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2 RPTS MEYERS

3 HIF201.030

4 MARKUP ON DISCUSSION DRAFT OF H.R. \_\_\_\_\_, THE ``U.S.

5 AGRICULTURAL SECTOR RELIEF ACT''; AND

6 DISCUSSION DRAFT OF H.R. \_\_\_\_\_, THE ``ASTHMA INHALERS RELIEF

7 ACT OF 2012''

8 THURSDAY, JULY 19, 2012

9 House of Representatives,

10 Subcommittee on Energy and Power

11 Committee on Energy and Commerce

12 Washington, D.C.

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

16 Members present: Representatives Whitfield, Sullivan,  
17 Shimkus, Walden, Terry, Burgess, Bilbray, Scalise, McMorris  
18 Rodgers, Olson, McKinley, Gardner, Pompeo, Griffith, Barton,

19 Upton (ex officio), Rush, Castor, Dingell, Engel, Green,  
20 Capps, Doyle and Waxman (ex officio).

21       Staff present: Nick Abraham, Legislative Clerk; Gary  
22 Andres, Staff Director; Charlotte Baker, Press Secretary;  
23 Mike Bloomquist, General Counsel; Sean Bonyun, Deputy  
24 Communications Director; Anita Bradley, Senior Policy Advisor  
25 to Chairman Emeritus; Maryam Brown, Chief Counsel, Energy and  
26 Power; Allison Busbee, Legislative Clerk; Patrick Currier,  
27 Counsel, Energy and Power; Paul Edattel, Professional Staff  
28 Member, Health; Cory Hicks, Policy Coordinator, Energy and  
29 Power; Peter Kielty, Associate Counsel; Heidi King, Chief  
30 Economist; Ben Lieberman, Counsel, Energy and Power; Mary  
31 Neumayr, Senior Energy Counsel; Katie Novaria, Legislative  
32 Clerk; Charlotte Savercool, Executive Assistant; Michael  
33 Aylward, Democratic Professional Staff Member; Jeff Baran,  
34 Democratic Senior Counsel; Phil Barnett, Democratic Staff  
35 Director; Jen Berenholz, Democratic Chief Clerk; Brian Cohen,  
36 Democratic Oversight Investigations Staff Director and Senior  
37 Policy Advisor; Greg Dotson, Democratic Energy and  
38 Environment Staff Director; Caitlin Haberman, Democratic  
39 Policy Analyst; Karen Lightfoot, Democratic Communications  
40 Director and Senior Policy Advisor; and Matt Siegler,  
41 Democratic Counsel.

|  
42 Mr. {Whitfield.} The committee will come to order.

43 At the conclusion of opening statements yesterday, the  
44 chair called up the Asthma Inhalers Relief Act of 2012, and  
45 the discussion draft was opened for amendment at any point.  
46 And so the question this morning would be, are there any  
47 bipartisan amendments to the discussion draft?

48 So there doesn't appear to be any bipartisan amendments  
49 to the discussion draft. Are there any amendments to the  
50 discussion draft?

51 Mr. {Waxman.} Mr. Chairman.

52 Mr. {Whitfield.} The gentleman from California, for  
53 what purpose does he seek recognition?

54 Mr. {Waxman.} To strike the last word.

55 Mr. {Whitfield.} The gentleman is recognized for 5  
56 minutes.

57 Mr. {Waxman.} I have concerns about the Primatene Mist  
58 bill. Primatene Mist was phased out at the end of 2011 on a  
59 schedule established years ago, and it has been off the  
60 shelves for 6 months. It just seems to me if this were a  
61 drug that did a lot of good and people didn't have another  
62 alternative, I would see the logic in it. But we had  
63 testimony from the Asthma Society and the Thoracic Society,  
64 and they were against the bill. So I took time last night to

65 call a very prestigious allergist specialist in my district,  
66 and he is Dr. Gary Rachelefsky at UCLA. He has been very  
67 active in the national organization. And I said to him, what  
68 do you think about this bill, and his response to me is, he  
69 didn't think that Primatene should be on the market. He said  
70 that it has got a lot of side effects. It has a short-term  
71 impact for an hour or so. But because it is bought off the  
72 shelf, it is cheaper, and so people don't go to see their  
73 doctors, they just buy some Primatene, so they can get the  
74 impact of taking the drug, but then if the asthma comes back,  
75 they take it again, and the consequence of taking this drug  
76 several times can lead to heart attacks and that is why he  
77 and others in the profession think it shouldn't be on the  
78 market.

79 Now, I think the argument that it is over the counter is  
80 an interesting one because it is cheaper but are we going to  
81 take the position that it is okay for people to take a drug  
82 that may be dangerous to them because it is cheaper and that  
83 is the best they can get, or do we think we ought to have a  
84 standard that drugs ought to be effective and safe for the  
85 underlying problem? In other words, I don't see a reason to  
86 bring buy Primatene Mist. It is off the market now. To  
87 bring it back serves a very important purpose for the  
88 manufacturing. They have got some inventory, and they would

89 like to get rid of the inventory, and then they hope that  
90 before the end of the inventory in 90 days they can develop  
91 their new over-the-counter product. Well, I hope they can  
92 develop that and get it approved as quickly as possible.

93         But I had a conversation with a friend of mine who used  
94 to work at the White House, and he said he was contacted by  
95 these people from Primatene and they wanted the executive  
96 branch to give them until May of this year because they said  
97 they will need a couple months. Well, I guess that didn't  
98 work out. So the drug was taken off the market at the end of  
99 this year. It is now July, so it hasn't been on the market  
100 for over six months. And they are asking for 9 months.  
101 Well, I guess if you can get legislation to give you more  
102 time, that is fine. The argument I heard was that the drug  
103 starts deteriorating so after 9 months it wouldn't be  
104 effective at all and they don't want it on the market after 9  
105 months.

106         So if it is not a drug that is essential for people and  
107 may even do them harm--and I am not raising the environmental  
108 issue because I would put the environmental issue aside if it  
109 is a drug that people need. But if it is a drug that people  
110 think they need and it is going to do them harm and there are  
111 alternatives, yes, more expensive, but nevertheless  
112 alternatives that don't have the side effects that could be

113 very serious--heart attacks are considered pretty serious  
114 side effects--then if it weren't for that, I would say go  
115 ahead with it. But I don't understand the rationale for  
116 this, or I have heard the rationale and I just can't accept  
117 it. I like the lobbyist who is lobbying on this bill. He is  
118 a former colleague of ours, and he did a very good job  
119 explaining his client's position. But I just can't accept  
120 that this is a thing we ought to do and therefore I am going  
121 to oppose the bill.

122 Mr. {Green.} Will the gentleman yield?

123 Mr. {Waxman.} Yes, I would be happy to yield.

124 Mr. {Green.} Thank you for the last 20 seconds.

125 I basically agree with you, but I think a number of us--  
126 I have actual constituents who literally bought up as much as  
127 they could of Primatene Mist and they have one bottle left,  
128 and there is nothing available to them now that they know of,  
129 and I think that is why some of us want to see the  
130 legislation move forward to say okay, let us see what the  
131 alternatives. But I appreciate the time.

132 Mr. {Waxman.} Well, I would rather hear what the  
133 doctors and medical professionals have to say than patients  
134 who think that they ought to have this because that is not  
135 persuasive to me if they want to have something they think  
136 will help them and can in fact harm them.

137 If the chairman will allow, I will yield to--

138 Mr. {Whitfield.} The gentleman's time is expired. We  
139 will come back and give you an opportunity.

140 The gentleman from Texas, for what purpose do you seek  
141 recognition?

142 Dr. {Burgess.} Move to strike the requisite number of  
143 words.

144 Mr. {Whitfield.} The gentleman is recognized for 5  
145 minutes.

146 Dr. {Burgess.} Well, I wanted to give Mr. Waxman an  
147 opportunity to hear from a colleague, a doctor, an asthma  
148 patient.

149 Look, I don't know why we have been involved in this  
150 elaborate game of hide the ball by the Environmental  
151 Protection Agency, by the Food and Drug Administration and  
152 yes, by the White House. I have asked both agencies and the  
153 executive branch to come in to explain, and I have gotten  
154 nothing. You have seen the hearings that we have had. You  
155 have seen Lisa Jackson just simply ignore me. You have seen  
156 Gina McCarthy burst into derisive laughter when I bring this  
157 point up. I mean, what in the heck is going on here? And  
158 now we are being told, well, it really wasn't so much the  
159 CFC, it is because it is a dangerous drug. What do you mean,  
160 it is a dangerous drug? It has been on the market over the

161 counter for 50 years since I was a child. I have used this  
162 drug probably every year for the last 50 years.

163 This is a multi-dose inhaler that is available to your  
164 constituents if they get into a tight spot in the middle of  
165 the night. No one is recommending that asthma patients just  
166 simply self-medicate and not see their physicians, but for  
167 crying out loud, when one of these attacks happen, you don't  
168 have any idea that it is coming. I had to fly into Dulles  
169 one night because for whatever reason I couldn't get into  
170 Reagan, and smoker in the car before me, I don't know, but I  
171 got tight on the way back to D.C. It is, what, a 45-, 50-  
172 minute ride. I was able to ask the driver to pull off the  
173 freeway and find a pharmacy and I can just walk in and buy an  
174 over-the-counter inhaler. Problem solved. If I had had to  
175 sit in that car all the way back to D.C., I would have said  
176 you are going to have to take me to Bethesda because I can't  
177 breathe.

178 Now, why do we do that to people? Well, I would like to  
179 know. I would have liked it if Gina McCarthy, I would have  
180 liked it if Dr. Hamburg when I asked her when she was here at  
181 our witness table, had told me something. Maybe Dr. Hamburg  
182 could have said you know, Dr. Burgess, we really looked at  
183 this and we think epinephrine is a dangerous drug and we are  
184 not going to allow it to be sold in any form in the future.

185 Well, okay, that is a conversation worth having, but we  
186 didn't have it. I was told by Dr. Hamburg that well, it is  
187 the new application in the process. I don't even see why it  
188 has to be a drug new application. We are only talking about  
189 the propellant. CFC is a much superior propellant to HFA if  
190 anyone is interested. As somewhat of a connoisseur of  
191 inhaled propellants, I will tell you CFC is far better. I  
192 accept the premise that we are trying to move away from CFCs  
193 but we are not talking about putting this back on the market  
194 indefinitely, we are talking about allowing the company that  
195 has these products in the warehouse to allow them to get into  
196 the hands of asthma patients until their expiration date.  
197 That is not a big ask.

198 I don't know why the Food and Drug Administration has  
199 taken so long approving the non-CFC over-the-counter  
200 epinephrine inhaler. They wouldn't answer my question. I  
201 don't know why Administrator Lisa Jackson will not give us a  
202 waiver to sell what is left. To tell you the truth, I was  
203 not lobbied by the lobbyist. They came and contacted me  
204 afterwards and said all right, we agree with you, but that  
205 wasn't the reason that I brought this up. I brought this up  
206 because this is what people don't understand about the  
207 federal government. Why do they do stuff like this to  
208 people? Why do they take away your toilet, your light bulb

209 and now your asthma inhaler when there is not a good reason?  
210 It is simply a whim of someone who happens to be sitting in  
211 the Speaker's office at some point and they say we want to do  
212 away with this inhaler. Why? Why? If you can produce  
213 scientific evidence--when I first came to Congress, there was  
214 a big brouhaha over Vioxx. You don't see Vioxx on the shelf  
215 anymore, prescription or non-prescription, and there is a  
216 reason for that, because the FDA withdrew the application.  
217 Is the FDA in the process of removing the availability of any  
218 type of over-the-counter epinephrine product? They haven't  
219 told us if they are. Maybe they ought to tell the  
220 manufacturer that is working hard to get this drug approved  
221 that under no circumstances are we going to approve an  
222 inhaled epinephrine product.

223         This makes no sense. And again, this is why Congress  
224 has a single-digit approval rating because we will do this  
225 stuff like this for no good reason. The political folks in  
226 charge at the agencies see no reason to bother explaining why  
227 they are doing it, and at the end of the day, the poor guy or  
228 lady that shows up at the pharmacy now at 3 o'clock in the  
229 morning, hey, I used to be able to buy one of these deals,  
230 they used to be right over here by the Snickers bars, they're  
231 not there anymore. But as long as we are talking about  
232 things by the Snicker bars, if you want to buy postcoital

233 contraception, yeah, it is right out front with the Tootsie  
234 Rolls. What is going on here? We shouldn't make political  
235 statements with people's ability to access safe medicines  
236 that they have availability to for years and years. The only  
237 way I was able to get any movement out of the agencies or the  
238 White House was to actually get this bill, and I thank the  
239 chairman for allowing it to come up before a markup.

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

241 Dr. {Burgess.} We have done more in the last week on  
242 this issue than we have in the last 3 years, so I thank the  
243 chairman and I yield back.

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

245 The chair recognizes the gentlelady from Florida, Ms.  
246 Castor, for 5 minutes.

247 Ms. {Castor.} Thank you, Mr. Chairman, and Mr. Chairman  
248 and colleagues, I think I have a little bit of good news but  
249 the committee would probably need to investigate it further.

250 I was contacted by a Florida company yesterday, Nephron  
251 Pharmaceuticals Corporation, the CEO, Lou Kennedy, and I  
252 suggested she send a letter to all the committee members, so  
253 this may have arrived in your offices as well, and what they  
254 have informed me is that ``Nephron Pharmaceuticals will be  
255 bringing to market an over-the-counter alternative to  
256 Primatene Mist. It will be known as Asthmanefrin.'' Nephron

257 is a Florida-based company in the Orlando area that  
258 specializes in manufacturing inhalation respiratory solutions  
259 and they have in the past in other products manufactured over  
260 a billion doses of lifesaving medication just over the past 2  
261 years. Asthmanefrin will provide temporary relief of  
262 bronchial asthma and will not contain CFCs. The product is  
263 going to be on the shelves in Walmarts and CVS drugstores in  
264 August. And then it will be introduced to other retail and  
265 drugstores by the end of the year. There will be I think  
266 committee investigation maybe. This does have the  
267 epinephrine in it that a lot of the medical community does  
268 not like, but now it does appear that there is a CFC-free  
269 over-the-counter option that will be made available shortly,  
270 and this could be a solution. They write that ``Asthmanefrin  
271 will not only provide treatment to those with bronchial  
272 asthma but will meet the EPA guidelines regarding ozone-  
273 depleting materials. It is preservative- and sulfite-free  
274 and will allow that those that self-medicate to purchase at a  
275 cost-effective price. I understand the market's need for an  
276 over-the-counter medication for the treatment of bronchial  
277 asthma, and I would like you to understand that my company is  
278 providing a solution to this problem.''

279         So I will ask unanimous consent that the correspondence  
280 from Lou Kennedy, Chief Executive Officer of Nephron

281    Pharmaceuticals, be entered into the record, and I will yield  
282    the balance of my time to Ranking Member Waxman.

283            [The information follows:]

284    \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
285 Mr. {Whitfield.} Without objection.

286 Dr. {Burgess.} I would like to see the information.

287 Mr. {Waxman.} Mr. Chairman and my colleagues, this  
288 particular company, as did all the companies involved in this  
289 area, knew since 2008 that they had to look for an  
290 alternative to the CFC that was being used, and all these  
291 different companies that make these inhalants made their move  
292 and made their investments to comply with the law. The  
293 company that makes Primatene knew they were going to have to  
294 phase out as well, and they asked for another year. In 2010,  
295 they asked for another year so they got another year until  
296 2011, and they still didn't have their alternative.

297 Now, is it fair to all the companies that did what they  
298 should be doing or this company in Florida that is making a  
299 product to see one other company that didn't comply with the  
300 law get special treatment?

301 I want to respond to Mr. Burgess. He is worried about  
302 hearing from FDA. FDA had to make a decision whether it was  
303 essential to have this drug, and they decided it is no  
304 essential to have Primatene Mist on the shelves. But if you  
305 want to know the scientific view, I think you ought to be  
306 more persuaded by the host of medical organizations that  
307 oppose this bill: the American Thoracic Society, the

308 American Lung Association, Mothers of Asthmatics. Those are  
309 people who work day in and day out with people who have  
310 asthma and they don't want this Primatene product to be back  
311 on the market. It is not on the market. They don't want it  
312 back on the market. They think that the new drugs that are  
313 complying with the CFC laws are not just complying with that  
314 environmental requirement but are making better products and  
315 they don't want people to self-medicate. Dr. Burgess can  
316 self-medicate. He knows a lot about what is going on. But  
317 someone else who hasn't seen a doctor, really doesn't know  
318 what is happening, they may think this drug is going to help  
319 them when in fact it is going to hurt them, and that is just  
320 to me a reason why we shouldn't now go and put a drug back on  
321 the market to help the manufacturer sell off their remaining  
322 inventory.

323 I thank the gentlelady for yielding to me.

324 Mr. {Whitfield.} Thank you for bringing that to our  
325 attention.

326 Does anyone else seek recognition to speak on this? The  
327 gentleman from Texas, Mr. Barton, is recognized for 5  
328 minutes.

329 Mr. {Barton.} Mr. Chairman, I just want to point out  
330 that we have got two issues here, like we said yesterday.  
331 You have got the medical issues of the efficaciousness of the

332 Primatene Mist and then you have the environmental issue of  
333 the propellant, and bottom line, all Dr. Burgess is trying to  
334 do is say this is a product that has been on the market for  
335 40 or 50 years. He is not aware and I am not aware of  
336 anybody who has been harmed by purchasing and using this  
337 product over the counter. Let that product that has already  
338 been manufactured according to FDA guidelines be consumed if  
339 consumers wish to purchase it over the counter.

340       It is an attack on any of the new drugs. It is not an  
341 attack on any of the new propellants. It is a consumer  
342 choice issue, and as was pointed out in answer to my  
343 question, if it allowed to be sold, it is in all probability  
344 substantially less expensive than any of the alternatives or  
345 replacements.

346       And with that, I will yield to Dr. Burgess such time as  
347 he wishes to consume.

348       Dr. {Burgess.} I thank the gentleman from Texas, and I  
349 thank the gentlelady from Florida for bringing the Nephron  
350 Pharmaceuticals Corporation letter to our attention. I do  
351 need to point out that it is not signed, and maybe we would  
352 be able to get it signed by the Chief Executive Officer.

353       But this letter makes my point. They are going to be  
354 marketing an epinephrine-containing multi-dose inhaler for  
355 the treatment of asthma with a compound that will be for sale

356 over the counter. Now, all this bill is doing is providing a  
357 bridge. Nephron has not yet gotten the okay to sell their  
358 product. There is going to be a gap in therapy options for  
359 asthmatic patients. All we are doing today is saying no one  
360 is going to manufacture new CFC-containing product. The  
361 product is in the warehouses and eventually those little  
362 canisters I guess will pop open and the CFC will go off into  
363 the environment without having done an asthmatic one bit of  
364 good. But rather than just letting those products degrade,  
365 until we have a suitable alternative, let us allow the  
366 company to continue to distribute the product that it already  
367 has, and the company spokesman that we heard from yesterday  
368 graciously said, ``And we will donate all of this money to  
369 whatever charity you want us to.'' I mean, they were pretty  
370 forthright about they were not here yesterday talking about  
371 trying to market a product before its availability to be sold  
372 was gone; they were simply trying to provide that bridge.

373       The company that was here yesterday wants to make a new  
374 inhaled epinephrine product. Nephron wants to make a new  
375 inhaled epinephrine product. If there is going to be a  
376 problem with inhaled epinephrine products, we will have to  
377 deal with the FDA. But this bill today provides a bridge for  
378 your asthmatic patients back in your home districts, and  
379 although we did hear testimony yesterday from a medical

380 doctor who said she didn't like patients self-medicating. We  
381 heard from another medical doctor who said that he actually  
382 disagreed with the position taken by the elites of the  
383 American Thoracic Society. The rank and file actually  
384 thought that inhaled epinephrine was good to have available  
385 to patients, so we had a duplicity of opinions heard on the  
386 witness stand yesterday.

387 All we are asking for is for this company to be able to  
388 sell a product that it already has. We are not asking for  
389 relief that they be able to make any CFC-containing product.  
390 What we are asking for is relief for the asthma patient who  
391 right now is going to find themselves running out of the  
392 inhalers that they bought on December 31st. It was  
393 impossible to store enough of them. Yes, you could move your  
394 100-watt light bulbs over a little bit and stack a few of  
395 those canisters in the shelf but no one could buy enough to  
396 last indefinitely, and that we are going to see patients run  
397 out of that product and they need to have an alternative.

398 Nephron is likely to be a good alternative but how many  
399 months away is it? We have already heard testimony when we  
400 reauthorized the Food and Drug Administration user fee that  
401 it takes them a long time to get things through the pipeline.

402 Mr. {Waxman.} Will the gentleman yield for a question?

403 Dr. {Burgess.} Yes, I will be happy to yield.

404 Mr. {Waxman.} There are alternatives on the market now.  
405 I heard the argument that they would have to get a doctor's  
406 prescription so it costs more, but it isn't that there aren't  
407 alternatives, and the Thoracic Society and the Asthma--

408 Dr. {Burgess.} Well, reclaiming my time--

409 Mr. {Waxman.} --said they were satisfied with those  
410 alternatives.

411 Dr. {Burgess.} Reclaiming my time. Those are  
412 alternatives. There is a compound called albuterol. I have  
413 albuterol inhalers. They have a propellant called HFA. I am  
414 not sure what the acronym stands for. I will tell you it is  
415 not as good as CFC, but okay, I will accept the fact that for  
416 the good of the global community and the hole in the ozone  
417 layer that I am going to have to put up with a less  
418 efficacious propellant.

419 The problem with albuterol inhalers is, they are not for  
420 sale over the counter. Now, maybe the Food and Drug  
421 Administration needs to look at the ability to sell HFA  
422 albuterol inhalers over the counter but right now you do not  
423 have that option.

424 A Primatene Mist inhaler on December 31st in  
425 Lewisville, Texas, cost about 16 bucks. I know because I  
426 bought 10 of them. An albuterol is a prescription item and  
427 notwithstanding the physician's fees and the clinic fees to

428 go get the prescription, it is between \$55 and \$65. So there  
429 is a significant cost differential just on the product but  
430 you also have to factor in the fact that you have to go see a  
431 trained professional and get them to write the prescription,  
432 which means it is not available if you get caught some night  
433 and you haven't got an inhaler handy or a prescription handy.  
434 That is the issue here.

435 I thank the gentleman from Texas and I will yield back.

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

437 At this time I will recognized the gentleman from  
438 Pennsylvania, Mr. Doyle, for 5 minutes.

439 Mr. {Doyle.} Thank you, Mr. Chairman. I find the whole  
440 discussion somewhat frustrating.

441 Mr. Chairman, was the FDA and the EPA invited to our  
442 hearing?

443 Mr. {Whitfield.} The EPA was invited to our hearing,  
444 and they did submit testimony, and we have that testimony in  
445 the record.

446 Mr. {Doyle.} And the FDA?

447 Mr. {Whitfield.} The FDA was not invited.

448 Mr. {Doyle.} I mean, Mr. Barton talked about there is  
449 two issues here. There is an environmental issue and there  
450 is a health safety issue. Mr. Waxman expressed concern after  
451 talking to some of the doctors or people in the field that he

452 knows that epinephrine isn't a safe drug. But here we have a  
453 letter from Nephron Pharmaceuticals dated today, or dated  
454 yesterday, basically saying that they are going to have this  
455 epinephrine on the market in August.

456         So what is frustrating to me is, if the FDA thinks this  
457 is a dangerous drug, how is Nephron Pharmaceutical putting  
458 this on Walmart and CVS counters in less than a month? This  
459 is the middle of July, and if I am reading this letter  
460 correctly, in a couple of weeks this is over the counter in  
461 drugstores and in the rest of the retail markets by the end  
462 of the year.

463         So, you know, we had this one discussion whether or not  
464 epinephrine is a safe drug to take, and by voting for this  
465 somehow we are putting people at risk when the agency that is  
466 charged with protecting us and our constituents seems to me  
467 has just approved another epinephrine drug to go on to the  
468 shelves in a couple of weeks.

469         I have been here long enough to watch experts sit in  
470 front of us and say completely different things about the  
471 same subject, and not being a doctor myself, you know, one  
472 has to wonder which one you want to believe but I would like  
473 to believe that the Food and Drug Administration is the  
474 agency that I count on to protect my constituents, and  
475 apparently they see epinephrine differently than some doctors

476 do because they have just approved another epinephrine drug  
477 to hit the markets in a couple of weeks. So that is issue  
478 number one. The environmental part of it, I think we all  
479 get. CFCs, they are gone. There is a couple left here in  
480 this Primatene Mist but we know that is not going to be done  
481 in the future. That is on its way out, and Primatene Mist  
482 has got an application in front of the FDA for an HFA  
483 dispenser for the drug, and I don't know where that is in the  
484 process but I have heard nothing from the FDA to suggest that  
485 this is dangerous and should be taken off the market. I  
486 would vote against this in 2 seconds if I thought it was  
487 dangerous. But it sure would have been nice to hear  
488 something from the FDA. I mean, they know what is going on  
489 in this committee. You know, this is a subcommittee markup.  
490 If between subcommittee and full committee the FDA contacts  
491 this member or anyone else on this committee and says hold  
492 up, guys, we are not going to approve this epinephrine  
493 anymore, we think it is a danger to you constituents, I  
494 guarantee you, it is not getting out of the full committee  
495 markup because a lot of us aren't going to take a vote like  
496 that.

497 But I think, you know, you hear these arguments about it  
498 is dangerous and now we hear well, the FDA doesn't think it  
499 is dangerous and then it is like well, they knew they weren't

500 going to be able to use CFCs anymore, and I don't know at  
501 what point they stopped production or any of that, but if  
502 there is going to be a gap, you know, if there is going to be  
503 a gap in people's ability to access it, then I think that it  
504 is not unreasonable to address the gap.

505         Now, I don't know how soon. I mean, if this is coming  
506 on the market in two or three weeks, maybe there isn't a gap,  
507 but let us get past this idea that we are voting to put  
508 something dangerous--I mean, I don't think there is a member  
509 on this committee that wants to approve any dangerous  
510 medicine to their constituents, and if it is, I am asking the  
511 FDA--I hope they are tuned into this hearing--to tell us  
512 before the full committee markup whether they have concerns  
513 about epinephrine and whether or not they are going to  
514 approve any more epinephrine drugs for the treatment of  
515 asthma. I am not a physician. I don't know.

516         Mr. {Waxman.} Will the gentleman yield?

517         Mr. {Doyle.} And I would appreciate hearing that.

518         Mr. {Waxman.} I think you made an excellent point and  
519 it really raises a serious question in our minds: is it  
520 epinephrine that is a problem or is it the Primatene which  
521 was sort of a grandfathered-in drug and therefore didn't  
522 stand the scrutiny of FDA? I think we could pass the bill  
523 out of subcommittee, but before we take it up in full

524 committee, perhaps the chair would say we will bring in FDA  
525 and let them tell us what the situation is.

526 Mr. {Doyle.} I think that is reasonable.

527 Mr. {Waxman.} It would be important, useful  
528 information.

529 Mr. {Whitfield.} The gentleman's time has expired.

530 Mr. {Doyle.} Thank you, Mr. Chairman.

531 Mr. {Whitfield.} The chair will recognize himself for 5  
532 minutes.

533 While we did not invite FDA here as a witness per se, we  
534 have had conversations with them, and as Mr. Doyle has  
535 indicated, there is no indication by FDA that there is any  
536 sort of movement being made to ban epinephrine from the  
537 marketplace.

538 Many people, all of us know people who have asthma. I  
539 have many people in my family who have asthma. They use this  
540 Primatene Mist primarily as a security blanket in case of  
541 emergencies. So we are talking about one company that has  
542 like a million units in storage. If this bill passes, they  
543 will be able to get that to the marketplace. They are not  
544 going to make any profit out of it. They are going to  
545 contribute it to charity. Once that supply is gone, it is  
546 over with. And I am delighted that Ms. Castor brought to our  
547 attention this company in Florida that is coming up with a

548 non-prescription substitute and she said in August it will be  
549 in some Walmarts, some CVS, and by the first of the year  
550 2013, hopefully it will be distributed nationwide.

551 So I don't think--

552 Mr. {Waxman.} Will the chairman yield for a question?

553 Mr. {Whitfield.} I would be happy to yield.

554 Mr. {Waxman.} I understand your thinking on this issue  
555 but FDA can enlighten us on what their scientific view is  
556 because if epinephrine is not a problem and they are going to  
557 approve new epinephrine products, why won't they let  
558 Primatene stay on the market? That is a real legitimate  
559 question.

560 Second question is, I want to know if people go out and  
561 buy Primatene because in 9 months it may not be available,  
562 the company's representative told me that the reason they  
563 selected is that after 9 months the product is no longer  
564 effective. Well, what about those people who run out and buy  
565 it and they save it for several months and then use it after  
566 that 9-month period? What is the impact of that? I think a  
567 lot of people will want to know. Those are the kinds of  
568 questions that I think we could ask FDA. I don't think it  
569 would be all that burdensome to have a hearing with FDA's  
570 representative to give us this information so we could all  
571 know what to say to our constituents, not just to vote on

572 this bill but they may ask us these questions.

573 So I underscore the request and--

574 Mr. {Whitfield.} I would reclaim my time and simply say  
575 it has been on the market for 40 years. There has been no  
576 indication that there is anything dangerous--

577 Mr. {Waxman.} Mr. Chairman, how can you say that when  
578 the Asthma Society, the Thoracic Society says there is  
579 dangerous? I heard Mr. Barton say he has never heard of  
580 anybody who had a problem. Obviously people in the field who  
581 are specialists in this area have seen problems.

582 Mr. {Whitfield.} Well, if you remember, when the other  
583 physician who was here testifying in support of this asked  
584 her for scientific evidence, she said there was no scientific  
585 evidence for her position, I mean, it is her experience. And  
586 she indicated they have a pilot program in Durham, North  
587 Carolina, to distribute this material on a non-prescription  
588 basis at times.

589 I am going to yield back the balance of my time. Is  
590 there anyone on this side of the aisle--

591 Mr. {Rush.} Mr. Chairman.

592 Mr. {Whitfield.} For what purpose does the gentleman  
593 seek recognition?

594 Mr. {Rush.} I ask to strike the last word.

595 Mr. {Whitfield.} The gentleman is recognized for 5

596 minutes.

597           Mr. {Rush.} Mr. Chairman, I have been listening to both  
598 sides of the debate, and I must say that both sides have some  
599 legitimate points that are well taken, but I would venture to  
600 say that I probably have more or as many, if not more,  
601 certainly as many asthmatics in my district than any other  
602 district in the nation, and I am not going to decide my  
603 position on this vote, how I vote for this based on the  
604 scientific issues that address broad-based on the safety  
605 issues that have been addressed, although I believe that both  
606 of those issues are cogent issues and they are issues that we  
607 certainly need to consider as we move forward. I in fact  
608 would like to ask the FDA some questions regarding the safety  
609 of epinephrine and other questions that I might have.

610           But to me, it is not a question of science or safety but  
611 of survival. In a perfect world, all citizens would have  
612 equal access to professional medical care, in a perfect  
613 world, but I am here to say that the world that I represent  
614 is not a perfect world. Access to professional care is a  
615 dire need, a necessity. It is a gaping hole in getting  
616 access to professional medical care for many of those in my  
617 district, far too many. As a matter of fact, my State  
618 legislature in order to balance the budget in the State of  
619 Illinois cut \$1.9 billion out of the Medicaid program. Now,

620 that is on top of the inequities, the lack of access that we  
621 already face. Primatene might not be--I know listening to  
622 the testimony on both sides, it is not a permanent solution,  
623 but right now, I am looking for immediate survival.

624         This bill is not a perfect bill and I would like to ask  
625 the chair whether or not he is open to friendly amendments to  
626 this bill before we reach the full committee because I would  
627 like to amend the bill with something I think would be more  
628 compatible and provide at least a level of comfort to myself  
629 as we move forward.

630         So Mr. Chairman, I would like to ask the proponent of  
631 the bill whether or not he is amenable to working with my  
632 staff to come up with some ideas that I might have that would  
633 help make this bill more palatable.

634         Mr. {Whitfield.} Well, I am not going to speak for Dr.  
635 Burgess, but we certainly would work with the gentleman and  
636 the gentleman would have ever opportunity at full committee  
637 to offer an amendment, but since you directed the question to  
638 Dr. Burgess, Dr. Burgess, would you be willing to work with  
639 Mr. Rush to consider his concerns?

640         Dr. {Burgess.} Sure. The lines of communication are  
641 always open. But I would just point out that we have been  
642 trying for well over a year to get the attention of the  
643 federal agencies on this issue. We tried to get some

644 activity before the ban actually went into effect on January  
645 1st and I got stonewalled by both the Food and Drug  
646 Administration and the Environmental Protection Agency and  
647 the health czar down at the White House when I asked for  
648 direct help, direct intervention by the President of the  
649 United States. So I am not willing to delay the vote on this  
650 bill in subcommittee today but I do recognize there is time  
651 between the subcommittee and the full committee markup and  
652 obviously the gentleman knows--

653 Mr. {Rush.} Mr. Chairman, my time is running up. I  
654 just want to say that, you know, I feel as though during this  
655 whole entire process that me and my staff, we have been  
656 stonewalled by not only the FDA, have had no communication  
657 with your staff nor have we had any communication with the  
658 manufacturer of Primatene or anybody else regarding this  
659 particular issue. But I would just respectfully request that  
660 you be open to ideas that we might have that would help make  
661 this bill better before the full committee.

662 Mr. {Whitfield.} Well, the gentleman's time is expired,  
663 and I certainly would commit that our staff on the  
664 subcommittee and full committee would be happy to sit down  
665 with your staff to listen to suggestions that you might make  
666 and work from there.

667 If there is no further discussion, I would like to have

668 a vote on this bill and I would ask all those in favor of  
669 reporting the bill out of subcommittee would signify by  
670 saying aye.

671 All those opposed, no.

672 The ayes have it and the discussion draft is favorably  
673 reported.

|

674 H.R. \_\_\_\_\_

675           Mr. {Whitfield.} The chair now would call up the U.S.  
676 Agricultural Sector Relief Act of 2012 and ask the clerk to  
677 report.

678           The {Clerk.} Discussion draft to ensure the viability  
679 and the competitiveness of the United States agricultural  
680 sector.

681           [H.R. \_\_\_\_\_ follows:]

682 \*\*\*\*\* INSERT 1 \*\*\*\*\*

|  
683           Mr. {Whitfield.} Without objection, the first reading  
684 of the discussion draft is dispensed with and it will be open  
685 for amendment at any point. So ordered.

686           Are there any bipartisan amendments to the discussion  
687 draft? Are there any amendments to the discussion draft?

688           Mr. {Terry.} Mr. Chairman.

689           Mr. {Whitfield.} Would the clerk dispense, disburse,  
690 give out--

691           The {Clerk.} Mr. Terry, could we have the number of  
692 your amendment, please?

693           Mr. {Whitfield.} It is 003.

694           [The amendment follows:]

695 \*\*\*\*\* INSERT 2 \*\*\*\*\*

|  
696 Mr. {Whitfield.} The gentleman is recognized for 5  
697 minutes to explain his amendment.

698 Mr. {Terry.} Thank you, Mr. Chairman.

699 The purpose of the U.S. Agricultural Sector Relief Act  
700 is to provide relief for American farmers who still continue  
701 to have a need for methyl bromide for certain critical  
702 issues. The central issue for American farmers is that for  
703 certain uses like cultivation of strawberries or tomatoes or  
704 peppers or eggplant or flowers or at food storage facilities,  
705 there are not effective alternatives to methyl bromide. The  
706 development of viable alternatives takes significant time and  
707 research.

708 In the past, the United States has sought critical-use  
709 exemptions to conduct research. Researchers use methyl  
710 bromide to test their trials for comparison against  
711 alternative fumigant and to test emission-reduction  
712 methodologies. The USDA's National Institute for Food and  
713 Agriculture, methyl bromide's program, currently requires  
714 that methyl bromide be included in its research projects.  
715 Although the United States has submitted critical-use  
716 exemption request for methyl bromide alternative research in  
717 the past in 2012, it was not included.

718 My amendment would simply direct the EPA to take action

719 to ensure that sufficient quantities of methyl bromide are  
720 available for continuing research on methyl bromide  
721 alternatives for the agriculture sector. This will help  
722 facilitate development of viable alternatives and advance the  
723 objectives of the Montreal Protocol treaty.

724 I urge my colleagues to support it.

725 Mr. {Waxman.} Will the gentleman yield?

726 Mr. {Terry.} Sure.

727 Mr. {Waxman.} This amendment is without controversy and  
728 I want to join you in supporting the amendment.

729 Mr. {Terry.} Thank you, Mr. Ranking Member Waxman.

730 Yield back.

731 Mr. {Whitfield.} The gentleman's amendment is accepted.

732 The chair has an amendment at the desk.

733 Oh, I am sorry. We still should vote on the amendment.

734 I believe in Mr. Waxman's influence so much that when he said  
735 it is okay, I assumed it was okay.

736 But those in favor of the amendment of the gentleman  
737 from Nebraska will signify by saying aye.

738 Those opposed, no.

739 In the opinion of the chair, the ayes have it, and the  
740 amendment is agreed to.

741 Now, the chair will recognize himself for the purpose of  
742 offering an amendment, and it is amendment number 01, and I

743 would ask the clerk to distribute the amendment.

744           The {Clerk.} Amendment to the discussion draft, U.S.

745 Agricultural Sector Relief Act of 2012, offered by Mr.

746 Whitfield of Kentucky.

747           [The amendment follows:]

748 \*\*\*\*\* INSERT 3 \*\*\*\*\*

|  
749           Mr. {Whitfield.} Without objection, I would ask that  
750 the reading of the entire amendment be dispensed with and I  
751 recognize myself for 5 minutes to explain the amendment.

752           The purpose of the Agricultural Sector Relief Act is  
753 simply to provide relief to American farmers. We heard  
754 yesterday from farmers from Michigan, from Florida, from  
755 California that grow strawberries, that grow all sorts of  
756 fruits and vegetables, flowers, and we want to ensure that  
757 they have methyl bromide for certain critical uses.

758           To achieve that goal, the bill directs EPA to continue  
759 to seek critical-use exemptions under the Montreal Protocol  
760 for all approved critical uses, the bill defines those uses  
761 to include all approved critical uses set forth in the Code  
762 of Federal Regulations of January 1, 2005, and that included  
763 a range of uses--strawberries, tomatoes, peppers, eggplant,  
764 flowers, et cetera. Now, while EPA did not testify yesterday  
765 at our legislative hearing, EPA Assistant Gina McCarthy did  
766 provide written testimony, and she provided some constructive  
767 comments. In particular, in her statement she noted the bill  
768 as currently drafted would exclude any array of critical uses  
769 that were identified after 2005, and this is an important  
770 point because it is true that EPA has identified certain  
771 types of crops and locations not previously listed in the

772 original 2005 list.

773           And so this amendment would simply address that concern  
774 by adding any critical uses identified by EPA after 2005 that  
775 have been added to the list of approved critical uses. This  
776 would simply ensure that more recently identified critical  
777 uses are not excluded from the exemption process, and that is  
778 what this amendment does, and I would appreciate the members  
779 supporting the amendment.

780           Mr. {Waxman.} Mr. Chairman.

781           Mr. {Whitfield.} For what purpose does the gentleman  
782 from California seek recognition?

783           Mr. {Waxman.} To strike the last word.

784           Mr. {Whitfield.} The gentleman is recognized for 5  
785 minutes.

786           Mr. {Waxman.} Mr. Chairman, this amendment illustrates  
787 the flaws in how this bill has been drafted because it  
788 freezes into law for all time an outdated list of approved  
789 critical uses.

790           I think there are gross drafting errors in this bill.  
791 The bill rolls back the clock on the list of approved  
792 critical uses to January 1, 2005, and says that whatever was  
793 on that list at that time is now permanent in law. The  
794 January 1, 2005, list does not reflect additions to and  
795 subtractions from the list since that date. As a result,

796 sectors that may have a legitimate need for methyl bromide  
797 could not get it under the Republican bill, and sectors that  
798 have completely phased out the use of methyl bromide during  
799 the last 7 years would be allowed to use methyl bromide  
800 again. For example, golf courses would once again be allowed  
801 to seek critical-use exemptions for methyl bromide. That  
802 doesn't make any sense. Why do we want to encourage use of  
803 methyl bromide for golf courses when we have already  
804 successfully eliminated the use of methyl bromide, and no one  
805 is asking for that use to be restored.

806         The amendment addresses only one side of the problem.  
807 It reflects the additions to the list of approved uses since  
808 2005 but not the subtractions from the list. I don't  
809 understand the reasoning there. The amendment doesn't  
810 correct the fundamental flaw of the underlying provision  
811 because it still locks into place a list of approved critical  
812 uses. As a result, there can't be any future additions to or  
813 subtractions from that list.

814         Michigan growers haven't applied for a critical-use  
815 exemption since 2007. Tobacco growers haven't sought a  
816 critical-use exemption since 2006--excuse me. They sought a  
817 critical-use exemption in 2006 but they didn't seek methyl  
818 bromide for 2007, 2008, 2009, 2010, 2011, 2012, 2013 or 2014.  
819 Well, why would we put them back in to be an exemption and

820 encourage them to start using it again?

821 I think this amendment and the whole bill reverses the  
822 progress we have made in reducing methyl bromide since 2005.  
823 I think that is bad policy and I urge my colleagues to reject  
824 this amendment and to reject the underlying bill as well. I  
825 yield back my time.

826 Mr. {Whitfield.} The gentleman yields back the balance  
827 of his time.

828 Is there further discussion on the amendment?

829 If not, then we will vote on the amendment. All those  
830 in support of the amendment would signify by saying aye.

831 All those opposed, nay.

832 In the opinion of the chair, the ayes have it and the  
833 amendment is agreed to.

834 At this time the chair would ask the clerk to report  
835 amendment 04 and distribute the amendment.

836 The {Clerk.} Amendment to discussion draft U.S.  
837 Agricultural Sector Relief Act of 2012 offered by Mr.  
838 Whitfield of Kentucky.

839 [The amendment follows:]

840 \*\*\*\*\* INSERT 4 \*\*\*\*\*

|  
841           Mr. {Whitfield.} Thank you. The chair will recognize  
842 himself for 5 minutes to explain the amendment.

843           In the legislative hearing and written documentation we  
844 have received on this issue, it has become quite clear that  
845 the United States does need to continue to seek critical-use  
846 exemptions under the Montreal Protocol process. We also  
847 learned that circumstances frequently change on these  
848 approved insecticides and so forth. And sometimes an  
849 alternative to methyl bromide is actually removed from the  
850 market. When that happens, it is not possible for farmers to  
851 return to using methyl bromide because the critical-use  
852 nomination was already submitted by EPA to the parties under  
853 the Montreal Protocol process and that critical-use  
854 nomination had assumed that the alternative product would be  
855 available. An example of that was how methyl iodide is no  
856 longer available and it was a substitute.

857           This amendment would simply fix that problem, and I  
858 think that the theme of this amendment is to, let us do  
859 everything possible to help our farmers, our agricultural  
860 growers the opportunity to have high yields and compete in  
861 the global marketplace with good products.

862           So this amendment, I believe, would fix that problem.  
863 It would simply require that when a substitute for methyl

864 bromide is pulled out of the market, then EPA must adjust the  
865 critical-use nomination to reflect the fact that a substitute  
866 that they thought would be available has become unavailable  
867 and so more methyl bromide should be made available for  
868 critical uses.

869         So that is the purpose of the amendment. It is very  
870 straightforward and I would ask members to support this  
871 amendment, and I yield back the balance of my time.

872         Does anyone seek recognition to speak in opposition to  
873 the amendment?

874         Mrs. {Capps.} Mr. Chairman.

875         Mr. {Whitfield.} For what purpose does the gentlelady  
876 from California seek recognition?

877         Mrs. {Capps.} To strike the last word.

878         Mr. {Whitfield.} The gentlelady is recognized for 5  
879 minutes.

880         Mrs. {Capps.} I hesitated because I thought our ranking  
881 member was going to speak first, but I want to comment  
882 because yesterday we heard testimony from strawberry and  
883 flower growers, and these happen to be two very important  
884 industries in my Congressional district. Both the strawberry  
885 and cut-flower industries are important economic drivers in  
886 the State of California, which has one of the highest  
887 concentrations of strawberry and flower farmers in the

888 country, and in their testimony before our subcommittee,  
889 these farmers emphasized the need to make the critical-use  
890 exemption process more responsive to their evolving needs but  
891 also made clear their commitment to the Montreal Protocol and  
892 finding alternatives. They are really trying to work with  
893 us.

894         While I am pleased the subcommittee is taking up this  
895 issue, I am really disappointed that we are marking up this  
896 bill so soon after yesterday's hearing. We simply haven't  
897 had enough time to fully consider both the testimony of the  
898 witnesses but also to get input from the Administration and  
899 other stakeholders and get to a solution that works for our  
900 growers and abides by the treaty, and that is where the crux  
901 of the issue is, Mr. Chairman. As we heard yesterday, our  
902 growers need help. In fact, I have already spoken with top  
903 officials at the EPA about this issue, and I am going to be  
904 continuing those discussions.

905         I appreciate that this bill is a first attempt to  
906 address some legitimate issues with the critical-use  
907 exemption process but I have real concerns about the approach  
908 that it takes and some of the unlikely unintended  
909 consequences that could undermine the very progress that we  
910 have made under the Montreal Protocol, and that is why I am  
911 hoping we are able to work together before the bill is

912 considered by full committee. We need to find a balanced,  
913 bipartisan solution that ensures the continued phase-out of  
914 methyl bromide but also addresses the legitimate needs of our  
915 growers and the variety of those needs, and that is why I  
916 want to thank the gentleman for offering this amendment.  
917 This is a very legitimate issue. It is one I am committed to  
918 solving, and we need some sort of mechanism in the EPA  
919 process to make necessary adjustments if a recommended  
920 alternative is removed from the market but not necessarily  
921 just one alternative. We need to respect the fact that this  
922 is an evolving, changing science.

923 I do share some of the concerns raised here that the  
924 amendment as drafted does not allow for consideration of all  
925 the available alternatives, and I think that is what is tying  
926 our hands by this very amendment. I will support this  
927 amendment to demonstrate my commitment to solving the problem  
928 but I hope that there is a commitment also on the other side  
929 to work with me at least and perhaps others to find a  
930 solution that is suitable for all the stakeholders.

931 Mr. {Waxman.} Will the gentlelady yield to me?

932 Ms. {Capps.} I will yield to my colleague?

933 Mr. {Waxman.} I thank you for yielding.

934 I understand the intent behind this amendment. If a  
935 methyl bromide alternative is removed from the market, then

936 the nomination for critical-use exemption should be adjusted,  
937 and I doubt any of us would object to that policy

938         But I do want to raise the concern for the proponents of  
939 this bill to recognize that the effect of this amendment  
940 could open the door to litigation into the implementation of  
941 the Montreal Protocol where we haven't seen litigation  
942 before, and litigation is not going to solve the problem.

943         So I would hope that--I am not going to object to your  
944 amendment. I just don't think it accomplishes what you want,  
945 and I think the gentlelady from California raised this  
946 points, so I think this bill needs continued work so that you  
947 don't undermine the purpose of the bill by putting everything  
948 into the courts. I think it will increase the likelihood  
949 that no one gets a critical-use exemption, and I don't think  
950 growers could benefit from that outcome.

951         Thank you for yielding to me.

952         Mr. {Whitfield.} Well, thank you for your comment, and  
953 I think all of us have a goal here of assisting our  
954 agricultural community as they try to deal with these issues,  
955 and if we can report this bill out of subcommittee today, I  
956 would invite any member there whose staff or individual  
957 member wants to sit down with us and go over it in more  
958 detail and see if we can perfect the bill in some way. I  
959 would look forward to working with you all to try to do that.

960           So if there is no further discussion on the amendment,  
961 then the chair would call for a vote on the amendment.

962           All those in favor by signify by saying aye.

963           Those opposed, no.

964           In the opinion of the chair, the ayes have it and the  
965 amendment is agreed to.

966           Are there any further amendments to the Agricultural  
967 Sector Relief Act of 2012?

968           Mr. {Dingell.} Mr. Chairman.

969           Mr. {Whitfield.} For what purpose does the gentleman  
970 from Michigan seek recognition?

971           Mr. {Dingell.} To strike the requisite number of words.

972           Mr. {Whitfield.} The gentleman is recognized for 5  
973 minutes.

974           Mr. {Dingell.} I say this with great respect and  
975 affection for the chair. This is not a bill that is going to  
976 go anywhere and it is not a bill that is going to help the  
977 farmers. I raised some serious questions yesterday about how  
978 I thought the bill was being handled and how it could be  
979 better dealt with. I have the theory that what we are going  
980 to have is a fine operation here which the patient falls off  
981 the table and dies, and I don't see the legislation becoming  
982 law.

983           I think our farmers have a legitimate complaint and I

984 would like to see the complaint addressed but the problem we  
985 have here is the way the bill is drafted, there is no  
986 assurance first of all that the bill is going to be signed by  
987 the President, that it is going to get through the Senate,  
988 and there is no assurance that even if the bill is passed and  
989 does get to the point where it is going to be administered,  
990 we will find that the administration of this bill will mean  
991 that the U.S. government will take the requests of the  
992 farmers up to the Montreal Protocol organization and find the  
993 requests of our farmers repudiated. I don't think that that  
994 serves our interests or the interests of our farmers.

995 I don't intend to oppose the bill with any vigor. I  
996 can't vote for it. But I would beg the chair to in his  
997 wisdom try and work out the concerns that exist here because  
998 this bill has some merit from the standpoint of the farmer  
999 but it does not have enough to convince the Montreal Protocol  
1000 that even if passed that it is going to be something that  
1001 they are going to be of assistance to us in.

1002 So I thank you for your courtesy, Mr. Chairman.

1003 Mr. {Whitfield.} Thank you for your comments, Mr.  
1004 Dingell. And as I said, if we are successful in getting this  
1005 reported out, we certainly look forward to sitting down with  
1006 you all and listening to you and trying to work out an  
1007 arrangement that is satisfactory to everyone.

1008 Mr. {Shimkus.} Mr. Chairman.

1009 Mr. {Whitfield.} For what purpose does the gentleman  
1010 seek recognition?

1011 Mr. {Shimkus.} To strike the last word.

1012 Mr. {Whitfield.} The gentleman is recognized for 5  
1013 minutes.

1014 Mr. {Shimkus.} And I will be real brief.

1015 You know, in teaching government history as I did for 4  
1016 years, the process of how a bill becomes law is that one  
1017 chamber passes it, another chamber may pass it. It is not  
1018 incumbent upon me to move a piece of legislation thinking  
1019 that the Senate may or may not pick it up nor the Senate pass  
1020 it. I have to represent my constituents, and my millers in  
1021 southern Illinois say this is a problem and this is a problem  
1022 that needs to be fixed, and by us passing a piece of  
1023 legislation and then putting people accountable in this  
1024 committee and in full committee and then maybe on the Floor,  
1025 other agricultural interests will understand whether you are  
1026 fighting with them, for them or against them.

1027 And so I relish this process and I don't think we should  
1028 diminish the process based upon whether the Senate will or  
1029 will not pick it up or whether the President will or will not  
1030 sign it. If we did that, we might as well not even have  
1031 hearings or have bill markups.

1032           So I have been on the committee 16 years. Methyl  
1033 bromide has been a problem every year for my 16 years, and  
1034 until there is a credible substitute, especially for milling  
1035 operations, it is still going to be an issue that has to be  
1036 resolved. And for us to stick our head underneath the sand  
1037 is not answering the needs of my constituents.

1038           So I appreciate the chairman's passion and commitment to  
1039 move this forward. He has my full support. And I yield back  
1040 my time.

1041           Mr. {Whitfield.} The gentleman yields back his time.

1042           If there is no further discussion, the question would  
1043 now occur on favorably reporting the U.S. Agricultural Sector  
1044 Relief Act of 2012 as amended.

1045           All those in favor shall signify by saying aye.

1046           All those opposed, no.

1047           In the opinion of the chair--

1048           Mr. {Sullivan.} I ask for a roll call vote, Mr.

1049 Chairman.

1050           Mr. {Whitfield.} The gentleman requests a roll call  
1051 vote. The clerk will call the roll.

1052           The {Clerk.} Mr. Sullivan?

1053           Mr. {Sullivan.} Aye.

1054           The {Clerk.} Mr. Sullivan votes aye.

1055           Mr. Shimkus?

1056 Mr. {Shimkus.} Yes.

1057 The {Clerk.} Mr. Shimkus votes aye.

1058 Mr. Walden?

1059 Mr. {Walden.} Aye.

1060 The {Clerk.} Mr. Walden votes aye.

1061 Mr. Terry?

1062 Mr. {Terry.} Aye.

1063 The {Clerk.} Mr. Terry votes aye.

1064 Mr. Burgess?

1065 Dr. {Burgess.} Aye.

1066 The {Clerk.} Mr. Burgess votes aye.

1067 Mr. Bilbray?

1068 Mr. {Bilbray.} Aye.

1069 The {Clerk.} Mr. Bilbray votes aye.

1070 Mr. Scalise?

1071 Mr. {Scalise.} Aye.

1072 The {Clerk.} Mr. Scalise votes aye.

1073 Mrs. McMorris Rodgers?

1074 [No response.]

1075 The {Clerk.} Mr. Olson?

1076 Mr. {Olson.} Aye.

1077 The {Clerk.} Mr. Olson votes aye.

1078 Mr. McKinley?

1079 Mr. {McKinley.} Yes.

1080 The {Clerk.} Mr. McKinley votes aye.  
1081 Mr. Gardner?  
1082 Mr. {Gardner.} Aye.  
1083 The {Clerk.} Mr. Gardner votes aye.  
1084 Mr. Pompeo?  
1085 Mr. {Pompeo.} Aye.  
1086 The {Clerk.} Mr. Pompeo votes aye.  
1087 Mr. Griffith?  
1088 Mr. {Griffith.} Aye.  
1089 The {Clerk.} Mr. Griffith votes aye.  
1090 Mr. Barton?  
1091 [No response.]  
1092 The {Clerk.} Mr. Upton?  
1093 The {Chairman.} Aye.  
1094 The {Clerk.} Mr. Upton votes aye.  
1095 Mr. Rush?  
1096 Mr. {Rush.} No.  
1097 The {Clerk.} Mr. Rush votes no.  
1098 Ms. Castor?  
1099 [No response.]  
1100 The {Clerk.} Mr. Sarbanes?  
1101 [No response.]  
1102 The {Clerk.} Mr. Dingell?  
1103 Mr. {Dingell.} Dingell votes no.

1104 Ms. {Clerk.} Mr. Dingell votes no.  
1105 Mr. Markey?  
1106 [No response.]  
1107 The {Clerk.} Mr. Engel?  
1108 [No response.]  
1109 The {Clerk.} Mr. Green?  
1110 [No response.]  
1111 The {Clerk.} Mrs. Capps?  
1112 Mrs. {Capps.} No.  
1113 The {Clerk.} Mrs. Capps votes no.  
1114 Mr. Doyle?  
1115 Mr. {Doyle.} No.  
1116 The {Clerk.} Mr. Doyle votes no.  
1117 Mr. Gonzalez?  
1118 [No response.]  
1119 The {Clerk.} Mr. Waxman?  
1120 Mr. {Waxman.} No.  
1121 The {Clerk.} Mr. Waxman votes no.  
1122 Chairman Whitfield?  
1123 Mr. {Whitfield.} Aye.  
1124 The {Clerk.} Chairman Whitfield votes aye.  
1125 Mr. {Whitfield.} Are there any additional votes? Mr.  
1126 Green?  
1127 Mr. {Scalise.} Mr. Chairman, can I ask how I am

1128 recorded?

1129 Mr. {Whitfield.} I am sorry?

1130 Mr. {Scalise.} Can I ask how I am recorded?

1131 Mr. {Whitfield.} Is Mr. Scalise recorded?

1132 The {Clerk.} Mr. Scalise votes aye.

1133 Mr. {Whitfield.} Ms. McMorris Rodgers?

1134 Mrs. {McMorris Rodgers.} Aye.

1135 The {Clerk.} Mrs. McMorris Rodgers votes aye.

1136 Mr. {Whitfield.} Mr. Green?

1137 Mr. {Green.} No.

1138 The {Clerk.} Mr. Green votes no.

1139 Mr. {Whitfield.} Does anyone else seek recognition to  
1140 vote?

1141 The clerk will report the vote, please.

1142 The {Clerk.} Mr. Chairman, on that vote, there were 15  
1143 ayes, six nays.

1144 Mr. {Whitfield.} Well, the ayes have it, and the  
1145 discussion is favorably reported.

1146 Now, in the notice, we had indicated that we were going  
1147 to mark up in the subcommittee the No More Solyndra Act. I  
1148 have been notified this morning that we have like 15  
1149 amendments to this piece of legislation, and in this  
1150 legislation we are making some significant changes. We are  
1151 trying to terminate the 1703, 1705 program. We are trying to

1152 change the process for those applications in the mill or in  
1153 the queue, and I know that people have very strong feelings  
1154 about this issue, and I made a decision that we are not going  
1155 to take it up today but we would like to delay it until maybe  
1156 one day next week so that everyone will have a full  
1157 opportunity to discuss their 15 amendments.

1158           And so at this time we will conclude the markup, and  
1159 without objection, staff is authorized to make technical and  
1160 conforming changes to the discussion drafts approved by the  
1161 subcommittee today. So ordered.

1162           Mr. {Rush.} Mr. Chairman.

1163           Mr. {Whitfield.} For what purpose does the gentleman  
1164 from Illinois seek recognition?

1165           Mr. {Rush.} Mr. Chairman, I just want to make an  
1166 inquiry. Do you intend--

1167           Mr. {Whitfield.} Can I have everyone's attention,  
1168 please?

1169           Mr. {Rush.} Do you intend, is it your intention between  
1170 now and the full committee markup to bring the FDA in and the  
1171 EPA in for hearing?

1172           Mr. {Whitfield.} It is not my intention to have a  
1173 hearing with them but I would be happy to bring them in and  
1174 sit down with you and talk to them about it.

1175           Mr. {Rush.} But you don't think it is necessary to have

1176 a subcommittee hearing with these two agencies?

1177 Mr. {Whitfield.} I don't think so myself but we can  
1178 talk about it and we can see about bringing EPA in.

1179 Mr. {Waxman.} If you do bring them in, invite all the  
1180 members.

1181 Mr. {Whitfield.} I will.

1182 Mr. {Waxman.} And of course, if you do that, it is like  
1183 a hearing, so I don't know why not do it, but you are the  
1184 chairman.

1185 Mr. {Walden.} Mr. Chairman, would that be like when we  
1186 only had one time with the head of the Congressional Budget  
1187 Office and it was closed door, no members, on the health care  
1188 bill?

1189 Mr. {Whitfield.} I might say that on the No Solyndra  
1190 Act, the mere fact that we are going to postpone it, we are  
1191 totally committed to ending this 1703, 1705 program and we  
1192 will be bringing that legislation up in the subcommittee some  
1193 time next week.

1194 So without objection, the subcommittee stands adjourned.

1195 [Whereupon, at 11:20 a.m., the Subcommittee was  
1196 adjourned.]