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1 {York Stenographic Services, Inc.}
2 RPTS MEYERS
3 HIF200.030

4 ``HEARING ON H.R.____, THE U.S. AGRICULTURAL SECTOR RELIEF ACT
5 OF 2012, AND H.R.____, THE ASTHMA INHALERS RELIEF ACT OF
6 2012''
7 WEDNESDAY, JULY 18, 2012
8 House of Representatives,
9 Subcommittee on Energy and Power
10 Committee on Energy and Commerce
11 Washington, D.C.

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

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

19 officio).

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

|

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

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

49 Now, this substance is used by many agricultural groups

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

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

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

73 At this time I would like recognize the gentleman from

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

75 [The prepared statement of Mr. Whitfield follows:]

76 ***** COMMITTEE INSERT *****

|
77 Dr. {Burgess.} I thank the chairman for the
78 recognition.

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

89 A replacement inhaler has been before the Food and Drug
90 Administration's Approval Board for some time, but the FDA
91 has taken no action to allow for another over-the-counter
92 inhaler to be available for consumers. When the January 1,
93 2012, ban went into effect, people expected that its
94 replacement would be available. They did not expect
95 disruption to health services for asthma patients. But this
96 is not the case. Because of the Food and Drug
97 Administration's intransigence, asthmatics currently do not
98 have an over-the-counter remedy when they have an unexpected
99 attack, especially if that attack happens when they are

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

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

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

124 supply left.

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

129 And I will yield back my time.

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

134 [The prepared statement of Dr. Burgess follows:]

135 ***** COMMITTEE INSERT *****

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

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

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

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

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

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

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

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

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

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

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

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

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

221 [The prepared statement of Mr. Waxman follows:]

222 ***** COMMITTEE INSERT *****

|
223 Mr. {Whitfield.} Thank you.

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

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

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

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

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

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

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

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

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

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

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

279 [The prepared statement of Mr. Upton follows:]

280 ***** COMMITTEE INSERT *****

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

287 I support the U.S. Agricultural Sector Relief Act of
288 2012 and I tend to support the Asthma Inhaler Relief Act of
289 2012 also, although I have got some concerns about that piece
290 of legislation.

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

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

304 too, Nancy, here.

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

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

320 [The prepared statement of Mr. Barton follows:]

321 ***** COMMITTEE INSERT *****

|

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

323 [The information follows:]

324 ***** COMMITTEE INSERT *****

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

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

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

337 My Republican colleagues, Mr. Chairman, continue to
338 ignore the fact that the U.S. has set more than 40,000 high
339 temperature records this year and that the last 12 months
340 have been the hottest ever recorded in U.S. history. And the
341 fact that more than 113 million Americans are living under
342 extreme health advisories, while the USDA has declared a
343 federal disaster area in more than 1,000 countries covering
344 26 States also does not seem to concern the majority party.

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

348 Americans other than a few industry lobbyists.

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

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

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

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

372 [The prepared statement of Mr. Rush follows:]

373 ***** COMMITTEE INSERT *****

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

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

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

397 but also their workers and the local economy.

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

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

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

415 [The prepared statement of Mrs. Capps follows:]

416 ***** COMMITTEE INSERT *****

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

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

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

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

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

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

440 supporting the U.S. Agricultural Sector Relief Act.

441 Mr. {Whitfield.} Without objection.

442 [The information follows:]

443 ***** COMMITTEE INSERT *****

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

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

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

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

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

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

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

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

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

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

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

|
493 ^STATEMENT OF RUSSELL COSTANZA

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

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

502 My name is Russ Costanza. I grew up on our family farm.
503 I am the owner of Russell Costanza Farms. My wife and I
504 established our farm in 1976 with 10 acres. Today, we have
505 grown that farm with our two kids and their families to over
506 500 acres of peppers, eggplant, squash, tomatoes, and

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

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

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

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

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

531 adequate crops.

532 I used to be able to purchase methyl bromide for about
533 \$1 a pound. Today, the cost averages \$9 a pound. It costs
534 over \$800 an acre to use methyl bromide. Between the
535 scarcity and high cost, it is impossible to compete with
536 inexpensive, quality produce from other countries whose
537 growers are able to legally use methyl bromide. Further, the
538 quality of our produce will deteriorate due to the lack of
539 methyl bromide use, further eroding our ability to compete
540 with foreign growers in our own markets.

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

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

554 Our farm has spent a great deal of money and effort

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

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

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

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

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

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

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

599 [The prepared statement of Mr. Costanza follows:]

600 ***** INSERT 1 *****

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

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

|
603 ^STATEMENT OF SCOTT M. DIMARE

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

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

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

615 With rising costs, we have a cost of about 2,500 to
616 3,000 an acre to lay our plastic mulch and do our fumigation
617 process before we ever put a plant in the ground. Methyl
618 bromide is the foundation for our operation. It allows for
619 uniformity and consistency, which is key in our industry. It
620 kills soil-borne diseases, pests, and weeds. The idea is to
621 sterilize the ground before you plant it. We used to call
622 methyl bromide idiot-proof. And basically, it is not a
623 reckless term; it is how we view under all conditions--and
624 the key being all conditions, okay, because the rest of the

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

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

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

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

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

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

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

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

687 [The prepared statement of Mr. Dimare follows:]

688 ***** INSERT 2 *****

|
689 Mr. {Whitfield.} Thank you very much.

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

|
692 ^STATEMENT OF DAVID DONIGER

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

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

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

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

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

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

738 U.S. critical use exemptions have been coming down.
739 California strawberries are now the only field use for which
740 the U.S. still seeks exemptions. And there are several other
741 structural and commodity uses. Together they amount to about
742 a little more than 400 tons. That is significantly down from
743 10,000 tons 7 years ago. And as I said, there is an
744 opportunity to keep asking for well supported exemptions.
745 There is also a stockpile of 1,200 tons, three times the
746 requests now being made.

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

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

762 requests that can't even get past first base.

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

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

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

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

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

790 [The prepared statement of Mr. Doniger follows:]

791 ***** INSERT 3 *****

|

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

793 At this time, Ms. Keeler, you are recognized for a 5-

794 minute opening statement.

|
795 ^STATEMENT OF MICHELLE CASTELLANO KEELER

796 } Ms. {Keeler.} Thank you.

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

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

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

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

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

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

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

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

865 industry do?

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

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

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

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

893 [The prepared statement of Ms. Keeler follows:]

894 ***** INSERT 4 *****

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

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

|
897 ^STATEMENT OF MARK MURAI

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

991 as quickly dissipating in about 1 year and having a
992 relatively smaller impact compared to other ozone-depleting
993 products. The newest scientific assessment by NOAA, NASA,
994 UNEF, WMO, and the EU concludes the ozone layer is improving
995 faster than predicted due to legacy products that were
996 required by 39 years to fully restore the ozone layer and
997 continued use of methyl bromide will add less than 73 days to
998 the 39 years. More specifically, the report stated, ``the
999 scientific assessment of ozone depletion 2010 is the product
1000 of 312 scientists from 39 countries of the developed and
1001 developing world who have contributed to its preparation and
1002 review, 191 scientists prepared the report, and 196
1003 scientists participated in the peer-review process''--196.
1004 They said methyl bromide ``continuing critical use exemptions
1005 at the approved 2011 level indefinitely would delay the
1006 return of the equivalent effective stratospheric chlorine
1007 1980 levels by .2 percent of a year.

1008 Mr. {Whitfield.} Mr. Murai, your testimony is very
1009 interesting and you have gone over considerably, so if you
1010 would try to summarize it here, we would appreciate it.

1011 Mr. {Murai.} Sorry about that.

1012 So what is the benefit to the economy of allowing
1013 continued use of methyl bromide while the California
1014 Department of Food and Agriculture commissioned an economic

1015 study and they said if there is no methyl bromide and no
1016 methyl iodide, the California communities will lose over 1.5
1017 billion annually and more than 23,000 jobs annually.

1018 So if all the scientists and economists are accurate and
1019 the environmental impact of continued use of methyl bromide
1020 CUEs would just add no more than 73 days to a 39-year
1021 schedule while the economic downside for not allowing this
1022 would be \$58 billion and 897,000 jobs over those same 39
1023 years, I just ask please bring some common sense to this
1024 issue and restore our CUE. Thank you for your time.

1025 [The prepared statement of Mr. Murai follows:]

1026 ***** INSERT 5 *****

1027 Mr. {Whitfield.} Thank you.

1028 And I thank all of you for your testimony.

1029 At this time, we will have some questions for you and I
1030 will recognize myself for 5 minutes of questions.

1031 Mr. Murai, Mr. Doniger in his testimony said that
1032 California strawberry growers have led the pack in coming to
1033 Congress playing the hardship violin. And he said that your
1034 growers have done very well, you have increased your yields,
1035 you have increased the strawberry acreage, and that you all
1036 are doing very well. But from what you said, that doesn't
1037 sound like that is the case. Now, have you increased your
1038 yields? Have you increased your acreage or--

1039 Mr. {Murai.} Yields have increased and it has barely
1040 kept us floating. The margins are razor thin. I think the
1041 economic studies only show one side of the story, and I don't
1042 think I would even really be here if we were doing well,
1043 right?

1044 Mr. {Whitfield.} Yeah.

1045 Mr. {Murai.} I think this is a priority and an
1046 important issue because the growers are in a risky situation,
1047 very difficult to plant. The bankers are even asking about
1048 what are you doing to ensure--

1049 Mr. {Whitfield.} How much do you borrow to put out a

1050 crop?

1051 Mr. {Murai.} It is about 20 to \$22,000 per acre per
1052 year.

1053 Mr. {Whitfield.} And what about you, Ms. Keeler?

1054 Ms. {Keeler.} At the high end, we are at \$60,000, so
1055 between 20 and 60,000 depending on the varieties. I--

1056 Mr. {Whitfield.} Per acre.

1057 Ms. {Keeler.} Per acre.

1058 Mr. {Whitfield.} And Mr. Dimare?

1059 Mr. {Dimare.} The operating costs alone are around
1060 \$10,000 an acre. That doesn't include harvesting or land
1061 cost or anything like that.

1062 Mr. {Whitfield.} Mr. Costanza?

1063 Mr. {Costanza.} Our operating cost per acre is between
1064 10 and \$12,000 an acre per year.

1065 Mr. {Whitfield.} Yeah. Now, from my understanding, it
1066 is very difficult to obtain a critical use exemption for
1067 methyl bromide, is that correct, Mr. Costanza?

1068 Mr. {Costanza.} Yes. In our case, we were told we were
1069 going to have Midas to use this year.

1070 Mr. {Whitfield.} Okay. What about you, Mr. Dimare?
1071 Have you tried to get a critical use exemption?

1072 Mr. {Dimare.} Yes, it is an exhausting process.

1073 Mr. {Whitfield.} Ms. Keeler?

1074 Ms. {Keeler.} Yeah, we have been part of the process
1075 from the beginning. And like I said earlier, it is a very
1076 time-consuming process, and private sector, we are doing a
1077 tremendous amount of research looking for these alternatives.
1078 There seems to be this idea that we are not doing this
1079 research looking--

1080 Mr. {Whitfield.} Right.

1081 Ms. {Keeler.} --for alternatives and we just want this
1082 simple free ticket for methyl--

1083 Mr. {Whitfield.} Right.

1084 Ms. {Keeler.} --bromide. It is not an easy process.

1085 Mr. {Whitfield.} Yeah. Mr. Murai?

1086 Mr. {Murai.} Yes, Mr. Chairman, every year.

1087 Mr. {Whitfield.} Yeah. Mr. Doniger mentioned that in
1088 other countries, Mexico, Italy, so forth, that they are using
1089 less methyl bromide and being quite successful. What would
1090 be your reaction or statement or comment about that? Or do
1091 you have any information about it, any of you?

1092 Ms. {Keeler.} In our industry, I can comment to that.
1093 Mexico produces some pretty unsophisticated flowers, so they
1094 have no need for it. And my family immigrated from Italy and
1095 we still have some connections there, and in the EU, the same
1096 thing is happening there. The EU is off-shoring a lot of
1097 their flowers over to Africa. And so like we are seeing

1098 flowers going down to the South American countries. The
1099 Italian growers are getting rid of the same products we are
1100 getting rid of for the same problem--

1101 Mr. {Whitfield.} Yeah.

1102 Ms. {Keeler.} --and they are being grown in Africa for
1103 some of those countries.

1104 Mr. {Whitfield.} You know, one of the common things
1105 that seems to be coming through a lot of hearings that we
1106 have is that we are hearing a lot of concerns about EPA that
1107 many people in various businesses dealing with EPA view them
1108 almost as an adversary. And I would just like to ask you, do
1109 you view EPA as a partner trying to help solve a problem or
1110 do you view them as an adversary?

1111 Mr. {Murai.} Well, the actions result in an adversarial
1112 result. I would say we work closely and try to collaborate
1113 and really flesh the data out. You know, like Mr. Doniger
1114 said, we want to put up a nomination that is credible and we
1115 are using the best data.

1116 Mr. {Whitfield.} Yeah.

1117 Mr. {Murai.} And so I think we try to have a
1118 collaborative effort but there is nobody listening over
1119 there.

1120 Mr. {Whitfield.} So you feel it is an adversarial
1121 relationship, is that correct?

1122 Mr. {Murai.} Yes, at times--

1123 Mr. {Whitfield.} Ms. Keeler, what about you?

1124 Ms. {Keeler.} Yeah, like Mr. Murai, I hate to use that

1125 word because we have been trying to work with them and so we

1126 are all going to this international body together--

1127 Mr. {Whitfield.} Yeah.

1128 Ms. {Keeler.} --but at the end when our application

1129 just gets denied and we don't really get the scientific

1130 research of why our crops were denied, it is--

1131 Mr. {Whitfield.} Okay. Mr. Dimare--

1132 Ms. {Keeler.} --hard to say we work together.

1133 Mr. {Whitfield.} --what about you?

1134 Mr. {Dimare.} I feel basically the same way they do.

1135 We try to work in concert with them--

1136 Mr. {Whitfield.} Mr. Costanza, how do you feel?

1137 Mr. {Costanza.} I invited EPA out to our farm--

1138 Mr. {Whitfield.} Yeah.

1139 Mr. {Costanza.} --and their minds were made up before

1140 they got there.

1141 Mr. {Whitfield.} Okay.

1142 Mr. {Costanza.} They didn't want to hear what we had to

1143 say.

1144 Mr. {Whitfield.} Okay.

1145 Mr. {Costanza.} They didn't want to see what we had to

1146 show them.

1147 Mr. {Whitfield.} Now, without methyl bromide and this
1148 methyl iodide, is there something else you can use?

1149 Mr. {Dimare.} Well, it depends on where you are at in
1150 the country. Even in the State of Florida we have from one
1151 end to the other Telone cannot be used in south Florida
1152 because of the groundwater issue--

1153 Mr. {Whitfield.} Yeah.

1154 Mr. {Dimare.} --but we do use that as one of the
1155 alternatives in other places--

1156 Mr. {Whitfield.} Yeah.

1157 Mr. {Dimare.} --as well as others. Methyl iodide that
1158 they are talking about is gone in the U.S. It is off the
1159 shelf. They have taken it away so that is not an alternative
1160 anymore.

1161 Ms. {Keeler.} And some of those alternatives have
1162 different buffer requirements, so for us in San Diego you
1163 can't really picture a farm like out in the middle of Iowa.

1164 Mr. {Whitfield.} Yeah.

1165 Ms. {Keeler.} We have houses and industry coming right
1166 up to us. So buffer zones, township caps put a lot of
1167 limitations on--

1168 Mr. {Whitfield.} Well, my time is expired but I mean it
1169 is pretty clear that all four of you feel like methyl bromide

1170 is essential and that is my impression.

1171 Mr. Rush, I recognize you for 5 minutes.

1172 Mr. {Rush.} Well, and thank you, Mr. Chairman.

1173 Mr. Doniger, somehow I am feeling like I am a
1174 registration clerk at heartbreak hotel when I listen to the
1175 testimony of some of the witnesses here. And, first of all,
1176 you raised your finger up because you wanted to react or
1177 respond to something that I think Ms. Keeler said. Is there
1178 something that you wanted to respond to?

1179 Mr. {Doniger.} Well, I wanted to make one point in
1180 connection with the issue of whether the relationship with
1181 EPA is adversarial. If anything from the environmental
1182 perspective I see the EPA bending over backwards to service
1183 these applications, to consider these applications. I
1184 thought they were grossly too large in the beginning. The
1185 numbers have come down. That is true. But I would offer you
1186 one factoid to think about. To my knowledge, there has not
1187 been one lawsuit filed against EPA for denying these
1188 applications. There has not been one agricultural
1189 association or individual grower who has taken EPA to court
1190 over these supposedly too-small allocations. What other
1191 industry hasn't sued EPA? It is very hard to take the matter
1192 that seriously if that is the situation we have. I mean I
1193 don't want to encourage these guys to sue EPA but everybody

1194 does.

1195 Mr. {Rush.} This industry is one of EPA's favorite
1196 industries, then, whether they are being adversarial.

1197 Let me just move on. What are some of your biggest
1198 concerns with the definition of critical use in the
1199 discussion draft that is before us today?

1200 Mr. {Doniger.} Well, the most serious problem is the--
1201 the two problems are, one, putting into law a list of
1202 critical uses. The idea is supposed to be dynamic, that some
1203 uses would start out being critical, and then as alternatives
1204 were found, they would no longer be critical and they would
1205 drop off the list. And that in fact is what has happened.
1206 Now, some of the growers can have concerns about individual
1207 decisions but that is the way it is supposed to work. You
1208 work your way to alternatives and then that use is no longer
1209 a critical use exemption. So why would we go back to the
1210 original list?

1211 The second thing is how is it going to work now? A
1212 grower can write on a piece of paper I need x tons. I don't
1213 have to tell you why. I don't have to give you any
1214 information or evidence about what I tried and whether it
1215 works and so on. It is now up to you, EPA, to tell me why I
1216 don't need that many tons and you would have the obligation,
1217 EPA, to go abroad to the other countries and say this is what

1218 my guys say they need. So where is the support for it? The
1219 reason that the exemptions have been granted--and more than
1220 88 percent, I think, nominations have been granted--is that
1221 the U.S. comes in frankly with a bulldozer of a case for each
1222 one. And that starts with the growers being challenged
1223 frankly to come up with a very convincing case, that they
1224 have tried all the alternatives, that they don't work in
1225 these particular situations and thus the methyl bromide is
1226 still needed. When you get a case that is sound, the
1227 nominations are forwarded and the nominations are granted.

1228 Mr. {Rush.} Do you share my concerns with the provision
1229 of the bill that would shift the burden of proof to the EPA
1230 and that a requested use of the exemption is unwarranted?

1231 Mr. {Doniger.} Yeah, I mean that is what I am say leads
1232 to the counterproductive result because if the U.S. goes to
1233 the other parties and says this is the piece of paper I got.
1234 I don't have any scientific backup or I don't have the full
1235 backup I used to have, but my guys say they need it so I say
1236 I need it. It is not a very persuasive case. And it is more
1237 likely to lead to the nominations being turned down than the
1238 current situation.

1239 Mr. {Rush.} How would this bill impact the Clean Air
1240 Act in your opinion?

1241 Mr. {Doniger.} Well, right now, the Clean Air Act

1242 allows for the critical use exemptions and that is the
1243 process under which the nominations have been made for the
1244 last seven years and the requests have been made by the
1245 government to the treaty parties and that is the process that
1246 is working. The folks here are concerned, some of them,
1247 that, gosh, there is some expense involved, there is some
1248 work involved in making the applications. And even the best
1249 applications you only get, you know, roughly 90 percent of
1250 them approved by the parties.

1251 Remember that all the other strawberry-growing and
1252 tomato-growing countries in the western world have stopped
1253 using methyl bromide. So they look at these applications and
1254 say what is going on? Why can't the U.S. do what we do in
1255 Australia, Greece, Italy, Spain with respect to strawberries
1256 and tomatoes? And it is a tough sell. So if EPA doesn't get
1257 the full dossier of data from the growers, they are not going
1258 to be able to make that sale and I don't think they should
1259 make that sale.

1260 Mr. {Whitfield.} Gentleman's time is expired.

1261 At this time, I recognize the gentleman from Oregon, Mr.
1262 Walden, for 5 minutes.

1263 Mr. {Walden.} Mr. Chairman, thank you. And I want to
1264 thank our panel of witnesses, appreciate your testimony and
1265 the answers to the questions the Subcommittee has posed.

1266 Mr. Murai, do you want to take what the gentleman just
1267 said, so when it comes to dealing with strawberries and all,
1268 what is your take on what he just said about the
1269 international situation and be able to explain why every
1270 other country doesn't use methyl bromide and we need to?

1271 Mr. {Murai.} I think those growers need a process that
1272 they can come to a hearing like this and voice their
1273 opinions, because I visited those growers and they are under
1274 extreme pressure of disease. They are exporting strawberry-
1275 growing to Morocco. They are exporting the problem rather
1276 than dealing with it in their own community and that is what
1277 our California strawberry growers are trying to do. We are
1278 trying to deal with it in our own community but the rules
1279 keep changing every page we turn. And that is what we want.
1280 We need transparency, we need accountability, we need data
1281 coming back that shows the argument coming back, not just
1282 arbitrary. The process is broken. I don't want to say we
1283 are adversaries but it is broken and it needs to be fixed. I
1284 want to go back to my growers and say this is the way it is,
1285 guys, or ladies. This is the way it is. But I can't say
1286 that with conviction because I know how broken it is.

1287 Mr. {Walden.} I appreciate that. You know, methyl
1288 bromide has obviously been used in nursery crops in Oregon.
1289 It is a nursery business, of course, one of our biggest in

1290 Oregon. I know they had a big outbreak of potato cyst
1291 nematode in Idaho recently. And while they don't usually use
1292 methyl bromide for potatoes, it has been successfully used
1293 against potato cyst nematode, which, as you know, can just
1294 wreak havoc on potatoes if it gets away from them. And I
1295 know the industry is conducting research to find alternatives
1296 but none have been found to date. Can any of you speak to
1297 the potato side of the world and what happens in that
1298 respect?

1299 Mr. {Murai.} I can't speak to the potato crop but I
1300 would only add that the strawberry industry went through the
1301 same types of mass destruction. And what we are trying to do
1302 is provide food for the world with a consistent supply of
1303 healthy nutritious food, and I think we go to school and we
1304 learn the newest techniques and we try to innovate--

1305 Mr. {Walden.} Um-hum.

1306 Mr. {Murai.} --to try to avoid mass destruction of
1307 crops. We don't need to go back to the potato famine days.
1308 Why do we have to revisit that where people are suffering?
1309 That is not what our intent is, and as farmers, we want to
1310 feel good about what we do and provide that food and we will
1311 work within the rules. But the rules and the structure and
1312 the process must be corrected.

1313 Mr. {Walden.} And can you elaborate on the efforts that

1314 have been undertaken by the strawberry sector to identify
1315 potential alternatives?

1316 Mr. {Murai.} We have invested over \$10 million over the
1317 last 15 years to look at steaming the soil using anaerobic
1318 soil disinfestations. We are looking at growing strawberries
1319 in substrate, peat moss, coconut coir, but there are other
1320 issues around that. How sustainable is that when our
1321 strawberry industry would use up the North American supply of
1322 peat moss in 1 year? Or steaming takes 21 hours to steam an
1323 acre of strawberries right now. How much fossil fuel is
1324 needed, how much emissions are needed to steam one acre? You
1325 know, 20 hours.

1326 Mr. {Walden.} How many acres do you have in production,
1327 strawberries in California?

1328 Mr. {Murai.} Thirty-eight thousand acres in California.

1329 Mr. {Walden.} That is a lot of steaming.

1330 Mr. {Murai.} And the--

1331 Mr. {Walden.} Or you could just try and grow them here
1332 where we have steam all the time, or at least today, or a lot
1333 of hot air.

1334 Mr. {Murai.} The funny part is you have to soften the
1335 water before you put it through the steamer. So we have to
1336 have a water softener on the road with the long hose that
1337 takes it to the big steaming machine, and the steaming

1338 machine creeps along, inches, and covers 1 acre in 21 hours.

1339 Mr. {Walden.} So what does that mean to your cost, your
1340 ability to compete?

1341 Mr. {Murai.} There is not enough time in the year to
1342 put your crop in.

1343 Mr. {Walden.} So I guess the question is how do these
1344 other countries grow strawberries without using methyl
1345 bromide? Do they just have different pests and different
1346 issues?

1347 Mr. {Murai.} They are trying to grow in substrate. If
1348 you go into like northern European areas, they are growing in
1349 a lot of the coconut coir --

1350 Mr. {Walden.} I see.

1351 Mr. {Murai.} --but even that is becoming controversial
1352 there. So, you know, you move to one solution but it creates
1353 other problems.

1354 Mr. {Walden.} Got it.

1355 Mr. {Murai.} And I think that is where we need a
1356 comprehensive look and a realistic look, right?

1357 Mr. {Walden.} Yeah, I appreciate that. I know my time
1358 is expired. I grew up on a cherry orchard and represented a
1359 lot of ag interests in Oregon, farmers and ranchers that just
1360 feel like there is a whole onslaught out of the Federal
1361 Government that is going to shut down our way of life in the

1362 West and especially on the farms.

1363 Mr. {Murai.} We are California farmers and we want to
1364 stay in California.

1365 Mr. {Walden.} Yeah. Well, we Oregonians want you to
1366 stay in California. It has been an issue dating back--no, I
1367 am just kidding. Yeah, but--

1368 Mr. {Murai.} That is a good one.

1369 Mr. {Walden.} --we want you to come up and spend your
1370 money in Oregon, then go back. Thank you. Thanks for your
1371 testimony.

1372 Mr. {Whitfield.} Mrs. Capps, you are recognized for 5
1373 minutes for questions.

1374 Mrs. {Capps.} Well, thank you, Mr. Chairman.

1375 As my colleague knows, I was trained as a nurse in
1376 Oregon and I moved to California so, you know, I guess it can
1377 go both ways, just an aside. And actually, I want to thank
1378 you because I know this is not the same as standing in the
1379 fields, but we are getting close to getting the feeling of
1380 what the various challenges are to complying with regulations
1381 that I believe in with all my heart but that are complicated
1382 and need to have a discussion. If you can't be there to
1383 smell the strawberries and see for ourselves what the peppers
1384 are like in the fields, we need this kind of discussion. We
1385 need this back-and-forth and this give-and-take.

1386 And I was going to continue the same line with you, Mr.
1387 Murai. I have got two Californians here I am going to pick
1388 on for my time. I know growers have put millions of dollars
1389 into developing alternatives to methyl bromide. Could you
1390 continue this explanation of why your growers are putting so
1391 many valuable resources into finding these alternatives? And
1392 you are not doing it just because of the Montreal Protocol.
1393 It is not just that.

1394 Mr. {Murai.} I think we are trying to improve and
1395 innovate our practices to be an example for the world. And
1396 the regulatory environment and the environmental laws are
1397 very strict in California. It is a whole other layer, and I
1398 believe that is what the world bodies don't understand is the
1399 sovereign power within California to have those laws, but the
1400 California growers will meet that challenge. We have
1401 invested our resources, we have put in a lot of time, we have
1402 lost a lot of crop--

1403 Mrs. {Capps.} Um-hum.

1404 Mr. {Murai.} --in this time frame and we have had a lot
1405 of hurt. And I think that is why we believe in what the
1406 Montreal Protocol is doing and we want to be part of the
1407 solution, but we also have to understand if there are
1408 exemptions due to critical use, they should be recognized and
1409 held to a standard as the applicant is doing. So if there is

1410 a change in the nomination put forth to the United Nations
1411 unbeknownst to the California strawberry growers and in our
1412 application, we should understand why they are doing that and
1413 what data backs that up.

1414 Mrs. {Capps.} Okay. Ms. Keeler, would you agree that
1415 the flower growers are similarly committed to phasing our
1416 methyl bromide and finding alternatives?

1417 Ms. {Keeler.} Absolutely. I can only repeat what Mr.
1418 Murai just said. Our industry is absolutely committed. We
1419 have a much more dynamic industry with so many different
1420 crops and varieties, so there has been a tremendous amount of
1421 research that maybe something works in one crop, we try it in
1422 a different crop. We have actually teamed up with the
1423 strawberry growers. We share our information--

1424 Mrs. {Capps.} Yeah.

1425 Ms. {Keeler.} --university, private sector, we put in
1426 so much research into this. And like Mr. Murai said, we want
1427 to cooperate. We believe in the Montreal Protocol.

1428 Mrs. {Capps.} Well, as Mr. Murai told me before, you
1429 are there, you breathe the air, your families are suffering
1430 whatever health consequences there are to whatever you put
1431 into the soil.

1432 I wanted to move on if I could--I didn't mean to
1433 interrupt you--but Mr. Murai, you mentioned the CUE process,

1434 which I am going to expand on just briefly. When the
1435 critical use exemption process is working, growers get the
1436 methyl bromide they need while you also phase out its use and
1437 incentivize the development of viable alternatives. No
1438 matter how well designed, however, no complex international
1439 system can fully anticipate every issue that may come up down
1440 the road, and that is why we always need to be looking at
1441 ways to improve and adapt the system to the current needs of
1442 its stakeholders while still moving forward, ultimately
1443 achieving its original goals.

1444 Mr. Murai, I am aware of several fields in Ventura
1445 County, California, which is in my district, that have had
1446 some issues transitioning to Telone. And I know that
1447 California has banned certain alternative chemicals like
1448 methyl bromide for its cancer-causing and water-polluting
1449 qualities, yet EPA has not responded accordingly. Perhaps,
1450 Mr. Murai, you could expand on that just a little, touch on
1451 the types of flexibility and coordination that could be built
1452 into the current system to help prevent these problems in the
1453 future.

1454 Mr. {Murai.} Well, we are very intentional on
1455 maximizing the alternatives that are available within the law
1456 and we explain that in our application every year. And what
1457 changes, though, sometimes when you are using some of these

1458 alternatives, they don't do a thorough enough job. And so in
1459 order for a family farm not to abandon their land, they need
1460 to be able to have a way to clean that soil up and make it
1461 healthy again. And, you know, in this global economy, we are
1462 moving products back and forth and think new pests are coming
1463 in, new diseases, and there has got to be a mechanism. The
1464 authors of the protocol were very smart and that is why they
1465 wrote it in the critical use exemption because they
1466 anticipated there might be critical needs.

1467 Mrs. {Capps.} Could I ask for time to ask one further
1468 question? I know I have used my time.

1469 Mr. {Whitfield.} Yeah, your time has expired.

1470 Mrs. {Capps.} All right.

1471 Mr. {Whitfield.} Thank you.

1472 Mrs. {Capps.} Thank you.

1473 Mr. {Whitfield.} At this time, I would like to
1474 recognize the gentleman from Texas, Mr. Barton.

1475 Mr. {Barton.} Mr. Chairman, my questions are for the
1476 second panel, so I am--

1477 Mr. {Whitfield.} Okay.

1478 Mr. {Barton.} --going to defer or yield back.

1479 Mr. {Whitfield.} Then I recognize the gentleman from
1480 California, Mr. Bilbray.

1481 Mr. {Bilbray.} David, would you upgrade me on the

1482 latest status? We are talking strawberries and I know we
1483 have had a conflict and have consistently had a conflict
1484 between EPA and ag on importation of certain issues. What
1485 alternative to methyl bromide has the ag people put on
1486 importation of strawberries, the fumigation of those fruits?
1487 Do you know--

1488 Mr. {Doniger.} I think you are asking, Congressman,
1489 about quarantine of pre-shipment?

1490 Mr. {Bilbray.} Yes.

1491 Mr. {Doniger.} And I am not sure I precisely understand
1492 your question--

1493 Mr. {Bilbray.} We have run into--

1494 Mr. {Doniger.} --and I am not sure I know the answer.

1495 Mr. {Bilbray.} You know, when I was working the Air
1496 Resources Board when I got over here we had this big conflict
1497 because the accord we were trying to follow but then we had
1498 the Federal Government mandating the use of methyl bromide as
1499 a condition of importing certain fruits--

1500 Mr. {Doniger.} Right.

1501 Mr. {Bilbray.} --and vegetables.

1502 Mr. {Doniger.} So one of the problems in that field,
1503 which is outside the scope of this bill, is double-dosing
1504 where the importing country requires the treatment even
1505 though it may have been treated on the way out of the

1506 exporting country. So I think there has been some progress
1507 made in reducing that kind of double-dosing.

1508 Mr. {Bilbray.} But they are still looking at methyl
1509 bromide as being their--

1510 Mr. {Doniger.} Well, this is an area where sulfuryl
1511 fluoride may be quite promising and--

1512 Mr. {Bilbray.} Maybe, but, you know, I--

1513 Mr. {Doniger.} No, I mean more than that. It is almost
1514 ready to be approved as a substitute for methyl bromide in
1515 certain quarantine uses. And sulfuryl fluoride was mentioned
1516 in the beginning if I may--

1517 Mr. {Bilbray.} No, no, no, no, wait, wait a minute.

1518 Mr. {Doniger.} I just want to make sure people--

1519 Mr. {Bilbray.} Let me double back--

1520 Mr. {Doniger.} --understand that NRDC is opposed to the
1521 withdrawal of the tolerances for sulfuryl fluoride.

1522 Mr. {Bilbray.} Okay. My biggest concern is that we
1523 have known since the early '90s there was a conflict between
1524 our mandated procedures in one department and a treaty that
1525 we were agreeing to in another. And it has been at least 15
1526 years, not 20 years, we still haven't kind of put that
1527 together.

1528 Mr. {Doniger.} The treaty doesn't cover quarantine and
1529 pre-shipment.

1530 Mr. {Bilbray.} Okay.

1531 Mr. {Doniger.} I believe it should but it doesn't. So
1532 there are no restrictions on quarantine and pre-shipment use
1533 of methyl bromide under the treaty.

1534 Mr. {Bilbray.} Okay. I appreciate you clarifying that.
1535 It is frustrating to me to see the government that says this
1536 is so essential that we reduce the use and everything else.

1537 And Mr. Chairman, you know, my family has been
1538 personally affected by diseases directly related to the ozone
1539 issue. So I really believe, you know, this is a concern.
1540 But it is a reasonable application of the concept. I think
1541 any law, no matter how good intentioned, if there isn't a
1542 reasonable application, there is going to be major problems
1543 of not only unforeseen adverse impact but also unforeseen
1544 inefficiency in acquiring the original goal. And that is one
1545 of the things I want to address.

1546 And Dave, why I asked you about that is that we talk
1547 about priorities in the Federal Government but it isn't
1548 reflected by our actions at getting to go. We always love to
1549 say no. It is easier to say. But getting to go, getting to
1550 an alternative answer, we know what is bad but getting to
1551 what we are willing to say is good takes 20 years at a time
1552 that we are saying the ozone is being depleted as we speak,
1553 people are going to be dying, but don't ask me to rush to

1554 finding a viable alternative. And I think there is an
1555 obligation that those of us in the system, if we want to
1556 claim the moral high ground like some members on this
1557 committee love to do, that we are saving lives and we are
1558 avoiding this and that, we have more of a responsibility than
1559 just saying no. We have a real obligation to find a yes and
1560 doing it quicker than 20 years down the pike.

1561 Mr. {Doniger.} Well, the one thing I think we can all
1562 agree on is that there has been--all of the witnesses here
1563 can agree on--is there has been a lot of progress in phasing
1564 down methyl bromide. If you had this hearing 5 years ago--
1565 actually, you did have this hearing 5 years ago--the crisis
1566 of impossibility of terrible impact was at the then current
1567 level where we are now down some 80 or 90 percent below that.
1568 And that is why the critical use exemption process is there.
1569 If the case can be made, the exemption should be granted.

1570 Mr. {Bilbray.} I just worry we are quick here to put
1571 regulations on to outlaw stuff and we are not quick here at
1572 creating the vehicles to create an opportunity to make that
1573 product obsolete. In other words, just outlawing something
1574 is not answering the problem. The problem is identifying the
1575 problem and then finding an alternative answer to be able to
1576 move things forward without the social economic impacts and
1577 the health impacts that may be related.

1578 Mr. {Doniger.} There has been a fair amount of USDA
1579 research and we would have supported there being more to help
1580 the growers find these alternatives.

1581 Mr. {Bilbray.} Well, I would just say 20 years is
1582 pretty slow.

1583 Mr. {Whitfield.} The gentleman's time is expired.

1584 At this time, I recognize the gentleman from Louisiana,
1585 Mr. Scalise, for 5 minutes.

1586 Mr. {Scalise.} Thank you, Mr. Chairman, appreciate you
1587 having this hearing on these two bills that--

1588 Mr. {Whitfield.} Mr. Scalise, I am sorry. I didn't see
1589 Mr.--

1590 Mr. {Scalise.} Oh, I will yield to the gentleman from
1591 Michigan.

1592 Mr. {Whitfield.} Okay, you go ahead and then I will
1593 come back to Mr. Dingell. Thank you.

1594 Mr. {Scalise.} All right. Thank you, Mr. Chairman. I
1595 thank the former chairman, the gentleman from Michigan.

1596 As we are talking about strawberries, I, you know,
1597 represent a city called Ponchatoula, and the Ponchatoula
1598 strawberries I would argue are the plumpest, juiciest, most
1599 bright red. We could probably have a taste test and we would
1600 both enjoy it. But, you know, I look at these new
1601 regulations and, you know, really have concern about what it

1602 is going to mean to those strawberry farmers in Ponchatoula
1603 just as it is a concern to those of you in whether it is
1604 California, Michigan, all across the country. Do you all
1605 have any estimates on how many jobs are at risk if this
1606 industry is threatened with the inability to use methyl
1607 bromide? I will just start with you, Mr. Costanza, and we
1608 can go down. Any kind of estimates on job losses that may be
1609 in play?

1610 Mr. {Costanza.} On our farm presently we have about 125
1611 employees. I am 30 employees short for harvest. We are
1612 leaving product in the field. In the local economy in the
1613 state and federal level, there is about four jobs for every
1614 farm worker I have on the farm. So the economic impact
1615 across the country if we are out of business is dramatic.

1616 And I would like to mention that I have been to your
1617 district and I have visited some of your growers, Anthony
1618 Liuzza being one of them--

1619 Mr. {Scalise.} I know him well.

1620 Mr. {Costanza.} --looking for an alternative to use
1621 other than methyl bromide.

1622 Mr. {Scalise.} And what have you all been able to come
1623 up with?

1624 Mr. {Costanza.} Nothing. We need a product that is
1625 affordable and that will produce--

1626 Mr. {Scalise.} And effective.

1627 Mr. {Costanza.} --a crop that the public demands. Now,
1628 these European countries, they will accept a lower quality
1629 berry. Americans won't accept that quality. So--

1630 Mr. {Scalise.} And it is my understanding that under
1631 the protocol, developing nations are exempt from this. They
1632 don't even have to comply what is being imposed on you, but a
1633 developing country that competes against you would not have
1634 to comply, is that correct?

1635 Mr. {Costanza.} My understanding that is correct but
1636 the other thing is accountability. How are you going to
1637 account for what goes into Mexico from China? How are you
1638 going to account for what goes into some of the European
1639 countries from China? How are you going to account for what
1640 goes into Morocco? Because they produce a lot of methyl
1641 bromide in China because we pay for the plant to be built.

1642 Mr. {Scalise.} Yeah. And then that would be just more
1643 jobs outsourced, exported that we lose that go to foreign
1644 countries.

1645 I want to ask Mr. Murai, because you represent the
1646 California growers, if you can give me any kind of estimates
1647 on jobs as well, kind of similar questions as I was asking
1648 Mr. Costanza. I am not sure if you have met Mr. Liuzza as
1649 well but he is a good man.

1650 Mr. {Murai.} Our California Department of Food and
1651 Agriculture commissioned an economic study with the
1652 University of California Davis, and their latest numbers show
1653 that without methyl bromide and without methyl iodide now,
1654 they are anticipating California communities would lose over
1655 \$1.5 billion annually and more than 23,000 jobs annually.

1656 Mr. {Scalise.} How many jobs?

1657 Mr. {Murai.} Twenty-three thousand.

1658 Mr. {Scalise.} Just in California that would be lost?

1659 Mr. {Murai.} Just California coastal communities.

1660 Mr. {Scalise.} Okay, thank you.

1661 Mr. Dimare, if you can answer the same question?

1662 Mr. {Dimare.} I can't speak from a study standpoint on
1663 the data or statistics but just from our own perspective, on
1664 the one farm location that we have where I am at in central
1665 Florida is about 5 to 600 people, but for the whole company
1666 we are in the thousands. We employ thousands of people.

1667 Mr. {Scalise.} Okay. And then Ms. Keeler.

1668 Ms. {Keeler.} I don't have specifically those numbers.
1669 I could get them to you. The California cut flower industry
1670 is a \$10 billion industry from farm to florist, so it is a
1671 pretty big industry. Our farm alone employs over 200 people
1672 for 400 acres. But I could get the stats to you afterwards.

1673 Mr. {Scalise.} Okay. And then we don't have any kind

1674 of indirect jobs. You know, we are looking at this
1675 regulation. Unfortunately, if this was the only one, you
1676 could kind of isolate it and deal with it, but we have seen
1677 time and time again it is far from this one. We have already
1678 seen job losses in other industries due to EPA coming out
1679 with regulations that do nothing to address the problems they
1680 are concerned about. I mean if you are concerned about
1681 carbon emissions, jobs that are being sent overseas from
1682 greenhouse gas regulations, those countries where we lose our
1683 jobs to, they emit even more carbon.

1684 You know, you look at this, you know, the farms, it is
1685 going to go to developing countries. These jobs will go to
1686 developing countries that under definition can still use the
1687 product. And so you just cost American jobs. You do nothing
1688 to reduce usage of the product. And again, it is one more
1689 regulation that makes no sense. I know we have got
1690 legislation that we passed called the REINS Act that tries to
1691 rein in some of these radical regulations.

1692 But I know I am out of time. I appreciate the
1693 discretion, Mr. Chairman, and I yield back.

1694 Mr. {Whitfield.} The gentleman's time is expired.

1695 Mr. Doniger, you want to make a comment.

1696 Mr. {Doniger.} I would just like to correct the record
1697 on a couple of points. 1) Mexico is ending its use of methyl

1698 bromide this year, 3 years before the obligation. They have
1699 an obligation under the protocol to end it in 2015. They are
1700 ending it in 2012.

1701 Mr. {Scalise.} I don't know if you are correcting the
1702 record because other witnesses are shaking their head no.

1703 Mr. {Doniger.} Well, I am sorry. That is fact. The
1704 second fact I want to correct is that the United States
1705 didn't pay for or contribute in any way to the production
1706 capacity of China from methyl bromide, and it is because of
1707 this treaty that their production and use is also coming
1708 down. The treaty protects Americans because it controls the
1709 dangerous chemicals and the impact on the stratosphere around
1710 the world. We cannot protect our people by ourselves. That
1711 is why we need--

1712 Mr. {Scalise.} Can Mr. Dimare respond? Because it
1713 looks like he disagrees--

1714 Mr. {Whitfield.} Well, now, the time is up but I am
1715 just going to make one other comment. You had asked the
1716 question about jobs and Mr. Murai in his testimony pointed
1717 out I believe that the California Department of Agriculture
1718 said without methyl bromide, that there would be a loss of
1719 23,000 jobs annually, is that correct?

1720 Mr. {Murai.} Yes.

1721 Mr. {Whitfield.} Okay. At this time I recognize the

1722 gentleman from California, Mr. Waxman, for 5 minutes.

1723 Mr. {Waxman.} Thank you, Mr. Chairman, and thank you,
1724 Mr. Dingell, for allowing me to ask my questions.

1725 Mr. Doniger, the whole idea of the protocol
1726 international agreement is that we are not going to give an
1727 advantage to other countries. We are going to require
1728 everybody to reduce what is a threat to all of us in this
1729 planet. And in the case of CFCs, U.S. acted unilaterally and
1730 then moved forward. I sometimes think if we had that problem
1731 today, we would probably treat it the way we are treating
1732 greenhouse gases. They are not doing anything, we are not
1733 going to do anything. Cost us jobs? Well, we are not going
1734 to allow that to happen. And of course the result is every
1735 day we hear about another drought destroying the crops and I
1736 am sure more crops are being destroyed by the drought which I
1737 think has to do with global warming and climate change than
1738 the issue that we are discussing today, which is an important
1739 one but a very narrow one.

1740 The bill freezes an outdated list of approved critical
1741 uses. As a result, sectors that have completely phased out
1742 the use of methyl bromide during the last 7 years would be
1743 allowed to use methyl bromide again. Incredibly, as I
1744 understand it, even gold courses would once again be allowed
1745 to seek critical use exemptions.

1746 Let me ask, does anyone on the panel think that we
1747 should amend the Clean Air Act to allow sectors that have
1748 completely eliminated the use of methyl bromide to start
1749 using it again? No one? Do you think that we ought to allow
1750 sectors of our economy that have completely eliminated the
1751 use of methyl bromide to start using it again?

1752 Mr. {Murai.} Yes, because they were eliminated under
1753 false pretenses of an alternative being available and that
1754 alternative has been now taken off the market.

1755 Mr. {Waxman.} I see. What alternative has been taken--

1756 Mr. {Murai.} Methyl iodide.

1757 Mr. {Waxman.} I see. So you would let them--we would
1758 go back and allow methyl bromide--

1759 Mr. {Murai.} For critical use exemption--

1760 Mr. {Waxman.} For critical use exemption.

1761 Mr. {Murai.} --under the critical use exemption
1762 process.

1763 Mr. {Waxman.} Well, do you think it makes sense to have
1764 a critical use exemption to allow golf courses--to allow the
1765 turf grass to be preserved with methyl bromide?

1766 Mr. {Murai.} I think if it is under the law, if it is
1767 within the law, it is within the law.

1768 Ms. {Keeler.} And I think that is what Congresswoman
1769 Capps was asking earlier when she was talking about the

1770 flexibility and her time ran out. I can't speak to golf
1771 courses. That is not my area. But in some areas we thought
1772 we found an alternative in a certain crop and we tried it,
1773 and this is our commitment to the protocol. But sometimes
1774 you try something new and after 3, 4, 5 years, you find out
1775 there is a problem. A new disease develops. Something you
1776 thought was taking place didn't. So I think what Mr. Murai
1777 is saying if there is adequate information for a critical use
1778 exemption, whether it is golf courses, strawberries, flowers,
1779 that is how the protocol was written.

1780 Mr. {Waxman.} Mr. Murai, the California strawberry
1781 growers are by far the largest remaining users of methyl
1782 bromide in the United States. I know you have concerns with
1783 the amount of methyl bromide available to your industry, but
1784 do you really think that this legislation is the most
1785 constructive way to go about addressing these concerns?

1786 Mr. {Murai.} I think there could be several approaches
1787 and I think this has probably gotten to a point where we were
1788 so frustrated that we needed people to listen. We tried to
1789 collaborate with EPA. We tried to introduce what we best
1790 thought best information, put forth a package of application
1791 for the critical use exemption. If they could tell us
1792 otherwise based on data, then, you know what, that is how it
1793 is. But they weren't providing that data back, Congressman,

1794 and that is what bothered me about the system is when you can
1795 make a cut based off methyl iodide and now methyl iodide is
1796 gone, so what happens now with all the CUEs that have gone by
1797 the wayside because of this alternative? There needs to be
1798 some resolution to that.

1799 Mr. {Waxman.} But I am concerned--

1800 Mr. {Murai.} There are no alternatives coming off the
1801 shelf ready for the field.

1802 Mr. {Waxman.} I am concerned about the provision of the
1803 bill that would allow growers to obtain methyl bromide
1804 without a critical use exemption for so-called emergency
1805 events. This could create a big loophole that would allow
1806 for the use of large quantities of additional methyl bromide.
1807 Mr. Doniger, my understanding is that a Montreal Protocol
1808 decision allows for the use of methyl bromide in true
1809 emergencies. Do you know how many times this emergency event
1810 provision has been invoked?

1811 Mr. {Doniger.} Yes, it has been invoked twice and they
1812 were true emergencies, once by Canada and once by Australia.
1813 It was not a routine thing and that is what this bill would
1814 allow. Emergencies would become routine. It would be like
1815 every time you don't have enough money in your bank account,
1816 you just declare an emergency and write another check.

1817 Mr. {Waxman.} Well, Ms. Keeler, in your testimony you

1818 argue that growers should be allowed to develop an emergency
1819 cleanup process that will allow you to go into your fields
1820 every few years and use methyl bromide to clean up any pests
1821 or diseases that have developed, is that right?

1822 Ms. {Keeler.} What I was referring to in our industry
1823 we have perennials we have to take out of the fields when
1824 certain diseases pop up. So we don't have situations in many
1825 of our crops where it is an every-year process. So the way
1826 that the protocol is set up in the application process, it is
1827 very difficult for us to fit in because we aren't scheduled.

1828 Mr. {Waxman.} So it is not an emergency. It is the
1829 opposite of emergency. They are planned, routine use of
1830 methyl bromide without a critical use exemption.

1831 Ms. {Keeler.} Well, I am referring to a cleanup process
1832 that would allow us to go in and clean those fields up when--

1833 Mr. {Waxman.} Mr. Doniger, what do you think of that
1834 idea?

1835 Mr. {Doniger.} Well, I think if this problem of not
1836 needing it every year, you figure that out, you build that
1837 into the critical use exemptions. If the case can be made
1838 for it, that is what the critical use exemption process is
1839 for. The Committee is approaching this as though there is no
1840 exemption and we need to create one. Actually, there is one
1841 already and it is working. We don't need to enlarge it.

1842 Mr. {Waxman.} Well, Mr. Murai doesn't think it is
1843 working.

1844 Mr. {Murai.} I think it has worked well for a while and
1845 I think lately in the last 2, 3 years it has gotten very
1846 tenuous because there hasn't been a real listening to what is
1847 really happening in the field. And so when we come to EPA
1848 with our package to demonstrate the need, it is very easily
1849 put forth, here is what you can do. In this case, methyl
1850 iodide was put forth and you are going to transition 21
1851 percent in 3 years. I don't think so but okay. That went
1852 away. Now, there is no restoration for any of the crops that
1853 were dependent on methyl iodide based on EPA's aggressive
1854 nature with that product.

1855 Mr. {Waxman.} So you think EPA is not being reasonable
1856 in deciding when emergency event should take place and this
1857 exemption should be allowed?

1858 Mr. {Murai.} Yes, I believe they are not being
1859 reasonable and I believe the rules change at every corner.
1860 And that is where I want to be able to go back to our growers
1861 and say, hey, the process is the process and it is correct,
1862 it is transparent, their interpretations are right on the
1863 science, and it is fair and we have to live with it. But I
1864 can't honestly go back to my growers and speak with
1865 conviction that that is the process right now. And that is

1866 what I am talking about today is that this process needs to
1867 be corrected.

1868 Mr. {Waxman.} Okay, thank you.

1869 Thank you, Mr. Chairman.

1870 Mr. {Whitfield.} At this time, I recognize the
1871 gentleman from Virginia, Mr. Griffith, for 5 minutes.

1872 Mr. {Dingell.} Mr. Chairman, I thank you for your
1873 courtesy. I am sorry.

1874 Mr. {Whitfield.} Go ahead, Mr. Griffith.

1875 Mr. {Griffith.} Thank you, Mr. Chairman. I do
1876 appreciate that.

1877 Mr. Dimare, a couple times Mr. Doniger has said that
1878 Mexico is outlawing the use this year or ending the use this
1879 year of methyl bromide, and each time you have indicated at
1880 least with your body language that you didn't agree with
1881 that, so I am giving you an opportunity now to explain what
1882 disagreement is with that or other statement regarding the
1883 use in other countries of methyl bromide you might have
1884 disagreed with Mr. Doniger on.

1885 Mr. {Dimare.} Well, you know, I don't know that that is
1886 written into law there, but I will believe that when I see
1887 it.

1888 Mr. {Griffith.} Trust but verify, is that what you are
1889 saying?

1890 Mr. {Dimare.} I am sorry?

1891 Mr. {Griffith.} Are you saying trust but verify?

1892 Mr. {Dimare.} That is correct.

1893 Mr. {Doniger.} It is a commitment that Mexico has made
1894 under the Multilateral Fund, which is part of the Montreal
1895 Protocol and it is in writing. It is referenced in my
1896 testimony.

1897 Mr. {Griffith.} I understand.

1898 Mr. {Doniger.} And it is firm.

1899 Mr. {Griffith.} I think what Mr. Dimare is saying,
1900 though, that illegal drug trafficking takes place, you know,
1901 on both sides of the border. It is written into law but he
1902 will believe that they stop using methyl bromide when he sees
1903 it because he is not sure they are going to follow the law.
1904 I understand what you are saying but I understand what he is
1905 saying, too.

1906 Mr. {Doniger.} It is harder to get methyl bromide than
1907 it is to get illegal drugs.

1908 Mr. {Griffith.} And that is what, apparently, even the
1909 people who want to use it legally are saying and it is one of
1910 the reasons we need the bill is that it is harder to get
1911 methyl bromide than it is to get the illegal drugs. And they
1912 have got a concern and they are hoping that maybe it can be a
1913 little easier so they can use this substance legally and

1914 appropriately.

1915 Along those lines, Mr. Doniger, is there anything in
1916 this bill that would force the EPA or the State Department
1917 out of compliance with the protocol?

1918 Mr. {Doniger.} I think what would happen, Congressman,
1919 is that if the United States went forward with unsupported
1920 applications, they would be turned down. And that would be
1921 the normal operation of the protocol but it wouldn't be a
1922 good result for my colleagues here on this panel. They want
1923 the nominations to succeed, not to fail because they weren't
1924 supported.

1925 Mr. {Griffith.} But inherently there is nothing in this
1926 bill that would put us out of--

1927 Mr. {Doniger.} Yeah, actually, I believe the emergency
1928 exemptions provision would be grossly out of line with the
1929 protocol and freezing the critical use list, you know,
1930 permanently at the 2005 list would be contrary to the
1931 protocol.

1932 Mr. {Griffith.} All right. And if I might ask Ms.
1933 Keeler and others who have talked about this, and feel free
1934 to jump in, because I am not as familiar with methyl bromide,
1935 I don't know what happened that made methyl iodide--what were
1936 the negative effects that we decided as a country to take
1937 methyl iodide out of the mix--either one of you--as a

1938 potential fix for using methyl bromide?

1939 Mr. {Murai.} I think methyl iodide was identified as an
1940 effective fumigant but the science on health effects was
1941 debated and there were two sides of the science. And it was
1942 deemed a cancer-causing agent and so it caused definite
1943 uproar in the communities. And as growers, we were just as
1944 sensitive to that and we believed that the process of science
1945 and examination should go forth. And so we weren't resting
1946 on that product as being the replacement for methyl bromide
1947 and that is what we tried to articulate back to EPA is that
1948 we aren't convinced this will be the tool for California or
1949 the Nation.

1950 Mr. {Griffith.} And then am I also hearing the
1951 testimony correctly when I was listening to your opening
1952 statements, the four of you that are in production of various
1953 types of vegetables or fruits that to replace the methyl
1954 bromide you are using a lot more pesticides and things that
1955 would get into the water supply? Is that accurate? And Mr.
1956 Costanza, you want to comment on that?

1957 Mr. {Costanza.} When using methyl bromide eliminates a
1958 lot of sprays across the field that we are going to have to
1959 do with methyl bromide. As far as Midas is concerned, I am
1960 concerned about my workers because it is not worker-friendly,
1961 whereas methyl bromide is easier to work with and it is less

1962 risky to my employees. But one of the biggest worries I had
1963 about Midas was the fact that it could affect my workers more
1964 than anything else. But this was the replacement the EPA
1965 gave us, said we were going to have, and then that is gone.
1966 So they promised us that we would have a drop-in replacement.
1967 And the reason I am here is because we don't. If somebody
1968 has got a magic wand here that I could use, I don't want
1969 methyl bromide. But you don't have a replacement.

1970 You know, if I need a blood transfusion today and I am A
1971 positive and you don't have A positive and you give me
1972 something else, you are going to kill me. But with methyl
1973 bromide it worked. And my customers demand the product that
1974 it produced. My employees liked the product because it
1975 yielded more fruit. And they get paid an incentive on
1976 volume. They made more money. So why don't produce it? The
1977 chain stores are going to go to where it is if they have to
1978 import it. It doesn't matter if it comes from--you know, you
1979 could fly anything anywhere from the world today. You know,
1980 I have got Chinese product in the stores in my hometown. My
1981 grandson was eating Chinese-produced diced pears, not
1982 American, Chinese. We don't need that. We can do it here.
1983 But all you are doing is eliminating jobs and exporting the
1984 production to other countries. Give me a break.

1985 Mr. {Whitfield.} The gentleman's time is expired.

1986 At this time I recognize the gentleman from Michigan,
1987 Mr. Dingell, for 5 minutes.

1988 Mr. {Dingell.} Thank you.

1989 I am very sympathetic with the witnesses here. I am
1990 very much concerned about their views and their need for a
1991 pesticide, but I have a feeling that we are like the surgeon
1992 who conducted a superb operation in which the patient died.
1993 I don't see here, Mr. Chairman, EPA. They have a story to
1994 tell. Where are they? I don't see here the Department of
1995 Agriculture. I don't see here others who could tell us
1996 whether there are substitutes or why those substitutes are
1997 available or not available.

1998 I note here as I am looking at it the annual critical
1999 use exemption summary. I don't know whether the panel has
2000 seen this or not but it shows a continuing decline in the
2001 exemption that has been given by the folks up at the Montreal
2002 Protocol. It started out they were getting about 10,000 tons
2003 and it is down now to less than 2,000 tons. My concern here
2004 is that every time we have seen this, it has gone down and
2005 down and down but I don't see any real prospect of getting
2006 relief through the Montreal Protocol. If I look, they have
2007 consistently been below what the farmers have requested and
2008 they have not given the amount that the farmers say they
2009 need.

2010 And we are going to take this legislation to the Floor
2011 after virtually no hearings. We have had a panel and I am
2012 sure the panel are most respectable of folks in their fields,
2013 but we haven't heard a word from the government agencies.
2014 Frankly, I am in the view we ought to have EPA up here and
2015 let us find out what the facts are from EPA's view. I am in
2016 the view we ought to hear from Department of Agriculture.
2017 Let them tell us what is the need but I don't see that. So
2018 we are going to take this bill to the Floor, probably pass,
2019 and then when it passes it goes to Senate. And it is going
2020 to sink out of sight.

2021 And if it doesn't sink out of sight in the Senate, it is
2022 probably not going to be signed by the President and it is
2023 going to be opposed with utmost diligence by the
2024 environmentalists, and I don't think this committee is going
2025 to afford the relief that quite frankly our agriculture
2026 community needs. I don't think that we are going to see them
2027 get the opportunity to have new pesticides that will address
2028 the concerns of our farmers. And I see us lining up if the
2029 dire predictions I hear today are to be realized, I see just
2030 nothing but trouble coming from this legislation. And I see
2031 under the legislation the farmers tell EPA what they go to
2032 the Montreal Protocol with and the Montreal Protocol takes a
2033 look at it and says, well, we are just not going to do that.

2034 So the farmers walk away and the farmers got nothing and
2035 there is no methyl bromide or anything else that is available
2036 to help our farmers with their problem.

2037 So we are giving our farmers the most successful
2038 operation, but when we are done, the patient is going to fall
2039 off the table and he is going to die. And we are going to
2040 have a huge fight on the Floor and everybody is going to get
2041 all torn up, but the farmers aren't going to get the relief
2042 that they need or they want. And to me that is not only bad
2043 policy but it is very bad legislating and it is going to
2044 leave this committee quite frankly looking kind of whoosh
2045 because we really didn't do the job that we should have done
2046 in terms of having an intelligent bunch of hearings where we
2047 heard the witnesses.

2048 And, you know, I warned about this in earlier times. I
2049 remember one morning Chairman Staggers brought in the swine
2050 flu bill and we had a great big hearing on swine flu and my
2051 friend John Moss, who was a member of the committee, and I,
2052 we said this is a hell of a way to do business. We don't
2053 have the vaguest idea what this is going to do. So we had a
2054 magnificent program for the production of vaccine. We
2055 produced a hell of a lot of vaccine. We absorbed liability
2056 for everything from the building burning down while the
2057 patient was in it to being raped or assaulted in the parking

2058 lot. And lawyers said oh, my, isn't this wonderful? So they
2059 rushed out and had swine flu seminars at which they told
2060 everybody how to sue the government. We wound up with about
2061 \$7 billion of liability. They developed this wonderful
2062 inoculant but they never found the damn disease and they
2063 never found the virus. And the government got about a \$7
2064 billion liability and the trial lawyers had a wonderful time
2065 and made lots and lots of money.

2066 I am not going to say that that is what is going to
2067 happen here but I think we are working most diligently to
2068 create red faces on the members of this committee, and I just
2069 hope, Mr. Chairman, that you will slow down and you will
2070 bring in the witnesses from the Department of Agriculture,
2071 witnesses from EPA, and maybe somebody else and let us find
2072 out why they are not producing what our agriculture needs and
2073 exposing them to what looks like is the work product of a
2074 snake oil salesman.

2075 I yield back the balance of my time.

2076 Mr. {Whitfield.} Thank you very much. I might add, Mr.
2077 Dingell, that we do have a document from the EPA making
2078 comments on this particular legislation, even though they are
2079 not here today. But we do have comments from them.

2080 At this time--

2081 Mr. {Dingell.} If you want EPA up here, they will come

2082 and the Committee will support you. And if you want the
2083 Department of Agriculture up here, they will come and the
2084 Committee will support you. And that is the way to do the
2085 business. Let us find out--

2086 Mr. {Whitfield.} We don't want to sit around and
2087 subpoena them every time we ask them. We try to work with
2088 them and--

2089 Mr. {Dingell.} Did you invite them, Mr. Chairman?

2090 Mr. {Whitfield.} We did invite them, absolutely.

2091 Mr. {Dingell.} And did you get on the phone and say we
2092 want to have you up here? I have run committees for about 20
2093 years and I am somewhat knowledgeable--

2094 Mr. {Whitfield.} We contacted them one month ago about
2095 this hearing.

2096 Mr. {Dingell.} I never had any trouble getting anybody
2097 in here. I have watched my Republican colleagues waiving
2098 subpoenas and throwing them around here like confetti and
2099 they don't get anything done. But it is fairly simple, let
2100 them know, By the Great Horn Spoon, you are coming and we are
2101 going to have you up here.

2102 Mr. {Whitfield.} See, our goal is to accumulate the
2103 esteem and respect that you have so that when we ask them,
2104 next time, they will show up immediately.

2105 Mr. {Rush.} Mr. Chairman, with all due respect I have

2106 to join in here with Mr. Dingell. You know, here we have
2107 this hearing and we are going to finish maybe these hearings
2108 by 1:30, maybe 2:00. And then at 4:00 the markup starts.
2109 You know, that is not enough time. I think that if we delay
2110 this pending markup, I will certainly join in with you and I
2111 am sure Mr. Waxman would and the chairman of the full
2112 committee would. We would join with you if you want to do a
2113 telephone call, request that the EPA appears before a hearing
2114 we could schedule tomorrow morning, I am sure we would be
2115 able to do that--or the following day. But just to rush
2116 pell-mell into a markup less than probably 2 hours after a
2117 hearing on this obviously very important matter in your
2118 opinion, I think that is ludicrous on its face.

2119 And so I would strongly suggest and recommend that you
2120 consider postponing your markup until we are able to get EPA
2121 and USDA here so they could have some testimony from the
2122 departments.

2123 Mr. {Whitfield.} Mr. Rush, you and I both know that
2124 whether Democrats are in control or Republicans are in
2125 control, there are times when the other party does not agree
2126 with the procedure. There were a lot of things, for example,
2127 about the healthcare procedure bill we didn't agree with, and
2128 I have a number of letters. I have farmers talking to me all
2129 the time, milling companies all the time about methyl

2130 bromide, the importance of methyl bromide. And we have this
2131 panel of witnesses that reflects the agriculture community,
2132 reflects the environmental groups, and we are going to intend
2133 to have opening statements today at 4:00. And I guess the
2134 markup is scheduled for tomorrow at 10:00.

2135 Mr. {Rush.} But Mr. Chairman, why the hurry? Why do we
2136 have to hurry up and get this done? Why--

2137 Mr. {Whitfield.} We are trying to be responsive to the
2138 agriculture community--

2139 Mr. {Rush.} I would like to have the opportunity to
2140 invite, along with yourself, along with Mr. Waxman, along
2141 with Mr. Upton, to request that the EPA appear before the
2142 markup. I would like to have that opportunity and I would
2143 respectfully request that we be given an opportunity. Mostly
2144 Democrats and the Republicans send invitation over the phone,
2145 however you want to send it, email it, asking them to show up
2146 for a hearing before we go into a markup.

2147 Mr. {Whitfield.} Now, have you had the opportunity to
2148 read their comments on this bill?

2149 Mr. {Rush.} Mr. Chairman, I want to ask them questions.
2150 I want them sitting right there at that table so that we can
2151 have a vigorous debate or discussion and ask questions and
2152 ask them some important questions that I and other members of
2153 the committee want to get some answers to. The departments

2154 need to be here.

2155 Mr. {Whitfield.} Well, we invited them and you know
2156 what, I would be happy to join with you, Mr. Waxman, and we
2157 can sit down with EPA between the subcommittee markup and the
2158 full committee markup and we can ask them all the questions
2159 you would like to ask them.

2160 Mr. {Rush.} It should be public and every member of
2161 this committee should have that opportunity.

2162 Mr. {Whitfield.} We will invite the public in.

2163 Mr. {Rush.} And in fact, Mr. Chairman, I don't know why
2164 we can't delay the markup for 24 hours if necessary so that
2165 we can be responsible and have some real deliberative
2166 discussions with the Administration, with the EPA, and
2167 Department of Agriculture. I don't see what--

2168 Mr. {Whitfield.} So you prefer to do it on Friday
2169 instead of tomorrow?

2170 Mr. {Rush.} Yeah, and we can do it on Friday. I don't
2171 have any reason why that isn't okay, but we need to get the
2172 EPA and the Department of Agriculture at the witness table.

2173 Mr. {Whitfield.} Well, listen, I really do thank you
2174 and Mr. Dingell for your comments. And like I said, we will
2175 make sure that you get a copy of this. And like I said, I
2176 would be happy to join you all in having EPA come up and talk
2177 to us, but we do believe that this is an important issue. A

2178 lot of jobs are at stake.

2179 And at this time I think, Mr. Olson, you are the only
2180 one who hasn't asked questions, so I recognize Mr. Olson from
2181 Texas for 5 minutes.

2182 Mr. {Olson.} And I thank the chair. And welcome to our
2183 witnesses. I appreciate your time and your expertise this
2184 afternoon.

2185 One of the largest annual festivals back home in Texas
2186 22 is the Strawberry Festival in Pasadena, Texas. It just
2187 was completed this past May and so because of those
2188 strawberries, American strawberries, strawberry production in
2189 America is important to me. Beyond strawberries, I am
2190 concerned about some of the comments you made, Mr. Doniger.
2191 You essentially said that citizens who are impacted by the
2192 loss of methyl bromide have an avenue to have their
2193 objections heard, and that is a lawsuit suing the EPA. That
2194 apparently is how the NRDC sees a remedy for people who are
2195 impacted by loss of methyl bromide. But I am curious if the
2196 people working on the farms think a lawsuit is a viable
2197 alternative.

2198 So my first question is for you, Mr. Costanza, and I
2199 will work down to the other three. Do you have the money,
2200 the time, and the resources to sue the EPA?

2201 Mr. {Costanza.} No. When I was using methyl bromide on

2202 the other crops, I was paying a lot higher income tax. My
2203 employees were paying a lot higher income tax than they are
2204 now. So both my employees and myself, our incomes have been
2205 reduced because we are not using methyl bromide. And to sue
2206 the EPA, where am I going to get this kind of money from?
2207 You know, we are a family farm. Our margins are 2, 3
2208 percent.

2209 Mr. {Olson.} So a lawsuit is not a viable alternative
2210 for yourself?

2211 Mr. {Costanza.} Not unless you got some money.

2212 Mr. {Olson.} We got a spending problem here in
2213 Washington, see. We don't have the money, sir.

2214 Same question to you, Mr. Murai. Do you have the time,
2215 money, and resources to sue the EPA?

2216 Mr. {Murai.} We are in the business of farming. We are
2217 not in the business of suing people. We are just looking for
2218 an alternative that is viable. If methyl bromide is the only
2219 product, this will not be disputed. The only product out
2220 there that did kill all the pathogens that it killed, all the
2221 weeds that it killed, all the alternatives that are out there
2222 are lesser, okay, which increases our cost, decreases our
2223 yield, which is not a productive way to do business.

2224 Mr. {Olson.} And probably lose jobs as well, just like-
2225 -

2226 Mr. {Murai.} Well, the jobs will follow, yes. As we
2227 know it, the type of farming we do will go under.

2228 Mr. {Olson.} Ms. Keeler, same question for you, ma'am.
2229 Do you have the time, money, resources to sue EPA?

2230 Ms. {Keeler.} No, we barely have profit margins. I
2231 have to repeat what Mr. Murai said earlier and we appreciate
2232 the opportunity to be here to tell you our story. It should
2233 be not an adversarial situation with EPA. We in our
2234 government should have a conversation about what is going on
2235 on our farms. We don't expect you all to know how to run a
2236 flower farm. That is what we do. But we can come here and
2237 tell you and tell EPA how that is taking place and the
2238 struggles that we have.

2239 And Mr. Murai made a wonderful comment earlier. Italy,
2240 Greece, they don't have the opportunity to come and talk to
2241 their governments. At the very first international meetings
2242 that I attended, I actually went and talked to the Italians
2243 and the French because we know what they are growing. And we
2244 basically said how are you guys going to grow these cut
2245 flower products without methyl bromide? And they said we are
2246 not. The EU came to us and told us this is what the EU is
2247 agreeing to. There was no discussion. The Italians were on
2248 a vacation and all these international locations at the
2249 meetings because there was nothing for them to talk about.

2250 So, no, we don't have the money, no, we don't want to
2251 sue EPA. We want to be here, discuss with you, discuss with
2252 EPA and follow the CUE process the way it is laid out and get
2253 our allocations when necessary.

2254 Mr. {Olson.} Thank you. And finally, for you, Mr.
2255 Murai, being a strawberry man, very special to my heart with
2256 the passing of the Strawberry Festival, so I mean again, same
2257 question. Do you have the time, resources, money to sue EPA?

2258 Mr. {Murai.} Our time and resources should be invested
2259 in researching alternatives to methyl bromide. That is where
2260 our efforts should be. And the process just broke down. It
2261 needs to get fixed. People need to listen, get their boots
2262 dirty, and clean their ears out because it is just not
2263 computing. And we are not making things up. It is based on
2264 real data, real science, and I think the EPA really needs to
2265 prove to all of us that they have legitimate reasons for
2266 reducing our nominations or eliminating them.

2267 Mr. {Doniger.} So instead what these folks are doing is
2268 coming to you at no small expense and asking you to change
2269 the law, not to get EPA to carry out the law but to change
2270 the law, to tilt the playing field in their direction. All I
2271 am saying is there is an existing law and an existing
2272 process. Let us make it work. It does work in my opinion.
2273 And use all the tools that people have under existing law.

2274 If we change it--

2275 Mr. {Olson.} Mr. Doniger, with all due respect, sir,
2276 the four panelists sitting next to you disagree completely
2277 with that statement there. I mean EPA is hurting their
2278 business, is killing their jobs, and again that is not EPA's
2279 role. I mean again we need to get the Federal Government off
2280 the peoples' backs and let the American people grow their
2281 products, create jobs in this country. That is the biggest
2282 challenge we have right now.

2283 I guess one more question for you, last one, Mr.
2284 Costanza.

2285 Mr. {Costanza.} I don't want the EPA to change their
2286 rules. I just want them to do what they told me they were
2287 going to do. They were going to get me a viable, affordable
2288 alternative and they have not. So until they give me a
2289 viable, affordable alternative, give me the CUEs.

2290 Mr. {Doniger.} Mr. Costanza hasn't even requested one--

2291 Mr. {Costanza.} That is not correct.

2292 Mr. {Doniger.} --since 2007.

2293 Mr. {Costanza.} No, that is not correct.

2294 Mr. {Olson.} Well, we will settle that later,
2295 gentlemen.

2296 Again, one commonsense thing from Mr. Murai--

2297 Mr. {Costanza.} We are in the process of doing it now.

2298 Mr. {Olson.} Dirt on the boots, wax out of the ears,
2299 that is how we get through this problem. Thank you. I yield
2300 the balance of my time.

2301 Mr. {Whitfield.} Okay. Time is expired.

2302 That concludes questions for the first panel. We
2303 appreciate all of you being here and talking to us about--

2304 Mr. {Rush.} Chairman, I ask unanimous consent to insert
2305 three items related to methyl bromide into the record. And
2306 one is a recent article from the Journal of Environmental
2307 Medicine citing that the California strawberry industry is
2308 experiencing rising crop yields while methyl bromide use
2309 declines. And there are also two letters from the California
2310 growers describing their success with alternatives to methyl
2311 bromide.

2312 Mr. {Whitfield.} Well, without objection.

2313 [The information follows:]

2314 ***** COMMITTEE INSERT *****

|
2315 Mr. {Whitfield.} And then we have some additional
2316 letters from millers and Agricultural Trade Services, Almond
2317 Processing Association, the American Farm Bureau, California
2318 Date Commission, California Walnut Commission, Florida Farm
2319 Bureau, Florida Tomato Exchange, Georgia Fruit and Vegetable
2320 Growers, Holsinger Flowers, Inc., Knappan Milling Company,
2321 Lassen Nursery, Maritime Exchange for the Delaware River and
2322 Bay, Ledbetter Fruits and Vegetables, Star of the West
2323 Milling Company, Sunkist, Sunshine, Sunsweet, and Western
2324 Industries. Without objection, so ordered.

2325 [The information follows:]

2326 ***** COMMITTEE INSERT *****

|

2327 Mr. {Whitfield.} At this time I would like to call up
2328 the second panel of witnesses for testimony on the Asthma
2329 Inhalers Relief Act of 2012. On that panel we have Mr. Jason
2330 Shandell, who is general counsel and secretary, Amphastar
2331 Pharmaceuticals. We have Dr. Monica Kraft, who is the
2332 professor of medicine at Duke University, president of the
2333 American Thoracic Society, and director of the Duke Asthma,
2334 Allergy, and Airway Center. We have Dr. Edward Kerwin, who
2335 is senior medical director, Allergy & Asthma Center of
2336 Southern Oregon. And we have Mr. Chris Ward, who is the
2337 former chairman of the Board of Directors of the Asthma and
2338 Allergy Foundation of America.

2339 And I would like at this time call on Mr. Walden for the
2340 purpose of introducing Dr. Kerwin.

2341 Mr. {Walden.} Thank you very much, Mr. Chairman. It is
2342 my honor to introduce Dr. Edward Kerwin, an allergy, asthma,
2343 and clinical research physician who traveled from Oregon out
2344 here today. We appreciate your being here. Dr. Kerwin
2345 founded the Allergy & Asthma Center of Southern Oregon in
2346 1997, and prior to that, practiced in the area since '93.

2347 Today, he is going to provide the Committee with insight
2348 on his years of experience as a physician serving patients in
2349 and around Medford, Grants Pass, Klamath Falls, and Ashland.

2350 In addition to his role as health provider, Dr. Kerwin is a
2351 leading clinical trial investigator on issues that we will
2352 discuss today. He authored over 25 medical publications on
2353 allergy and asthma, and even previously worked for NASA on
2354 solar energy technology and space antenna projects in the
2355 '80s. So maybe Mr. Olson will be back and we can talk NASA
2356 antennas.

2357 He is active in multiple professional trade
2358 associations, even finds time to participate in the Medford
2359 Rotary Club. And after this hearing he will be able to
2360 testify before Congress to his long and impressive résumé.
2361 And with that, Mr. Chairman, we thank you for having Dr.
2362 Kerwin invited to testify today.

2363 Mr. {Whitfield.} We have got a meeting in here for just
2364 a minute, but Dr. Burgess is going to go on and get the
2365 opening statements started and then we will be right back.

2366 Dr. {Burgess.} [Presiding] So again, welcome to our
2367 witnesses. We will first hear from Mr. Jason Shandell, 5
2368 minutes for opening statement, please.

|
2369 ^STATEMENTS OF JASON SHANDELL, VICE PRESIDENT AND GENERAL
2370 COUNSEL, AMPHASTAR PHARMACEUTICALS, INC.; DR. MONICA KRAFT,
2371 PROFESSOR OF MEDICINE, DUKE UNIVERSITY, PRESIDENT, AMERICAN
2372 THORACIC SOCIETY, AND DIRECTOR, DUKE ASTHMA, ALLERGY AND
2373 AIRWAY CENTER; CHRIS WARD, FORMER CHAIRMAN OF THE BOARD OF
2374 DIRECTORS, ASTHMA AND ALLERGY FOUNDATION OF AMERICA; AND DR.
2375 EDWARD M. KERWIN, SENIOR MEDICAL DIRECTOR, ALLERGY & ASTHMA
2376 CENTER OF SOUTHERN OREGON

|
2377 ^STATEMENT OF JASON SHANDELL

2378 } Mr. {Shandell.} Thank you. Good afternoon and thank
2379 you for this opportunity to testify. I am Jason Shandell,
2380 Vice President and General Counsel for Amphastar
2381 Pharmaceuticals, which is the parent company of Armstrong
2382 Pharmaceuticals. We are grateful to the Members and
2383 professional staff of the Energy and Commerce Committee for
2384 their assistance in helping us to hopefully distribute the
2385 remaining units of Primatene Mist. We strongly believe that
2386 allowing Americans to have access to Primatene Mist is better
2387 than leaving it to expire in a warehouse in California.
2388 Primatene Mist, an epinephrine inhaler with CFC as
2389 propellant was developed by Wyeth Labs in July 2008.

2390 Primatene Mist is approved for temporary relief of occasional
2391 symptoms of mild asthma. There are at least 2 to 3 million
2392 loyal Primatene Mist users in the U.S.

2393 When our company purchased Primatene Mist brand in 2008,
2394 we knew it would be going off the market and that there were
2395 technical challenges in creating an epinephrine inhaler
2396 without CFCs. This is referred to as Primatene HFA. We
2397 accepted the challenge, and in fact, we have developed
2398 Primatene HFA and we are targeting to file a new drug
2399 application with the FDA in the fourth quarter of this year.

2400 Because Primatene Mist was removed from the market on
2401 January 1, 2012, there is currently no over-the-counter
2402 inhaler for asthmatic patients on the U.S. market. An
2403 individual who previously used Primatene Mist must now pay to
2404 see a doctor and then buy a prescription inhaler that costs
2405 four to five times more than Primatene Mist.

2406 We have received thousands of inquiries from users of
2407 Primatene Mist who are desperate for availability of an over-
2408 the-counter inhaler. Unfortunately, these inquiries have
2409 also cited two possible deaths because of the lack of such an
2410 over-the-counter inhaler, and I have these emails here.

2411 Last December, we submitted a request to the EPA to
2412 allow for the sale of the remaining units of Primatene Mist
2413 based on public health and economic interests. The public

2414 health interest is growing since the untreated and
2415 undertreated asthma patient population is largely comprised
2416 of uninsured, economically disadvantaged black and Hispanic
2417 communities. This includes a large number of women and
2418 children. Without Primatene Mist, those asthmatics who have
2419 no insurance, they may have to seek care in emergency rooms,
2420 which can take many hours and cost thousands of dollars.

2421 The company's request for enforcement discretion was
2422 denied by the EPA on December 30, 2011, citing that it would
2423 not be in the public interest to allow for the sale of the
2424 remaining units of Primatene Mist. Since the EPA did not
2425 address the economic factors raised in our original request,
2426 we again requested enforcement discretion from the EPA on
2427 January 4, 2012. The 2008 Final Rule stated that removing
2428 Primatene Mist from the market will cost consumers between
2429 \$300 million to \$1.1 billion. That is based on 2007
2430 estimates. The cost to the Federal Government and taxpayers
2431 for Medicare and Medicaid could run as high as \$75 million in
2432 each program, not to mention the severe financial burden that
2433 an emergency room bill can place on a family.

2434 We have not received a response from the EPA on this
2435 subsequent request based on economic concerns.

2436 Amphastar understands that Members of Congress have also
2437 written to the EPA expressing their concerns, and they have

2438 not received any response from the EPA as far as I can tell.
2439 The company has repeatedly asked why Primatene Mist was
2440 pulled from the market when actually there are two
2441 prescription drug inhalers that also use CFC as their
2442 propellants and they have been allowed to stay on the market
2443 through December of 2013. No one from EPA has ever explained
2444 why these two inhalers, with CFC, are allowed to remain but
2445 Primatene Mist is not.

2446 Primatene Mist has been on the market for almost 50
2447 years and has a safe and effective track record. To remove
2448 Primatene Mist from the market because it contains CFC with
2449 no over-the-counter replacement inhaler jeopardizes the
2450 health and safety of the 2 to 3 million Americans that have
2451 relied on this product for many years.

2452 Amphastar believes in putting people over profits, and
2453 throughout our efforts, we have offered to distribute all of
2454 the remaining units of Primatene Mist as a donation to public
2455 health clinics. This offer has been rejected by the
2456 government. We are not interested in profiting from the sale
2457 of the remaining inventory. Therefore, we hereby commit that
2458 we will donate all the net profits from the sale of the
2459 remaining units of Primatene Mist to charity.

2460 Amphastar believes in its product, Primatene Mist. It
2461 should be available in the United States over-the-counter so

2462 individuals who are suffering from asthma and depend on this
2463 product can enjoy instant relief when they experience asthma
2464 symptoms such as shortness of breath. We sincerely believe
2465 that there must be a readily available over-the-counter
2466 inhaler for Americans who have difficulty accessing a doctor
2467 to obtain a prescription and cannot afford to pay four to
2468 five times more for a prescription inhaler.

2469 In closing, let me again thank the members of this
2470 committee, specifically Dr. Michael Burgess and also
2471 Congressman Mike Ross and your professional staff for holding
2472 this hearing. Our goal is to get the remaining units of
2473 Primatene Mist out of the warehouse and into the hands of the
2474 American people.

2475 Thank you.

2476 [The prepared statement of Mr. Shandell follows:]

2477 ***** INSERT 6 *****

|

2478 Dr. {Burgess.} I thank the gentleman for his testimony.

2479 Dr. Kraft, you are recognized 5 minutes for testimony,

2480 please.

|
2481 ^STATEMENT OF DR. MONICA KRAFT

2482 } Dr. {Kraft.} Very good, thank you. I would like to
2483 thank the Committee for allowing me to speak to you today.

2484 I am Dr. Monica Kraft and I am a professor medicine at
2485 Duke University and currently the president of the American
2486 Thoracic Society. This is a specialty society made up of
2487 about 16,000 physicians who are pulmonologists with an
2488 interest in obviously respiratory issues, critical care
2489 physicians, and sleep physicians. So I also direct the Duke
2490 Asthma, Allergy, and Airway Center and have been involved in
2491 both research and care of patients with asthma. And my group
2492 and I have over 140 publications along these lines.

2493 So it is with this professional scientific background
2494 that I come to you today to present testimony on the behalf
2495 of the American Thoracic Society on this issue of restoring
2496 epinephrine inhalers back to the U.S. marketplace. It is my
2497 strongly held view and the view of the American Thoracic
2498 Society that returning these inhalers to the U.S. market even
2499 for a limited time is ill-advised. But this view isn't just
2500 shared by me or my societies. It is also shared by several
2501 other societies, including the American Academy of
2502 Pediatrics, two asthma and allergy societies, and two

2503 respiratory therapy societies. So we are not unique in this
2504 view.

2505 Now, when we think about asthma we think of it as a very
2506 common disease. It affects between 5 and 10 percent of the
2507 population, so most of us know someone with asthma. We also
2508 have this perception--this is at least what I hear from
2509 people--that asthma is relatively mild and not a problem when
2510 actually I certainly take care of patients with very severe
2511 disease who die of their asthma. And one of the reasons that
2512 is is because the airways are red and swollen in asthma so
2513 they become narrowed. And it is somewhat like breathing
2514 through a straw. So really the mainstay of therapy is anti-
2515 inflammatory therapy like inhaled corticosteroids. You may
2516 have heard of that.

2517 We also use bronchodilators, which dilate the airways
2518 and we use this combination together. And in more severe
2519 asthma we may need to use oral steroids like prednisone or
2520 adopt other strategies such as focusing our allergic
2521 symptoms, which are very big triggers of asthma.

2522 So I am here to tell you that healthcare professionals
2523 play a really critical role in the management of asthma in
2524 that we form partnerships with our patients to get them not
2525 only the best combination of medications that they need that
2526 are safe and effective but also to educate them so that they

2527 can control their disease.

2528 So the takeaway message is the majority of cases asthma
2529 can be managed and patients with the appropriate therapy can
2530 live full and active lives.

2531 But I would say to you today that epinephrine is not one
2532 of those medications considered safe. So I am coming to you
2533 from a safety perspective. So epinephrine is a nonselective
2534 bronchodilator. So yes, it dilates. It bronchodilates.
2535 That is good, but it also has other effects, primarily
2536 cardiac that is very concerning to me and my colleagues.
2537 This can lead to excessive cardiac stimulation, heart rate,
2538 that can lead to heart attacks, especially in the older
2539 patients or those folks who have heart disease. And
2540 sometimes we don't always know who has heart disease.

2541 Now, for years, the medical community has recognized the
2542 dangerous side effects of epinephrine in the treatment of
2543 asthma and recommended against its use. The American Medical
2544 Association has urged warning labels. They have encouraged
2545 FDA to consider removing inhaled epinephrine. They have
2546 requested studies to really determine does it contribute to
2547 increased asthma morbidity and mortality.

2548 Now, I would be interested in hearing more about these
2549 deaths that we just heard mentioned in the last testimony
2550 because in speaking to my colleagues in emergency medicine--

2551 and my husband runs the emergency department at the
2552 University of North Carolina Chapel Hill--and my colleagues
2553 at Duke, their perception is since Primatene Mist has been
2554 off the market, there have been fewer severe exacerbations.
2555 And so we hypothesize that in fact patients are now getting
2556 the care that they need.

2557 We have a mechanism to take care of those patients who
2558 are uninsured, those underrepresented minority patients. I
2559 live in Chapel Hill. I see patients from Durham. We have a
2560 very significant contingent of underserved patients that we
2561 take care of at our institution. And we can provide them
2562 with the right medication. So I don't necessarily think it
2563 is all about access.

2564 So furthermore, the guidelines that put forth the
2565 treatment of asthma do not mention epinephrine as a viable
2566 option for treatment and I want to make sure that that is
2567 clear. The National Asthma Education and Prevention Program,
2568 put together by our own National Institutes of Health here in
2569 Washington, the U.S., have emphasized that inhaled
2570 medications are critical for asthma therapy but not
2571 epinephrine.

2572 So the American Thoracic Society strongly encourages any
2573 patient who is using over-the-counter medications like
2574 Primatene Mist to seek care from a provider and there are

2575 ways that these patients can get help. And I am a strong
2576 advocate, again, for allowing patients to learn how to take
2577 care of their own asthma and manage their disease because it
2578 is really all about putting the power in the hands of the
2579 patient and teaching them what they need.

2580 So if one of the goals of today's hearing is to discuss
2581 the pros and cons of enacting legislation to permanently or
2582 temporarily restore inhaled epinephrine for the treatment of
2583 asthma to the U.S. market, if the intent is to restore a safe
2584 and effective medication, I think that is a laudable cause
2585 but it is misinformed. Inhaled epinephrine is not safe for
2586 the treatment of asthma and no current clinical practice
2587 guideline calls for the use of epinephrine.

2588 If the legislative intent is to provide access to an
2589 inexpensive drug for the treatment of asthma, then I think
2590 that is laudable but misdirected. In my opinion and that of
2591 my society and other societies, the epinephrine's risk
2592 outweigh its benefits.

2593 And lastly, I am concerned about the message we are
2594 sending to patients. We spent a lot of time preparing
2595 patients for this transition when Primatene Mist was being
2596 taken off the market, moving towards approved asthma
2597 therapies that are effective and safe, and I worry that
2598 putting Primatene Mist back on the market, even temporarily,

2599 may send a confusing message.

2600 I would like to propose that Congress should be
2601 considering ways to increase patient access to healthcare
2602 professions who can work with patients to find an effective
2603 combination of drugs to control asthma. We should not be
2604 abandoning patients with serious medical conditions like
2605 asthma to self-diagnosis and self-medication with less-
2606 effective drugs that have known side effects.

2607 So I hope this committee will keep the view of the
2608 American Thoracic Society in mind as it considers legislation
2609 on inhaled epinephrine for the treatment of asthma. I thank
2610 you for the opportunity to speak to you today.

2611 [The prepared statement of Dr. Kraft follows:]

2612 ***** INSERT 7 *****

|

2613 Dr. {Burgess.} Time is expired.

2614 Mr. Ward, recognized 5 minutes for the purposes of an

2615 opening statement.

|
2616 ^STATEMENT OF CHRIS WARD

2617 } Mr. {Ward.} Thank you, Dr. Burgess, members of the
2618 committee, for your invitation to speak today. My name is
2619 Chris Ward. I live here in Washington, D.C., and I am past
2620 chairman of the volunteer Board of Directors of the Asthma
2621 and Allergy Foundation of America, and I have had asthma all
2622 my life. When I was a child, there were very few choices for
2623 treating my asthma. I have been fortunate, however, that
2624 more and better asthma treatments have come into use. I have
2625 also been fortunate to be under the care of an allergist, a
2626 specialist in the care of patients with asthma, since
2627 childhood when I was diagnosed. Now that there are a variety
2628 of safe, effective medications from which to choose to treat
2629 my asthma, I am a grateful beneficiary.

2630 Making the epinephrine bronchodilators, Primatene Mist
2631 or others, available over-the-counter may give patients a
2632 false sense of security. I know that from a personal
2633 perspective. If patients use this medication to achieve
2634 short-term control of asthma, which is a chronic disease,
2635 when long-term control is warranted, asthma is a chronic
2636 disease and short-term symptom relief may lull patients into
2637 a false sense of security and think they have no need to

2638 follow up with a healthcare practitioner physician.

2639 Asthma patients need professionals who can recognize
2640 levels of asthma control and recommend the most appropriate,
2641 effective medication to achieve control. Left on their own--
2642 I as well as other patients and a lot of us know that with
2643 medication over-the-counter, that patients can get into
2644 trouble. Sound public policy should provide patients with
2645 opportunities to get appropriate treatment directed by
2646 skilled professionals. Having access to epinephrine
2647 bronchodilators over-the-counter may put patients at risk if
2648 they delay getting an appropriate diagnosis and effective
2649 treatment to keep their asthma in control.

2650 Some may argue that in the case of an asthma attack,
2651 patients need to be able to go to a drugstore or a market and
2652 buy an over-the-counter inhaler like Primatene Mist or other
2653 epinephrine inhaler. Should we recommend, however, that
2654 someone who is having an asthma emergency go to a store to
2655 buy a device rather than calling 9-1-1 or going to an
2656 emergency room or hospital? If patients need unplanned
2657 refills or replacement devices, they can contact their
2658 prescriber or even get those medications prescribed for them
2659 by a physician in an emergency room and then follow up
2660 otherwise.

2661 Another assumption that may prove false is that patients

2662 of low-income need these medications because they are low-
2663 cost. I grew up in an area of the country where there were a
2664 lot of low-income patients, and I certainly was not a child
2665 of means. While the price of Primatene Mist may be lower
2666 than the total cost or co-pay for more effective
2667 bronchodilators, the relief from these epinephrine devices
2668 does not last as long. Thus, the long-term control and long-
2669 term cost is actually higher.

2670 Over-the-counter access to this product may seem to
2671 erase the cost of visiting a prescriber. However, over-the-
2672 counter bronchodilators can promote self-diagnoses, and we
2673 are all subject to those kinds of self-treatment sometimes,
2674 which is particularly unsafe for the symptoms of asthma
2675 because it can be deadly. With proper diagnoses and
2676 treatment, people can control their asthma symptoms, avoiding
2677 high-cost interventions like emergency department visits and
2678 hospitalizations. Cutting out care by a qualified medical
2679 practitioner could be dangerous for the patient and costly to
2680 the healthcare system.

2681 The decision to withdraw Primatene Mist from the U.S.
2682 market was made years ago. Lifting the ban may now lead to
2683 confusion. There will be little opportunity to inform
2684 patients about the nature of the change and to urge them to
2685 seek care from a professional if they think they have asthma.

2686 I have worked with professionals like Dr. Kraft many years of
2687 my life in the industry of healthcare and life sciences,
2688 worked for pharmaceutical companies and other healthcare
2689 organizations. I have also been a volunteer as a volunteer
2690 leader of the Asthma and Allergy Foundation of America, and I
2691 know that asthma is a serious chronic condition, and I know
2692 what a difference effective treatment can make and even as a
2693 child with very few available to me, I was very fortunate.

2694 I urge you, for all asthma patients, to reject an
2695 attempt to re-release an epinephrine inhaler to the market as
2696 an over-the-counter product. Again, I thank all the members
2697 of the committee for inviting me here to testify today.

2698 [The prepared statement of Mr. Ward follows:]

2699 ***** INSERT 8 *****

|

2700 Dr. {Burgess.} I thank the gentleman for his testimony.

2701 Dr. Kerwin, you are recognized for 5 minutes for an

2702 opening statement.

|
2703 ^STATEMENT OF DR. EDWARD KERWIN

2704 } Dr. {Kerwin.} Thank you very much to the Committee and
2705 the Subcommittee for inviting me to testify.

2706 As Congressman Walden explained, I am an allergy
2707 researcher, asthma researcher. I have conducted over 300
2708 clinical trials with over 200 new state-of-the-art medicines
2709 for asthma and I care for 10,000 asthma patients. And I
2710 trained with Monica. I will say that I am a member of the
2711 American Thoracic Society, a fellow of the American College
2712 of Allergy, and the American Academy of Allergy and never
2713 once have those organizations polled me or any of their
2714 general membership on the issue of Primatene.

2715 Now, my comments today briefly--

2716 Dr. {Burgess.} I am sorry, sir. Your microphone
2717 popped. Could you make that statement again? I missed it.

2718 Dr. {Kerwin.} I thought the microphone was on. I
2719 wanted to just state that I am a member of the American
2720 Thoracic Society for the last 10 years, a fellow of the
2721 American College of Allergy, and the American Academy of
2722 Allergy and never once have those organizations polled myself
2723 or any others of the general membership on the issue of
2724 Primatene and the safety of Primatene. So what I will tell

2725 you is these organizations are speaking on behalf of the
2726 administrative doctors working there but not on behalf of the
2727 general membership.

2728 Now, what I want to say is that I think we live in a
2729 difficult era in science and culture. There are major
2730 scientific advances happening all the time, and I will just
2731 say that that is how I spend 90 percent of my time, doing
2732 clinical research with some of the latest, most advanced
2733 medicines for asthma. Science tells us CFCs can be harmful
2734 to the ozone layer and they do need to be removed gradually
2735 over time and that has happened with hairsprays and air
2736 conditions and refrigerators. And I am happy to say that
2737 there are many new HFA medications that are available for
2738 asthma. So science is moving forward. We hope that there
2739 will be an HFA Primatene perhaps within a year.

2740 But I have to say that there are also many issues of
2741 practicalities that critically need to be considered when any
2742 new law is implemented. And science cannot just be
2743 implemented as a blanket process. It has to be implemented
2744 in a rational way.

2745 Asthma, as you have heard, is a disease that strikes in
2746 the middle of the night, and I don't know many private
2747 practice doctors who are going to be available 24/7 if you
2748 suddenly need a prescription medicine. Asthma occurs at your

2749 4th of July picnic and it is going to occur when you visit
2750 your least favorite relatives who have five cats at home.
2751 Asthma may affect your college daughter when she moves into a
2752 basement apartment that has mold in it. It may occur when
2753 you get out and run a 5K or a 10K running race, and it will
2754 hit you when you come to visit me in Oregon where we have
2755 horse farms and hay farms.

2756 What I need to make clear is that despite all of the
2757 science, which I am happy to discuss endlessly, Primatene
2758 Mist is a first aid situation kind of medicine. The reason
2759 it is over-the-counter is that there need to be immediate
2760 access, immediate use medicines available to children,
2761 poverty-stricken patients, elderly people who have acute
2762 airway disease. It is similar to choking where a Heimlich
2763 maneuver is needed. It is similar to a bee sting where
2764 Benadryl can be picked up at any convenience store. We need
2765 regular access to emergency medicines.

2766 Now, the American Thoracic Society and others may say
2767 you can get albuterol HFA but I challenge them that is simply
2768 not true. There are many, many Americans who have no
2769 insurance, they have no doctor, they have no prescriptions.
2770 They cannot simply get albuterol HFA.

2771 The best analogy that comes to my mind is basically a
2772 life vest or a life raft on a ship. We have all seen the

2773 Titanic movie. We know what happens if there are not enough
2774 life vests or life rafts. Now, we have seen the Costa
2775 Concordia ship. The question is should all the life vests be
2776 locked up where only the ship's doctor or the ship's captain
2777 has the key? That simply does not make sense for a medicine
2778 that can be lifesaving for poor people in inner cities.

2779 I am going to end by reading a brief poem. This is a
2780 little over the top but this is the poem engraved on the
2781 bottom of the Statute of Liberty, a little excerpt that says,
2782 ``Give me your tired, your poor, Your huddled masses yearning
2783 to breathe free, The wretched refuse of your teeming shore.
2784 Send these, the homeless, tempest-tost to me, I lift my lamp
2785 beside the golden door!'' Now, what that means really is
2786 that we live in a country where there are many people who
2787 don't have opportunities to see fine and wonderful doctors.
2788 They need some temporary relief medicines. Scientifically,
2789 we are all in favor of HFA over-the-counter medicines, but
2790 there are none.

2791 So I would ask the Committee to consider extending the
2792 use of Primatene. It is the only available rescue medicine
2793 for up to 30 million Americans who don't have healthcare.

2794 Thank you.

2795 [The prepared statement of Dr. Kerwin follows:]

2796 ***** INSERT 9 *****

|
2797 Dr. {Burgess.} The gentleman's time is expired.

2798 We thank all witnesses for their testimony. I am going
2799 to start with myself.

2800 If I was sitting down there, I would complain to the
2801 chairman that we don't have the EPA here and we don't have
2802 the Food and Drug Administration here because really that is
2803 who needs to be at this hearing. And I do want to thank all
2804 of you. I mean this has been difficult for me because I just
2805 simply did not understand what in the hell was going on. You
2806 have got the EPA saying the Montreal Protocol says we have
2807 got to take this stuff off the market. The FDA is saying,
2808 yeah, yeah, we are working on a replacement; we are going to
2809 get to it. But it just wasn't happening and I couldn't get
2810 anyone to answer my questions. Lisa Jackson, Gina McCarthy
2811 were not only dismissive, they were derisive. Dr. Hamburg at
2812 the EPA just simply evaded the question but now I understand.
2813 There is a contingent of people who do not think that
2814 epinephrine belongs as part of the armamentarium for treating
2815 asthma. Okay.

2816 Dr. Kraft, have you talked to the FDA about the
2817 withdrawal of epinephrine as an asthma therapy? I mean it
2818 has been around for 50 years. Presumably it was approved at
2819 some point. So have you provided testimony or documentation

2820 to the FDA on this subject?

2821 Dr. {Kraft.} What I have done is we have been involved
2822 as a society in looking at--

2823 Dr. {Burgess.} So the answer to the question is no, you
2824 have not--

2825 Dr. {Kraft.} No, I have not talked to them directly
2826 other than offline. So you won't find any documented
2827 testimony. One thing I would like to put forth, however--

2828 Dr. {Burgess.} Well, could you provide us those things
2829 that you have sent to them offline? You have communications?

2830 Dr. {Kraft.} And I am just being told the ATS other
2831 than myself personally has commented on the transition
2832 process.

2833 Dr. {Burgess.} Okay, so you will--

2834 Dr. {Kraft.} We can provide that.

2835 Dr. {Burgess.} On the transition process, but I mean
2836 look, if you want a drug withdrawn from the market--and this
2837 happens all the time--I mean you go to the FDA and say we
2838 have post-market surveillance. This stuff is as bad as key
2839 tech. This stuff is as bad as--I forgot what the anti-
2840 inflammatory was--

2841 Dr. {Kraft.} VIOXX.

2842 Dr. {Burgess.} VIOXX. And things happen.

2843 Dr. {Kraft.} Sure.

2844 Dr. {Burgess.} Have you done that?

2845 Dr. {Kraft.} We can provide you with--absolutely. We
2846 have been to the FDA. We have two issues actually if you
2847 permit me to--

2848 Dr. {Burgess.} Well, what did the FDA tell you?

2849 Dr. {Kraft.} --speak. We have issues on--there is a
2850 CFC issue. To be honest, I am here today as a physician
2851 caring for patients. I am really here for the patients'
2852 safety piece because we have been calling for the removal of
2853 inhaled epinephrine well before Montreal Protocol really
2854 became an issue.

2855 Dr. {Burgess.} Right. So that is the issue that you
2856 are coming to discuss today, but the hearing is on the
2857 Montreal Protocol and the CFC prohibition preventing
2858 asthmatic patients--

2859 Dr. {Kraft.} Right.

2860 Dr. {Burgess.} --from having a rescue inhaler.

2861 Dr. {Kraft.} Absolutely. So--

2862 Dr. {Burgess.} And I am speaking to you not just as a
2863 Member of Congress. I am also a physician. I am also an
2864 asthma patient--

2865 Dr. {Kraft.} Right.

2866 Dr. {Burgess.} --and I use over-the-counter epinephrine
2867 multi-dose inhalers and I have for some time. I use them as

2868 part of the rescue phenomenon that we have all heard talked
2869 about, and yeah, okay. I am a doctor. I can go down to the
2870 all-night pharmacy and write my own prescription for
2871 albuterol. But if I get trapped in a situation without an
2872 inhaler, it happened to me in Chicago at an NRCC fundraiser a
2873 few years ago. The hotel put me in a room where somebody had
2874 been smoking. So at 2:00 in the morning, guess what? I
2875 can't breathe. So I got two options. I can stay up the rest
2876 of the night holding onto the chair using the accessory
2877 muscles of respiration and have a sleepless night or I can go
2878 down to the front desk clerk and say where is your nearest
2879 24-hour pharmacy? He says one block over, two blocks up. I
2880 say thank you very much, take my life in my hands, walk
2881 across the streets of Chicago at 2:00 in the morning, but a
2882 rescue inhaler is available to me.

2883 Dr. {Kraft.} Right.

2884 Dr. {Burgess.} And I could do this without being a
2885 physician, just being a regular Joe you can go and get that
2886 but not anymore. And this is the difficulty that I have is
2887 you have the product in the warehouses. If you are really
2888 concerned about CFC, if this is really about the hole in the
2889 ozone, what is going to happen to those canisters? I mean at
2890 some point they degrade to the point where they blow up I
2891 guess. I mean I don't know. I don't know what the lifecycle

2892 is of one of those things. But the CFC is going to go into
2893 the environment. So what are we preventing here? Are we
2894 going to go put them in Yucca Mountain and entomb them in
2895 concrete so that they don't ever get out? I mean I don't
2896 even know how much CFC we are talking about here.

2897 But it is just preposterous that we are having this
2898 argument around CFC, around the propellant under the Montreal
2899 Protocol when really your beef is with epinephrine and we
2900 should have the FDA here and you should be asking them--

2901 Dr. {Kraft.} I agree.

2902 Dr. {Burgess.} --to explain what studies have you done?
2903 Why do you still allow this stuff to be sold? And I would
2904 have some questions for them about that as well. But no one
2905 would answer my questions. Can you understand the
2906 frustration? I have had Lisa Jackson here at this table and
2907 she just looks at me like I am nuts. I have had Gina
2908 McCarthy and she laughs that I am even concerned about this.

2909 Dr. {Kraft.} Um-hum.

2910 Dr. {Burgess.} Margaret Hamburg won't even answer the
2911 question. Can you understand why there is such frustration
2912 with this?

2913 Dr. {Kraft.} I do.

2914 Dr. {Burgess.} And at the same time I am getting these
2915 same letters from constituents, Doc, how come I can't go buy

2916 this stuff anymore? How come you took it away from me? How
2917 come you know better than I do about what is best to treat my
2918 asthma? It is not just breathing through a straw; it is
2919 breathing through a straw that is packed full of cotton. I
2920 mean this--

2921 Dr. {Kraft.} Absolutely.

2922 Dr. {Burgess.} --you know, Mr. Ward. I mean this is a
2923 dreadful set of symptoms to have visited upon someone. You
2924 have got a rescue inhaler. If the issue is that it is not a
2925 satisfactory pharmacologic agent, let us work on getting
2926 albuterol over-the-counter--

2927 Dr. {Kraft.} I agree.

2928 Dr. {Burgess.} --and I will just share with you my
2929 personal preference is CFC is a much better propellant--

2930 Dr. {Kraft.} Right.

2931 Dr. {Burgess.} --than HFA. HFA is for wimps. CFC
2932 delivers the right dose at the right time.

2933 I am going to yield to the ranking member of the
2934 subcommittee.

2935 Dr. {Kraft.} Would I be permitted to answer?

2936 Dr. {Burgess.} Oh, please.

2937 Dr. {Kraft.} Thank you. So I agree with your
2938 frustration. I can understand that. If I were your doc, I
2939 would make sure you had three separate albuterol inhalers. I

2940 would have you put one in your briefcase, I would have you
2941 put on in the glove box of your car, and I would have you put
2942 one in your wife's purse to make sure that you always have
2943 albuterol with you. So that is the first part.

2944 Dr. {Burgess.} I do that, but the best laid plans don't
2945 always work out. And sorry that I wasn't prepared that night
2946 but it happens. It happened on a flight into Dulles where,
2947 you know, I didn't have an inhaler. I had a long cab ride
2948 back. Oh, my lands, I am really in trouble. I asked the
2949 cabdriver, would you stop at a pharmacy and let me pick up a
2950 rescue inhaler so I am not sitting here in the backseat of
2951 your cab suffocating--

2952 Dr. {Kraft.} Right.

2953 Dr. {Burgess.} --and he was happy to accommodate me. I
2954 mean those are real-world situations and they happen all the
2955 time. My wife will likely not carry one in her purse for me,
2956 but I do have one in my glove box. I do have one in my
2957 backpack. I don't carry a briefcase but, yeah, I have got
2958 them scattered all over my life--

2959 Dr. {Kraft.} Okay.

2960 Dr. {Burgess.} --but sometimes I wander away from them.
2961 I will let you respond.

2962 Dr. {Kraft.} Okay, thank you. The other issue is
2963 regard over-the-counter. There actually is a movement going

2964 on to start talking about over-the-counter bronchodilators
2965 that are safe. It is still in the very early stages. It is
2966 somewhat controversial because we are still on the same issue
2967 where we want to make sure that practitioners interact with
2968 their patients to be able to educate them on the principles
2969 of asthma and know what combinations of medications work best
2970 for them.

2971 So I don't know if you are aware of that or not. So I
2972 wanted to just put that forth as something that is in the
2973 works. If we are really focusing on this over-the-counter
2974 piece, I think there is a thoughtful way to consider over-
2975 the-counter medications for asthma that aren't necessarily
2976 Primatene Mist per se.

2977 I am also a critical care physician and I have seen more
2978 patients coming into my intensive care unit with their
2979 Primatene Mist inhaler clutched to their chest with a severe
2980 asthma exacerbation on a ventilator. And I don't see that
2981 when they are on proper therapy. We have seen a much lower
2982 incidence of really severe asthma exacerbations because of
2983 people getting in with their docs, getting on anti-
2984 inflammatory inhalers. Because I worry this reliance on
2985 going down to the drugstore and getting Primatene Mist and
2986 not being on something daily for asthma--because it is about
2987 redness and swelling of the airways is a problem.

2988 Dr. {Burgess.} We need to go to Mr. Rush. I don't want
2989 you to be concerned for my health and safety. I do have an
2990 ADVAIR inhaler and I do use it--

2991 Dr. {Kraft.} Well, I am.

2992 Dr. {Burgess.} --regularly. But there are times when
2993 you need that extra boost.

2994 And I will yield to Mr. Rush, 5 minutes for questions.

2995 Mr. {Rush.} Well, thank you, Mr. Chairman. Mr.
2996 Chairman, I was headed along the same path. I think you
2997 might have inadvertently--didn't mean any harm--mentioned the
2998 fact that you took your life in your hands by walking outside
2999 of a hotel in Chicago and I really take offense to that. But
3000 I have been working on this issue of asthma for quite a while
3001 and it is a real acute concern of mine and it has been and
3002 always will be because it disproportionately impacts my
3003 community. In the year 2000, Congress passed the Asthma
3004 Reduction Act, which incorporated aspects of a bill that I
3005 sponsored into the Children's Health Act of 2000. And it
3006 came along and I still am very much concerned about the issue
3007 of asthma. And I have to say I am somewhat torn but I have
3008 to come down on the side of my constituents.

3009 Mr. Chairman, a month and a half ago I had a pastor at a
3010 church and the person who is one of my--not my key person at
3011 the church--had asthma and I think you might recall I had to

3012 go and bury him. And he was a member of my church and he was
3013 an asthmatic patient and he died of congestive heart failure.
3014 But he was an asthmatic patient also. And his memory keeps
3015 overpowering me and overwhelming me even now. And he was
3016 under a doctor's care. But now, many, many people who are my
3017 constituents, I have one of my long-time staff members is an
3018 asthmatic patient. Every Tuesday she takes half a day off
3019 and this has been going on for years. She goes to the doctor
3020 to get the shots that I have seen her go into crisis
3021 situation on more than one occasion.

3022 And I know that the science and the goodhearted folks--
3023 but I just have to say to Dr. Burgess, I think that this
3024 legislation that you come up with, I don't like the fact that
3025 we have to do this, but I just don't see, given the absence
3026 of any other approach that this Congress can make, I don't
3027 see how we can avoid it. I for one just find that there are
3028 too many of my constituents who don't have access to
3029 healthcare, who don't have a doctor, and who even think it
3030 would take too much time right now if they would be able to
3031 do--they just don't have the wherewithal. They are missing
3032 so many elements keeping them from living productive lives,
3033 and asthma is becoming more and more of an issue. It is
3034 probably one of the leading health issues in my community.

3035 And I hear the arguments but I think that this Primatene

3036 should be allowed back on a temporary basis, understanding
3037 what the problems are with it, what the short-term solution
3038 might mean to other long-term issues--I haven't addressed the
3039 long-term issues. But I don't see the solution to these
3040 issues. I don't see that being eminent and overnight,
3041 reality, because it has to do with access to healthcare. And
3042 this Congress, we have tried to address it but we can't agree
3043 on what access to healthcare really means to the American
3044 people. I know my time is expired. I had some questions but
3045 I just had to get out what I had to say about this particular
3046 issue.

3047 I yield back.

3048 Mr. {Whitfield.} Well, thank you, Mr. Rush.

3049 At this time, I recognize the gentleman from Texas, Mr.
3050 Barton, for 5 minutes.

3051 Mr. {Barton.} Thank you, Mr. Chairman.

3052 When I go to Chicago, which I don't do very often, I
3053 just carry around Bobby Rush-is-my-friend cards and I have
3054 never had a problem on the streets of Chicago. I just show
3055 them that card and they say what can we do for you? They
3056 just couldn't be friendlier.

3057 So when Dr. Burgess indicated he was going to introduce
3058 this bill, I was encouraging of him introducing the bill.
3059 You know, but this goes under the heading of no good deed

3060 goes unpunished because apparently a lot of the people in the
3061 asthmatic community are fairly opposed to his bill.

3062 My first question would be to the panel. Each of you
3063 indicate you support the bill, oppose the bill, or are
3064 neutral on the bill. Just start and go right down the line.

3065 Mr. {Shandell.} Yeah, I definitely support the bill. I
3066 find it ironic that these third parties are now raising
3067 safety issues when this really was an environmental issue.
3068 Primatene Mist has been around for half a century.

3069 Mr. {Barton.} So you support the bill?

3070 Mr. {Shandell.} I support the bill.

3071 Mr. {Barton.} I don't need the editorial right now.

3072 Mr. {Shandell.} I support the bill.

3073 Mr. {Barton.} Okay. Dr. Kraft?

3074 Dr. {Kraft.} I oppose the bill. Am I allowed to say
3075 anything?

3076 Mr. {Barton.} Well, in a minute.

3077 Dr. {Kraft.} Okay.

3078 Mr. {Barton.} Right now, we have got one for and one
3079 against.

3080 Dr. {Kraft.} All right.

3081 Mr. {Barton.} Mr. Ward?

3082 Mr. {Ward.} As a patient, I think I would oppose the
3083 bill--

3084 Mr. {Barton.} Oppose the--

3085 Mr. {Ward.} --as it is currently constructed.

3086 Mr. {Barton.} As it is currently constructed, okay.

3087 And Dr. Kerwin?

3088 Dr. {Kerwin.} And I definitely support the bill--

3089 Mr. {Barton.} Support the bill.

3090 Dr. {Kerwin.} --only alternative out there for people

3091 who don't have a doctor right next to--

3092 Mr. {Barton.} So we are two to two. We have two for
3093 and two against. That is not bad. I mean, you know, that is
3094 a tie. In this committee, the tie goes to the sponsor of the
3095 bill.

3096 So my next question, Primatene Mist, if it were allowed
3097 to be sold over-the-counter, the existing stocks, what would
3098 that cost an individual who just walked in and purchased it?
3099 What would it--

3100 Mr. {Shandell.} I can answer that. So we sell to the
3101 retailers who then mark up, but we will not raise the price
3102 of Primatene. As I said, we will donate all the profits. So
3103 based on the past sales, we are looking at about \$20 at the
3104 retail--

3105 Mr. {Barton.} If it were allowed to be sold, it would
3106 be around \$20?

3107 Mr. {Shandell.} Correct.

3108 Mr. {Barton.} Now, if I don't have it and I have to go
3109 to a doctor and get a prescription, what does that
3110 prescription cost for the equivalent amount of dosages?

3111 Mr. {Shandell.} Well, the prescription itself let us
3112 not forget the doctor's bill but the actual inhaler is \$110.

3113 Mr. {Barton.} Okay, Dr. Kraft, you have got--

3114 Dr. {Kraft.} I would like to respectfully disagree.
3115 Yes, there are places where in fact it is \$120. If you look,
3116 which I just did today, not in Canada, \$30--

3117 Mr. {Barton.} Thirty dollars.

3118 Dr. {Kraft.} --you can find--

3119 Mr. {Barton.} You can get--

3120 Dr. {Kerwin.} Well, I will just have to say that having
3121 practiced allergy and asthma care for 20 years, there is
3122 nowhere in my State of Oregon where you can get albuterol
3123 inhaler HFA for less than \$60 to \$70 a canister.

3124 Mr. {Barton.} All right. So--

3125 Dr. {Kerwin.} So that is the fact--

3126 Mr. {Barton.} We are--

3127 Dr. {Kraft.} Well, I guess I practice in a part of the
3128 country that is a little less--

3129 Mr. {Barton.} We are all in agreement that the
3130 prescription is going to be somewhat more expensive. If you
3131 are an informed consumer like Dr. Kraft, you can get it much

3132 less expensively, but there is nowhere you can get it for the
3133 same price. That is fair?

3134 Now, the next question--which of you a medical doctor,
3135 which of the two doctors? So we have two medical doctors.
3136 This is great because you are on each side of the issue.
3137 What is wrong with allowing the sale of the existing stocks
3138 and use that as an emergency but also have your prescription
3139 where you get the treatment regime that actually seems to be
3140 more effective? What is wrong with that, Dr. Kerwin?

3141 Dr. {Kerwin.} Well, thank you for making that point.
3142 That is exactly the kind of care we think Americans should
3143 get. Like Dr. Burgess does, they should see a doctor, they
3144 should get educated about their asthma, they should reduce
3145 their allergy exposures, they should get anti-inflammatory
3146 inhalers, and they should have access to Primatene just for
3147 emergencies. I live in a rural State. Many patients in
3148 southern Oregon live 50 miles from the nearest doctor. That
3149 is quite common. Certainly, 100 miles from an emergency
3150 room. We believe there is a role for Primatene or
3151 epinephrine or any over-the-counter inhaler. I would support
3152 over-the-counter albuterol but it is not--

3153 Mr. {Barton.} My time is about to expire.

3154 Dr. Kraft, my friends at the Allergy and Asthma Network
3155 Mothers of Asthmatics point out that there is a product

3156 manufactured by Nephron Pharmaceutical that is a handheld
3157 bulb nebulizer. What does that cost? And is that effective?

3158 Dr. {Kraft.} That is epinephrine also is my
3159 understanding and so I do not know the cost of that. But I
3160 would like to comment on your first statement--

3161 Mr. {Barton.} I mean that would take care of the
3162 Montreal Protocol issue I think because it is a handheld. It
3163 doesn't use a CFC.

3164 Dr. {Kraft.} Right. The issue I see is that Primatene
3165 has been around for 50 years, so that is one issue that
3166 people like to bring up. I would argue that 50 years ago we
3167 didn't have a lot of particularly effective asthma therapies.
3168 So that is all there was. Now, we do.

3169 Now, I am also in favor of over-the-counter options for
3170 asthma and that is actually, as I was mentioning earlier,
3171 that is in the works at the FDA.

3172 Mr. {Barton.} Well, it has been in the works for--

3173 Dr. {Kraft.} Well--

3174 Mr. {Barton.} --a number of years.

3175 Dr. {Kraft.} --actually I think there have been
3176 hearings. It is actually heating up quite vigorously and we
3177 are right in there part of it as supportive with thought.

3178 Mr. {Barton.} Well, my time is expired and I appreciate
3179 the chairman's courtesy.

3180 Dr. {Kraft.} Okay.

3181 Mr. {Whitfield.} The gentleman's time is expired.

3182 Mr. {Barton.} I do think Dr. Burgess has a good idea
3183 here. If we can work with the community so it is not two to
3184 two, we may have a bill that actually goes somewhere.

3185 Mr. {Whitfield.} At this time, I will recognize the
3186 gentleman from California, Mr. Waxman, for 5 minutes.

3187 Mr. {Waxman.} Thank you, Mr. Chairman.

3188 Obviously, if you have two on each side, it doesn't
3189 produce a tie; it just means it is a balanced presentation
3190 and that is always a good idea so we hear both sides of the
3191 issue.

3192 But I am going to ask about the health effects of all of
3193 this. Dr. Kraft, you are the president of the American
3194 Thoracic Society and a recognized expert on asthma. And
3195 there is a long list of medical and public health
3196 organizations who have raised concern about the over-the-
3197 counter epinephrine inhalers. In your testimony, you said
3198 epinephrine inhalers like Primatene Mist are not a safe
3199 treatment for asthma and are not recommended by expert
3200 guidelines. Why is that?

3201 Dr. {Kraft.} You are absolutely right. That is true.
3202 The reason is it is the compound itself, the chemical
3203 epinephrine. It is nonselective. So yes, it can

3204 bronchodilate, so that is the good news, but it has effects
3205 on other organs. And the major concern is cardiac, excessive
3206 cardiac stimulation and can lead to myocardial infarction,
3207 heart attack in patients who have heart disease. And that is
3208 really the concern. I am not against over-the-counter
3209 medications for asthma necessarily if done in a thoughtful
3210 way. I think that this particular medication is concerning.
3211 And there have been voices for many years calling for the
3212 removal of this particular agent because of the dangers and
3213 the side effect profile. That is really where we are sort of
3214 coming from today.

3215 Mr. {Barton.} But it is not easy for FDA to take a drug
3216 off the market. Do you know what the standard of proof is?
3217 I assume it is pretty tough.

3218 Dr. {Kraft.} I am sorry. Repeat that question, please.

3219 Mr. {Waxman.} Has FDA tried to take it off the market?
3220 Is it something that FDA should take off the market?

3221 Dr. {Kraft.} You mean Primatene?

3222 Mr. {Waxman.} Yeah.

3223 Dr. {Kraft.} Well, it has been off the market for 6
3224 months because of--

3225 Mr. {Waxman.} But did they ever move to take it off the
3226 market?

3227 Dr. {Kraft.} There have been calls from the American

3228 Medical Association--

3229 Mr. {Waxman.} Um-hum.

3230 Dr. {Kraft.} --to the FDA to consider it. But I think
3231 it is a difficult situation because the question is can we
3232 look at alternatives and can we improve access to care for
3233 patients--

3234 Mr. {Waxman.} Um-hum.

3235 Dr. {Kraft.} --so that they can actually get the right
3236 medications. So I like the idea of having something
3237 available for patients but I would argue let us make it the
3238 best medication and a safe medication.

3239 Mr. {Waxman.} Well, Dr. Kerwin argues in his testimony
3240 that Primatene Mist is necessary for an emergency situation
3241 where someone suffering from asthma does not have a
3242 prescription medication. He says people would die or could
3243 die without it. What do you think in a potentially life-
3244 threatening situation, should asthmatics use Primatene Mist?

3245 Dr. {Kraft.} I have actually seen the ramifications of
3246 using it in an emergency situation and relying upon it to
3247 improve asthma symptoms. And the issues--it is very short-
3248 term in terms of its action and the excessive additional side
3249 effects of the cardiac piece actually, in my opinion, is not
3250 a safe alternative. So I would actually recommend--and we
3251 have done this in the community that I practice--we have the

3252 ability for patients to get albuterol very easily and to have
3253 access to emergency departments and follow up with us so they
3254 can get the medications they need. And we have a big
3255 community program in Durham for this purpose exactly to help
3256 the underserved because I think that is who we are talking
3257 about today, those patients who don't have the access that
3258 perhaps the rest of us do.

3259 Mr. {Waxman.} Well, I take seriously when the health
3260 professionals take a point of view that something is not
3261 safe, particularly if it is--this bill would go to
3262 extraordinary lengths to put it back on the market. It is
3263 not on the market now. If I were convinced, however, that it
3264 is necessary, then I would say fine. Let us keep it out
3265 there. But I don't think we have got to push legislation to
3266 put a product back on the market in the face of such strong
3267 opposition by public health and physician organizations.

3268 Am I correct that public health and physician
3269 organizations take the same point of view you do?

3270 Dr. {Kraft.} Yes, many.

3271 Mr. {Waxman.} Now, I want to go into the question of
3272 how fair this is to the company. The company obviously wants
3273 to sell the product that they still have and they are not
3274 going to pursue it after that. The initial proposal by FDA
3275 was to phase out the drug and it was agreed upon it would be

3276 December 31, 2010. Armstrong submitted comments to FDA
3277 requesting it be extended 1 year, and FDA granted Armstrong's
3278 request for a 1-year extension. Isn't that right, Mr.
3279 Shandell?

3280 Mr. {Shandell.} Yes. I would like to address that
3281 because--

3282 Mr. {Waxman.} Well, I just want your answer because--

3283 Mr. {Shandell.} Yes, that is correct.

3284 Mr. {Waxman.} No, my understanding is that about a
3285 dozen other types of inhalers containing CFCs were phased out
3286 before Primatene Mist. That includes the albuterol phase-out
3287 in 2008 which involved moving millions of asthmatics to new
3288 treatments--

3289 Mr. {Shandell.} Which was our product as well.

3290 Mr. {Waxman.} --only two CFC-based inhalers remain to
3291 be phased out and both are scheduled to be taken off the
3292 market at the end of 2013. So Primatene Mist was actually
3293 phased out several years later than many other types of
3294 inhalers. Would it be fair to them to have you come back on
3295 the market when they--

3296 Mr. {Shandell.} Well, that is what I would like to
3297 address because, you know, this is an environmental issue
3298 regarding CFC. It is not a safety issue because otherwise--

3299 Mr. {Waxman.} Well, this is not a safety question that

3300 I am asking. I am just asking you in basic fairness--

3301 Mr. {Shandell.} Well, yeah, the--

3302 Mr. {Waxman.} --if other companies follow the rules--

3303 Mr. {Shandell.} --fairness question is that we have

3304 been working with FDA since 2007 for HFA Primatene. So

3305 obviously the FDA believes in Primatene because we have spent

3306 tens of millions of dollars on clinical trials and we are

3307 looking to get an approval next year. So obviously--

3308 Mr. {Waxman.} No other company--

3309 Mr. {Shandell.} --new drug applications--

3310 Mr. {Waxman.} --came back and said we are not--

3311 Mr. {Shandell.} And the only reason we are--

3312 Mr. {Waxman.} Excuse me, sir.

3313 Mr. {Shandell.} Yes.

3314 Mr. {Waxman.} I have already exceeded my time but I get

3315 to ask the questions.

3316 Mr. {Shandell.} Sure.

3317 Mr. {Waxman.} And other companies phased out--not other

3318 company was allowed to come back and sell off its remaining

3319 inventory after the phase-out date. Isn't that right?

3320 Mr. {Shandell.} That is correct. No other company is

3321 over-the-counter so there is no--

3322 Mr. {Waxman.} What difference does it makes if it is

3323 over-the-counter or prescription?

3324 Mr. {Shandell.} Because if you don't have a
3325 prescription, you can't afford insurance, you have no choice.

3326 Mr. {Waxman.} That is a different issue but a drug to
3327 be extended and allowed to come back and sell off the--

3328 Mr. {Shandell.} We have a million units remaining--

3329 Mr. {Waxman.} --inventory.

3330 Mr. {Shandell.} We don't need to sell the inventory.

3331 We are advocating on behalf of our customers who have been
3332 complaining saying that people have died actually. So we are
3333 just coming out not for money. We are saying, look, let the
3334 million we sold. We are really interested in getting HFA
3335 approved so there is an over-the-counter. In terms of
3336 fairness, there are two prescriptions that are still not the
3337 market with CFC and nobody has answered why those are allowed
3338 to stay if it is an environmental issue and not a safety
3339 issue.

3340 Mr. {Whitfield.} Gentleman's time is expired.

3341 I will recognize myself for 5 minutes of questions now.

3342 We have a situation here where we have in storage some
3343 Primatene Mist. This legislation relates only to that. This
3344 is a product that has been used 40, 50 years, was accepted by
3345 people who used it and obviously people benefitted from it or
3346 they wouldn't continue to buy it. We have a lot of letters
3347 or emails here from people--`I just spent my last \$200 on my

3348 son at a doctor's appointment for asthma medicine. We will
3349 no longer be able to go to the doctors because Primatene Mist
3350 is gone.' ' We have a lot to that effect. I understand a
3351 genuine concern about, oh, this is not safe for people, and
3352 Dr. Kraft, you have said that this is not a safe treatment.
3353 There are side effects. There are cardiac problems with it.
3354 And now, Dr. Kerwin, would you reply to that comment that Dr.
3355 Kraft made?

3356 Dr. {Kerwin.} Yes, I would be delighted to reply to
3357 that. You know, Primatene was released and approved by the
3358 FDA either in 1957 or 1963, and at that time, the approval
3359 process was less rigorous than it is now. So Primatene has
3360 been what we would call a grandfathered medicine that has
3361 been out for many, many years. Every drug company is
3362 required to collect safety reports if there is any episode
3363 where a drug fails a patient or where they die for any reason
3364 that could be related to the drug. And my understanding is
3365 Amphastar has received no complaints of patients who have had
3366 life-threatening cardiac problems or other what we call
3367 serious adverse events with this medicine. It is truly
3368 unfair to say that it is not a safe drug. That is 100
3369 percent speculative. The way safety is assessed is through a
3370 clinical trial process, and epinephrine in the HFA form is
3371 going through a very careful and rigorous FDA-authorized

3372 safety process.

3373 Mr. {Whitfield.} Thank you. I might--

3374 Dr. {Kerwin.} Safety is roughly parallel. It is
3375 slightly more cardiac stimulating.

3376 Mr. {Whitfield.} I mean I can understand in Durham that
3377 there may be a program developed that really addresses this
3378 emergency need, but there are lots of places in the country
3379 that do not have programs like that. And from my personal
3380 perspective, I don't see what is wrong with giving patients a
3381 choice. If it is available and they want it for a period of
3382 time, why not?

3383 But I would like to yield the balance of my time to Dr.
3384 Burgess.

3385 Dr. {Burgess.} Well, Mr. Chairman, I would just
3386 reiterate the observation that we are here today having this
3387 hearing. The legislation has been introduced essentially
3388 because two federal agencies decline to be truthful with the
3389 Committee. And that is the real tragedy here. Yes, we
3390 should have the EPA here. They should be answering the
3391 question why are there two prescription products that are
3392 continuing to use CFCs still sold, not affected under the
3393 ban? We should hear from the FDA. Have you had post-market
3394 surveillance data on inhaled epinephrine products that lead
3395 you to believe that it is unsafe?

3396 But instead, we have got this mishmash, this backdoor
3397 banning of a product that has been approved for 50 years on
3398 which people depend under the Montreal Protocol. I mean this
3399 really makes no sense. If we are really frightened of the
3400 CFC in those remaining canisters that Mr. Shandell has
3401 secreted away somewhere, I submit that we ought to reopen
3402 Yucca Mountain and take them deep into the Earth and entomb
3403 them in cement like we would radioactive waste.

3404 But those canisters are eventually going to degrade, pop
3405 open, and the CFC floats over the Antarctic and widens the
3406 hole in the ozone. At least that is what we are led to
3407 believe that this small amount of CFC is going to lead to all
3408 sorts of global calamities.

3409 Dr. Kerwin, look, I have been in the ICU when a young
3410 patient has died from an aspirin overdose. I mean that is
3411 tragic, the acidosis that accompanies like 24, 36 hours
3412 later. Everybody thinks the kid is out of the woods and then
3413 he dies. So we know people can die from over-the-counter
3414 products. Yet, people take aspirin all the time for
3415 headaches. Would it make sense that we told people if you
3416 have a headache, you really shouldn't take aspirin anymore.
3417 Come to the emergency room, let us give a CAT scan to make
3418 sure you are not dying of a brain tumor and then we will get
3419 you something. I mean that is kind of what we are saying

3420 here, isn't it?

3421 Dr. {Kerwin.} I would say that the principle of having
3422 medicines available over-the-counter is sort of a twofold
3423 principle. One is America was settled by frontiers people
3424 who came out to many of the big States and they didn't have a
3425 doctor on their Oregon Trail wagon train. So we live in a
3426 country where people have a fundamental right to try to treat
3427 themselves first before they take the radical step of seeing
3428 a doctor. The second thing I would say is medicines over-
3429 the-counter are designed in order to help the many even if
3430 overuse of the medicine or misuse might harm a few. And I
3431 think Tylenol, 20 pills of that can hurt your liver.
3432 Benadryl, 20 pills of that could put you in a car crash, and
3433 yeah, 20 puffs of epinephrine might make your heart race.
3434 But these medicines are consistent with the values that
3435 patients should have a right to treat themselves initially
3436 and they should then seek better medical care.

3437 Dr. {Burgess.} Well, Mr. Chairman, I will just close
3438 with the observation that we should require the two federal
3439 agencies involved--Environmental Protection Agency and the
3440 Food and Drug Administration--to come before this committee
3441 and be honest with us for a change, none of this hide-the-
3442 ball, oh, it is a Montreal Protocol thing. If there is a
3443 danger to inhaled epinephrine, then why the hell has the FDA

3444 not prevented it? We have been through this round and round
3445 with the FDA where they say, oh, we know that something is
3446 dangerous but we can't prevent it being sold. That is
3447 nonsense. That is their job. That is what they are there to
3448 do. If they have post-market surveillance that says inhaled
3449 epinephrine multi-dose inhalers are damaging to people's
3450 health, they owe it to this committee to come here and share
3451 that with us.

3452 Mr. {Whitfield.} At this time, I would like to
3453 recognize the gentleman from Michigan, Mr. Dingell, for 5
3454 minutes.

3455 Mr. {Dingell.} I thank you for your courtesy. And I
3456 would like to ask these questions of Mr. Shandell, yes or no.

3457 It is my understanding that there are 1.2 million units
3458 of Primatene Mist remaining in inventory, is that correct?

3459 Mr. {Shandell.} Yes, approximately.

3460 Mr. {Dingell.} Now, is this remaining inventory being
3461 stored under safe and proper conditions?

3462 Mr. {Shandell.} Yes, it is.

3463 Mr. {Dingell.} You are sure of that?

3464 Mr. {Shandell.} Yes.

3465 Mr. {Dingell.} When will the remaining inventory
3466 expire?

3467 Mr. {Shandell.} It expires at varying times, mostly in

3468 August of 2013.

3469 Mr. {Dingell.} Okay.

3470 Mr. {Shandell.} Starting in January.

3471 Mr. {Dingell.} The remaining inventory has been stored
3472 properly and has not yet expired. Do you know the reason or
3473 do you have reason to believe then that any of the remaining
3474 inventory is unsafe for use by patients?

3475 Mr. {Shandell.} No, we do not. It should be very safe
3476 for patients--

3477 Mr. {Dingell.} Does anybody at the table have any
3478 reason to believe that the storage of the remaining inventory
3479 of Primatene Mist is creating an unsafe product? Yes or no?

3480 Dr. {Kraft.} I just had a question on the expiration.
3481 It is January to August of '13, right?

3482 Mr. {Dingell.} Well, is anybody down there going to sit
3483 there and tell me that this Primatene Mist is going to be
3484 unsafe when it is put on the market if it is so?

3485 Dr. {Kraft.} Based on the way it is stored, sir?

3486 Mr. {Dingell.} Based on any fact. Yes or no. It is a
3487 yes-or-no question. You should have no trouble doing it.

3488 Dr. {Kraft.} Yes. Then I would say yes.

3489 Mr. {Dingell.} You believe it is unsafe?

3490 Dr. {Kraft.} Yes.

3491 Mr. {Dingell.} Why?

3492 Dr. {Kraft.} For the reasons that I stated previously.
3493 It has nothing to do with storage. I think they have been
3494 storing their product--

3495 Mr. {Dingell.} Do you have knowledge of this or is this
3496 supposition?

3497 Dr. {Kraft.} That it is unsafe? I have had personal
3498 experience with patients who have taken it and had severe
3499 asthma--I am talking about safety from a mechanism
3500 perspective.

3501 Mr. {Dingell.} Thank you very much for that unhelpful
3502 response.

3503 Now, according to your testimony, Mr. Shandell, there
3504 have been between 2 and 3 million Primatene Mist users. If
3505 Amphastar is allowed to distribute and sell the remaining
3506 inventory of Primatene Mist, how would your company do so
3507 equitably?

3508 Mr. {Shandell.} Yes, we will do it equitably. We will
3509 not raise the price from what it was previously. We also, as
3510 I have stated, this is for the goodwill of our customers. We
3511 are not looking to make any profit here, so we will actually
3512 donate all the net profits to charity. And I really want to
3513 go back to people are saying that this is an unsafe drug,
3514 then why has the FDA been working with us since 2007 for an
3515 HFA version?

3516 Mr. {Dingell.} May I persist in my questions?

3517 Mr. {Shandell.} Yeah, sure.

3518 Mr. {Dingell.} Is there any reason to fear that
3519 pharmacies may not be willing to restock Primatene Mist for
3520 any reason?

3521 Mr. {Shandell.} There is some concern to that but if it
3522 is as sought after as we believe by our customers, they can
3523 always get it online by CVS.com. There are--

3524 Mr. {Dingell.} So there is the fear that they would
3525 refuse to stock it?

3526 Mr. {Shandell.} No. Well, there is some fear on the
3527 shelf life stocking--

3528 Mr. {Dingell.} Yes or no?

3529 Mr. {Shandell.} Yes. Yes.

3530 Mr. {Dingell.} You have no reason?

3531 Mr. {Shandell.} I have no--

3532 Mr. {Dingell.} You have no fear that the customers
3533 would refuse to stock this if it is put back on the market?

3534 Mr. {Shandell.} I believe that there is a strong demand
3535 for it.

3536 Mr. {Dingell.} All right. Now, in order to assure the
3537 proper education of patients regarding the phase-out of
3538 Primatene Mist, these inhalers were packaged with labeling
3539 noting that Primatene Mist would no longer be available after

3540 December 31, 2011, and encouraged patients to talk to your
3541 doctor or pharmacist about other asthma medicines. How is
3542 your company going to address potential confusion that will
3543 be caused among your patient population when these inhalers
3544 become again available?

3545 Mr. {Shandell.} Yes. This message is on the box. If
3546 we are allowed to sell the remaining inventory, such units
3547 will be moved to our subsidiary. They will be relabeled to
3548 eliminate this statement and then released by quality
3549 assurance.

3550 Mr. {Dingell.} All right. Now, I have another
3551 question. There are two remaining prescription products
3552 containing CFCs that are not being phased out until 2013.
3553 These products are Combivent CFC, which contains albuterol
3554 and ipratropium bromide in combination; and Maxair, which
3555 contains pirbuterol. These two drugs are subject of the
3556 separate rulemaking that was financed on April 14, 2010. It
3557 seems to me that this tells me that FDA and EPA didn't feel
3558 that there was a significant problem with regard to the
3559 carrying medium that they have in your product. Is that
3560 right?

3561 Mr. {Shandell.} Yeah. I have never received clarity as
3562 to why the prescriptions are still out--

3563 Mr. {Dingell.} All right. Thank you. My time has

3564 expired.

3565 Mr. Chairman, your courtesy is much appreciated. I
3566 would ask that the chair would be supportive of me. I am
3567 going to send a letter down to FDA asking a number of
3568 questions. And I am going to ask that the FDA would respond,
3569 and if they are slow, I am going to look to you for your
3570 assistance in seeing to it that they are properly responsive.

3571 Mr. {Whitfield.} Thank you.

3572 Mr. {Dingell.} Thank you, Mr. Chairman.

3573 Mr. {Whitfield.} We would be happy to assist in any way
3574 possible.

3575 At this time, I would like to recognize the gentleman
3576 from New York, Mr. Engel, for 5 minutes.

3577 Mr. {Engel.} Thank you, Mr. Chairman. And I don't
3578 think I will take 5 minutes because I think we have a vote on
3579 the floor, and a lot of the questions have been asked.

3580 But there are a lot of swirling issues here. I am co-
3581 chair of the Asthma and Allergy Caucus and I have worked with
3582 the asthma and allergy advocacy community for many years, and
3583 I have been surprised by their strong opposition to allowing
3584 Primatene Mist to continue to be sold. I signed a letter in
3585 January asking Commissioner Hamburg to allow the remaining
3586 units of Primatene Mist to be sold past the December 31,
3587 2011, deadline.

3588 I mean I think there have been good points on both
3589 sides, but I really want to ask Mr. Shandell. What is in it
3590 for you? Tell me what is in it for you. You are not going
3591 to make a profit on it because you are going to donate
3592 everything to charity. You mentioned your company offered to
3593 distribute all the remaining units as a donation to public
3594 health clinics and the offer was rejected. So if you are not
3595 going to make a profit, why are you fighting so hard to get
3596 another exception--

3597 Mr. {Shandell.} Yes.

3598 Mr. {Engel.} --from FDA and EPA?

3599 Mr. {Shandell.} It is a good question because it is
3600 rare to see corporations not doing something for profit, but
3601 we are a private company in California. We are founded in
3602 science and this is a discontinued product. It is not in our
3603 sales forecast and we could walk away. However, we have
3604 received thousands of complaints from our customers who just
3605 don't understand why they cannot access this. So we really
3606 are advocating on behalf of our customers.

3607 Mr. {Engel.} I think I am going to leave it there, Mr.
3608 Chairman. I do have a bunch of questions but I am concerned
3609 about, you know, the vote. I mean the bottom line is is
3610 epinephrine safe? That is also a question. What do you say
3611 to people like Dr. Kraft who say it is not?

3612 Mr. {Shandell.} Well, see I would love to answer that
3613 because as a company, we receive all of the adverse events,
3614 and if something is significant, we are required to report it
3615 to FDA within 15 days. So I have talked to the departments
3616 that receive these adverse events and people talk about heart
3617 problems. We have never had any adverse event related to
3618 heart. All we have is glass sometimes breaks.

3619 Mr. {Engel.} Let me ask Dr. Kraft because she said
3620 before in her testimony that she feels it is not safe.

3621 Dr. {Kraft.} Right. I would argue that the mechanism
3622 to get the reports depending on when the patient has taken
3623 the medication and what their status is may or may not
3624 actually be filed. And so I worry that there is some
3625 underreporting.

3626 Mr. {Shandell.} After 50 years, nothing?

3627 Dr. {Kraft.} Also, I would like to make another
3628 statement. The company has done two trials to look at the
3629 HFA preparation, which is good. But I was interested that
3630 they didn't have a comparison armed with albuterol. They had
3631 a placebo armed with--do the patients use albuterol in the
3632 placebo arm presumably? Because I thought that would be a
3633 perfect situation to compare albuterol HFA with Primatene.

3634 Mr. {Shandell.} Thank you. Actually, we have submitted
3635 data to the FDA, and as I indicated, we will be submitting

3636 the new drug application in the fourth quarter, and we
3637 actually have evidence that show that albuterol actually
3638 causes more adverse events than our product.

3639 Dr. {Kraft.} And the question is is these are mild
3640 patients. I can tell from clinicaltrials.gov--

3641 Mr. {Shandell.} Correct.

3642 Dr. {Kraft.} --they are mild patients?

3643 Mr. {Shandell.} Correct.

3644 Dr. {Kraft.} So that was one of the concerns I wanted
3645 to bring up. I think in mild asthma a lot of things may work
3646 but what I worry about with having this drug available and
3647 looking at my more severe patients, they are often the ones
3648 who will go and get this medication in lieu of--

3649 Mr. {Shandell.} But it has been available for 50--

3650 Dr. {Kraft.} --medical care.

3651 Mr. {Shandell.} --years, and, you know, to this day
3652 people get good medical care but there are people that don't.
3653 There are people who can't afford it.

3654 Mr. {Engel.} Mr. Ward, let me ask you quickly. If
3655 Primatene Mist is on the market for 13 months and then it is
3656 not, what is the harm? Is there going to be people who are
3657 going to die in 13 months if they--

3658 Dr. {Kraft.} Well, I think it is sort of an ethical
3659 issue. I am not against over-the-counter medication for

3660 asthma, nor is my society. I would like to have a safe and
3661 effective one out there for patients. And so I would
3662 actually think that this work being done at the FDA to put
3663 medications out there over the counter such as albuterol, it
3664 should continue.

3665 Mr. {Shandell.} But the work at FDA, they are working
3666 with us on Primatene for 5 years now.

3667 Dr. {Kraft.} But it is not approved yet.

3668 Mr. {Shandell.} It is not approved yet but we have
3669 great phase three trial data.

3670 Mr. {Engel.} I would love to stay longer but we are
3671 going to miss a vote, Mr. Chairman. So thank you and--

3672 Mr. {Whitfield.} Well, thank you. And that would
3673 conclude today's--

3674 Mr. {Rush.} Mr. Chairman, I just want to reiterate and
3675 restate my call that rather than us moving so quickly to
3676 markup, especially in light of this discussion, that we take
3677 time to invite the FDA and the EPA here so that we can get to
3678 the bottom of some of these outstanding questions that we
3679 have and get some real answers to these questions. And I
3680 want to reiterate my request.

3681 Mr. {Whitfield.} And Mr. Rush has asked unanimous
3682 consent to enter into the record various testimonies from the
3683 International Pharmaceutical Aerosol Consortium, various

3684 health groups, Alliance for Responsible Atmospheric Policy,
3685 and a letter from Teva Pharmaceuticals. And then we also
3686 have letters from the National Association of Chain
3687 Drugstores, the National Community of Pharmacists
3688 Association, EPA, et cetera. So without objection, they will
3689 be entered.

3690 [The information follows:]

3691 ***** INSERT 10 *****

|

3692 [The information follows:]

3693 ***** INSERT 11 *****

|
3694 Mr. {Whitfield.} I want to thank all of you for being
3695 with us today. We appreciate your testimony very much and
3696 your concern about this important issue.

3697 And with that, this hearing is adjourned.

3698 [Whereupon, at 1:45 p.m., the Subcommittee was
3699 adjourned.]