, are allowed to remain but Primatene Mist is not.

Primatene Mist has been on the market for almost 50 years and has a safe and effective track record. To remove Primatene Mist from the market because it contains CFC with no over-the-counter replacement inhaler jeopardizes the health and safety of the 2 to 3 million Americans that have relied on this product for many years.

Amphastar believes in putting people over profits, and throughout our efforts, we have offered to distribute all of the remaining units of Primatene Mist as a donation to public health clinics. This offer has been rejected by the government. We are not interested in profiting from the sale of the remaining inventory. Therefore, we hereby commit that we will donate all the net profits from the sale of the remaining units of Primatene Mist to charity.

Amphastar believes in its product, Primatene Mist. It should be available in the United States over-the-counter so

individuals who are suffering from asthma and depend on this product can enjoy instant relief when they experience asthma symptoms such as shortness of breath. We sincerely believe that there must be a readily available over-the-counter inhaler for Americans who have difficulty accessing a doctor to obtain a prescription and cannot afford to pay four to five times more for a prescription inhaler.

In closing, let me again thank the members of this committee, specifically Dr. Michael Burgess and also Congressman Mike Ross and your professional staff for holding this hearing. Our goal is to get the remaining units of Primatene Mist out of the warehouse and into the hands of the American people.

Thank you.

[The prepared statement of Mr. Shandell follows:]

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Dr. {Burgess.} I thank the gentleman for his testimony.

Dr. Kraft, you are recognized 5 minutes for testimony, please.

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^STATEMENT OF DR. MONICA KRAFT

} Dr. {Kraft.} Very good, thank you. I would like to thank the Committee for allowing me to speak to you today.

I am Dr. Monica Kraft and I am a professor medicine at Duke University and currently the president of the American Thoracic Society. This is a specialty society made up of about 16,000 physicians who are pulmonologists with an interest in obviously respiratory issues, critical care physicians, and sleep physicians. So I also direct the Duke Asthma, Allergy, and Airway Center and have been involved in both research and care of patients with asthma. And my group and I have over 140 publications along these lines.

So it is with this professional scientific background that I come to you today to present testimony on the behalf of the American Thoracic Society on this issue of restoring epinephrine inhalers back to the U.S. marketplace. It is my strongly held view and the view of the American Thoracic Society that returning these inhalers to the U.S. market even for a limited time is ill-advised. But this view isn't just shared by me or my societies. It is also shared by several other societies, including the American Academy of Pediatrics, two asthma and allergy societies, and two

respiratory therapy societies. So we are not unique in this view.

Now, when we think about asthma we think of it as a very common disease. It affects between 5 and 10 percent of the population, so most of us know someone with asthma. We also have this perception--this is at least what I hear from people--that asthma is relatively mild and not a problem when actually I certainly take care of patients with very severe disease who die of their asthma. And one of the reasons that is is because the airways are red and swollen in asthma so they become narrowed. And it is somewhat like breathing through a straw. So really the mainstay of therapy is anti-inflammatory therapy like inhaled corticosteroids. You may have heard of that.

We also use bronchodilators, which dilate the airways and we use this combination together. And in more severe asthma we may need to use oral steroids like prednisone or adopt other strategies such as focusing our allergic symptoms, which are very big triggers of asthma.

So I am here to tell you that healthcare professionals play a really critical role in the management of asthma in that we form partnerships with our patients to get them not only the best combination of medications that they need that are safe and effective but also to educate them so that they

can control their disease.

So the takeaway message is the majority of cases asthma can be managed and patients with the appropriate therapy can live full and active lives.

But I would say to you today that epinephrine is not one of those medications considered safe. So I am coming to you from a safety perspective. So epinephrine is a nonselective bronchodilator. So yes, it dilates. It bronchodilates. That is good, but it also has other effects, primarily cardiac that is very concerning to me and my colleagues. This can lead to excessive cardiac stimulation, heart rate, that can lead to heart attacks, especially in the older patients or those folks who have heart disease. And sometimes we don't always know who has heart disease.

Now, for years, the medical community has recognized the dangerous side effects of epinephrine in the treatment of asthma and recommended against its use. The American Medical Association has urged warning labels. They have encouraged FDA to consider removing inhaled epinephrine. They have requested studies to really determine does it contribute to increased asthma morbidity and mortality.

Now, I would be interested in hearing more about these deaths that we just heard mentioned in the last testimony because in speaking to my colleagues in emergency medicine--

and my husband runs the emergency department at the University of North Carolina Chapel Hill--and my colleagues at Duke, their perception is since Primatene Mist has been off the market, there have been fewer severe exacerbations. And so we hypothesize that in fact patients are now getting the care that they need.

We have a mechanism to take care of those patients who are uninsured, those underrepresented minority patients. I live in Chapel Hill. I see patients from Durham. We have a very significant contingent of underserved patients that we take care of at our institution. And we can provide them with the right medication. So I don't necessarily think it is all about access.

So furthermore, the guidelines that put forth the treatment of asthma do not mention epinephrine as a viable option for treatment and I want to make sure that that is clear. The National Asthma Education and Prevention Program, put together by our own National Institutes of Health here in Washington, the U.S., have emphasized that inhaled medications are critical for asthma therapy but not epinephrine.

So the American Thoracic Society strongly encourages any patient who is using over-the-counter medications like Primatene Mist to seek care from a provider and there are

ways that these patients can get help. And I am a strong advocate, again, for allowing patients to learn how to take care of their own asthma and manage their disease because it is really all about putting the power in the hands of the patient and teaching them what they need.

So if one of the goals of today's hearing is to discuss the pros and cons of enacting legislation to permanently or temporarily restore inhaled epinephrine for the treatment of asthma to the U.S. market, if the intent is to restore a safe and effective medication, I think that is a laudable cause but it is misinformed. Inhaled epinephrine is not safe for the treatment of asthma and no current clinical practice guideline calls for the use of epinephrine.

If the legislative intent is to provide access to an inexpensive drug for the treatment of asthma, then I think that is laudable but misdirected. In my opinion and that of my society and other societies, the epinephrine's risk outweigh its benefits.

And lastly, I am concerned about the message we are sending to patients. We spent a lot of time preparing patients for this transition when Primatene Mist was being taken off the market, moving towards approved asthma therapies that are effective and safe, and I worry that putting Primatene Mist back on the market, even temporarily,

may send a confusing message.

I would like to propose that Congress should be considering ways to increase patient access to healthcare professions who can work with patients to find an effective combination of drugs to control asthma. We should not be abandoning patients with serious medical conditions like asthma to self-diagnosis and self-medication with less-effective drugs that have known side effects.

So I hope this committee will keep the view of the American Thoracic Society in mind as it considers legislation on inhaled epinephrine for the treatment of asthma. I thank you for the opportunity to speak to you today.

[The prepared statement of Dr. Kraft follows:]

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Dr. {Burgess.} Time is expired.

Mr. Ward, recognized 5 minutes for the purposes of an opening statement.

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^STATEMENT OF CHRIS WARD

} Mr. {Ward.} Thank you, Dr. Burgess, members of the committee, for your invitation to speak today. My name is Chris Ward. I live here in Washington, D.C., and I am past chairman of the volunteer Board of Directors of the Asthma and Allergy Foundation of America, and I have had asthma all my life. When I was a child, there were very few choices for treating my asthma. I have been fortunate, however, that more and better asthma treatments have come into use. I have also been fortunate to be under the care of an allergist, a specialist in the care of patients with asthma, since childhood when I was diagnosed. Now that there are a variety of safe, effective medications from which to choose to treat my asthma, I am a grateful beneficiary.

Making the epinephrine bronchodilators, Primatene Mist or others, available over-the-counter may give patients a false sense of security. I know that from a personal perspective. If patients use this medication to achieve short-term control of asthma, which is a chronic disease, when long-term control is warranted, asthma is a chronic disease and short-term symptom relief may lull patients into a false sense of security and think they have no need to

follow up with a healthcare practitioner physician.

Asthma patients need professionals who can recognize levels of asthma control and recommend the most appropriate, effective medication to achieve control. Left on their own-- I as well as other patients and a lot of us know that with medication over-the-counter, that patients can get into trouble. Sound public policy should provide patients with opportunities to get appropriate treatment directed by skilled professionals. Having access to epinephrine bronchodilators over-the-counter may put patients at risk if they delay getting an appropriate diagnosis and effective treatment to keep their asthma in control.

Some may argue that in the case of an asthma attack, patients need to be able to go to a drugstore or a market and buy an over-the-counter inhaler like Primatene Mist or other epinephrine inhaler. Should we recommend, however, that someone who is having an asthma emergency go to a store to buy a device rather than calling 9-1-1 or going to an emergency room or hospital? If patients need unplanned refills or replacement devices, they can contact their prescriber or even get those medications prescribed for them by a physician in an emergency room and then follow up otherwise.

Another assumption that may prove false is that patients

of low-income need these medications because they are low-cost. I grew up in an area of the country where there were a lot of low-income patients, and I certainly was not a child of means. While the price of Primatene Mist may be lower than the total cost or co-pay for more effective bronchodilators, the relief from these epinephrine devices does not last as long. Thus, the long-term control and long-term cost is actually higher.

Over-the-counter access to this product may seem to erase the cost of visiting a prescriber. However, over-the-counter bronchodilators can promote self-diagnoses, and we are all subject to those kinds of self-treatment sometimes, which is particularly unsafe for the symptoms of asthma because it can be deadly. With proper diagnoses and treatment, people can control their asthma symptoms, avoiding high-cost interventions like emergency department visits and hospitalizations. Cutting out care by a qualified medical practitioner could be dangerous for the patient and costly to the healthcare system.

The decision to withdraw Primatene Mist from the U.S. market was made years ago. Lifting the ban may now lead to confusion. There will be little opportunity to inform patients about the nature of the change and to urge them to seek care from a professional if they think they have asthma.

I have worked with professionals like Dr. Kraft many years of my life in the industry of healthcare and life sciences, worked for pharmaceutical companies and other healthcare organizations. I have also been a volunteer as a volunteer leader of the Asthma and Allergy Foundation of America, and I know that asthma is a serious chronic condition, and I know what a difference effective treatment can make and even as a child with very few available to me, I was very fortunate.

I urge you, for all asthma patients, to reject an attempt to re-release an epinephrine inhaler to the market as an over-the-counter product. Again, I thank all the members of the committee for inviting me here to testify today.

[The prepared statement of Mr. Ward follows:]

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Dr. {Burgess.} I thank the gentleman for his testimony.

Dr. Kerwin, you are recognized for 5 minutes for an opening statement.

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^STATEMENT OF DR. EDWARD KERWIN

} Dr. {Kerwin.} Thank you very much to the Committee and the Subcommittee for inviting me to testify.

As Congressman Walden explained, I am an allergy researcher, asthma researcher. I have conducted over 300 clinical trials with over 200 new state-of-the-art medicines for asthma and I care for 10,000 asthma patients. And I trained with Monica. I will say that I am a member of the American Thoracic Society, a fellow of the American College of Allergy, and the American Academy of Allergy and never once have those organizations polled me or any of their general membership on the issue of Primatene.

Now, my comments today briefly--

Dr. {Burgess.} I am sorry, sir. Your microphone popped. Could you make that statement again? I missed it.

Dr. {Kerwin.} I thought the microphone was on. I wanted to just state that I am a member of the American Thoracic Society for the last 10 years, a fellow of the American College of Allergy, and the American Academy of Allergy and never once have those organizations polled myself or any others of the general membership on the issue of Primatene and the safety of Primatene. So what I will tell

you is these organizations are speaking on behalf of the administrative doctors working there but not on behalf of the general membership.

Now, what I want to say is that I think we live in a difficult era in science and culture. There are major scientific advances happening all the time, and I will just say that that is how I spend 90 percent of my time, doing clinical research with some of the latest, most advanced medicines for asthma. Science tells us CFCs can be harmful to the ozone layer and they do need to be removed gradually over time and that has happened with hairsprays and air conditions and refrigerators. And I am happy to say that there are many new HFA medications that are available for asthma. So science is moving forward. We hope that there will be an HFA Primatene perhaps within a year.

But I have to say that there are also many issues of practicalities that critically need to be considered when any new law is implemented. And science cannot just be implemented as a blanket process. It has to be implemented in a rational way.

Asthma, as you have heard, is a disease that strikes in the middle of the night, and I don't know many private practice doctors who are going to be available 24/7 if you suddenly need a prescription medicine. Asthma occurs at your

4th of July picnic and it is going to occur when you visit your least favorite relatives who have five cats at home. Asthma may affect your college daughter when she moves into a basement apartment that has mold in it. It may occur when you get out and run a 5K or a 10K running race, and it will hit you when you come to visit me in Oregon where we have horse farms and hay farms.

What I need to make clear is that despite all of the science, which I am happy to discuss endlessly, Primatene Mist is a first aid situation kind of medicine. The reason it is over-the-counter is that there need to be immediate access, immediate use medicines available to children, poverty-stricken patients, elderly people who have acute airway disease. It is similar to choking where a Heimlich maneuver is needed. It is similar to a bee sting where Benadryl can be picked up at any convenience store. We need regular access to emergency medicines.

Now, the American Thoracic Society and others may say you can get albuterol HFA but I challenge them that is simply not true. There are many, many Americans who have no insurance, they have no doctor, they have no prescriptions. They cannot simply get albuterol HFA.

The best analogy that comes to my mind is basically a life vest or a life raft on a ship. We have all seen the

Titanic movie. We know what happens if there are not enough life vests or life rafts. Now, we have seen the Costa Concordia ship. The question is should all the life vests be locked up where only the ship's doctor or the ship's captain has the key? That simply does not make sense for a medicine that can be lifesaving for poor people in inner cities.

I am going to end by reading a brief poem. This is a little over the top but this is the poem engraved on the bottom of the Statute of Liberty, a little excerpt that says, ``Give me your tired, your poor, Your huddled masses yearning to breathe free, The wretched refuse of your teeming shore. Send these, the homeless, tempest-tost to me, I lift my lamp beside the golden door!'' Now, what that means really is that we live in a country where there are many people who don't have opportunities to see fine and wonderful doctors. They need some temporary relief medicines. Scientifically, we are all in favor of HFA over-the-counter medicines, but there are none.

So I would ask the Committee to consider extending the use of Primatene. It is the only available rescue medicine for up to 30 million Americans who don't have healthcare.

Thank you.

[The prepared statement of Dr. Kerwin follows:]

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Dr. {Burgess.} The gentleman's time is expired.

We thank all witnesses for their testimony. I am going to start with myself.

If I was sitting down there, I would complain to the chairman that we don't have the EPA here and we don't have the Food and Drug Administration here because really that is who needs to be at this hearing. And I do want to thank all of you. I mean this has been difficult for me because I just simply did not understand what in the hell was going on. You have got the EPA saying the Montreal Protocol says we have got to take this stuff off the market. The FDA is saying, yeah, yeah, we are working on a replacement; we are going to get to it. But it just wasn't happening and I couldn't get anyone to answer my questions. Lisa Jackson, Gina McCarthy were not only dismissive, they were derisive. Dr. Hamburg at the EPA just simply evaded the question but now I understand. There is a contingent of people who do not think that epinephrine belongs as part of the armamentarium for treating asthma. Okay.

Dr. Kraft, have you talked to the FDA about the withdrawal of epinephrine as an asthma therapy? I mean it has been around for 50 years. Presumably it was approved at some point. So have you provided testimony or documentation

to the FDA on this subject?

Dr. {Kraft.} What I have done is we have been involved as a society in looking at--

Dr. {Burgess.} So the answer to the question is no, you have not--

Dr. {Kraft.} No, I have not talked to them directly other than offline. So you won't find any documented testimony. One thing I would like to put forth, however--

Dr. {Burgess.} Well, could you provide us those things that you have sent to them offline? You have communications?

Dr. {Kraft.} And I am just being told the ATS other than myself personally has commented on the transition process.

Dr. {Burgess.} Okay, so you will--

Dr. {Kraft.} We can provide that.

Dr. {Burgess.} On the transition process, but I mean look, if you want a drug withdrawn from the market--and this happens all the time--I mean you go to the FDA and say we have post-market surveillance. This stuff is as bad as key tech. This stuff is as bad as--I forgot what the anti-inflammatory was--

Dr. {Kraft.} VIOXX.

Dr. {Burgess.} VIOXX. And things happen.

Dr. {Kraft.} Sure.

Dr. {Burgess.} Have you done that?

Dr. {Kraft.} We can provide you with--absolutely. We have been to the FDA. We have two issues actually if you permit me to--

Dr. {Burgess.} Well, what did the FDA tell you?

Dr. {Kraft.} --speak. We have issues on--there is a CFC issue. To be honest, I am here today as a physician caring for patients. I am really here for the patients' safety piece because we have been calling for the removal of inhaled epinephrine well before Montreal Protocol really became an issue.

Dr. {Burgess.} Right. So that is the issue that you are coming to discuss today, but the hearing is on the Montreal Protocol and the CFC prohibition preventing asthmatic patients--

Dr. {Kraft.} Right.

Dr. {Burgess.} --from having a rescue inhaler.

Dr. {Kraft.} Absolutely. So--

Dr. {Burgess.} And I am speaking to you not just as a Member of Congress. I am also a physician. I am also an asthma patient--

Dr. {Kraft.} Right.

Dr. {Burgess.} --and I use over-the-counter epinephrine multi-dose inhalers and I have for some time. I use them as

part of the rescue phenomenon that we have all heard talked about, and yeah, okay. I am a doctor. I can go down to the all-night pharmacy and write my own prescription for albuterol. But if I get trapped in a situation without an inhaler, it happened to me in Chicago at an NRCC fundraiser a few years ago. The hotel put me in a room where somebody had been smoking. So at 2:00 in the morning, guess what? I can't breathe. So I got two options. I can stay up the rest of the night holding onto the chair using the accessory muscles of respiration and have a sleepless night or I can go down to the front desk clerk and say where is your nearest 24-hour pharmacy? He says one block over, two blocks up. I say thank you very much, take my life in my hands, walk across the streets of Chicago at 2:00 in the morning, but a rescue inhaler is available to me.

Dr. {Kraft.} Right.

Dr. {Burgess.} And I could do this without being a physician, just being a regular Joe you can go and get that but not anymore. And this is the difficulty that I have is you have the product in the warehouses. If you are really concerned about CFC, if this is really about the hole in the ozone, what is going to happen to those canisters? I mean at some point they degrade to the point where they blow up I guess. I mean I don't know. I don't know what the lifecycle

is of one of those things. But the CFC is going to go into the environment. So what are we preventing here? Are we going to go put them in Yucca Mountain and entomb them in concrete so that they don't ever get out? I mean I don't even know how much CFC we are talking about here.

But it is just preposterous that we are having this argument around CFC, around the propellant under the Montreal Protocol when really your beef is with epinephrine and we should have the FDA here and you should be asking them--

Dr. {Kraft.} I agree.

Dr. {Burgess.} --to explain what studies have you done? Why do you still allow this stuff to be sold? And I would have some questions for them about that as well. But no one would answer my questions. Can you understand the frustration? I have had Lisa Jackson here at this table and she just looks at me like I am nuts. I have had Gina McCarthy and she laughs that I am even concerned about this.

Dr. {Kraft.} Um-hum.

Dr. {Burgess.} Margaret Hamburg won't even answer the question. Can you understand why there is such frustration with this?

Dr. {Kraft.} I do.

Dr. {Burgess.} And at the same time I am getting these same letters from constituents, Doc, how come I can't go buy

this stuff anymore? How come you took it away from me? How come you know better than I do about what is best to treat my asthma? It is not just breathing through a straw; it is breathing through a straw that is packed full of cotton. I mean this--

Dr. {Kraft.} Absolutely.

Dr. {Burgess.} --you know, Mr. Ward. I mean this is a dreadful set of symptoms to have visited upon someone. You have got a rescue inhaler. If the issue is that it is not a satisfactory pharmacologic agent, let us work on getting albuterol over-the-counter--

Dr. {Kraft.} I agree.

Dr. {Burgess.} --and I will just share with you my personal preference is CFC is a much better propellant--

Dr. {Kraft.} Right.

Dr. {Burgess.} --than HFA. HFA is for wimps. CFC delivers the right dose at the right time.

I am going to yield to the ranking member of the subcommittee.

Dr. {Kraft.} Would I be permitted to answer?

Dr. {Burgess.} Oh, please.

Dr. {Kraft.} Thank you. So I agree with your frustration. I can understand that. If I were your doc, I would make sure you had three separate albuterol inhalers. I

would have you put one in your briefcase, I would have you put on in the glove box of your car, and I would have you put one in your wife's purse to make sure that you always have albuterol with you. So that is the first part.

Dr. {Burgess.} I do that, but the best laid plans don't always work out. And sorry that I wasn't prepared that night but it happens. It happened on a flight into Dulles where, you know, I didn't have an inhaler. I had a long cab ride back. Oh, my lands, I am really in trouble. I asked the cabdriver, would you stop at a pharmacy and let me pick up a rescue inhaler so I am not sitting here in the backseat of your cab suffocating--

Dr. {Kraft.} Right.

Dr. {Burgess.} --and he was happy to accommodate me. I mean those are real-world situations and they happen all the time. My wife will likely not carry one in her purse for me, but I do have one in my glove box. I do have one in my backpack. I don't carry a briefcase but, yeah, I have got them scattered all over my life--

Dr. {Kraft.} Okay.

Dr. {Burgess.} --but sometimes I wander away from them. I will let you respond.

Dr. {Kraft.} Okay, thank you. The other issue is regard over-the-counter. There actually is a movement going

on to start talking about over-the-counter bronchodilators that are safe. It is still in the very early stages. It is somewhat controversial because we are still on the same issue where we want to make sure that practitioners interact with their patients to be able to educate them on the principles of asthma and know what combinations of medications work best for them.

So I don't know if you are aware of that or not. So I wanted to just put that forth as something that is in the works. If we are really focusing on this over-the-counter piece, I think there is a thoughtful way to consider over-the-counter medications for asthma that aren't necessarily Primatene Mist per se.

I am also a critical care physician and I have seen more patients coming into my intensive care unit with their Primatene Mist inhaler clutched to their chest with a severe asthma exacerbation on a ventilator. And I don't see that when they are on proper therapy. We have seen a much lower incidence of really severe asthma exacerbations because of people getting in with their docs, getting on anti-inflammatory inhalers. Because I worry this reliance on going down to the drugstore and getting Primatene Mist and not being on something daily for asthma--because it is about redness and swelling of the airways is a problem.

Dr. {Burgess.} We need to go to Mr. Rush. I don't want you to be concerned for my health and safety. I do have an ADVAIR inhaler and I do use it--

Dr. {Kraft.} Well, I am.

Dr. {Burgess.} --regularly. But there are times when you need that extra boost.

And I will yield to Mr. Rush, 5 minutes for questions.

Mr. {Rush.} Well, thank you, Mr. Chairman. Mr. Chairman, I was headed along the same path. I think you might have inadvertently--didn't mean any harm--mentioned the fact that you took your life in your hands by walking outside of a hotel in Chicago and I really take offense to that. But I have been working on this issue of asthma for quite a while and it is a real acute concern of mine and it has been and always will be because it disproportionately impacts my community. In the year 2000, Congress passed the Asthma Reduction Act, which incorporated aspects of a bill that I sponsored into the Children's Health Act of 2000. And it came along and I still am very much concerned about the issue of asthma. And I have to say I am somewhat torn but I have to come down on the side of my constituents.

Mr. Chairman, a month and a half ago I had a pastor at a church and the person who is one of my--not my key person at the church--had asthma and I think you might recall I had to

go and bury him. And he was a member of my church and he was an asthmatic patient and he died of congestive heart failure. But he was an asthmatic patient also. And his memory keeps overpowering me and overwhelming me even now. And he was under a doctor's care. But now, many, many people who are my constituents, I have one of my long-time staff members is an asthmatic patient. Every Tuesday she takes half a day off and this has been going on for years. She goes to the doctor to get the shots that I have seen her go into crisis situation on more than one occasion.

And I know that the science and the goodhearted folks--but I just have to say to Dr. Burgess, I think that this legislation that you come up with, I don't like the fact that we have to do this, but I just don't see, given the absence of any other approach that this Congress can make, I don't see how we can avoid it. I for one just find that there are too many of my constituents who don't have access to healthcare, who don't have a doctor, and who even think it would take too much time right now if they would be able to do--they just don't have the wherewithal. They are missing so many elements keeping them from living productive lives, and asthma is becoming more and more of an issue. It is probably one of the leading health issues in my community.

And I hear the arguments but I think that this Primatene

should be allowed back on a temporary basis, understanding what the problems are with it, what the short-term solution might mean to other long-term issues--I haven't addressed the long-term issues. But I don't see the solution to these issues. I don't see that being eminent and overnight, reality, because it has to do with access to healthcare. And this Congress, we have tried to address it but we can't agree on what access to healthcare really means to the American people. I know my time is expired. I had some questions but I just had to get out what I had to say about this particular issue.

I yield back.

Mr. {Whitfield.} Well, thank you, Mr. Rush.

At this time, I recognize the gentleman from Texas, Mr. Barton, for 5 minutes.

Mr. {Barton.} Thank you, Mr. Chairman.

When I go to Chicago, which I don't do very often, I just carry around Bobby Rush-is-my-friend cards and I have never had a problem on the streets of Chicago. I just show them that card and they say what can we do for you? They just couldn't be friendlier.

So when Dr. Burgess indicated he was going to introduce this bill, I was encouraging of him introducing the bill. You know, but this goes under the heading of no good deed

goes unpunished because apparently a lot of the people in the asthmatic community are fairly opposed to his bill.

My first question would be to the panel. Each of you indicate you support the bill, oppose the bill, or are neutral on the bill. Just start and go right down the line.

Mr. {Shandell.} Yeah, I definitely support the bill. I find it ironic that these third parties are now raising safety issues when this really was an environmental issue. Primatene Mist has been around for half a century.

Mr. {Barton.} So you support the bill?

Mr. {Shandell.} I support the bill.

Mr. {Barton.} I don't need the editorial right now.

Mr. {Shandell.} I support the bill.

Mr. {Barton.} Okay. Dr. Kraft?

Dr. {Kraft.} I oppose the bill. Am I allowed to say anything?

Mr. {Barton.} Well, in a minute.

Dr. {Kraft.} Okay.

Mr. {Barton.} Right now, we have got one for and one against.

Dr. {Kraft.} All right.

Mr. {Barton.} Mr. Ward?

Mr. {Ward.} As a patient, I think I would oppose the bill--

Mr. {Barton.} Oppose the--

Mr. {Ward.} --as it is currently constructed.

Mr. {Barton.} As it is currently constructed, okay.

And Dr. Kerwin?

Dr. {Kerwin.} And I definitely support the bill--

Mr. {Barton.} Support the bill.

Dr. {Kerwin.} --only alternative out there for people who don't have a doctor right next to--

Mr. {Barton.} So we are two to two. We have two for and two against. That is not bad. I mean, you know, that is a tie. In this committee, the tie goes to the sponsor of the bill.

So my next question, Primatene Mist, if it were allowed to be sold over-the-counter, the existing stocks, what would that cost an individual who just walked in and purchased it? What would it--

Mr. {Shandell.} I can answer that. So we sell to the retailers who then mark up, but we will not raise the price of Primatene. As I said, we will donate all the profits. So based on the past sales, we are looking at about $20 at the retail--

Mr. {Barton.} If it were allowed to be sold, it would be around $20?

Mr. {Shandell.} Correct.

Mr. {Barton.} Now, if I don't have it and I have to go to a doctor and get a prescription, what does that prescription cost for the equivalent amount of dosages?

Mr. {Shandell.} Well, the prescription itself let us not forget the doctor's bill but the actual inhaler is $110.

Mr. {Barton.} Okay, Dr. Kraft, you have got--

Dr. {Kraft.} I would like to respectfully disagree. Yes, there are places where in fact it is $120. If you look, which I just did today, not in Canada, $30--

Mr. {Barton.} Thirty dollars.

Dr. {Kraft.} --you can find--

Mr. {Barton.} You can get--

Dr. {Kerwin.} Well, I will just have to say that having practiced allergy and asthma care for 20 years, there is nowhere in my State of Oregon where you can get albuterol inhaler HFA for less than $60 to $70 a canister.

Mr. {Barton.} All right. So--

Dr. {Kerwin.} So that is the fact--

Mr. {Barton.} We are--

Dr. {Kraft.} Well, I guess I practice in a part of the country that is a little less--

Mr. {Barton.} We are all in agreement that the prescription is going to be somewhat more expensive. If you are an informed consumer like Dr. Kraft, you can get it much

less expensively, but there is nowhere you can get it for the same price. That is fair?

Now, the next question--which of you a medical doctor, which of the two doctors? So we have two medical doctors. This is great because you are on each side of the issue. What is wrong with allowing the sale of the existing stocks and use that as an emergency but also have your prescription where you get the treatment regime that actually seems to be more effective? What is wrong with that, Dr. Kerwin?

Dr. {Kerwin.} Well, thank you for making that point. That is exactly the kind of care we think Americans should get. Like Dr. Burgess does, they should see a doctor, they should get educated about their asthma, they should reduce their allergy exposures, they should get anti-inflammatory inhalers, and they should have access to Primatene just for emergencies. I live in a rural State. Many patients in southern Oregon live 50 miles from the nearest doctor. That is quite common. Certainly, 100 miles from an emergency room. We believe there is a role for Primatene or epinephrine or any over-the-counter inhaler. I would support over-the-counter albuterol but it is not--

Mr. {Barton.} My time is about to expire.

Dr. Kraft, my friends at the Allergy and Asthma Network Mothers of Asthmatics point out that there is a product

manufactured by Nephron Pharmaceutical that is a handheld bulb nebulizer. What does that cost? And is that effective?

Dr. {Kraft.} That is epinephrine also is my understanding and so I do not know the cost of that. But I would like to comment on your first statement--

Mr. {Barton.} I mean that would take care of the Montreal Protocol issue I think because it is a handheld. It doesn't use a CFC.

Dr. {Kraft.} Right. The issue I see is that Primatene has been around for 50 years, so that is one issue that people like to bring up. I would argue that 50 years ago we didn't have a lot of particularly effective asthma therapies. So that is all there was. Now, we do.

Now, I am also in favor of over-the-counter options for asthma and that is actually, as I was mentioning earlier, that is in the works at the FDA.

Mr. {Barton.} Well, it has been in the works for--

Dr. {Kraft.} Well--

Mr. {Barton.} --a number of years.

Dr. {Kraft.} --actually I think there have been hearings. It is actually heating up quite vigorously and we are right in there part of it as supportive with thought.

Mr. {Barton.} Well, my time is expired and I appreciate the chairman's courtesy.

Dr. {Kraft.} Okay.

Mr. {Whitfield.} The gentleman's time is expired.

Mr. {Barton.} I do think Dr. Burgess has a good idea here. If we can work with the community so it is not two to two, we may have a bill that actually goes somewhere.

Mr. {Whitfield.} At this time, I will recognize the gentleman from California, Mr. Waxman, for 5 minutes.

Mr. {Waxman.} Thank you, Mr. Chairman.

Obviously, if you have two on each side, it doesn't produce a tie; it just means it is a balanced presentation and that is always a good idea so we hear both sides of the issue.

But I am going to ask about the health effects of all of this. Dr. Kraft, you are the president of the American Thoracic Society and a recognized expert on asthma. And there is a long list of medical and public health organizations who have raised concern about the over-the-counter epinephrine inhalers. In your testimony, you said epinephrine inhalers like Primatene Mist are not a safe treatment for asthma and are not recommended by expert guidelines. Why is that?

Dr. {Kraft.} You are absolutely right. That is true. The reason is it is the compound itself, the chemical epinephrine. It is nonselective. So yes, it can

bronchodilate, so that is the good news, but it has effects on other organs. And the major concern is cardiac, excessive cardiac stimulation and can lead to myocardial infarction, heart attack in patients who have heart disease. And that is really the concern. I am not against over-the-counter medications for asthma necessarily if done in a thoughtful way. I think that this particular medication is concerning. And there have been voices for many years calling for the removal of this particular agent because of the dangers and the side effect profile. That is really where we are sort of coming from today.

Mr. {Barton.} But it is not easy for FDA to take a drug off the market. Do you know what the standard of proof is? I assume it is pretty tough.

Dr. {Kraft.} I am sorry. Repeat that question, please.

Mr. {Waxman.} Has FDA tried to take it off the market? Is it something that FDA should take off the market?

Dr. {Kraft.} You mean Primatene?

Mr. {Waxman.} Yeah.

Dr. {Kraft.} Well, it has been off the market for 6 months because of--

Mr. {Waxman.} But did they ever move to take it off the market?

Dr. {Kraft.} There have been calls from the American

Medical Association--

Mr. {Waxman.} Um-hum.

Dr. {Kraft.} --to the FDA to consider it. But I think it is a difficult situation because the question is can we look at alternatives and can we improve access to care for patients--

Mr. {Waxman.} Um-hum.

Dr. {Kraft.} --so that they can actually get the right medications. So I like the idea of having something available for patients but I would argue let us make it the best medication and a safe medication.

Mr. {Waxman.} Well, Dr. Kerwin argues in his testimony that Primatene Mist is necessary for an emergency situation where someone suffering from asthma does not have a prescription medication. He says people would die or could die without it. What do you think in a potentially life-threatening situation, should asthmatics use Primatene Mist?

Dr. {Kraft.} I have actually seen the ramifications of using it in an emergency situation and relying upon it to improve asthma symptoms. And the issues--it is very short-term in terms of its action and the excessive additional side effects of the cardiac piece actually, in my opinion, is not a safe alternative. So I would actually recommend--and we have done this in the community that I practice--we have the

ability for patients to get albuterol very easily and to have access to emergency departments and follow up with us so they can get the medications they need. And we have a big community program in Durham for this purpose exactly to help the underserved because I think that is who we are talking about today, those patients who don't have the access that perhaps the rest of us do.

Mr. {Waxman.} Well, I take seriously when the health professionals take a point of view that something is not safe, particularly if it is--this bill would go to extraordinary lengths to put it back on the market. It is not on the market now. If I were convinced, however, that it is necessary, then I would say fine. Let us keep it out there. But I don't think we have got to push legislation to put a product back on the market in the face of such strong opposition by public health and physician organizations.

Am I correct that public health and physician organizations take the same point of view you do?

Dr. {Kraft.} Yes, many.

Mr. {Waxman.} Now, I want to go into the question of how fair this is to the company. The company obviously wants to sell the product that they still have and they are not going to pursue it after that. The initial proposal by FDA was to phase out the drug and it was agreed upon it would be

December 31, 2010. Armstrong submitted comments to FDA requesting it be extended 1 year, and FDA granted Armstrong's request for a 1-year extension. Isn't that right, Mr. Shandell?

Mr. {Shandell.} Yes. I would like to address that because--

Mr. {Waxman.} Well, I just want your answer because--

Mr. {Shandell.} Yes, that is correct.

Mr. {Waxman.} No, my understanding is that about a dozen other types of inhalers containing CFCs were phased out before Primatene Mist. That includes the albuterol phase-out in 2008 which involved moving millions of asthmatics to new treatments--

Mr. {Shandell.} Which was our product as well.

Mr. {Waxman.} --only two CFC-based inhalers remain to be phased out and both are scheduled to be taken off the market at the end of 2013. So Primatene Mist was actually phased out several years later than many other types of inhalers. Would it be fair to them to have you come back on the market when they--

Mr. {Shandell.} Well, that is what I would like to address because, you know, this is an environmental issue regarding CFC. It is not a safety issue because otherwise--

Mr. {Waxman.} Well, this is not a safety question that

I am asking. I am just asking you in basic fairness--

Mr. {Shandell.} Well, yeah, the--

Mr. {Waxman.} --if other companies follow the rules--

Mr. {Shandell.} --fairness question is that we have been working with FDA since 2007 for HFA Primatene. So obviously the FDA believes in Primatene because we have spent tens of millions of dollars on clinical trials and we are looking to get an approval next year. So obviously--

Mr. {Waxman.} No other company--

Mr. {Shandell.} --new drug applications--

Mr. {Waxman.} --came back and said we are not--

Mr. {Shandell.} And the only reason we are--

Mr. {Waxman.} Excuse me, sir.

Mr. {Shandell.} Yes.

Mr. {Waxman.} I have already exceeded my time but I get to ask the questions.

Mr. {Shandell.} Sure.

Mr. {Waxman.} And other companies phased out--not other company was allowed to come back and sell off its remaining inventory after the phase-out date. Isn't that right?

Mr. {Shandell.} That is correct. No other company is over-the-counter so there is no--

Mr. {Waxman.} What difference does it makes if it is over-the-counter or prescription?

Mr. {Shandell.} Because if you don't have a prescription, you can't afford insurance, you have no choice.

Mr. {Waxman.} That is a different issue but a drug to be extended and allowed to come back and sell off the--

Mr. {Shandell.} We have a million units remaining--

Mr. {Waxman.} --inventory.

Mr. {Shandell.} We don't need to sell the inventory. We are advocating on behalf of our customers who have been complaining saying that people have died actually. So we are just coming out not for money. We are saying, look, let the million we sold. We are really interested in getting HFA approved so there is an over-the-counter. In terms of fairness, there are two prescriptions that are still not the market with CFC and nobody has answered why those are allowed to stay if it is an environmental issue and not a safety issue.

Mr. {Whitfield.} Gentleman's time is expired.

I will recognize myself for 5 minutes of questions now.

We have a situation here where we have in storage some Primatene Mist. This legislation relates only to that. This is a product that has been used 40, 50 years, was accepted by people who used it and obviously people benefitted from it or they wouldn't continue to buy it. We have a lot of letters or emails here from people--``I just spent my last $200 on my

son at a doctor's appointment for asthma medicine. We will no longer be able to go to the doctors because Primatene Mist is gone.'' We have a lot to that effect. I understand a genuine concern about, oh, this is not safe for people, and Dr. Kraft, you have said that this is not a safe treatment. There are side effects. There are cardiac problems with it. And now, Dr. Kerwin, would you reply to that comment that Dr. Kraft made?

Dr. {Kerwin.} Yes, I would be delighted to reply to that. You know, Primatene was released and approved by the FDA either in 1957 or 1963, and at that time, the approval process was less rigorous than it is now. So Primatene has been what we would call a grandfathered medicine that has been out for many, many years. Every drug company is required to collect safety reports if there is any episode where a drug fails a patient or where they die for any reason that could be related to the drug. And my understanding is Amphastar has received no complaints of patients who have had life-threatening cardiac problems or other what we call serious adverse events with this medicine. It is truly unfair to say that it is not a safe drug. That is 100 percent speculative. The way safety is assessed is through a clinical trial process, and epinephrine in the HFA form is going through a very careful and rigorous FDA-authorized

safety process.

Mr. {Whitfield.} Thank you. I might--

Dr. {Kerwin.} Safety is roughly parallel. It is slightly more cardiac stimulating.

Mr. {Whitfield.} I mean I can understand in Durham that there may be a program developed that really addresses this emergency need, but there are lots of places in the country that do not have programs like that. And from my personal perspective, I don't see what is wrong with giving patients a choice. If it is available and they want it for a period of time, why not?

But I would like to yield the balance of my time to Dr. Burgess.

Dr. {Burgess.} Well, Mr. Chairman, I would just reiterate the observation that we are here today having this hearing. The legislation has been introduced essentially because two federal agencies decline to be truthful with the Committee. And that is the real tragedy here. Yes, we should have the EPA here. They should be answering the question why are there two prescription products that are continuing to use CFCs still sold, not affected under the ban? We should hear from the FDA. Have you had post-market surveillance data on inhaled epinephrine products that lead you to believe that it is unsafe?

But instead, we have got this mishmash, this backdoor banning of a product that has been approved for 50 years on which people depend under the Montreal Protocol. I mean this really makes no sense. If we are really frightened of the CFC in those remaining canisters that Mr. Shandell has secreted away somewhere, I submit that we ought to reopen Yucca Mountain and take them deep into the Earth and entomb them in cement like we would radioactive waste.

But those canisters are eventually going to degrade, pop open, and the CFC floats over the Antarctic and widens the hole in the ozone. At least that is what we are led to believe that this small amount of CFC is going to lead to all sorts of global calamities.

Dr. Kerwin, look, I have been in the ICU when a young patient has died from an aspirin overdose. I mean that is tragic, the acidosis that accompanies like 24, 36 hours later. Everybody thinks the kid is out of the woods and then he dies. So we know people can die from over-the-counter products. Yet, people take aspirin all the time for headaches. Would it make sense that we told people if you have a headache, you really shouldn't take aspirin anymore. Come to the emergency room, let us give a CAT scan to make sure you are not dying of a brain tumor and then we will get you something. I mean that is kind of what we are saying

here, isn't it?

Dr. {Kerwin.} I would say that the principle of having medicines available over-the-counter is sort of a twofold principle. One is America was settled by frontiers people who came out to many of the big States and they didn't have a doctor on their Oregon Trail wagon train. So we live in a country where people have a fundamental right to try to treat themselves first before they take the radical step of seeing a doctor. The second thing I would say is medicines over-the-counter are designed in order to help the many even if overuse of the medicine or misuse might harm a few. And I think Tylenol, 20 pills of that can hurt your liver. Benadryl, 20 pills of that could put you in a car crash, and yeah, 20 puffs of epinephrine might make your heart race. But these medicines are consistent with the values that patients should have a right to treat themselves initially and they should then seek better medical care.

Dr. {Burgess.} Well, Mr. Chairman, I will just close with the observation that we should require the two federal agencies involved--Environmental Protection Agency and the Food and Drug Administration--to come before this committee and be honest with us for a change, none of this hide-the-ball, oh, it is a Montreal Protocol thing. If there is a danger to inhaled epinephrine, then why the hell has the FDA

not prevented it? We have been through this round and round with the FDA where they say, oh, we know that something is dangerous but we can't prevent it being sold. That is nonsense. That is their job. That is what they are there to do. If they have post-market surveillance that says inhaled epinephrine multi-dose inhalers are damaging to people's health, they owe it to this committee to come here and share that with us.

Mr. {Whitfield.} At this time, I would like to recognize the gentleman from Michigan, Mr. Dingell, for 5 minutes.

Mr. {Dingell.} I thank you for your courtesy. And I would like to ask these questions of Mr. Shandell, yes or no.

It is my understanding that there are 1.2 million units of Primatene Mist remaining in inventory, is that correct?

Mr. {Shandell.} Yes, approximately.

Mr. {Dingell.} Now, is this remaining inventory being stored under safe and proper conditions?

Mr. {Shandell.} Yes, it is.

Mr. {Dingell.} You are sure of that?

Mr. {Shandell.} Yes.

Mr. {Dingell.} When will the remaining inventory expire?

Mr. {Shandell.} It expires at varying times, mostly in

August of 2013.

Mr. {Dingell.} Okay.

Mr. {Shandell.} Starting in January.

Mr. {Dingell.} The remaining inventory has been stored properly and has not yet expired. Do you know the reason or do you have reason to believe then that any of the remaining inventory is unsafe for use by patients?

Mr. {Shandell.} No, we do not. It should be very safe for patients--

Mr. {Dingell.} Does anybody at the table have any reason to believe that the storage of the remaining inventory of Primatene Mist is creating an unsafe product? Yes or no?

Dr. {Kraft.} I just had a question on the expiration. It is January to August of '13, right?

Mr. {Dingell.} Well, is anybody down there going to sit there and tell me that this Primatene Mist is going to be unsafe when it is put on the market if it is so?

Dr. {Kraft.} Based on the way it is stored, sir?

Mr. {Dingell.} Based on any fact. Yes or no. It is a yes-or-no question. You should have no trouble doing it.

Dr. {Kraft.} Yes. Then I would say yes.

Mr. {Dingell.} You believe it is unsafe?

Dr. {Kraft.} Yes.

Mr. {Dingell.} Why?

Dr. {Kraft.} For the reasons that I stated previously. It has nothing to do with storage. I think they have been storing their product--

Mr. {Dingell.} Do you have knowledge of this or is this supposition?

Dr. {Kraft.} That it is unsafe? I have had personal experience with patients who have taken it and had severe asthma--I am talking about safety from a mechanism perspective.

Mr. {Dingell.} Thank you very much for that unhelpful response.

Now, according to your testimony, Mr. Shandell, there have been between 2 and 3 million Primatene Mist users. If Amphastar is allowed to distribute and sell the remaining inventory of Primatene Mist, how would your company do so equitably?

Mr. {Shandell.} Yes, we will do it equitably. We will not raise the price from what it was previously. We also, as I have stated, this is for the goodwill of our customers. We are not looking to make any profit here, so we will actually donate all the net profits to charity. And I really want to go back to people are saying that this is an unsafe drug, then why has the FDA been working with us since 2007 for an HFA version?

Mr. {Dingell.} May I persist in my questions?

Mr. {Shandell.} Yeah, sure.

Mr. {Dingell.} Is there any reason to fear that pharmacies may not be willing to restock Primatene Mist for any reason?

Mr. {Shandell.} There is some concern to that but if it is as sought after as we believe by our customers, they can always get it online by CVS.com. There are--

Mr. {Dingell.} So there is the fear that they would refuse to stock it?

Mr. {Shandell.} No. Well, there is some fear on the shelf life stocking--

Mr. {Dingell.} Yes or no?

Mr. {Shandell.} Yes. Yes.

Mr. {Dingell.} You have no reason?

Mr. {Shandell.} I have no--

Mr. {Dingell.} You have no fear that the customers would refuse to stock this if it is put back on the market?

Mr. {Shandell.} I believe that there is a strong demand for it.

Mr. {Dingell.} All right. Now, in order to assure the proper education of patients regarding the phase-out of Primatene Mist, these inhalers were packaged with labeling noting that Primatene Mist would no longer be available after

December 31, 2011, and encouraged patients to talk to your doctor or pharmacist about other asthma medicines. How is your company going to address potential confusion that will be caused among your patient population when these inhalers become again available?

Mr. {Shandell.} Yes. This message is on the box. If we are allowed to sell the remaining inventory, such units will be moved to our subsidiary. They will be relabeled to eliminate this statement and then released by quality assurance.

Mr. {Dingell.} All right. Now, I have another question. There are two remaining prescription products containing CFCs that are not being phased out until 2013. These products are Combivent CFC, which contains albuterol and ipratropium bromide in combination; and Maxair, which contains pirbuterol. These two drugs are subject of the separate rulemaking that was financed on April 14, 2010. It seems to me that this tells me that FDA and EPA didn't feel that there was a significant problem with regard to the carrying medium that they have in your product. Is that right?

Mr. {Shandell.} Yeah. I have never received clarity as to why the prescriptions are still out--

Mr. {Dingell.} All right. Thank you. My time has

expired.

Mr. Chairman, your courtesy is much appreciated. I would ask that the chair would be supportive of me. I am going to send a letter down to FDA asking a number of questions. And I am going to ask that the FDA would respond, and if they are slow, I am going to look to you for your assistance in seeing to it that they are properly responsive.

Mr. {Whitfield.} Thank you.

Mr. {Dingell.} Thank you, Mr. Chairman.

Mr. {Whitfield.} We would be happy to assist in any way possible.

At this time, I would like to recognize the gentleman from New York, Mr. Engel, for 5 minutes.

Mr. {Engel.} Thank you, Mr. Chairman. And I don't think I will take 5 minutes because I think we have a vote on the floor, and a lot of the questions have been asked.

But there are a lot of swirling issues here. I am co-chair of the Asthma and Allergy Caucus and I have worked with the asthma and allergy advocacy community for many years, and I have been surprised by their strong opposition to allowing Primatene Mist to continue to be sold. I signed a letter in January asking Commissioner Hamburg to allow the remaining units of Primatene Mist to be sold past the December 31, 2011, deadline.

I mean I think there have been good points on both sides, but I really want to ask Mr. Shandell. What is in it for you? Tell me what is in it for you. You are not going to make a profit on it because you are going to donate everything to charity. You mentioned your company offered to distribute all the remaining units as a donation to public health clinics and the offer was rejected. So if you are not going to make a profit, why are you fighting so hard to get another exception--

Mr. {Shandell.} Yes.

Mr. {Engel.} --from FDA and EPA?

Mr. {Shandell.} It is a good question because it is rare to see corporations not doing something for profit, but we are a private company in California. We are founded in science and this is a discontinued product. It is not in our sales forecast and we could walk away. However, we have received thousands of complaints from our customers who just don't understand why they cannot access this. So we really are advocating on behalf of our customers.

Mr. {Engel.} I think I am going to leave it there, Mr. Chairman. I do have a bunch of questions but I am concerned about, you know, the vote. I mean the bottom line is is epinephrine safe? That is also a question. What do you say to people like Dr. Kraft who say it is not?

Mr. {Shandell.} Well, see I would love to answer that because as a company, we receive all of the adverse events, and if something is significant, we are required to report it to FDA within 15 days. So I have talked to the departments that receive these adverse events and people talk about heart problems. We have never had any adverse event related to heart. All we have is glass sometimes breaks.

Mr. {Engel.} Let me ask Dr. Kraft because she said before in her testimony that she feels it is not safe.

Dr. {Kraft.} Right. I would argue that the mechanism to get the reports depending on when the patient has taken the medication and what their status is may or may not actually be filed. And so I worry that there is some underreporting.

Mr. {Shandell.} After 50 years, nothing?

Dr. {Kraft.} Also, I would like to make another statement. The company has done two trials to look at the HFA preparation, which is good. But I was interested that they didn't have a comparison armed with albuterol. They had a placebo armed with--do the patients use albuterol in the placebo arm presumably? Because I thought that would be a perfect situation to compare albuterol HFA with Primatene.

Mr. {Shandell.} Thank you. Actually, we have submitted data to the FDA, and as I indicated, we will be submitting

the new drug application in the fourth quarter, and we actually have evidence that show that albuterol actually causes more adverse events than our product.

Dr. {Kraft.} And the question is is these are mild patients. I can tell from clinicaltrials.gov--

Mr. {Shandell.} Correct.

Dr. {Kraft.} --they are mild patients?

Mr. {Shandell.} Correct.

Dr. {Kraft.} So that was one of the concerns I wanted to bring up. I think in mild asthma a lot of things may work but what I worry about with having this drug available and looking at my more severe patients, they are often the ones who will go and get this medication in lieu of--

Mr. {Shandell.} But it has been available for 50--

Dr. {Kraft.} --medical care.

Mr. {Shandell.} --years, and, you know, to this day people get good medical care but there are people that don't. There are people who can't afford it.

Mr. {Engel.} Mr. Ward, let me ask you quickly. If Primatene Mist is on the market for 13 months and then it is not, what is the harm? Is there going to be people who are going to die in 13 months if they--

Dr. {Kraft.} Well, I think it is sort of an ethical issue. I am not against over-the-counter medication for

asthma, nor is my society. I would like to have a safe and effective one out there for patients. And so I would actually think that this work being done at the FDA to put medications out there over the counter such as albuterol, it should continue.

Mr. {Shandell.} But the work at FDA, they are working with us on Primatene for 5 years now.

Dr. {Kraft.} But it is not approved yet.

Mr. {Shandell.} It is not approved yet but we have great phase three trial data.

Mr. {Engel.} I would love to stay longer but we are going to miss a vote, Mr. Chairman. So thank you and--

Mr. {Whitfield.} Well, thank you. And that would conclude today's--

Mr. {Rush.} Mr. Chairman, I just want to reiterate and restate my call that rather than us moving so quickly to markup, especially in light of this discussion, that we take time to invite the FDA and the EPA here so that we can get to the bottom of some of these outstanding questions that we have and get some real answers to these questions. And I want to reiterate my request.

Mr. {Whitfield.} And Mr. Rush has asked unanimous consent to enter into the record various testimonies from the International Pharmaceutical Aerosol Consortium, various

health groups, Alliance for Responsible Atmospheric Policy, and a letter from Teva Pharmaceuticals. And then we also have letters from the National Association of Chain Drugstores, the National Community of Pharmacists Association, EPA, et cetera. So without objection, they will be entered.

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Mr. {Whitfield.} I want to thank all of you for being with us today. We appreciate your testimony very much and your concern about this important issue.

And with that, this hearing is adjourned.

[Whereupon, at 1:45 p.m., the Subcommittee was adjourned.]