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1 {York Stenographic Services, Inc.}

2 HIF154.140

3 HEARING ON FOOD SAFETY ENHANCEMENT ACT OF 2009 DISCUSSION

4 DRAFT

5 WEDNESDAY, JUNE 3, 2009

6 House of Representatives,

7 Subcommittee on Health

8 Committee on Energy and Commerce

9 Washington, D.C.

10 The subcommittee met, pursuant to call, at 10:05 a.m.,  
11 in Room 2123 of the Rayburn House Office Building, Hon. Frank  
12 Pallone (chairman of the subcommittee) presiding.

13 Members present: Representatives Pallone, Dingell,  
14 Eshoo, Green, DeGette, Schakowsky, Baldwin, Ross, Matheson,  
15 Harman, Barrow, Christensen, Castor, Sarbanes, Murphy of  
16 Connecticut, Space, Sutton, Braley, Waxman (ex officio),  
17 Stupak, Markey, Deal, Whitfield, Shimkus, Buyer, Rogers,  
18 Murphy of Pennsylvania, Burgess, Blackburn, Gingrey and

19 Barton (ex officio).

20           Staff present: Karen Nelson, Staff Director/Chief Health  
21 Counsel; Rachel Sher, Health Counsel; Eric Flamm, FDA Detail;  
22 Elana Leventhal, Legislative Assistant; Virgil Miller,  
23 Professional Staff; Alvin Banks, Staff Assistant; Ryan Long,  
24 Minority Chief Health Counsel; and Chad Grant, Minority  
25 Legislative Assistant.

|

26           Mr. {Pallone.} The meeting of the subcommittee is  
27 called to order, and today we are meeting to review the Food  
28 Safety Enhancement Act of 2009 Discussion Draft. I will  
29 recognize myself for an opening statement initially. This  
30 discussion draft was released by Chairman Waxman, Chairman  
31 Emeritus Dingell, Chairman Stupak, Representative DeGette,  
32 Representative Sutton and myself early last week. And the  
33 draft builds on several bills already introduced in this  
34 Congress including H.R. 759, a bill that I, along with  
35 Chairman Dingell and Stupak, introduced earlier this year.

36           The Energy and Commerce Committee has done a lot of work  
37 on the issue of food safety. In this subcommittee alone, we  
38 have had four hearings on this topic in the last two years.  
39 The information we learned during these hearings as well as  
40 during the numerous conversation we had with stakeholders  
41 groups and the FDA has been incorporated into the draft  
42 before us today.

43           And I believe this draft bill represents a strong, well  
44 thought out approach to improving the FDA and its food safety  
45 activities. We have heard time and again that our current  
46 food safety system is broken. It is a system that relies  
47 heavily on the FDA rather than placing the responsibilities  
48 on the manufacturers to ensure the safety of their products.

49 It is a system that is geared towards responding to food  
50 outbreaks rather than one that is aimed at preventing them.

51 And this system does not work, and recent outbreaks of  
52 E.coli in spinach and salmonella in peppers and peanut butter  
53 highlight that fact. Unfortunately, these are not isolated  
54 instances. Each year, 76 million Americans get sick due to  
55 unsafe food products. Every year, 325,000 individuals will  
56 be hospitalized and 5,000 will die from food borne hazards.

57 It is estimated that the medical costs and lost  
58 productivity due to food borne diseases cost us \$44 billion  
59 annually. And these illnesses are completely preventable.

60 The good news is that there seems to be agreement that  
61 something must be done and that it must be done quickly. The  
62 President has made food safety one of his priorities. He has  
63 assembled a food safety working group to come up with  
64 principles on this issue.

65 Chairman Waxman, Mr. Dingell, Mr. Stupak and I have  
66 worked closely with key stakeholders on this discussion  
67 draft, and as we move forward with the legislation, we hope  
68 to continue those conversations as well as conversations with  
69 our counterparts on this committee.

70 The bill we are discussing today will modernize the food  
71 safety laws currently in place. It places a strong emphasis  
72 on prevention and shifts the responsibility for food safety

73 onto those who actually make the food. It also provides the  
74 FDA with the necessary resources and enforcement authorities  
75 to ensure that all companies are in compliance with the new  
76 requirements. This draft bill would require all food  
77 manufacturing companies to register annually with the FDA so  
78 that the agency has an up-to-date list of all facilities who  
79 sell products in the United States.

80 It focuses on prevention by requiring companies to  
81 conduct thorough hazard and risk analysis of the products  
82 that they are making. It mandates that companies put in  
83 place preventive controls to mitigate and minimize those  
84 identified hazards. And it requires companies to document  
85 all the steps they have taken to implement and verify the  
86 controls to ensure they are effectively minimizing hazards.

87 The bill also addresses the shortfalls of our current  
88 traceback system by requiring the FDA to establish an  
89 electronic interoperable record keeping system that  
90 manufacturers would be required to use. This measure will  
91 allow the agency to quickly trace the source of an outbreak  
92 back to its origin and prevent and minimize the number of  
93 individuals affected by a food borne illness.

94 While shifting responsibility for food safety onto the  
95 manufacturers, the draft also recognizes the crucial role the  
96 FDA needs to play in this realm. This draft requires the

97 agency to set standards for food safety and hold the food  
98 industry accountable for meeting those standards. It  
99 provides the FDA with stronger enforcement authorities, such  
100 as recall authority and access to records.

101 The bill also increases the inspection frequency for  
102 food facilities, requiring that the FDA inspect facilities at  
103 an established minimum frequency.

104 Now we are going to hear today from industry experts  
105 about the various provisions in this discussion draft, and I  
106 look forward to those conversations. I hope that we can all  
107 continue to work in this collaborative manner as we move to  
108 markup of food safety legislation in this committee.

109 I am very pleased to welcome Dr. Margaret Hamburg of the  
110 FDA today. We had a meeting last week while we were doing  
111 the Energy markup. We were in the back having some  
112 conversations, and I was very impressed with her. This is  
113 the first time she will be testifying before this committee,  
114 and I thank her for being here.

115 I also want to thank our other witnesses for appearing  
116 before us today. I especially want to welcome back Mike  
117 Ambrosio. He is, of course, from my home state. Good to see  
118 you again, Mike. And I will now recognize Mr. Deal for an  
119 opening statement.

120 [The prepared statement of Mr. Pallone follows:]

121 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
122           Mr. {Deal.} Thank you, Chairman Pallone, for holding  
123 this hearing today, and thanks to our distinguished witnesses  
124 who have joined us to review this draft of the Food Safety  
125 Enhancement Act of 2009. I look forward to your testimony  
126 and to the questions that our committee will actually have of  
127 the panels.

128           As a resident of the state of Georgia, which has already  
129 received a focal point focus of the issue of food safety, I  
130 know firsthand the perspective that our Nation has on the  
131 issue of the lack of safeguards and fallback measures that  
132 many people expect of a 21st century food supply chain in our  
133 country.

134           We all agree food safety is a priority, and I support  
135 giving FDA the resources it needs to ensure our Nation's food  
136 supply remains safe and reliable for American dinner tables  
137 across the country.

138           Additionally implementation of preventive controls such  
139 as hazard analysis and critical point plans included in the  
140 draft under discussion is an important step forward in  
141 ensuring unsafe food products don't reach store shelves in  
142 the first place.

143           As we know, preventing compromised good from entering  
144 the market is the best line of defense to preventing food

145 related illnesses. I also believe it is important to enhance  
146 FDA's ability to conduct onsite inspections of food  
147 facilities. The inspection schedule established under the  
148 draft does recognize risk profiles for food in terms of how  
149 frequently facilities should be inspected. But the regimen  
150 set forth in the discussion draft fails to address the  
151 cost/benefit factor of conducting such frequent inspections  
152 and could possibly result in insufficient oversight of  
153 certain higher-risk facilities due to time and manpower  
154 limitations of our inspectors.

155 It is my hope that our witnesses today can provide input  
156 with regard to an appropriate inspection schedule, which  
157 achieves the goal of ensuring safe food for the American  
158 people without placing an undue burden and strain on the FDA,  
159 which is already challenged under current food safety  
160 obligations.

161 This legislation authorizes an annual pay-to-play  
162 registration fee for domestic and foreign food facilities of  
163 \$1,000 to supplement appropriations made by Congress to FDA.  
164 In discussion, however, we have not been able to determine  
165 from the majority or the FDA exactly how much funding is  
166 necessary to meet the requirements of this bill.

167 I believe it would be premature to impose significant  
168 fees on industry and in turn the American consumers without

169 any reference as to how much funding is actually needed. If  
170 the majority remains intent on imposing such registration  
171 fees, we must also be certain these fees are limited to cover  
172 the activities such as a minimal fee paid to the FDA for an  
173 application to cover the cost of review and processing.

174 If the goal is to improve food safety, we must ensure  
175 that funds are not funneled into other activities that may or  
176 may not have anything to do with improving food safety, a  
177 situation which I believe could occur under the language of  
178 the current proposal. Obviously these are issues, among many  
179 others, that I feel hopefully this committee will be able to  
180 address as we move this issue forward, and I look forward to  
181 the hearing today and the results that come out of it.

182 I appreciate Chairman Pallone and Chairman Waxman's  
183 bipartisan efforts on this issue, and look forward to having  
184 a product that all the members of this committee can support.  
185 And thank you, Mr. Chairman, for the time.

186 [The statement prepared of Mr. Deal follows:]

187 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
188 Mr. {Pallone.} Thank you, Mr. Deal. Chairman Waxman.

189 The {Chairman.} Thank you very much, Mr. Chairman.

190 This subcommittee and our full committee is beginning the  
191 process today of passing critically important legislation  
192 designed to revamp our Nation's food safety system. The Food  
193 Safety Enhancement Act of 2009 and this hearing marks a key  
194 milestone.

195 Over the past few years, a series of food borne disease  
196 outbreaks in spinach, peanuts, and peppers, just to name a  
197 few, have laid bare some major gaps in our antiquated food  
198 safety laws. Oversight work by GAO and by our own Oversight  
199 Committee has also helped us understand where we need to  
200 focus our efforts to bring our food safety laws into the 21st  
201 century.

202 The draft legislation that is the subject of today's  
203 hearing is based on the FDA Globalization Act of 2009  
204 introduced by Chairman Emeritus Dingell, Chairman Pallone,  
205 and Chairman Stupak. And I commend them for their work on  
206 that bill and their continued efforts in shaping this new  
207 bill.

208 I also want to recognize the assistance we have received  
209 from the Obama administration. We have worked closely with  
210 the FDA to identify problems with the current food safety law

211 and to find workable solutions. We will not be passing  
212 legislation that sets up the agency to fail. The bill  
213 requires that the agency set tough standards, but we have  
214 given them the flexibility to prioritize and address the most  
215 important risks first.

216         The draft also incorporates helpful suggestions from  
217 Ranking Members Barton and Deal and Representative Shimkus.  
218 I believe we can reach a bipartisan agreement and look  
219 forward to continuing to work with all the members of this  
220 committee.

221         In working with the FDA on this legislation, one thing  
222 was abundantly clear. The administration is absolutely  
223 committed to overhauling FDA's food safety program. I think  
224 we will all see that commitment today when we hear from  
225 Commissioner Hamburg.

226         The recent food outbreaks have exposed glaring holes in  
227 FDA's basic food safety authorities. FDA does not have  
228 routine access to any records kept by the food manufacturers.  
229 FDA cannot require companies to conduct a recall of unsafe  
230 foods. The agency can only ask and hope that the company  
231 complies. FDA also lacks basic modern enforcement tools like  
232 administrative civil monetary penalties. The Food Safety  
233 Enhancement Act will give FDA these and other critical  
234 authorities.

235           One of the most important changes that will occur under  
236 this bill is a focus on prevention. The legislation does not  
237 anticipate that FDA alone will protect us from unsafe food.  
238 The hallmark of any effective food safety goal must be a  
239 shared responsibility for food safety oversight between FDA  
240 and industry.

241           The act will strike the right balance in this shared  
242 responsibility. The bill will require manufacturers to  
243 implement preventive systems to stop outbreaks before they  
244 occur and will give FDA the tools it needs to hold them  
245 accountable if they fail. Under the bill, FDA will also have  
246 clear authority to issue and require manufacturers to meet  
247 strong enforceable performance standards to ensure the safety  
248 of various types of food.

249           I commend many of those in industry for recognizing the  
250 importance of this prevention model and coming to the table  
251 to support it.

252           Let me turn briefly to one of the more contentious  
253 issues in the bill, the registration fees. I wish we did not  
254 have to resort to industry fees to supplement funding for  
255 FDA's work. However, when it comes to FDA's food program,  
256 the shortfall in revenues is extreme. The FDA's own science  
257 board told us that the FDA is so starved for resources that  
258 American lives are at risk. We cannot realistically expect

259 appropriations alone to provide sufficient resources to close  
260 that gap.

261         The recent outbreaks have also taken a major toll on the  
262 food industry. In the recent peanut outbreak, Kellogg's  
263 alone lost \$70 million. Faced with such a dire situation, I  
264 think it is reasonable to ask the food industry to chip in.  
265 A robust food safety oversight system will provide a great  
266 benefit to industry by preventing future outbreaks and  
267 rebuilding consumer confidence.

268         Let me be clear. We are not asking industry to cover  
269 the entire cost of the bill or any single part of the bill  
270 like the cost of inspections. The bill establishes a set fee  
271 of \$1,000 per year per facility. FDA is prohibited from  
272 increasing that fee in future years except to cover the cost  
273 of inflation. The bill simply asks industry to chip in its  
274 fair share.

275         I also want to address another concern I have heard, the  
276 presence of FDA on farms. FDA has always had the authority  
277 of foods on farms, and they have generally relied on state  
278 and local authorities for food safety oversight on farms  
279 because they have a strong on-farm presence. I am confident  
280 that farmers have nothing to fear from this bill. The bill  
281 calls for FDA to set its standards through regulation, which  
282 means that FDA will go through a public notice and comment

283 process.

284           Our committee is busy in the middle of three months  
285 period. Last month, we passed a comprehensive energy and  
286 climate change legislation. Soon we will take up health care  
287 reform, but food safety is so critical that I have carved out  
288 time right in between to pass this legislation. Over the  
289 next few weeks, I intend to work with all our committee  
290 members, Democratic and Republican, with the FDA, with the  
291 affected industries, to achieve a consensus on a food safety  
292 bill that we can pass out of committee. We can't afford to  
293 wait any longer.

294           I look forward to hearing from our witnesses today.  
295 Thank you, Mr. Chairman.

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

297 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
298 Mr. {Pallone.} Thank you, Chairman Waxman. The  
299 gentleman from Kentucky, Mr. Whitfield.

300 Mr. {Whitfield.} Well, thank you, Mr. Chairman, and we  
301 appreciate your having this hearing on this very important  
302 issue today. We all recognize that FDA has many very  
303 important responsibilities, and we have known through  
304 hearings for the last number of years that the resources  
305 available are always in question, but we recognize also that  
306 there is a definite need for reform of FDA. And we are  
307 delighted that Dr. Hamburg is here with us today to provide  
308 testimony and the other panel of witnesses as well.

309 We look forward to working with the majority on this  
310 important legislation. And having said that, we do have some  
311 significant concerns about some provisions in this  
312 legislation, particularly the risk-based inspection portion,  
313 particularly that relating to the low-risk facilities. Also  
314 the traceability provisions that I understand, for example,  
315 would apply to every convenience store in the country. In  
316 addition to that, the recall provisions in this legislation,  
317 the country of origin provisions, particularly as it relates  
318 to the website requirements and then also, of course, the  
319 power that we give to FDA for subpoenas and other instruments  
320 to obtain company records. I think we need to look at those

321 provisions much more closely.

322           But obviously this is an important piece of legislation.

323 We look forward to working with you and listening to the

324 testimony of our witnesses today. Thank you.

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

326 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
327           Mr. {Pallone.} Thank you. Next is our Chairman  
328 Emeritus, Mr. Dingell, and thank you for all you have done on  
329 this legislation.

330           Mr. {Dingell.} Mr. Chairman, thank you, and thank you  
331 for holding today's legislative hearing on the Food Safety  
332 Enhancement Act of 2009 Discussion Draft. We have worked  
333 together, you and I, with Chairman Stupak and others over the  
334 years. And I am delighted to say that this legislation is  
335 ready for enactment and is almost old enough to vote.

336           I want to say that I am delighted that Chairman Waxman  
337 and my good colleagues, Ms. DeGette and Ms. Sutton, have  
338 joined us in our work on this bill.

339           We are about to try and fund an agency which is hollow,  
340 which does not have either the personnel or the revenue or  
341 the money or the or the resources which it needs to do its  
342 job. And we are about for the first time since 1962, when I  
343 was a young member of this body, to try and see to it that it  
344 gets its authorities updated to deal with the real problems  
345 in the world of trade and in the world marketplace.

346           I am pleased that we are taking the necessary steps to  
347 advance this legislation and address the important issue of  
348 food safety. I am hopeful that we will shortly be doing  
349 something with regard to pharmaceuticals.

350 I want to thank the witnesses who have joined us today  
351 and look forward to hearing their testimony. And, Dr.  
352 Hamburg, welcome to the committee. Congratulations on your  
353 confirmation. I was encouraged by the administration's early  
354 recognition that food safety is a problem that needs to be  
355 addressed. The administration food safety working group is a  
356 signal to how serious the President considers this issue.

357 And I want to thank you for the way that you and your  
358 staff have provided timely and helpful technical advice on  
359 the legislation.

360 I want to note that I am hearing complaints from folks  
361 about the fee system. I want to make a note that the only  
362 part of Food and Drug that seems to be working is that which  
363 functions under PDUFA and that and which has the advantage of  
364 having industry participate in the funding. I want to note  
365 that the industry seems to be prospering mightily under that  
366 particular section and be getting service from Food and Drug  
367 in a proper way. And that seems to be about the only place  
368 that the industry is getting protection or the American  
369 consumers are receiving necessary safety.

370 In 1938, the Congress comprehensively addressed the  
371 issue of food and safety. Seventy years later, Food and Drug  
372 Administration is still trying to protect the larger,  
373 increasingly global supply with outdated statutes and

374 inadequate resources. As a result, the American consumer  
375 confidence in the Nation's food supply and the Food and Drug  
376 Administration and, quite frankly, in this body, the  
377 Congress, has declined. And American consumers are being  
378 forced to pay a heavy price, not only with recall after  
379 recall but also the fact that people are being sickened and  
380 killed by unsafe foods and also by pharmaceuticals.

381         And again I wish to hope that we will commence work on  
382 pharmaceuticals as soon as this business is attended to. The  
383 Food Safety Enhancement Act is a measured and effective  
384 response to the dire situation we are faced with today  
385 regarding food safety.

386         Mr. Chairman, the legislation is based on a bill you,  
387 Chairman Stupak, and I have introduced earlier this year and  
388 also on a bill that was introduced by me during the past  
389 Congress. It includes good technical advice from FDA and  
390 valued input from the minority and other stakeholders. And I  
391 want to make it clear that I am working with the minority to  
392 try and resolve their concerns, and that we are also working  
393 with the industry.

394         And I want to thank my friends in the industry for the  
395 goodwill which they have shown in working with us. And I  
396 also want to thank Chairman Waxman for his leadership on this  
397 point. I look forward to continued deliberations in the hope

398 of producing speedily a bipartisan piece of legislation that  
399 will pass the committee and the House, as I have indicated,  
400 both in a correct and a speedy fashion.

401       Amongst other things, this bill will prevent safety  
402 problems before they occur. It will require manufacturers to  
403 implement food safety plans that identify and protect against  
404 food hazards. It will see that Food and Drug has the  
405 authority to see to it that good manufacturing practices are  
406 adhered to here in the United States and elsewhere,  
407 especially in places like China which is in fact the Wild  
408 West in this particular matter.

409       It will advance the science of food safety, increase  
410 inspection frequency of food facilities, something which can  
411 happen more often on dog food manufacturers under the  
412 jurisdiction of the Department of Agriculture than it happens  
413 with regard to manufacturers who manufacture food products  
414 for the safety of our people.

415       It will enhance FDA's ability to trace the origin of  
416 tainted food in the event of an outbreak or food borne  
417 illness. And it should be noted that the Food and Drug  
418 Administration and the industry are totally incapable of  
419 providing speedy service in this particular.

420       It will enhance the safety of imported food. FDA will  
421 be allowed to require that certain foods be certified as

422 meeting U.S. safety standards and again to trace. But also  
423 Food and Drug will be able to finally get enough people at  
424 the doors of this country to see to it that safety is  
425 properly enforced and that good manufacturing practices are  
426 adhered to around the world for the protection of our people.

427 It will provide strong enforcement tools including  
428 mandatory food recall authority, stronger criminal and civil  
429 penalties for bad actors, subpoena authority, and it will  
430 increase and strengthen Food and Drug's detention authority.

431 Finally, and I would argue more importantly, the  
432 legislation addresses the very important question of  
433 resources of the agency. We will give the agency the  
434 authorities it needs, and we would do them a grave disservice  
435 if we did not give them the resources they need.

436 The legislation includes the registration fee, which  
437 will fund food safety activities at FDA. The revenue from  
438 this fee, coupled with additional appropriations which we  
439 hope we can get out of those skinflints at the Appropriations  
440 Committee, the office of managing the budget, will ensure  
441 that Food and Drug can do its job.

442 For those who argue there is no benefit for the industry  
443 to pay a fee for safety activities at Food and Drug, I offer  
444 the following. U.S. peanut industry could lose \$1 billion  
445 this year because of the outbreak of salmonella that forced

446 the biggest food recall in history. That has just been  
447 replicated by other recalls in the food industry. Tomato  
448 industry lost \$100 million in sales during the 2008  
449 salmonella outbreak that ultimately was attributed to  
450 jalapeno peppers. Spinach growers took a \$200 million hit to  
451 their industry during a 2006 bagged spinach recall.

452         And let us not forget that wonderful Chilean grape scare  
453 of 1989, which Food and Drug had neither the authority nor  
454 the competence to address. I ask unanimous consent to revise  
455 and extend my remarks. I have a few other things I would  
456 like to say that I know everybody will want to read. Thank  
457 you, Mr. Chairman.

458         [The prepared statement of Mr. Dingell follows:]

459 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
460 Mr. {Pallone.} Thank you, Chairman Dingell. The  
461 gentleman from Illinois, Mr. Shimkus.

462 Mr. {Shimkus.} Thank you, Mr. Chairman. Dr. Hamburg,  
463 welcome. I see Chairman Waxman has left the room. I  
464 appreciate his comments about there being some discussions.  
465 I do have to have admit that the discussions that we have had  
466 when we point out a point that is correct, they accept. When  
467 there is a debatable point, Mr. Chairman, there does not seem  
468 to be any movement and compromise. So I would encourage more  
469 discussions on some of these issues if we really want this to  
470 be a bipartisan bill.

471 You know the other thing I have trouble with is draft  
472 hearings. If we are going to have a legislative hearing, let  
473 us have the legislation. This is the draft legislation, and  
474 if we had the great draft legislation hearing on climate  
475 change and then when the bill came before us, it had 300  
476 additional pages in it. And there is fear on our part that  
477 this is a sneaky way to say yeah, we had a legislative  
478 hearing, but you really don't have a legislation hearing if  
479 you don't have the legislation before you.

480 This is the Democratic majority operandi. We claim a  
481 crisis. Only government can be the savior. Government must  
482 get bigger, and the middle class pays. And that is the issue

483 here. And I was on ONI in the last Congress with Bart  
484 Stupak, readily accepting the premise that we have to get  
485 inspectors into these facilities, and we are ready to address  
486 an issue that is thoughtful and respectful and pays for the  
487 inspectors and facilities where they are not going into.

488 And it is not like we haven't done anything. Congress,  
489 last Congress, approximately \$57 million from the  
490 supplemental went to food safety. The House passed the 2009  
491 omnibus appropriated an additional \$325 million for the FDA  
492 with \$140 million of the \$325 million would go for food  
493 safety programs. In the President's 2010 budget, he included  
494 \$1 billion additional to FDA for food safety.

495 So there is a huge commitment already for massive  
496 federal funds to go to food safety. Now we have, as our  
497 concern, a bill, a draft that has, what, \$325 million for no  
498 explanation, no earmarking, no direction, and that is where a  
499 lot of our questions will be today is why that amount? What  
500 justifies that amount? How are we going to ensure that it is  
501 not going to be used for other purposes? And the like.

502 So I would ask the leadership on the other side that if  
503 they really want a bipartisan, let us get some bipartisan  
504 negotiations, sincere negotiations. I would be honored to  
505 yield.

506 Mr. {Dingell.} I am very fond of the gentleman. He is

507 very well noticed, and I have great respect for him. And I  
508 have been talking, as the gentleman well knows, to the  
509 leadership on the minority side both in the last Congress and  
510 this Congress. I want this legislation to be bipartisan. I  
511 don't want the gentleman to be surprised.

512 I would note to my good friend that we have been having  
513 hearings after hearings after hearings not only here but up  
514 in the Oversight Subcommittee. And during that time, I have  
515 been continually talking to my good friends on the minority  
516 side because I want you to be aboard. This should not be a  
517 partisan issue. And when we go to the next step in this  
518 process, I will assure the gentleman that most of the changes  
519 that will be made that will be changes that will be made as a  
520 result of discussions with my friends on the minority side.  
521 And I say that with respect.

522 Mr. {Shimkus.} And I thank my colleague, and I look  
523 forward to working with you. I yield back, Mr. Chairman.

524 [The prepared statement of Mr. Shimkus follows:]

525 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
526 Mr. {Pallone.} Next is the gentlewoman from Colorado,  
527 Ms. DeGette.

528 Ms. {DeGette.} Thank you, Mr. Chairman. Mr. Chairman,  
529 this is the first step towards realizing a long-held dream,  
530 not just by me and other members of this committee but by the  
531 millions of Americans who have been concerned about the  
532 safety of our food, especially in light of the cascading  
533 litany of food borne illnesses that we have heard about from  
534 other members of this committee.

535 We have had a dozen Oversight hearings and also  
536 legislative hearings. We have had bills dropped by many  
537 members of Congress for many years, and I am so excited under  
538 your leadership and the leadership of Chairman Waxman and  
539 Chairman Dingell that we are finally on the verge of enacting  
540 comprehensive food legislation.

541 The most important thing about this bill is it would be  
542 a definitive statement by this committee and this Congress  
543 that food safety is a priority in the United States of  
544 America.

545 I want to highlight two of the sections of this bill,  
546 and I want to thank you and Mr. Dingell and others and Mr.  
547 Stupak for including the provisions of my two bills in this  
548 draft mark because they are critically important in the

549 future to assuring safe food for everybody.

550       As you know, Mr. Chairman, I have been working on these  
551 traceability issues for many, many years. And when I first  
552 started, people said it couldn't be done. But then as we  
553 realized with time, not only can it be done and in slightly  
554 different ways in every industry, but if we want to assure  
555 this integrity of the food system, it has to be done. What I  
556 fondly call the salsa scare of last year is the perfect  
557 example of why.

558       We found people being sickened by salsa, and we couldn't  
559 figure out why. This destroyed pretty much the entire profit  
560 of the tomato crop for that whole year because everybody  
561 thought it was tomatoes that had the salmonella. As it  
562 turned out, after months and months and months of increased  
563 sickness, of increased scrutiny, we found out that no, it  
564 wasn't the tomatoes at all. It was jalapenos, and they were  
565 from Texas.

566       And what I found out is that we can go to this  
567 particular sector of the field and find those jalapenos, and  
568 we can do it quickly. So traceability is going to be  
569 essential. And I look forward to working with my friends on  
570 the other side of the aisle to make sure it is not onerous.  
571 But I will say this. It is not just in the interest of  
572 consumers. It is in the interest of businesses who want to

573 protect their profits to have traceability.

574           Mandatory recall is a second provision of this bill that  
575 I have been working on for many years and I am so grateful  
576 has been included.

577           And I want to say finally, Mr. Chairman, all of this  
578 policy that we talk about, it is all well and good. But I  
579 can't help but think about young Jacob Hurley, who you might  
580 have seen. He was in our last ONI committee hearing.

581           Jacob is from Portland, Oregon, and he got sick from  
582 eating peanut butter crackers, his favorite food. When his  
583 parents took him to the doctor, they said they finally got  
584 him stabilized, and he wouldn't eat. So they told the  
585 parents have Jacob just eat what he loves, the peanut butter  
586 crackers, the very food that had made him sick in the first  
587 place.

588           And the only way we found out about this was because the  
589 alert commissioner of Consumer Protection in Oregon showed up  
590 personally at his door and confiscated the peanut butter  
591 crackers. We need to fix this. We need to fix it now, and I  
592 am so grateful that we are. Thank you, Mr. Chairman.

593           [The prepared statement of Ms. DeGette follows:]

594 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
595 Mr. {Pallone.} Thank you, Ms. DeGette. Next is the  
596 gentleman from Indiana, Mr. Buyer.

597 Mr. {Buyer.} Ma'am, welcome to the committee. Is it  
598 Hamburg or Hamburg?

599 Dr. {Hamburg.} Hamburg.

600 Mr. {Buyer.} Hamburg. Welcome, and my first reaction  
601 to the discussion draft is going to lead to some questions  
602 that I will have for you today. It appears that Congress a  
603 lot of times would like to pound our chest and then show the  
604 American people that we are doing something well.

605 But we really end up creating legislation within our own  
606 areas of jurisdiction, and we create problems. We create  
607 things that are multiplicitious and redundancies. And if we  
608 really wanted to couple substance with the words that I have  
609 heard here from some of my colleagues today, we would be  
610 working with other committees of jurisdiction. We would have  
611 a very comprehensive bill. And so I am going to be asking  
612 you questions, ma'am, about clear lines of delineations and  
613 responsibilities between USDA and FDA, and who should really  
614 have what responsibility.

615 Or should we as a Nation put all food under one agency  
616 and work cooperatively with the Ag Committee to do something  
617 like that? What we have is a discussion draft that has been

618 cleverly drafted only within the jurisdiction of our own  
619 committee, and so what we end up doing is are we exasperating  
620 a problem? And so I am interested in your leadership. You  
621 are representing an administration, and so I am interested in  
622 your best counsel to us and your willingness to work with  
623 leaders of other agencies to truly protect the American  
624 people.

625         And the other point I make is that Congress, as of late,  
626 has been beating up on FDA. I would say the FDA, the  
627 individuals that I have met and the ones that you have the  
628 privilege to lead are some pretty fine and capable and  
629 dedicated individuals.

630         In the last, gosh, 16 years, 17 years that I have been  
631 here, whether it has been Republicans in control or  
632 Democrats, we continue to pass legislation that leaps more  
633 and more responsibilities upon your core missions. And so  
634 here is your challenge to maintain the gold standards, not  
635 only with regard to pharmaceuticals but also in food, you  
636 know, we are about to send you legislation for a new mission  
637 on tobacco that is counter to your even cultural mission.

638         Yet we are going to continue to make you the whipping  
639 post, and so I am really concerned about the more  
640 responsibilities we give you, how much does that dilute your  
641 responsibilities? And so these are some of the questions

642 that I am going to be posing to you. And with that, I yield  
643 back.

644 [The prepared statement of Mr. Buyer follows:]

645 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
646           Mr. {Pallone.} Thank you. Gentleman from Georgia, Mr.  
647 Barrow.

648           Mr. {Barrow.} I thank the chair, and I appreciate the  
649 leadership you are showing on this issue. This is a matter  
650 of particular interest to me since, as Mr. Deal has already  
651 pointed out, two of the most egregious recent cases of  
652 tainted food in the food supply originate in my state of  
653 Georgia, and I think this bill represents a major step  
654 forward in trying to prevent this from happening again.

655           One of the things that is a particular bone of  
656 contention with me is that in the last outbreak, we got  
657 evidence in this committee that the manufacturer had test  
658 results which were showing positive presence of salmonella.  
659 The food that was sent out in the marketplace was tainted,  
660 and yet they didn't report that to the FDA.

661           Seems to me that we need to have, in addition to the  
662 good measures that have been incorporated in this bill, is an  
663 effective testing regime that has integrity in terms of  
664 sampling and integrity in terms of testing. And I think we  
665 have to make it easy for folks to be able to do this, to  
666 comply with this, and mandatory for them to report the  
667 results of any testing.

668           This way I think we can pick the bad actors out very

669 early on and perhaps even do a better job of arresting trends  
670 at a very early stage, detecting problems before they become  
671 serious.

672         Above all, I want to make sure that we don't bring about  
673 the Sergeant Shultz syndrome. You know he was the comic  
674 characters in Hogan's Heroes, and he had a big, loud comic  
675 demonstration every now and then of not knowing what was  
676 inconvenient for him to know. So we want to make sure that  
677 folks don't have the option of opting out or have a  
678 disincentive to know what they need to know when they need to  
679 know it. And that we know what they know when they need to  
680 know it. So that is the balance I think we need to strike  
681 here. I look forward to working with my colleagues on this  
682 as we try and incorporate provisions like that in this bill.  
683 And with that, Mr. Chairman, I yield back. Thank you.

684         [The prepared statement of Mr. Barrow follows:]

685 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
686           Mr. {Pallone.} Thank you. Gentleman from Texas, Mr.  
687 Burgess.

688           Mr. {Burgess.} Thank the chairman. Dr. Hamburg, Dr.  
689 Sharpstein, good to see you again. Spent some time yesterday  
690 out at the FDA's facility, and I will echo the comments of  
691 Mr. Buyer. You have a wonderful staff that you lead out  
692 there. They are obviously very, very dedicated individuals,  
693 sometimes working under the adverse conditions that we  
694 supply. But certainly I know you are very proud of the  
695 organization of which you lead, and I believe that pride is  
696 justified.

697           Mr. Chairman, I am going to stipulate to all of the  
698 difficulties that the Food and Drug Administration is  
699 encountering that have already been well-documented, and I  
700 would ask unanimous consent to insert my entire statement  
701 into the record. Let me just concentrate on the aspect that  
702 we are now finally, after I don't know how many hearings on  
703 this, getting down to somewhat of the business of acting for  
704 the FDA and talking about legislation that would give the  
705 Food and Drug Administration some tools.

706           But we are also giving them a timeframe, which may prove  
707 to be a very difficult timeframe for implementation. And we  
708 are also putting some additional burden on businesses at a

709 time that our economy is in some difficulty. The legislation  
710 proposed will mandate the largest change in food safety in at  
711 least two decades, and it will give the entire food industry  
712 a compressed time to do so. In a few short months, we will  
713 have to turn the current system of paper-based records into  
714 electronic form. Businesses will have to find the money to  
715 register as a food facility, and additional user fees, if we  
716 deem them appropriate in the future, and they will have to be  
717 able to fully trace the food to its place of origin.

718 All those may be laudable goals, but I am not certain  
719 that what we are proposing as a timeframe is adequate. And  
720 then the Food and Drug Administration itself, in that  
721 shortened compressed timeframe, will have to hire enough  
722 inspectors to meet the new inspection standards, create  
723 unique identifier numbers for every food facility, be they  
724 domestic or foreign, set up a new administrative law position  
725 for the new criminal and civil penalties, and make certain  
726 that each center has a food safety plan, all of this  
727 instantly demanded in one piece of legislation.

728 I would just point out when we did the Consumer Products  
729 Safety Improvement Act last year, H.R. 4040, we acted in good  
730 faith, and we acted with some dispatch. But we created some  
731 situations that are absolutely untenable. We have had to go  
732 back and try to amend some of those. We have driven some

733 small businesses to the point of bankruptcy. We have created  
734 a situation where our resale shops, because they cannot  
735 measure the lead standard that we required, are in a position  
736 that they don't know whether they can sell the goods that  
737 have been donated or not.

738         So I urge us to take every due caution. The law of  
739 unintended consequences has a very short turnaround time in  
740 our current globalized world, and we need to be cognizant of  
741 that.

742         And then finally, let me just, you know, a word about  
743 bipartisanship. A bill is bipartisan if it is bipartisan at  
744 the beginning. And Chairman Dingell, I appreciate the  
745 courtesy that you showed me in the last Congress at involving  
746 me in at least some of the preliminary discussions of the  
747 draft that you were considering. But really when the draft  
748 comes to the committee for consideration, it really ought to  
749 have had input from both sides, and the fact that there are  
750 five or six Democrats on the bill and no Republican. Was  
751 there no Republican on this side of the dais with which you  
752 could sit down and talk and perhaps get to a point where  
753 there could be some general agreement?

754         We have done this before on other pieces of legislation.  
755 We did it on the Food and Drug Reauthorization Act in June of  
756 2007. And I frankly do not understand why it is not worth

757 the effort to make these pieces of legislation--we are not  
758 talking about points for the next election. We are talking  
759 about the regime that will be in place that will ensure the  
760 safety of the food for my grandson and Marsha's  
761 grandchildren. This is the legacy that we are going to be  
762 leaving, and it is too important to be left to partisan  
763 politics.

764           And I thank you for the additional time, Mr. Chairman, I  
765 will yield back.

766           [The prepared statement of Mr. Burgess follows:]

767 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
768 Mr. {Pallone.} Thank you. The gentlewoman from  
769 California, Ms. Harman.

770 Ms. {Harman.} Thank you, Mr. Chairman. I would like to  
771 welcome Peggy Hamburg, an old friend, a brilliant physician,  
772 and a superbly qualified person to this committee and to her  
773 new role as FDA commissioner. I think you bring a lot to  
774 this job and will help this committee which has worked on the  
775 issue of food safety for years and years and years come to a  
776 thoughtful, careful, healthful decision on the shape of this  
777 legislation. So welcome.

778 Mr. Chairman, I am very comfortable with the discussion  
779 draft, and I do know that it reflects many, many years of  
780 input from members. I thought that John Dingell's comment  
781 that it is almost old enough to vote was particularly apt.  
782 That applies to me too.

783 And I think that coming from a state like California,  
784 which is the largest agricultural producer in the country, we  
785 ignore food safety at our peril. The vice chairman, Diana  
786 DeGette was chronicling some of the recent outbreaks and how  
787 important it is to have traceability and mandatory recall. I  
788 agree. And we could have saved a lot of pain, a lot of cost,  
789 and a lot of health problems had we had those measures in  
790 place.

791           So I just want to conclude by saying that we have a able  
792 and willing partner facing us this morning. I think we have  
793 an able and willing committee on a bipartisan basis to engage  
794 with her, and I am very eager to see us make progress and to  
795 enact legislation close to the committee draft as soon as  
796 possible. It is in our national interest, and surely as we  
797 talk about grandchildren, it is in our grandchildren's  
798 interest. I yield back the balance of my time.

799           [The prepared statement of Ms. Harman follows:]

800 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
801           Mr. {Pallone.} Thank you. Gentlewoman from Tennessee,  
802 Ms. Blackburn.

803           Ms. {Blackburn.} Thank you, Mr. Chairman, and I want to  
804 welcome Dr. Tim Jones who is going to be on our second panel.  
805 He is hiding over here in the back. He must be one of these  
806 Baptists from Tennessee. He is going to sit in the back row  
807 until time for him to come forward. But Dr. Jones is an  
808 epidemiologist with the Department of Health in our great  
809 state. Does a wonderful job for our state, and I am  
810 absolutely delighted that we are going to be able to hear  
811 from him today on the second panel. So, Dr. Jones, thank you  
812 for taking the time to come.

813           While the draft legislation before us today attempts to  
814 improve the safety and the efficacy of the Nation's food  
815 supply, it appears that there is still a lot of room for  
816 improvement. And I am appreciative that we are having the  
817 hearing, and I am hopeful that we are going to be able to  
818 work in a bipartisan way on this issue.

819           I appreciate the majority's attempt to improve the  
820 country's food safety system, but I think that we all know,  
821 especially those of us who are mothers, we know that you  
822 can't inspect your way to food safety. We know that this  
823 legislation is going to have to do more than be reactive.

824 This legislation broadly increases the FDA authority to make  
825 it one of the largest federal agencies in the existence.

826 My concern is the growth of bureaucracy, and what is  
827 going to happen as that bureaucracy grows. What I do think is  
828 necessary and I think it is necessary that our system be  
829 risk-based, that it be preventative, and take that approach,  
830 and that it effectively target bad actors.

831 It is imperative that resources are focused on issues of  
832 high risk and innovations that are most effective. However,  
833 this bill places undue burden on small businesses, and they  
834 would be harmed by burdensome and expensive provisions that  
835 are found in this current draft of this legislation.

836 The FDA has provided no evidence that it has improved  
837 its internal processes in order to improve the review of the  
838 Nation's food supply. This is something we have talked about  
839 endlessly in this committee and in hearings. So we are  
840 looking forward to having some questions on this.

841 There seems to be--and you haven't proven otherwise--  
842 that there are established protocols and lines of  
843 communication between different jurisdictions. You have not  
844 shown that there are best practices. Indeed, about 13 months  
845 ago, I asked for a list of best practices on intra-agency  
846 communication and how you are sharing this information, how  
847 you are working with your affiliates so that everyone can

848 more easily pinpoint and get to the bottom of problems and  
849 bad actors and issues that are coming forward.

850           And yesterday, the FDA announced that they are studying  
851 ways to make the agency more transparent. This should have  
852 been done before we pass a bill that would give the agency  
853 millions of dollars in user fees. And I am going to yield my  
854 time back and submit my full statement for the record and  
855 look forward to the questions.

856           [The prepared statement of Ms. Blackburn follows:]

857 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
858           Mr. {Pallone.} Thank you. Gentlewoman from the Virgin  
859 Islands, Ms. Christensen.

860           Ms. {Christensen.} Thank you, Mr. Chairman, and welcome  
861 back, Dr. Hamburg. I know New York has suffered a great  
862 loss, but the Nation needs you more. I also think it is very  
863 fitting that as we have come back to Congress and begin to  
864 put the nuts and bolts on our health care reform legislation  
865 that the first hearing that this committee is having is with  
866 FDA because I believe we will begin that reform with an  
867 overhaul and a better resourcing of the Food and Drug  
868 Administration.

869           From the Food Safety Enhancement Act of 2009 that we are  
870 looking at in draft today and the Family Smoking Prevention  
871 and Control Act of 2009, we are looking at a new FDA, and you  
872 have the challenge as well as the opportunity to remake this  
873 important institution in ways that it better serves the  
874 health of the American public while also fostering, guiding,  
875 and supporting the bringing of new and better treatments to  
876 us as well.

877           I have confidence in a better resource FDA with more  
878 authority and one that is not overly prescriptive. I don't  
879 want to be overly prescriptive on what we tell the agency to  
880 do, but I hope that we will be able to allow the agency to do

881 its job based on clear authority, adequate resources, and  
882 sound science.

883         In the case of food safety, in this my first few months  
884 on this committee, I have really been alarmed to find out  
885 what has happened that has put the public's health in  
886 jeopardy from salmonella to some questions about even the IRB  
887 process and several other areas. So we are here to help you  
888 create a better, stronger FDA, and this hearing is part of  
889 that process. And I thank you and all of the panelists for  
890 sharing their experience and expertise with us this morning.

891         [The prepared statement of Ms. Christensen follows:]

892 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
893           Mr. {Pallone.} Thank you. Gentleman from Pennsylvania,  
894 Mr. Murphy.

895           Mr. {Murphy of Pennsylvania.} Thank you, Mr. Chairman,  
896 and welcome, Dr. Hamburg. Pennsylvania's number one industry  
897 is agriculture, and with that comes a lot of food processing.  
898 We are honored to have national companies located in  
899 Pennsylvania like Hershey's. We have companies like Welch's  
900 grows a lot of grapes there. And more locally in the  
901 Pittsburgh area, regional distributors of groceries like  
902 Giant Eagle, national distributors of olive products like  
903 Delalow's, and of course big names like Del Monte and the  
904 corporate headquarters of Heinz, and small companies like  
905 Sarah's Chocolates that sells around the country.

906           All of them have talked with us about concerns for this  
907 bill and certainly are very supportive of making sure we have  
908 a strong FDA, and we want to make sure that happens.

909           A few questions were raised, and I hope I will be able  
910 to remain for part of this hearing; although, I have to run  
911 to the floor, and I apologize for that. I will miss some of  
912 this, but a number of issues: making sure that there is no  
913 unintended consequences of the bill that leads to increased  
914 price for consumers. Let us work on that, on the  
915 registration fee, particularly as it may affect some smaller

916 businesses trying to work.

917         Also, with regard to the traceability, need to be clear  
918 what exactly the obligations are for both the processed and  
919 fresh food industry. Are we talking about traceability of  
920 final product or traceability of every ingredient that went  
921 into the product?

922         For example, if a local restaurant chain makes cookies  
923 or someone else makes cookies, trying to track every single  
924 ingredient that comes up with a specific food color dye may  
925 be a problem for them and would like to make sure we make  
926 that work for the safety of consumers but not in a way that  
927 impairs companies from doing their work.

928         And also unintended consequences of giving the FDA  
929 copies of all test results could be less testing. As  
930 companies go through lots and lots of test for products that  
931 never make it to market, would it be--to test the hundreds of  
932 samples each day have to be available or change to the  
933 testing of products that are in the marketplace?

934         With regard to the country of origin labeling and  
935 disclosure, to list every ingredient on a website could  
936 increase the costs and resources and not necessarily bring  
937 added value. Could there be some general labels such as some  
938 statement that this product may contain ingredients from one  
939 or more of the follow countries?

940           Also how about raising the importance of making sure  
941 that all enforcement officers and auditors are well-trained  
942 and calibrated to work to define audit standard? There is  
943 also concern of what happens with the family farm that may  
944 sell to local grocery stores. To what level would they have  
945 to comply? And would it be that the fees for them would be  
946 so high that they simply could not sell any products outside  
947 of their own farm store? And as that impairs some smaller  
948 distributors, how do we help them?

949           Another issue for grocery stores, what if they make  
950 packaged food at their stores such as some value-added ground  
951 beef products made in the meat departments? What happens if  
952 they mix in other foods at their store? How does the bill  
953 affect them in other ways?

954           So certainly in Pennsylvania we want strong food safety  
955 bills. We want ones that protect consumers. We want small  
956 businesses to be encouraged and large businesses to be  
957 supported but also encourage new startups. But more than  
958 anything else this week we want the Penguins to win the  
959 Stanley Cup, and I yield back.

960           [The prepared statement of Mr. Murphy of Pennsylvania  
961 follows:]

962           \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
963           Mr. {Pallone.} Thank you. Gentleman from Texas, Mr.  
964 Green.

965           Mr. {Green.} Mr. Chairman, I want to thank you for  
966 holding the hearing today on the discussion draft of the food  
967 safety legislation. Over the past year or so, there have  
968 been several high profile food contamination incidents in the  
969 United States involving spinach, cantaloupes, peanut butter,  
970 and tomatoes. This committee has diligently investigated all  
971 of these incidents.

972           These hearings on the FDA have clearly shown us that the  
973 FDA simply does not have the resources, funding, or manpower  
974 and technology it needs to protect the American food supply  
975 and fulfill its mission.

976           Chairman Dingell, Chairman Pallone, and Chairman Stupak  
977 have worked tirelessly on this proposed legislation. I would  
978 like to applaud them for their dedication on this issue. I am  
979 hopeful for this hearing and the discussion draft will bring  
980 us one step closer to passing food safety legislation out of  
981 the House.

982           I had a brief chance to review the legislation. I would  
983 like to briefly discuss a couple of issues that concern me.  
984 The discussion draft allows for food imported to be inspected  
985 by third-party accredited labs to conduct sample analysis. I

986 support the provision, but I would like to see an investment  
987 in instruction in FDA labs.

988         The port of Houston is the largest port in the U.S. in  
989 terms of foreign tonnage, and a large portion of that is  
990 related to our energy industry. But the port imported  
991 606,000 tons of imported food in 2007. The port of Houston  
992 does not have an FDA lab, and surprisingly there is no FDA  
993 lab in Texas even though we share the longest border with  
994 Mexico. I have yet to understand why Texas with its level of  
995 trade and southern border with Mexico does not have an FDA  
996 lab. In fact, there are over 300 ports of entry in the  
997 United States, and only 13 ports actually have FDA labs.

998         I hope my colleague from Arkansas will forgive me, but  
999 the closest FDA lab to Houston and the entire state of Texas  
1000 is located in Arkansas.

1001         Houston is not the only import area in Texas. Cities  
1002 like Laredo, Texas that is one of the largest land-locked  
1003 ports of entry in the world imports from Mexico literally  
1004 thousands of trailers on a weekly basis. It seems unwise and  
1005 frankly unsafe to have the FDA lab for the entire state of  
1006 Texas located 100 miles away in another state.

1007         The location of FDA labs throughout the U.S. needs to be  
1008 evaluated and a report should be submitted to Congress on  
1009 whether the FDA labs are located where they are most needed.

1010 The discussion draft allows FDA to assess current FDA lab  
1011 locations and to relocate labs as necessary.

1012 I would like to hear from the FDA on whether they have  
1013 any plans to evaluate current lab, FDA lab locations.  
1014 Congress also needs allocated funds to the building of more  
1015 FDA labs. I was pleased to see the President's budget. The  
1016 allocation of funds was three high-volume FDA labs. If we  
1017 want FDA to truly ensure the safety of our food supply, we  
1018 need to build more FDA labs in areas where food imports are  
1019 arriving, such as Houston, so the FDA can quickly and  
1020 accurately test our food imports and ensure food safety.

1021 Again thank you, Mr. Chairman. Look forward to hearing  
1022 our witnesses, and thank our new FDA director for appearing  
1023 before the committee.

1024 [The prepared statement of Mr. Green follows:]

1025 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1026 Mr. {Pallone.} Thank you, Mr. Green. Our ranking  
1027 member, Mr. Barton.

1028 Mr. {Barton.} Thank you, Mr. Chairman. I will be very  
1029 brief. We support there being a legislative hearing and  
1030 hearing on food safety. We think it is time to address this  
1031 problem in a bipartisan fashion if at all possible. We do  
1032 think it is important that we try to get it right if at all  
1033 possible.

1034 We understand that it is your wish and the full  
1035 committee chairman's wish and former Chairman Dingell's wish  
1036 to move with legislation sometime this month. Republicans  
1037 are ready to help if we can agree on a bill that provides the  
1038 FDA with the tools that it needs to ensure the safety of our  
1039 food supply. But we will not support new blanket authorities  
1040 that are designed merely to empower the bureaucracy.

1041 Nearly everybody says that ``we cannot inspect our way  
1042 to foods safety.'' We need systems that reliably prevent  
1043 sickness by applying resources in those places that are most  
1044 susceptible to contamination. The draft before us proposes  
1045 several areas to strengthen prevention of food illness  
1046 outbreaks such as requiring all manufacturers to have food  
1047 safety plans and also the creation of appropriate produce  
1048 standards.

1049           These ideas make sense and have near universal support.  
1050 We are concerned however that parts of the draft add more  
1051 weight than quality to the regulations and, in our opinion,  
1052 provide too much discretion to the FDA without any  
1053 corresponding food safety benefit.

1054           For example, country of origin labeling is not about  
1055 food safety. AS a practical matter, it will simply increase  
1056 the cost of groceries at the store. We know this because  
1057 expert after expert has testified at the committee that this  
1058 provision has absolutely no effect on safety.

1059           There are several other specific concerns with the  
1060 draft, including the level and the scope of the registration  
1061 fees. I will say that the registration fees are less in this  
1062 draft than they have been in some previous drafts so that I  
1063 can at least say that we are moving in the right direction.

1064           Having said that, it does appear that the majority  
1065 simply wants \$300 to \$400 million in additional funds for the  
1066 FDA, and we can't see that there is any clear purpose for  
1067 that amount of funding.

1068           Having said that, we look forward to the hearings, and  
1069 if we can work on some of these problems, we are prepared to  
1070 be positively engaged in the markup that comes after the  
1071 hearings. With that, Mr. Chairman, I will yield back.

1072           [The prepared statement of Mr. Barton follows:]

1073 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1074 Mr. {Pallone.} Thank you, Mr. Barton. The gentlewoman  
1075 from Ohio, Ms. Sutton.

1076 Ms. {Sutton.} Thank you, Mr. Chairman. Thank you for  
1077 holding this hearing on this extraordinarily important issue.  
1078 I want to extend my appreciation to the sponsor of this bill  
1079 and all of those who, for so long, have been fighting the  
1080 fight to fix our food safety system and make sure that the  
1081 food that is on the table to feed our families is safe for  
1082 their consumption. And that which goes with them to school,  
1083 they can fear not that it will be safe for their children to  
1084 eat.

1085 Chairman Emeritus Dingell, I thank you very much for  
1086 your long effort in improving our food safety network, along  
1087 with Representative Dingell, Representative Stupak and others  
1088 on both sides of the aisle. And look forward to working with  
1089 you.

1090 As you may know, the very first bill that I introduced  
1091 in the House, I believe, was a bill to call for mandatory  
1092 recall authority for the FDA. And there is a reason for  
1093 that. I mean we have seen these problems arise again and  
1094 again and again within our food safety network. And the  
1095 American people, I think, would have been shocked, as I was,  
1096 to learn that our government did not have the authority to

1097 issue a mandatory recall when it became apparent that it was  
1098 necessary.

1099 Ohio has suffered the effects of problems with our food  
1100 safety system. Most recently, the salmonella outbreak has  
1101 claimed lives and harmed many throughout the Buckeye State,  
1102 and it is critical that we are moving forward with a  
1103 comprehensive bill to finally address and ensure the safety  
1104 of America's tables and our system. Thank you so much. I  
1105 yield back.

1106 [The prepared statement of Ms. Sutton follows:]

1107 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1108 Mr. {Pallone.} Thank you. Gentleman from Michigan, Mr.  
1109 Rogers.

1110 Mr. {Rogers.} Thank you, Mr. Chairman. Appreciate the  
1111 hearing and congratulations, Commissioner, for your  
1112 confirmation. I look forward to working with you. Some  
1113 difficult issues ahead.

1114 I am glad this committee is focused on food safety. I  
1115 think we can all agree that the FDA needs more resources to  
1116 protect our food supply and strengthen public health. I am  
1117 concerned, however, that this might be a ready-shoot-aim  
1118 event. We just passed a fairly onerous bill and added a lot  
1119 of authority to the FDA that had a huge loophole in it that  
1120 allowed tobacco regulation to be borrowed from the general  
1121 fund of the FDA.

1122 So you have this hole of millions and millions of  
1123 dollars, of which you are going to have to try to apply to  
1124 thousands and thousands of new regulators. At the same time,  
1125 we are trying to improve food safety, and I can't think of  
1126 anything more important than our food supply.

1127 My hat is off to you, Commissioner, on the challenge of  
1128 what you have just accepted. As we all know, the FDA is  
1129 currently unable to inspect the majority of the Nation's food  
1130 facilities. Worse, many high-risk facilities have gone

1131 without inspection and oversight at all. Over the last two  
1132 years, we have seen the impact of this failure: numerous  
1133 salmonella and E.coli outbreaks, which have sickened  
1134 thousands and even lead to death.

1135 I hope that this bill could eventually be a bipartisan  
1136 bill. However, many of the concerns that we have expressed  
1137 have not been addressed, and we have not had the opportunity  
1138 to sit down and have a discussion before this bill has come  
1139 before the committee. And I think that is horribly  
1140 unfortunate when you are talking about food safety and food  
1141 safety issues.

1142 The user fees in this draft are concerning to me. As  
1143 written, the bill would require \$1,000 in registration fee  
1144 per food facility, but these funds totaling about \$375  
1145 million which will be passed along to consumers, which are  
1146 regular families trying to pay their bills already, there is  
1147 nothing in there that dedicates this to new inspections.

1148 So we have come up with a new tax regimen that doesn't  
1149 benefit the FDA in getting it to the place where you need it  
1150 most, which is inspectors for food facilities and food  
1151 supply. Makes no sense to me, and that is something we  
1152 absolutely have to change in this bill, or, Madam  
1153 Commissioner, you are going to be looking at a very tough  
1154 hole to fill again. There is nothing in here that tells the

1155 appropriators where to put that money so that you can best  
1156 use it to accomplish the mission of which this bill will tell  
1157 you it has to do without telling you where the money is  
1158 coming from.

1159         That is almost dangerous when you think about this plus  
1160 the FDA tobacco regulation authority that allows them to take  
1161 your money for food supply inspections and drug approval and  
1162 use it for hiring new regulators for tobacco. That is a real  
1163 problem that we need to fix not only in this bill, at least I  
1164 hope we can.

1165         If food producers are required to pay this new tax, they  
1166 should absolutely have the certainty that the funds are going  
1167 to be used for food safety inspections. I think that is  
1168 common sense. I think we can all agree on it. I would hope  
1169 to work with the majority to get that taken care of.

1170         In addition, the draft's inspections schedule seems  
1171 almost impossible to achieve. Today I hope, Commissioner,  
1172 that you can shed some light on what a practical, risk-based  
1173 inspection schedule should look like. And I hope you can  
1174 cover that today in your statement and through questions.

1175         I also have several other concerns: the new, broad  
1176 recall authorities. Recall authority is important, but how  
1177 it is done is incredibly important. An expansive new civil  
1178 penalty regime, new labeling requirements that don't seem to

1179 have anything to do with food safety.

1180           Again I think all of these issues we can address if we  
1181 work together in a bipartisan manner and, I think, come  
1182 around something that we all believe needs to happen. And  
1183 that is more resources for food inspection and food safety  
1184 regimes that the FDA has a primary responsibility for.

1185           I look forward to working with you and thank you, Mr.  
1186 Chairman, for this I think all important hearing.

1187           [The prepared statement of Mr. Rogers follows:]

1188 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1189           Mr. {Pallone.} Thank you, Mr. Rogers. Gentlewoman from  
1190 Wisconsin, Ms. Baldwin.

1191           Ms. {Baldwin.} Thank you, Mr. Chairman. I appreciate  
1192 the fact that you are holding today's hearing and also want  
1193 to join my colleagues in commending you and Chairman Stupak  
1194 and Chairman Emeritus Dingell and Chairman Waxman for putting  
1195 this very important discussion draft before us that addresses  
1196 very serious challenges that we face with respect to food  
1197 safety.

1198           Before I begin my remarks, I would like to submit for  
1199 the record written testimony from the Secretary of the  
1200 Department of Agriculture Trade and Consumer Protection in  
1201 the state of Wisconsin.

1202           Mr. {Pallone.} Without objection, so ordered.

1203           [The statement follows:]

1204 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1205 Ms. {Baldwin.} Thank you, Mr. Chairman. Food safety is  
1206 an issue of great concern to me and my constituents.  
1207 Approximately one in four people in this country are affected  
1208 or sickened by food borne disease each year. As Americans,  
1209 we rely on government to keep us safe, and as government, we  
1210 have fallen down on the job.

1211 As we consider this draft legislation, I know that our  
1212 goal is to empower the FDA to prevent food contamination  
1213 incidents before they occur. I hope that we do so with  
1214 appropriate and sufficient resources, but also with precise  
1215 coordination between other federal agencies, the states, and  
1216 the private sector.

1217 Currently with its limited resources, the FDA focuses  
1218 its inspections on large manufacturers engaged in interstate  
1219 commerce, and it leaves much of the front line work to the  
1220 states. This bill creates a risk-based inspection system  
1221 that significantly increases the frequency of inspections. I  
1222 want to make sure that we are not duplicating efforts and  
1223 that we can empower states to perform their work on the  
1224 ground with logistical and financial support.

1225 I urge the FDA to use this legislation to create a  
1226 stronger, more integrated food safety system that leverages  
1227 state and local resources.

1228           As another result of limited resources, FDA relies on  
1229 many private sector firms to conduct food safety testing on a  
1230 contractual basis. I am pleased that the discussion draft  
1231 includes a provision that would allow a laboratory  
1232 accreditation process facilitating the FDA's use of third-  
1233 party laboratories to perform testing.

1234           And I want to make sure that the conflict of interest  
1235 language in the bill does not prevent some of the most  
1236 experienced laboratories from maintaining their strong  
1237 partnership with the FDA moving forward.

1238           I look forward to hearing your testimony, Dr. Hamburg,  
1239 and that of the other witnesses today. And I thank you  
1240 again, Mr. Chairman, for this hearing.

1241           [The prepared statement of Ms. Baldwin follows:]

1242           \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1243           Mr. {Pallone.} Thank you. Gentleman from Georgia, Mr.  
1244 Gingrey.

1245           Mr. {Gingrey.} Thank you, Mr. Chairman. Mr. Chairman,  
1246 public health officials estimate that 76 million people  
1247 become sick, 325,000 are actually hospitalized, and 5,000 die  
1248 each year from food borne illnesses caused by contamination.  
1249 Incidents like those in my own home state of Georgia, where  
1250 the actions of a few bad actors and a breakdown in effective  
1251 government oversight sickened more than 677 people in 45  
1252 states and caused at least nine deaths underscores the need  
1253 for action.

1254           I agree with my colleagues that more needs to be done to  
1255 ensure that the food products American consumers buy are  
1256 safe. Additionally, I support the efforts of this committee  
1257 as it reviews ways to streamline and improve the food  
1258 inspection system in this country.

1259           Mr. Chairman, I hope that these hearings will continue  
1260 to allow us the opportunity to reflect on the breakdowns in  
1261 our current system, as well as the appropriate solutions to  
1262 safeguard the health and welfare of all Americans.

1263           Madam Commissioner, I commend you for your recent  
1264 appointment. Look forward to hearing from you and from the  
1265 next panel of witnesses. And with that, Mr. Chairman, I

1266 yield back my time.

1267 [The prepared statement of Mr. Gingrey follows:]

1268 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1269 Mr. {Pallone.} Thank you. Gentleman from Iowa, Mr.  
1270 Braley.

1271 Mr. {Braley.} Thank you, Mr. Chairman. Welcome, Dr.  
1272 Hamburg. I don't think anyone sitting over here has anything  
1273 but good wishes for you and the enormous challenges you face,  
1274 and we wish you well and look forward to many fruitful and  
1275 productive conversations with you. As vice chairman of the  
1276 Oversight and Investigations Subcommittee, I have been very  
1277 involved in the hearing that we have had up to this point on  
1278 this important subject, and I am glad to see us finally  
1279 getting to the point of considering legislation that is so  
1280 critical to the health and safety of Americans.

1281 Throughout this process, we have seen examples of both  
1282 good and bad actors in the food industry. Some companies  
1283 like Nestle USA set the standard with proactive food safety  
1284 audits and showed us what can happen when companies do the  
1285 right thing in reaching out and doing their own  
1286 investigations.

1287 On the other hand, we heard extensively about Peanut  
1288 Corporation of America and its unsanitary and unsafe  
1289 conditions and about its action to misrepresent the results  
1290 of audits that were done, which put people at risk and cost  
1291 people their lives.

1292           That is why we are here today to talk about what we can  
1293 do to improve the current state of the situation. This Food  
1294 Safety Enhancement Act will solve many of the FDA's current  
1295 limitations, and I am glad that it requires increased  
1296 inspections of food facilities, tiered inspection systems  
1297 that distinguish between high-risk facilities, low-risk  
1298 facilities, and warehouses. And I also support the  
1299 provisions to ensure the safety of imported foods, which is  
1300 something I fought for since introduction of the Fresh  
1301 Produce Safety Act last Congress.

1302           Also very importantly I am very proud that this bill has  
1303 strong whistle-blower protections. And I believe that it  
1304 will help keep America's food supply safe. Many might  
1305 consider some of the provisions in this bill burdensome.  
1306 However it is important to look at opportunity costs of  
1307 failing to take action to improve food safety.

1308           In our March 19 Oversight hearing, I asked David Mackey,  
1309 who is the CEO of Kellogg, how much the PCA Salmonella  
1310 outbreak had cost his company, and he replied between \$65 and  
1311 \$70 million. The legislation before us today might have  
1312 prevented that outbreak and saved those costs.

1313           Most important, however, is what we owe to the families  
1314 of this country who have been injured or killed by unsafe  
1315 foods and the desire to take real action to keep our food

1316 supply safe.

1317           In 2006, a graduate of Dubuque Wallard High School in my  
1318 district, a marathon runner named Jill Cole contracted E.coli  
1319 from a spinach salad that she ate. After 17 days in the  
1320 hospital, she was released with just eight percent of her  
1321 kidney function, and she now has to see a doctor twice a year  
1322 to monitor her kidneys. Jill and all other Americans should  
1323 be able to have faith that their food is safe, and we are  
1324 here today to try to restore that faith. Thank you, Mr.  
1325 Chairman.

1326           [The prepared statement of Mr. Braley follows:]

1327 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1328           Mr. {Pallone.} Thank you. Gentleman from Maryland, Mr.  
1329 Sarbanes.

1330           Mr. {Sarbanes.} Thank you, Mr. Chairman. Welcome, Dr.  
1331 Hamburg. We are so excited to see you in this position, and  
1332 we look forward to your testimony on the proposed  
1333 legislation. The comment has been made a couple of times  
1334 that we can't inspect our way to food safety, and that may be  
1335 true. But we can non-inspect our way to food danger, which I  
1336 think has been unfortunately the hallmark of what has  
1337 happened in recent past. And so this bill that is proposed  
1338 is going to put so much more emphasis and inspection on the  
1339 front end, which is going to make a tremendous difference.

1340           When you look at the provisions that are contained in  
1341 this proposed legislation, so many of them go under the  
1342 heading of no-brainers. In other words, these are things  
1343 that the average citizen would imagine are already in place  
1344 and I think would be surprised to learn are not in place.

1345           And so there is so much about this bill that represents  
1346 some of the pent-up needs and concerns of the American public  
1347 that we need to address. On the economics, and there has  
1348 been a fair amount of discussion about that already just in  
1349 the opening statements. The better we do on the front end,  
1350 of course, with monitoring and inspection, the less cost we

1351 are going to have on the back end, both in terms of FDA  
1352 needing to scramble to deal with outbreaks of food borne  
1353 illness, but also to save cost of businesses of not having to  
1354 deal with the effects of that.

1355         And I think that those save costs will far outweigh the  
1356 investment that we put in on the front end and certainly  
1357 justify many of the measures that are contained in this bill.  
1358 So we look forward to your testimony, welcome, and good luck  
1359 to you. Yield back my time.

1360         [The prepared statement of Mr. Sarbanes follows:]

1361 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

1362 Mr. {Pallone.} Gentleman from Connecticut, Mr. Murphy.

1363 Mr. {Murphy of Connecticut.} Thank you, Mr. Chairman.

1364 I look forward to Dr. Hamburg's testimony and members of the  
1365 other panel. I think what we are talking about here today is  
1366 setting very high but very reasonable expectations for what  
1367 we can do out of the FDA. And I think that if that is our  
1368 goal, we can get a product that both parties can be proud of.

1369 As the former chair of Connecticut's public health  
1370 committee, I know I speak for a lot of state policymakers in  
1371 our feeling of helplessness over the past 5 to 10 years  
1372 especially, and I think you are going to find, as this  
1373 committee will find, a lot of allies in state public health  
1374 networks. They are going to be very supportive of this  
1375 transformation that you are undergoing to try to assist in  
1376 their efforts, which have been very difficult over the past  
1377 several years.

1378 Last thing, Mr. Chairman, I am very appreciative to you  
1379 and to Mr. Dingell and others for including in this bill  
1380 several aspects of the work that my colleague in Connecticut,  
1381 chairwoman of the Agricultural Subcommittee of Appropriations  
1382 Committee, Rosa Delaro. She has been working as a tireless  
1383 advocate on this issue. Parts of this bill relative to the  
1384 inspection frequency for the riskiest foods out there,

1385 enforceable performance standards for food borne standards  
1386 are parts of her efforts incorporated into the underlying  
1387 bill. And I appreciate you paying attention to her work here  
1388 as well. Look forward to your testimony. Thank you for  
1389 being here. Yield back.

1390 [The prepared statement of Mr. Murphy of Connecticut  
1391 follows:]

1392 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1393 Mr. {Pallone.} Thank you. Gentlewoman from Florida,  
1394 Ms. Castor.

1395 Ms. {Castor.} Thank you, Mr. Chairman. And kudos as  
1396 well to Rosa Delaro and Bart Stupak and John Dingell, our  
1397 colleagues here that have worked for many years to improve  
1398 food safety in America. And welcome to Dr. Hamburg. Based  
1399 upon your background, obviously you enjoy a challenge, and  
1400 food safety is an important challenge for our country.

1401 Of all the issues we deal with in this subcommittee,  
1402 food is the most ubiquitous. It is relevant to all  
1403 Americans. I wanted to remind my colleagues that the  
1404 Government Accountability Office remember keeps that very  
1405 short list of major government problems that require broad  
1406 transformation before they can ever hope to be effective.  
1407 The list called the high-risk series includes notorious  
1408 government failures such as the financial regulatory system,  
1409 which failed to prevent the largest financial collapse in  
1410 generations. It includes the implementation of the Homeland  
1411 Security Department, which has been plagued from the  
1412 beginning by cost overruns. And no surprise, it also include  
1413 federal oversight of food safety.

1414 And here is an example from last year that really hurt  
1415 in my home state of Florida. Tomatoes last year from Florida

1416 were blamed for a nationwide salmonella outbreak that was  
1417 eventually traced to jalapeno and Serrano peppers from  
1418 Mexico. In the meantime, FDA intimated at the time not to  
1419 consume Florida tomatoes, and that cost our state and  
1420 agricultural producers and hard working folks over \$100  
1421 million. All of the time and effort spent hinting and  
1422 suggesting that Florida tomatoes were the problem only served  
1423 to delay the solution to the real problem and allow more  
1424 Americans to get sick.

1425         Our committee understands the problem. This committee  
1426 has held several hearings, and we understand that we must act  
1427 expeditiously. Part of the problem lies in the lack of  
1428 federal authority to effectively respond to a crisis. When  
1429 FDA does not have incontrovertible proof of a specific food  
1430 contamination, it cannot today issue a mandatory recall.  
1431 Instead it must rely on corporations to voluntarily choose to  
1432 pull inventory from the shelves.

1433         The FDA does not even have the ability to assess civil  
1434 penalties. This legislation before us gives the FDA that  
1435 long overdue enforcement authority. The problems facing food  
1436 safety and oversight are legion, and they are difficult. But  
1437 they are not insurmountable, and I am confident that we will  
1438 move the Food Safety Enhancement Act of 2009 quickly and  
1439 provide American consumers with a safe, transparent and

1440 reliable food supply. I yield back my time.

1441 [The prepared statement of Ms. Castor follows:]

1442 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1443 Mr. {Pallone.} Thank you. Gentlewoman from California,  
1444 Ms. Eshoo.

1445 Ms. {Eshoo.} Thank you, Mr. Chairman, for having this  
1446 important hearing on the Food Safety Enhancement Act of 2009,  
1447 and I want to extend the warmest welcome and congratulations  
1448 to Dr. Hamburg. She is a woman of exceptional talent, high  
1449 intellect, a person with great character, and someone that  
1450 has given much to their country already and comes from one of  
1451 the most outstanding families, I think, in our country. You  
1452 can tell how elated I am that the President chose so wisely  
1453 in appointing you as FDA commissioner. We all look forward  
1454 to working with you. To the extent that you succeed, the  
1455 country is going to succeed.

1456 I also think that your tenure can be and will be the  
1457 mark where the FDA returns to being the gold standard in  
1458 terms of a public agency. The American people believe in the  
1459 FDA. They want the FDA to succeed because what you do they  
1460 can't do for themselves. And the decisions that are taken  
1461 can be the difference between life and death. That is how  
1462 profound the decisions are.

1463 So I can't tell you how thrilled I am that you are the  
1464 one. I am pleased that the legislation that we are  
1465 considering is going to improve the traceability of food

1466 because when tainted food is discovered, it is critical that  
1467 we know where it has come from, where it has gone and what  
1468 stores it is sold in. If sales are limited to a certain  
1469 area, targeted recall could take place, which would be more  
1470 effective for consumers and businesses.

1471 And I am also pleased to see the mandatory country of  
1472 origin labeling for food is included in the bill. I think in  
1473 today's environment, this is really essential information for  
1474 consumers to know where their food comes from. This is a  
1475 long and complex bill, and I too, along with my colleague Mr.  
1476 Murphy from Connecticut, really want to salute those that  
1477 have worked on this issue.

1478 Rosa Delaro has just been tireless, and you know that  
1479 she brings passion and intellect to what she does. And so  
1480 some of the ideas from her legislation are embedded in this.  
1481 I look forward to our conversation. I hope that what we are  
1482 asking the FDA to do that you are really up to it.

1483 I think we have lived on fees for a long time, and I  
1484 still have questions and would like to know directly from you  
1485 whether you really think you are going to have the resources  
1486 that are necessary to do this. Because if you don't, then  
1487 the print of the legislation or law would be wonderful to  
1488 read like some constitutions around the world that are  
1489 absolutely magnificent, but they are not worth the paper they

1490 are written on.

1491           We have fallen off the edge of a cliff in terms of what  
1492 is coming into the country and what has happened to the  
1493 American people. We have to get this right this time. And  
1494 some think that there should be a stand-alone food inspection  
1495 agency. Can the FDA actually do all of this? Do you have  
1496 the resources for it?

1497           I mean if there is pizza that has pepperoni on it versus  
1498 pizza that doesn't have any meat on it, should there be a  
1499 split jurisdiction between agriculture and the FDA in terms  
1500 of inspection? I think the more splits there are, that there  
1501 is more of an opportunity for things to fall between the  
1502 cracks. I may be entirely wrong, but I still have some  
1503 questions.

1504           I don't think this is a perfect piece of legislation,  
1505 but I am sure glad that we are considering the issue. So I  
1506 wish you nothing but the best. I have great, great  
1507 confidence and respect for you, and I am very proud that the  
1508 President chose to pick the best in the country for this job.  
1509 Thank you.

1510           [The prepared statement of Ms. Eshoo follows:]

1511 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1512 Mr. {Pallone.} Thank you. Gentlewoman from Illinois,  
1513 Ms. Schakowsky.

1514 Ms. {Schakowsky.} Thank you, Mr. Chairman, and  
1515 congratulations, Dr. Hamburg. I come to this issue with a  
1516 lot of history and also this particular issue with a lot of  
1517 emotion. My good friend Nancy Donnelly whose only child Alex  
1518 was lost because of eating hamburger with E.coli and then  
1519 dedicated her life to creating an organization, Safe Tables  
1520 are Priority, has worked tirelessly for food safety.

1521 And year after year, we have people coming before us  
1522 telling these devastating stories, and every time we say we  
1523 are going to do something so it never happens again. And yet  
1524 it does.

1525 In February, we heard testimony from Peter Hurley whose  
1526 young son was made ill by eating Austin peanut butter  
1527 crackers. They were found in millions of homes, and we were  
1528 all shocked by documents presented at that hearing that  
1529 showed that the Peanut Corporation of America knew that their  
1530 products were tainted and yet released them into the food  
1531 supply anyway.

1532 So the discussion draft that is before us includes  
1533 provisions that will seriously fill many of the gaps in our  
1534 current food system. I wanted to just mention a couple of

1535 things that I think ought to be considered for review. There  
1536 is just a brief mention in the bill dealing with the issue of  
1537 antibiotic-resistant pathogens and the extent to which  
1538 antibiotics that are used in livestock contributes to this  
1539 resistance. We don't always think about this as food safety,  
1540 but I think it is a truly important issue with H1N1. I know  
1541 it was a virus, but nonetheless everybody is waiting for that  
1542 kind of a plague that we don't have the care for partly  
1543 because of antibiotic resistance.

1544         Second, I believe the companies who have positive test  
1545 results for possibly dangerous contaminants should be  
1546 required to report those results to the FDA. We heard how  
1547 PCA, nobody knew about it, and I think there are many other  
1548 examples. It is a question on how the FDA effectively can  
1549 ensure the safety of our food if we don't even know where  
1550 there might be a problem.

1551         And finally I believe the collecting and disseminating  
1552 of information about food safety and food borne illness to  
1553 consumers is a critical component of any food safety plan. I  
1554 am encouraged by the provisions of the bill, but I think  
1555 there may be more that we can do to ensure that Americans are  
1556 adequately informed. Thank you so much.

1557         [The prepared statement of Ms. Schakowsky follows:]

1558 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
1559           Mr. {Pallone.} Thank you, and I believe that completes  
1560 our members' opening statements. So we will now turn to our  
1561 witness. And let me say, Dr. Hamburg, I appreciate your  
1562 being here. I want to welcome you. We have, as you know,  
1563 five-minute opening statements that become part of the  
1564 record, and then you may get some questions afterwards from  
1565 members of the committee. So thank you and if you would  
1566 begin.

|  
1567 ^STATEMENT OF MARGARET HAMBURG, COMMISSIONER, FOOD AND DRUG  
1568 ADMINISTRATION

1569 } Dr. {Hamburg.} Chairman Pallone and members of the  
1570 subcommittee, I am Dr. Margaret Hamburg, commissioner of the  
1571 Food and Drug Administration. Thank you for the opportunity  
1572 to appear before you today to discuss the urgent need for  
1573 reform of our Nation's food safety system. I commend you,  
1574 Chairman Waxman, Chairman Stupak, Chairman Emeritus Dingell,  
1575 and other members of the committee and your staffs for your  
1576 leadership and hard work in developing this draft  
1577 legislation.

1578 The food safety bill under consideration represents  
1579 significant reforms needed to modernize our food safety  
1580 system. I am honored to have been chosen by President Obama  
1581 to lead this great agency, and I am inspired by the  
1582 President's personal commitment to improving food safety,  
1583 including the progress being made by his food safety working  
1584 group.

1585 The President has backed up his commitment with  
1586 resources, proposing historic increases in funding for FDA's  
1587 food safety efforts. I also appreciate the support of  
1588 Secretary Kathleen Sebelius and the Department of Health and

1589 Human Services and of Secretary Tom Vilsac and the U.S.  
1590 Department of Agriculture for major progress on food safety.

1591 In addition, a coalition of consumer groups is fighting  
1592 for improvement in the food safety system so that more  
1593 families do not have to suffer tragic consequences from food  
1594 borne disease. Major sectors in the food industry also  
1595 support and are advocating for fundamental change, but even  
1596 with all this support and momentum, our efforts will fall  
1597 short unless Congress modernizes food safety laws to deal  
1598 with the challenges of the 21st century. That is why this  
1599 hearing is so important.

1600 From the perspective of FDA, there are three key  
1601 questions to ask about food safety legislation. First, does  
1602 the legislation support a new system focused on prevention?  
1603 Second, does the legislation provide FDA the legal tools  
1604 necessary to match its existing and new food safety  
1605 responsibilities? And third, does the legislation provide or  
1606 anticipate resources for the agency to match its  
1607 responsibilities?

1608 To comment on the discussion draft, let me address each  
1609 of these issues in turn. The first, does the legislation  
1610 support a new food safety system focused on prevention? The  
1611 draft legislation would indeed transform our Nation's  
1612 approach to food safety from responding to outbreaks to

1613 preventing them. It would do so by requiring and then  
1614 holding companies accountable for understanding the risks to  
1615 the food supply under their control and then implementing  
1616 effective measures to prevent contamination.

1617 Does the legislation provide FDA the legal tools  
1618 necessary to match its existing and new responsibilities? In  
1619 a new food safety system, FDA has the fundamental  
1620 responsibility of overseeing and verifying the implementation  
1621 of preventive measures by hundreds of thousands of companies.  
1622 The agency also retains the existing critical role of  
1623 protecting the public during an outbreak. FDA needs new  
1624 legal authorities to be able to succeed in these roles and  
1625 protect the public health. This legislation would provide  
1626 these critical tools.

1627 My written testimony provides several examples, but I  
1628 would like to highlight one of the most important new  
1629 authorities now. Section 106 provides FDA with explicit  
1630 authority to access food records during routine inspections,  
1631 thereby addressing one of the most significant gaps in FDA's  
1632 existing authority. The authority provided in this provision  
1633 is essential to enable FDA to identify problems and require  
1634 corrections before people become ill.

1635 It also enables the agency to verify, during routine  
1636 inspections, that firms are maintaining proper distribution

1637 records. Records access and record keeping by all persons in  
1638 the distribution chain are the key mechanisms of providing  
1639 regulators with information on plant operations, product  
1640 safety, and product distribution. Such information is  
1641 necessary to verify compliance and to identify problems.

1642         Lastly, does the legislation provide or anticipate  
1643 resources for the agency to match its existing and new  
1644 responsibilities? The draft legislation makes an important  
1645 investment in the resources needed for major progress. After  
1646 all, FDA must have the resources necessary to meet its  
1647 responsibilities. Otherwise, the public will not benefit  
1648 from the promise of a modern food safety system, and the  
1649 agency will fail to meet the expectations of the President,  
1650 Congress, and the public.

1651         The bill authorizes three fees that are also requested  
1652 in the President's fiscal year 2010 budget. One of these is  
1653 in Section 101, which provides for a registration fee. This  
1654 fee is of critical importance to enable the agency to improve  
1655 and expand its food safety activities, including to increase  
1656 its inspection coverage of the approximately 378,000  
1657 registered facilities and to enhance its other food safety  
1658 activities.

1659         Section 105 proposes a rigorous inspection schedule for  
1660 food facilities. These requirements start 18 months after

1661 the enactment. To meet these requirements, Section 105  
1662 allows the agency to use inspections conducted by inspectors  
1663 from recognized state, local, other federal agencies, and  
1664 foreign government officials.

1665 FDA would like to raise three issues about Section 105.  
1666 First, the amount of resources required to achieve these  
1667 inspection goals would far exceed even the historic increases  
1668 in the President's fiscal year 2010 budget. Moreover, it  
1669 would be difficult, if not impossible, for FDA to hire and  
1670 train thousands of additional staff so quickly, even while  
1671 relying on inspections by state, local and other federal and  
1672 foreign government officials.

1673 As a result, FDA encourages the committee to modify this  
1674 section to take into account the operational and resource  
1675 challenges involved.

1676 Second, as we develop a new food safety system, FDA will  
1677 gain better information to guide the agency's approach to  
1678 inspection and oversight. We will understand where we must  
1679 inspect more frequently because of the high risk of certain  
1680 foods, facilities, and processes, and understand where we can  
1681 protect public health without conducting inspections as  
1682 frequently.

1683 As a result, FDA would support flexibility to modify the  
1684 inspection requirements based on the best available data on

1685 risk.

1686           Third, Section 105 could do more to provide flexibility  
1687 to FDA in meeting the inspection challenge. The draft  
1688 legislation allows the agency to rely on inspections by other  
1689 federal agencies as well as by state, local, and foreign  
1690 governments. An additional promising mechanism for  
1691 international inspections is certification by accredited  
1692 third parties. FDA would like the flexibility to explore the  
1693 use of such an accreditation system and audit the performance  
1694 of accredited third parties. With strong standards and  
1695 robust oversight by FDA, this approach could help address the  
1696 oversight challenge posed by the more than 220,000 registered  
1697 foreign facilities exporting to the United States.

1698           This is a historic moment for food safety in the United  
1699 States, a moment for FDA and its sister agencies in the  
1700 federal government to rise to the challenge of the 21st  
1701 century. Success means fewer hospitalizations and deaths,  
1702 fewer devastating recalls, and greater health for the  
1703 American people.

1704           The draft legislation is a major step in the right  
1705 direction. I commend the committee for its leadership, and  
1706 on behalf of the hundreds of dedicated staff devoted to food  
1707 safety at FDA, I look forward to assisting with the  
1708 legislative process. I welcome any questions you may have.

1709 [The prepared statement of Dr. Hamburg follows:]

1710 \*\*\*\*\* INSERT 1 \*\*\*\*\*

|  
1711           Mr. {Pallone.} Thank you, Dr. Hamburg. We will have a  
1712 series of questions now from the members. Each of them gets  
1713 five minutes, and I will start with myself. Under the bill,  
1714 all facilities, both domestic and foreign, seeking to market  
1715 food in the U.S. must register each year and provide certain  
1716 information about the facility to the FDA. If the facility  
1717 is not registered, it is illegal to market food from that  
1718 facility in the U.S. And in order to register, each facility  
1719 would be required to pay \$1,000 per year as a registration  
1720 fee.

1721           Now, my understanding is in 2002, there was bioterrorism  
1722 legislation, and under that legislation, food facilities were  
1723 required to register, but there was no requirement to update  
1724 that registration. So my questions reference that  
1725 registration under the 2002 bill. Has that system resulted  
1726 in problems in terms of FDA's ability to accurately account  
1727 for all facilities selling food in the U.S. And maybe you  
1728 can tell us what problems exist.

1729           And then the second part is do you believe that linking  
1730 a fee to the requirement to register would help address  
1731 whatever problems exist under this system that dates back to  
1732 that 2002 bioterrorism legislation.

1733           Dr. {Hamburg.} Thank you. I think it is clear, based

1734 on the experience since the bioterrorism act in 2002, that we  
1735 do need the extended authorities that would be offered in  
1736 this bill. We know that when a facility registers once but  
1737 doesn't have to register again, that it does create problems  
1738 in terms of our ability to fully understand the nature of the  
1739 food-related activities in that facility.

1740         The Peanut Corporation of America, I think, is one good  
1741 example. When they first registered, they weren't actually  
1742 making peanut butter, and then they added that to their  
1743 activities. With annual registration, we would have a much  
1744 better record and understanding of the activities. And it  
1745 would provide us with the tools to be more responsible in our  
1746 oversight and in our inspections.

1747         With respect to the issue of fees, I think it is a very  
1748 important component of any food safety plan that Congress  
1749 would enact. We absolutely need to have the resources to do  
1750 our job. I understand that fees represent a burden on  
1751 companies, and I wish that we were not dependent on that  
1752 mechanism in all cases. But I do think that that fee is an  
1753 investment in a robust and effective food safety system.  
1754 That fee will go to enable the FDA to provide certain  
1755 specific services and put in place the board and modernized  
1756 food safety system that American consumers expect and need.

1757         Mr. {Pallone.} All right, let me go back to this fee

1758 because in the President's budget, he asked \$75 million in  
1759 registration and re-inspection fees. So obviously the  
1760 administration has already shown support for the concept of a  
1761 registration fee for food facilities in the budget.

1762         However in our bill, with its \$1,000 per facility fee,  
1763 we would generate much more than the \$75 million that is in  
1764 the President's budget. So I want you to explain, if you  
1765 could, what was contemplated in the President's budget  
1766 request of the \$75 million. Did that request seek to address  
1767 the new authorities provided in this bill?

1768         Dr. {Hamburg.} Well, the President's budget request  
1769 was, of course, put together before the specifics of this  
1770 proposed legislation was put forward. So it wasn't  
1771 addressing all of the specific requirements laid out in this  
1772 bill, importantly including the inspection schedule.

1773         In my written testimony, there is an appendix that  
1774 actually lays out some of the food safety highlights in the  
1775 President's bill and some of the targeted areas for that \$75  
1776 million increase in the budget.

1777         It was to include many elements that are a part of this  
1778 legislation, increased inspections but not to the degree that  
1779 this legislation would call for, the implementation of  
1780 preventive controls, strengthened laboratory testing, a  
1781 stronger integration of FDA and federal food safety efforts

1782 with the state and local activities which is ultimately very,  
1783 very essential to the--

1784 Mr. {Pallone.} Well, I know that the bill allows these  
1785 fees to be applied towards a broad array of FDA's food safety  
1786 activities. You know, in other words, it allows the fees to  
1787 be used to boost FDA's ability to develop standards like  
1788 performance standards and preventive controls. Do you agree  
1789 that the fees should be applied towards all these activities  
1790 that we mention in the bill?

1791 Dr. {Hamburg.} I think we want a robust, comprehensive  
1792 program, and those fees should be applied to putting in place  
1793 that suite of activities. The preventive controls are  
1794 directly related to what companies must do under the new  
1795 legislation, and I think it is very appropriate that the fees  
1796 cover that aspect. For example, the inspections obviously  
1797 are directly related. Very important that the fees cover  
1798 that aspect and many other aspects of the portfolio of  
1799 activities outlined in the legislation really are essential  
1800 to what needs to be done to protect consumers and ultimately  
1801 to protect the food industry. So that the public and  
1802 consumers can be assured that the products are safe.

1803 Mr. {Pallone.} Thank you. Thank you very much. Mr.  
1804 Deal. I am sorry. Mr. Whitfield.

1805 Mr. {Whitfield.} Thank you. Mr. Deal had to leave.

1806 Dr. Hamburg, as you probably know, Senator Kennedy and Durban  
1807 and Burr and Greg have introduced a food safety bill on the  
1808 Senate side. And has the administration endorsed that bill,  
1809 or has it endorsed this bill, or has it endorsed any bill?

1810 Dr. {Hamburg.} You know I have to be honest that I have  
1811 not--I have only been on the job seven days, and I have been  
1812 focused on your piece of legislation.

1813 Mr. {Whitfield.} Okay.

1814 Dr. {Hamburg.} And so I would be happy at a later time  
1815 to discuss in more detail the bill on the Senate side.

1816 Mr. {Whitfield.} But as far as you know, the  
1817 administration has not endorsed either bill?

1818 Dr. {Hamburg.} I don't believe so.

1819 Mr. {Whitfield.} Okay. Well, the reason I brought that  
1820 up, there are some significant differences in this Senate  
1821 bill and the House bill. And one area of difference relates  
1822 to recall authority of the FDA. And under this bill, the FDA  
1823 would have the authority for recall if an article of food may  
1824 cause adverse health consequences. That would be the legal  
1825 standard, may cause. But in the Senate bill, it says that  
1826 there must be a reasonable probability of serious adverse  
1827 health consequences or death. So those standards are  
1828 significantly different, and I would just ask you, since you  
1829 are now going to be responsible for this. That first

1830 standard that is in this bill seems so general and so  
1831 nebulous in a way. Does that bother you? Don't you think it  
1832 would be better to have a more precise identified standard  
1833 for recall?

1834 Dr. {Hamburg.} Well, I certainly understand the concern  
1835 that you are raising, and I think there may be some  
1836 opportunities for some wordsmithing. Certainly we would  
1837 never seek to recall a product without, you know, some  
1838 reasonable expectation that there was serious adverse  
1839 consequences and harm related to that product. A recall is  
1840 no small issue both in terms of resources and efforts on the  
1841 part of the FDA and also its implications on industry and  
1842 consumers who want access to those products.

1843 So I think it is an area that we would like to work with  
1844 you on for language. We wouldn't want it to be too  
1845 overwhelmingly prescriptive because you want to have the  
1846 flexibility in that kind of potentially emergency situation  
1847 to move forward.

1848 Mr. {Whitfield.} Well, I agree. I mean I think this is  
1849 an area that we should look at because we know the  
1850 ramifications of a recall, the expense involved, and  
1851 certainly we want to have a balancing of protecting the  
1852 public versus preventing undue expenses to companies as well.  
1853 So I am glad to see that that is at least an area that you

1854 would be willing to talk about.

1855 I might also say the same thing would apply to these  
1856 access of records. There really is no standard at all in  
1857 this bill, but in the Senate bill, it says that if FDA has a  
1858 reasonable belief that an article of food presents a threat  
1859 of serious adverse health consequences or death, FDA would  
1860 have access to and be able to copy all records and so forth  
1861 and so forth. But under this bill, it appears that FDA would  
1862 just have blanket authority to request any records at any  
1863 time without any sort of standard being met.

1864 Dr. {Hamburg.} Well, here I would like to stress that I  
1865 think access to routine records is extremely important to  
1866 assuring a safe food supply. It is very important that when  
1867 inspectors go into a facility, they can examine certain  
1868 aspects of what have been the procedure during a preceding  
1869 period of time and not just inspect what is happening at that  
1870 moment. Had we been able to better access to routine records  
1871 in the case of PCA, which has been talked about already this  
1872 morning, we would have been able to see that there was  
1873 documentation of contamination several years earlier, which  
1874 had not been adequately addressed.

1875 Mr. {Whitfield.} My time has about expired, but I would  
1876 like to ask just one additional question. It relates to Jan  
1877 Schakowsky's comment in her opening statement about the use

1878 of antibiotics in the agricultural community and the fact  
1879 that more and more people seem to be establishing immunity to  
1880 certain antibiotics. Is that a concern of yours?

1881 Dr. {Hamburg.} It is a huge concern of mine in terms of  
1882 the growing problem of antibiotic resistance in this country  
1883 and around the world and the implications that it has for our  
1884 armamentarium of antibiotics to address serious and life-  
1885 threatening diseases. I think it is an area that merits a  
1886 lot of attention by the FDA, working in partnership with  
1887 others. It is a topic I would be happy to come back and  
1888 discuss in more detail with you. And it is very high  
1889 priority for me in terms of overall goals to improve public  
1890 health.

1891 Mr. {Pallone.} Thank you. Chairman Dingell.

1892 Mr. {Dingell.} Mr. Chairman, thank you. Welcome again,  
1893 Dr. Hamburg. Congratulations. My first question, it will be  
1894 a yes or no--well, inspections are an important part of  
1895 finding and addressing food safety problems. Isn't this  
1896 correct?

1897 Dr. {Hamburg.} Yes.

1898 Mr. {Dingell.} Your agency does not have a good record  
1899 when it comes to inspecting food facilities. Last year, you  
1900 inspected 6,562 food facilities in the United States, 152  
1901 foreign facilities in the same time. Was that enough

1902 inspections? How many should you have? And what resources  
1903 would you need to do the job?

1904 Dr. {Hamburg.} I think we can do better. With respect  
1905 to the question of exactly how many, you know, I cannot tell  
1906 you that now. But--

1907 Mr. {Dingell.} I will submit you a letter asking these  
1908 questions in greater detail.

1909 Dr. {Hamburg.} I was warned that you would do that.

1910 Mr. {Dingell.} And I ask unanimous consent that the  
1911 record remain open to include both my letter and the response  
1912 of the administrator.

1913 Mr. {Pallone.} So ordered.

1914 Mr. {Dingell.} Would you support an increased frequency  
1915 requirement?

1916 Dr. {Hamburg.} We clearly need to do more frequent  
1917 inspections. We also need to do smarter inspections, and we  
1918 need not to rely simply on inspections as our tool for a  
1919 safer food supply.

1920 Mr. {Dingell.} We agree on that. I am keenly aware  
1921 that there is a substantial cost associated with conducting  
1922 foreign and domestic facility inspections. How much do you  
1923 need to do this properly in terms of personnel and money? If  
1924 you can't give it now, I will ask the record be kept open to  
1925 receive that.

1926 Dr. {Hamburg.} All right, well it is a complicated  
1927 answer, and there are some unknowables, but we need a lot  
1928 more money.

1929 Mr. {Dingell.} Mr. Chairman, I ask unanimous consent  
1930 that the record remain open so that this can be inserted at  
1931 the appropriate time.

1932 Mr. {Pallone.} Mr. Chairman, the record will remain  
1933 open. You don't have to keep saying it.

1934 Mr. {Dingell.} Thank you. And it is clear with new  
1935 inspection requirements, FDA is going to need new additional  
1936 resources to meet that requirement. Is it not?

1937 Dr. {Hamburg.} That is absolutely true.

1938 Mr. {Dingell.} The President has asked additional  
1939 resources for food safety activities at the agency. He  
1940 requested, I am told, about \$259 million in additional money.  
1941 Is that correct?

1942 Dr. {Hamburg.} Yes.

1943 Mr. {Dingell.} It was the President's intent that these  
1944 additional dollars, amounting to \$164.8 million in new budget  
1945 authority and \$94.4 million in new fees, registrations, re-  
1946 inspection and export certification would be used for  
1947 increasing the number of food facility inspections conducted  
1948 by your agency. Is that not correct?

1949 Dr. {Hamburg.} It would be used for that as well as

1950 other components of a more comprehensive modernized food  
1951 safety system.

1952 Mr. {Dingell.} Thank you. It is correct that the  
1953 President's budget request for food safety's activity did not  
1954 include any new requirements that may come with the food  
1955 safety legislation that we are considering here. Is that  
1956 correct?

1957 Dr. {Hamburg.} I am sorry, but could you repeat the  
1958 question?

1959 Mr. {Dingell.} The President's request for new monies  
1960 did not include monies to address the questions that you will  
1961 be compelled to face under the new legislation. Is that  
1962 correct?

1963 Dr. {Hamburg.} It addressed some components but not the  
1964 full--

1965 Mr. {Dingell.} But not all?

1966 Dr. {Hamburg.} --panoply of requirements that are  
1967 outlined in this legislation.

1968 Mr. {Dingell.} There are many who have resisted new  
1969 money for improving food inspection frequency by the agency.  
1970 They ask that the use of these dollars for such activity be  
1971 prohibited. Would you agree with that or disagree?

1972 Dr. {Hamburg.} I hate to do this, but this style of  
1973 questioning--

1974 Mr. {Dingell.} I am sorry. I have limited time.

1975 Dr. {Hamburg.} I know.

1976 Mr. {Dingell.} I have 12 seconds left.

1977 Dr. {Hamburg.} Could you just repeat the question?

1978 Mr. {Dingell.} Question: do you agree with the idea  
1979 that we should prohibit the use of registration fees for  
1980 inspection?

1981 Dr. {Hamburg.} I think we need registration fees to  
1982 enable the agency to do its inspectional activities and other  
1983 components of a food safety plan.

1984 Mr. {Dingell.} As a matter of fact, one of the few  
1985 successful activities of Food and Drug at this particular  
1986 time is what you do under PDUFA, which is supported by fees.  
1987 Is that not correct?

1988 Dr. {Hamburg.} That is correct.

1989 Mr. {Dingell.} And you are starving in almost every  
1990 other place. Isn't that so?

1991 Dr. {Hamburg.} Correct.

1992 Mr. {Dingell.} Can you state with any certainty the  
1993 number of people, importers, customs brokers, filers, who  
1994 import products under FDA's jurisdiction to the United States  
1995 in any year? I believe the answer to that question is no.

1996 Dr. {Hamburg.} Is no, and this legislation would enable  
1997 us to get a much better handle on who is out there producing

1998 and distributing food for U.S. consumption.

1999 Mr. {Dingell.} And the reason is that they are not  
2000 currently required to register with FDA. Isn't that the  
2001 reason?

2002 Dr. {Hamburg.} That is a large part of the reason, yes.

2003 Mr. {Dingell.} Isn't it important to FDA to have an  
2004 accurate, up-to-date accounting of who these people are?

2005 Dr. {Hamburg.} Very important.

2006 Mr. {Dingell.} Now, these individuals are not required  
2007 to comply with certain requirements to ensure the safety of  
2008 these products that they import. They can handle any type of  
2009 FDA-related products and are not required to have any  
2010 specific training so do to. Is that not correct?

2011 Dr. {Hamburg.} That is correct. We would like to make  
2012 sure that individuals importing food into the United States  
2013 followed standards and guidelines that we expect with  
2014 domestic food production.

2015 Mr. {Dingell.} Good. The discussion draft establishes  
2016 a program to require importers, U.S. custom brokers of foods,  
2017 drugs, and devices and others to register with the FDA and  
2018 require that good importer practices are maintained as a  
2019 condition for maintaining registration. Do you agree with  
2020 that requirement?

2021 Dr. {Hamburg.} We would like importers to be

2022 registered.

2023           Mr. {Dingell.} Now, one more question, and then--well,  
2024 I tell you what. I note my time is up. Madam Administrator,  
2025 I will be submitting you a letter. Mr. Chairman, thank you  
2026 for your patience, and I would thank my colleagues. I would  
2027 note that the changes in the draft that we have before us  
2028 today are those which have been largely done in consultation  
2029 with FDA and in consultation with my minority colleagues. The  
2030 next changes that you see will originate in about the same  
2031 way. Thank you, Mr. Chairman.

2032           Mr. {Pallone.} Thank you, Chairman Dingell. Next is  
2033 the gentleman from Indiana, Mr. Buyer.

2034           Mr. {Buyer.} Thank you. In your statement, you support  
2035 the FDA's ability to trace foods more quickly during an  
2036 outbreak, so you would support a track and trace system with  
2037 regard to food. Is that correct?

2038           Dr. {Hamburg.} I would. I think it is very important  
2039 to our ability to respond quickly to outbreaks of concern.

2040           Mr. {Buyer.} And since you appear to be endorsing the  
2041 bill, this draft discussion bill in front of us, you also  
2042 support then the FDA's ability to increase inspections of  
2043 food processing facilities. Is that correct?

2044           Dr. {Hamburg.} I think we need to do more inspections,  
2045 but as I said earlier, I think we also need to recognize that

2046 it isn't simply increasing the number of inspections that  
2047 will get us to the food safety system that we need. But it  
2048 is also instituting the preventive controls and really  
2049 shifting the way we think about food safety and also, you  
2050 know, stronger partnerships with the locals and foreign  
2051 government.

2052 Mr. {Buyer.} Ma'am, when you discover a contaminated  
2053 food, you believe it is your responsibility then to prevent  
2054 the distribution of that contaminated food into the  
2055 marketplace. Am I correct?

2056 Dr. {Hamburg.} Yes.

2057 Mr. {Buyer.} So you are asking for that ability to do a  
2058 recall. Would that be correct?

2059 Dr. {Hamburg.} Yes.

2060 Mr. {Buyer.} And that once that contaminated food has  
2061 been discovered, do you believe that you should have the  
2062 ability to order the destruction of the contaminated food?

2063 Dr. {Hamburg.} It depends on the specific circumstance.  
2064 Sometimes with a contaminated food, it might be possible to  
2065 reprocess it and make it available in a safe way. But it is  
2066 contaminated and putting consumers at risk and such an option  
2067 does not exist, then that food should not be allowed to be  
2068 provided to consumers.

2069 Mr. {Buyer.} Since you support a federal tracking

2070 system for food, would you also be willing to support a  
2071 electronic pedigree system for an interoperable tracking  
2072 system for pharmaceuticals?

2073 Dr. {Hamburg.} You know I think that in both realms, it  
2074 is very important to know where things came from--

2075 Mr. {Buyer.} Is this yes?

2076 Dr. {Hamburg.} --and where they are going.

2077 Mr. {Buyer.} Is this a yes?

2078 Dr. {Hamburg.} Well, you know, I am reluctant to--

2079 Mr. {Buyer.} You are going to choose contaminated  
2080 lettuce over adulterated drugs? I don't think so.

2081 Dr. {Hamburg.} No, I am not. I didn't think your  
2082 question was either/or. I thought it was--

2083 Mr. {Buyer.} My question is if you are going to support  
2084 a pedigree system for the tracking and tracing of  
2085 contaminated food, don't you also believe that it is  
2086 important for us to have an electronic pedigree for the  
2087 tracking and tracing of pharmaceuticals?

2088 Dr. {Hamburg.} In concept, I think, as I said, that  
2089 traceability is very important to assure that what consumers  
2090 get is--

2091 Mr. {Buyer.} All right, let me get to this. We have 11  
2092 international mail facilities. Add three other mail  
2093 facilities, DHL, UPS, and FedEx, of which 30,000 to 35,000

2094 pharmaceutical packages come into those mail facilities every  
2095 day. So do the math. When you do your inspections about 80  
2096 percent of them are either adulterated or they are  
2097 counterfeit knockoffs. Yet FDA claims they do not have the  
2098 ability to destroy.

2099         So you are sitting here before this committee today  
2100 saying that you know believe that you should have increased  
2101 ability to inspect and to go after this contaminated food. I  
2102 want to make sure that you also believe that you should have  
2103 the ability to destroy these counterfeit, knockoff drugs.  
2104 Because if you just do the math, that has got to be in excess  
2105 of 350,000 counterfeit adulterate, knockoff drug packages per  
2106 day. That is millions of packages per year that are harming  
2107 people. So let me go right to you. Do you believe that FDA  
2108 should have the authority, equal authority, to destroy these  
2109 counterfeit adulterated drugs?

2110         Dr. {Hamburg.} As I indicated earlier, this is my  
2111 seventh day on the job, and I haven't been briefed in full on  
2112 all these issues. The problem of counterfeit drugs is huge  
2113 concern, and I am eager to work with you since you clearly  
2114 care very much about it.

2115         Mr. {Buyer.} All right, you know what is happening  
2116 right now? Here is customs, and right over here is FDA.  
2117 There is not even a wall, yet customs has the ability to

2118 destroy. But you claim you don't have the ability to  
2119 destroy. Please don't come before this committee and tell  
2120 our country that you think we ought to be able to protect you  
2121 with regard to food, but with regard to drugs, I can't  
2122 believe as a doctor you would say--

2123 Dr. {Hamburg.} And I am not telling you that, sir, but  
2124 I am--

2125 Mr. {Buyer.} Well, then be clear.

2126 Dr. {Hamburg.} --telling you that these are issues that  
2127 are at the heart of the FDA mission and as a physician,  
2128 extremely important to me. They are issues that I am  
2129 determined to work on, determined to work with members of  
2130 Congress to find appropriate solutions. But I am not  
2131 comfortable at this time discussing the specifics of that  
2132 program which I haven't been fully briefed on.

2133 Mr. {Buyer.} All right, ma'am, I will be willing to  
2134 work with you because I can't believe that this would be an  
2135 issue that you would equivocate on. I yield back.

2136 Mr. {Pallone.} Gentlewoman from Colorado, Ms. DeGette.

2137 Ms. {DeGette.} Thank you very much, Mr. Chairman and  
2138 Dr. Hamburg. I want to add my welcome to that of my  
2139 colleagues to your appointment. I know you are going to be  
2140 working with this committee on a lot of different issues.

2141 I want to talk to you about the trace back system

2142 because we have worked very closely over the years and most  
2143 particularly on this latest iteration of the legislation on  
2144 setting forth mandatory characteristics that would be  
2145 contained in the tracing system that the FDA sets up through  
2146 the regulatory process.

2147         For example, the bill requires that the origin and  
2148 previous distribution history of food must be maintained, and  
2149 that history must be linked with the subsequent distribution  
2150 history of the food. And it also requires--to me this is a  
2151 really key component--that the system be interoperable. So  
2152 for different types of food, they can figure it out.

2153         Some people question whether it will ever be feasible to  
2154 implement this type of system, and I am wondering if you can  
2155 give your opinion on the feasibility of this type of a trace  
2156 back provision.

2157         Dr. {Hamburg.} Well, as you indicated, it is very, very  
2158 important and key to our success in being able to respond  
2159 swiftly to outbreaks and make the appropriate interventions  
2160 to protect the American public. Interoperability is  
2161 absolutely key because it involves a whole range of different  
2162 players along the full life cycle of the product, and that is  
2163 one of the great challenges.

2164         I think as we move forward in developing and  
2165 implementing a traceability program, we need to work very

2166 carefully with industry and with the different components of  
2167 the food production system. We need to do it in the context  
2168 of public meetings and open exchange, but that should be our  
2169 goal absolutely.

2170 Ms. {DeGette.} And in the draft legislation, that is  
2171 exactly what we do is we give the FDA the authority to work  
2172 with industry and consumer groups to develop both the  
2173 specific types of traceability technology and also the  
2174 interoperability, correct?

2175 Dr. {Hamburg.} Yes.

2176 Ms. {DeGette.} In other words, we are not saying--  
2177 different sectors of the food industry have different types  
2178 of traceability requirements, and we are not saying that we  
2179 have a one-size-fits-all, correct?

2180 Dr. {Hamburg.} Correct.

2181 Ms. {DeGette.} Do you think that there is an economic  
2182 case to be made to the industry for better traceability?

2183 Dr. {Hamburg.} I think absolutely because with the  
2184 opportunity to really do adequate trace back, we can really  
2185 target what are the components of a food or the specific food  
2186 products that are causing the problem and remove those or put  
2187 in place the interventions to decrease the risk to that  
2188 particular component of the food life cycle. In that way, we  
2189 can both save lives and reduce illness.

2190 But I think also reduce the cost to companies who, as we  
2191 have heard about this morning, you know, have occasionally  
2192 been inappropriately targeted when the trace back was  
2193 inadequate and we didn't identify the correct product. And  
2194 also when there is a whole industry, but there is only one  
2195 processor or manufacturer that is the problem, then we can  
2196 protect the rest of the industry by really honing in on the  
2197 particular product at risk.

2198 Ms. {DeGette.} And once we develop this system, it  
2199 should also make identification and removal of the specific  
2200 contaminated food much more speedy than it has been--

2201 Dr. {Hamburg.} Absolutely.

2202 Ms. {DeGette.} --which again benefits consumer health,  
2203 and it benefits the economic interests of that sector. Just  
2204 one last question. The draft legislation that we have  
2205 prepared exempts farms that sell directly to consumers or to  
2206 restaurants from the traceability requirements, the farmers  
2207 markets and so on. Do you think that that is an appropriate  
2208 carveout for them?

2209 Dr. {Hamburg.} I think that we have to recognize the  
2210 burdens on smaller businesses, but we also, from a public  
2211 health point of view, have to assure that when there is a  
2212 problem we can get access to the information that is needed  
2213 to identify the source of a contaminated food. So we need to

2214 work very closely with--

2215 Ms. {DeGette.} You know one thing is that these farmers  
2216 markets, for example, they are not broadly distributing their  
2217 food. It is just local. So if someone did get sick, the  
2218 state health department could easily trace it back.

2219 Dr. {Hamburg.} It certainly makes it easier to do the  
2220 outbreak investigation.

2221 Ms. {DeGette.} Right. Thank you very much.

2222 Mr. {Pallone.} Thank you. Gentleman from Illinois is  
2223 ready?

2224 Mr. {Shimkus.} Thank you, Mr. Chairman. Mr. Chairman,  
2225 can I ask you a process question first?

2226 Mr. {Pallone.} Sure.

2227 Mr. {Shimkus.} Is there a possibility that the  
2228 subcommittee may consider this legislation next week?

2229 Mr. {Pallone.} Yes.

2230 Mr. {Shimkus.} And if so, I would ask then if members  
2231 who could submit questions for the record by the close of  
2232 business tomorrow, could we have witnesses respond to those  
2233 questions by the close of business Monday?

2234 Mr. {Pallone.} Sounds like a good idea to me since we  
2235 are likely to mark up next week. You have no problem with  
2236 that?

2237 Dr. {Hamburg.} I think that is very appropriate

2238 approach.

2239 Mr. {Pallone.} Okay.

2240 Mr. {Shimkus.} And we do know--

2241 Mr. {Pallone.} Without objection, that is what we will  
2242 do.

2243 Mr. {Shimkus.} We know that is challenging, but, of  
2244 course, this is a draft as I said in the opening statement.  
2245 So we appreciate that. And again we do appreciate your  
2246 testimony and welcome on board and we are all working for  
2247 really on the same team trying to get responsible legislation  
2248 that protects human health while ensuring that fees go to  
2249 where fees need to go. So I just have two.

2250 One, and this goes back in history. Two decades ago  
2251 when Congress was deliberating on how to improve the state  
2252 clinical laboratory testing--and I have been in the lab tech  
2253 issue a lot--this committee under the leadership of now  
2254 Chairman Emeritus Mr. Dingell, Mr. Waxman, and my own former  
2255 colleague Mr. Madigan issued a conference report stating that  
2256 proficiency testing is considered one of the best measures of  
2257 laboratory performance and arguably the most important  
2258 measure since it reviews actual test results rather than  
2259 merely gauging the potential for good results.

2260 As we examine the discussion draft and its call for  
2261 accreditation standards for laboratories to perform

2262 analytical testing on food, in your opinion, should  
2263 proficiency testing be explicitly included here too?

2264 Dr. {Hamburg.} I think that we would only want to work  
2265 with accredited labs, and the accreditation process addresses  
2266 those kinds of concerns. The accuracy of the testing is key  
2267 to making the right decisions, and, you know, I think that as  
2268 we move forward, laboratory testing needs to be a strong  
2269 component of what we do. And so efforts to ensure the  
2270 accuracy of testing results is absolutely key to protect  
2271 businesses and to provide the public health system with the  
2272 information it needs to take action on.

2273 Mr. {Shimkus.} And I would agree with that. I think  
2274 that is as close to a yes as I will get, and that is fine.  
2275 But I think that is a critical component if we are going to  
2276 do this, that the proficiency test be a process by which we,  
2277 you know, test the tester so we have some certainty.

2278 Let me go back, and I know we have talked about this \$75  
2279 million in the President's budget and \$375 million in  
2280 revenue. I mentioned this in my opening statement before  
2281 some of the discussion, and I understand that, you know, this  
2282 legislation offers more authority. And so that is why there  
2283 may be a differing number than what the President proposed.

2284 But I think a lot of us are going to be challenged by  
2285 the fact--and what would be helpful before we move to markup

2286 is, you know, show us the money. Show us where we came up  
2287 with this amount. As I have said also, there has already  
2288 been millions of dollars put into food safety over the past  
2289 six months.

2290 A lot of us are trying to understand where \$375 million  
2291 came out. We understand that there was \$1,000 per facility,  
2292 and you add up the facilities, you get \$375 million. But  
2293 that doesn't answer the question as to where is that money?  
2294 Is that money going to go to an inspection regime? And what  
2295 does it cost to do an inspection regime?

2296 I have been really a strong spokesperson for a risk-  
2297 based system. Now, the risk-based system promoted in this  
2298 draft legislation is nowhere near what I believe a risk-based  
2299 system should be. I think you should go after risky  
2300 individuals. And facilities that in essence offer no risk,  
2301 you ought to incentivize them, and this has been statements  
2302 that I have made for a long time. So I think even this risk-  
2303 based approach that we are saying can be modified somewhat.

2304 So is there a way to get up a better handle, or do you  
2305 have better numbers that support this discussion draft that  
2306 \$375 million actually means \$374 million more dollars worth  
2307 of ability to inspect?

2308 Dr. {Hamburg.} Well, regrettably, I don't believe that  
2309 the \$375 million will cover the costs of inspecting on the

2310 schedule outlined in the bill. We actually would need  
2311 considerably more resources to do that. We know, you know,  
2312 based on--estimates vary, but that domestic inspections cost  
2313 a little over \$9,000. International inspections are probably  
2314 threefold higher, and the number of facilities requiring  
2315 inspection are very, very large, numbering in the hundreds of  
2316 thousands. The numbers add up quickly.

2317 Mr. {Shimkus.} And my time has expired, and I  
2318 apologize. I would just say that there is going to be  
2319 skeptics that say okay, we have \$375 million on a fee  
2320 schedule, and it is not going to go for inspection.

2321 Dr. {Hamburg.} It will go for inspection.

2322 Mr. {Shimkus.} It will go to other aspects of the FDA,  
2323 and it would help provide some clarity. And, Mr. Chairman,  
2324 if I could just end on this because the chairman emeritus  
2325 mentioned this once again that there has been negotiation  
2326 with his Republican colleagues. I would call them  
2327 information positions of the answer of no. Not really  
2328 negotiations on addresses of the bill, and I would encourage,  
2329 maybe this is going to be a member-member discussion. But if  
2330 we want a bipartisan bill, we ought to have some just not  
2331 dictates, this is what we are going to do, but this is where  
2332 we need to work together. And I yield back my time.

2333 Mr. {Pallone.} Thank you. Let me just reiterate again

2334 what Mr. Shimkus suggested in terms of the questions. We are  
2335 going to ask the witnesses, including you in the next panel,  
2336 and I will not remind the next panel that they submit their  
2337 questions--the members submit question by the end of tomorrow  
2338 night, which would be Thursday night and that we have  
2339 responses by the end of business day on Monday, okay. I will  
2340 mention that again. I mean I don't know. It may be  
2341 difficult to meet that schedule.

2342 Mr. {Shimkus.} Yeah, would the chairman yield? And we  
2343 understand that is a lot to ask, but for us to move, I think  
2344 it--

2345 Mr. {Pallone.} Yeah, that is fine and--

2346 Dr. {Hamburg.} No, we are happy to comply with that.  
2347 We appreciate that you are taking this--

2348 Mr. {Pallone.} Okay.

2349 Dr. {Hamburg.} --so seriously and wanting to move it  
2350 forward swiftly.

2351 Mr. {Pallone.} All right, thank you. Gentlewoman from  
2352 California, Ms. Harman.

2353 Ms. {Harman.} Thank you, Mr. Chairman. I have sat here  
2354 for a few hours listening to this hearing, and I think the  
2355 content is very important. And I do think this committee has  
2356 developed an enormous record on this subject. This is not  
2357 new information for members of this committee, and I do think

2358 we will be able to move legislation next week. And I hope it  
2359 will be bipartisan, and I agree with Mr. Shimkus that there  
2360 should be opportunity for the other side to participate.

2361 I wanted to acknowledge a comment that Mr. Buyer made  
2362 before he left the hearing room. He was in some fashion  
2363 implying that Dr. Hamburg is not focused on drug safety. My  
2364 response to that is of course she is. She has been here for  
2365 10 minutes and the first topic up is food safety, so let us  
2366 give her and this committee time to focus on that subject in  
2367 the near future and not be accusing each other in some way of  
2368 perhaps inadequate attention.

2369 On the subject of food safety, which is what we are  
2370 talking about, there is a section in the legislation about  
2371 testing by accredited labs. Last year, I recall a huge worry  
2372 about whether the prior administration was going to cut back  
2373 on the number of accredited labs and the impact that that  
2374 would have on major ports of entry like the ports of Los  
2375 Angeles and Long Beach. My district happens to be there.  
2376 That are the place where enormous amounts of imported food  
2377 enter the country.

2378 So I just want to give you a chance, Dr. Hamburg, not in  
2379 terms of a yes-and-no answer session, but could you assure us  
2380 that lab capacity is a priority of yours and assure us that  
2381 there will be adequate lab capacity for the anticipated

2382 importation of food and for the standards in this legislation  
2383 to work?

2384 Dr. {Hamburg.} Absolutely. Laboratory testing is an  
2385 essential component of a strong, science-based food safety  
2386 system. And we do not have any plans to restrict our  
2387 laboratory capacity. And I think, you know, as we move  
2388 forward, we will want to make sure that we are applying the  
2389 best possible science, including laboratory science, to our  
2390 testing and screening activities. I hope that there will be  
2391 advances in laboratory science and technology that will  
2392 enable us to do our inspections in a more efficient and cost-  
2393 effective way. But it is a pillar of what we do, and we will  
2394 continue to support it. And we may, as resources become  
2395 available and needs suggest, actually expand our capacity.

2396 Ms. {Harman.} Well, I appreciate that, and I am not  
2397 suggesting that our current lab structure be frozen in time.  
2398 Obviously if there are improvements either in location or in  
2399 function, we ought to embrace that.

2400 But another one of the concerns that has been expressed  
2401 is the ability to get the results from the lab to the FDA in  
2402 a timely manner. Do you think the current system is adequate  
2403 in that respect, and are you thinking about improvements to  
2404 that?

2405 Dr. {Hamburg.} Well, we are eager to implement a system

2406 for reportable foods that will include laboratories reporting  
2407 positive tests to FDA, and I think that will be a very  
2408 important additional element to our activities.

2409 Ms. {Harman.} Good. Well, I appreciate that too.  
2410 Obviously in light of some of the recent outbreaks and their  
2411 devastating impact on human life and health, it is important  
2412 to get that information out and accurate as soon as possible.

2413 Mr. Chairman, I don't have further questions of the  
2414 witness. I am just thrilled that she is here. I yield back.

2415 Mr. {Pallone.} Thank you. Gentlewoman from the Virgin  
2416 Islands, Ms. Christensen.

2417 Ms. {Christensen.} Thank you, Mr. Chairman, and I think  
2418 your time is almost up. Thank you for your patience with all  
2419 of the questions and listening to all of our opening  
2420 statements.

2421 In your testimony, you reference Section 106 that  
2422 provides the more explicit authority for FDA to access food  
2423 records during inspections. Do you think that that is enough,  
2424 or should we go further in the legislation to mandate that  
2425 those records be forwarded to FDA?

2426 Dr. {Hamburg.} You know I think what is outlined in the  
2427 legislation is certainly a very good starting point. We  
2428 don't want to be inundated with information. We don't want  
2429 to put too much of a burden on industry, but we do need that

2430 access to records. We need companies to keep appropriate  
2431 records, and we need to be able to have it to be able to  
2432 inform our routine inspectional activities, to be able to  
2433 work with the companies to make sure that they have adequate  
2434 preventive controls in place. And we need it certainly in  
2435 the event of a serious outbreak of public health concern to  
2436 enable us to swiftly get the information we need for action.

2437 Ms. {Christensen.} So you think that requiring them to  
2438 have their plans and to have their plans audited in  
2439 conjunction with your authority to have access to the records  
2440 should be sufficient?

2441 Dr. {Hamburg.} You know I think we would want this to  
2442 be a dynamic process as we learn more, putting in place the  
2443 programs and policies and then learning from experience. But  
2444 I think the bill lays out a very sensible and doable  
2445 approach.

2446 Ms. {Christensen.} Okay, and you also talk about the  
2447 huge task of hiring and training inspectors. And if I  
2448 understand correctly, you are asking for some more  
2449 flexibility in the legislation to be able to do that. Are  
2450 you asking for general flexibility, or would a transitional  
2451 timetable with times certain in the legislation work just as  
2452 well?

2453 Dr. {Hamburg.} Well, I think we just have to recognize

2454 that this would be an enormous scale-up of activity and that  
2455 we need the timeframe to enable us to do it right, to recruit  
2456 the people and train the people to work with industry to  
2457 develop the systems that work. So we like flexibility in  
2458 that way, and we would like more general flexibility so that  
2459 we can learn as we go in terms of the inspection schedule and  
2460 some of the requirements in that regard.

2461 Ms. {Christensen.} Okay, my last question is kind of a  
2462 general one. I don't think it was asked before, but even as  
2463 late as yesterday, someone asked the secretary the question  
2464 about one single entity to secure food safety with the  
2465 authority over the food safety program for the country.

2466 I don't think the secretary supported it. I am sure you  
2467 don't support it, but what can you say about, if you have had  
2468 a chance to look at how FDA and USDA work together or don't  
2469 work as well together as they should? What can you say about  
2470 addressing the concerns that give rise to the legislation  
2471 that would put it in a single entity?

2472 Dr. {Hamburg.} Well, a couple of responses to your  
2473 important question. One is that clearly as the new FDA  
2474 commissioner, I have a first and urgent priority to  
2475 strengthen food safety within the FDA and I think that there  
2476 are many things that we can do to strengthen our program to  
2477 improve accountability, to raise the issue as high priority.

2478 Part of strengthening food safety within FDA is strengthening  
2479 coordination with critical partners as well, and that  
2480 certainly means with USDA, and I look forward to a working  
2481 relationship with them.

2482         It also means strengthening the working partnerships  
2483 with state and local public health organizations, and it very  
2484 importantly also involves working with other international  
2485 agencies and foreign governments because I think we are going  
2486 to see the percentage of food coming in from overseas  
2487 increasing in the years to come. And the globalization has a  
2488 profound impact on the work of the FDA.

2489         And I also do think that the authorities and tools that  
2490 this new draft legislation could potentially provide to the  
2491 FDA will be extremely important in moving the federal  
2492 government and the FDA in the direction that we need to for  
2493 robust and modernized food safety system.

2494         Ms. {Christensen.} Thank you for your answers. Thank  
2495 you, Mr. Chairman.

2496         Mr. {Pallone.} Thank you. Gentlewoman from Ohio, Ms.  
2497 Sutton.

2498         Ms. {Sutton.} Thank you, Mr. Chairman, and thank you  
2499 very much, Dr. Hamburg, for your service and for all that I  
2500 am confident you are going to do to improve food safety in  
2501 this country.

2502           As I mentioned in my opening statement, Ohio has been  
2503 hit hard by issues arising from food safety. In the past  
2504 year, there have been 105 cases of salmonella reported in  
2505 Ohio and sadly three deaths resulting from the most recent  
2506 peanut-based strain.

2507           Nellie Napier was a constituent of mine who  
2508 unfortunately died from salmonella poisoning that she  
2509 contracted in a nursing facility, and just in April of this  
2510 year, in Cuyahoga County there were three incidences of  
2511 illness from E.coli and another death, this time a seven-  
2512 year-old girl. So this is an urgent issue for the people tht  
2513 I am so honored to represent.

2514           I mentioned that I introduced the Protect Consumers Act,  
2515 which was a bill that would give the FDA mandatory recall  
2516 authority, and I am happy to see that it is a part of this  
2517 comprehensive bill. And I would just like to get a little  
2518 bit more of your opinion about the need for recall authority.  
2519 And this bill, of course, seeks to remedy the situation of  
2520 the FDA not having the mandatory recall authority by laying  
2521 out two different types of recall authorities.

2522           First if the FDA believes that a certain food may cause  
2523 adverse health consequences or death, the FDA can require a  
2524 recall. But in that scenario, FDA must first give the  
2525 company an opportunity to voluntarily recall its own

2526 products. And if that doesn't work, then the FDA can order a  
2527 mandatory recall.

2528         And then, of course, the second type of recall is an  
2529 emergency recall if the FDA finds that a certain food  
2530 presents a threat of serious adverse health consequences or  
2531 death. You may do that immediately.

2532         Can you just tell me about whether you think that the  
2533 need and the approach, the two-tiered approach, is addressed  
2534 in a good way in this bill and why it makes sense?

2535         Dr. {Hamburg.} Well, I think the history is that  
2536 voluntary recall is often effective in getting those  
2537 potentially harmful products off the shelves and protecting  
2538 consumers but that you do need that emergency mandatory  
2539 recall function as a backup. There certainly have been cases  
2540 where the mandatory recall of a dangerous product has been  
2541 delayed because of a reluctance on the part of the company to  
2542 pull that product, and there has been a back-and-forth and  
2543 lawyers involved and delays of weeks, putting consumers at  
2544 risk.

2545         So I think that to have the mandatory recall as a  
2546 emergency measure is very, very important. And sadly in a  
2547 world where we might also need to address intentional  
2548 contamination of food, that emergency mandatory recall  
2549 becomes a very, very important tool. You know I think the

2550 reality is that having that as an enforcement tool probably  
2551 makes it easier to also work with companies on the voluntary  
2552 recall.

2553           So I think it is a continuum that we need. We need  
2554 both.

2555           Mr. {Shimkus.} Will the gentlelady yield just on this  
2556 same point, just a follow up on this?

2557           Ms. {Sutton.} I have very little time, but I will  
2558 yield.

2559           Mr. {Shimkus.} Yeah, just to follow up. One of the  
2560 issues would be may cause. That is kind of a low standard.  
2561 I think there is going to be concern about the may cause  
2562 language in here and how do you define that.

2563           Dr. {Hamburg.} Yes, well we discussed that earlier, and  
2564 I think perhaps there is some wordsmithing that could be done  
2565 on that point.

2566           Mr. {Shimkus.} Thank you. I thank my colleague.

2567           Ms. {Sutton.} Sure, and if I could just follow up on  
2568 the suggestion that has been made and some have argued that  
2569 because mandatory recall is such a strong tool that only the  
2570 commissioner should be able to exercise the authority to  
2571 order a recall with no further delegation. And I just wanted  
2572 to know about your thoughts on the approach of having only  
2573 the commissioner order a recall and how that would work for

2574 the FDA. And frankly, while I am at it, would such an  
2575 approach work with regard to suspensions and subpoenas, and  
2576 what are your thoughts about those subjects?

2577 Dr. {Hamburg.} Well, these are important and powerful  
2578 authorities that shouldn't be used lightly. However, I think  
2579 that experience shows that senior level officials can be  
2580 entrusted with these authorities along with the commissioner,  
2581 but it is certainly something that we would want to work with  
2582 Congress on in order to put in place the system that people  
2583 have the most confidence in.

2584 Ms. {Sutton.} I thank you, and I am certain that we  
2585 share concerns about expediency and making sure things happen  
2586 in a quick time. And I think that your answer on the way  
2587 that the recall authority would work, you having the  
2588 mandatory authority would give you an opportunity to  
2589 encourage even more strongly--or they would be necessarily  
2590 encouraged, the companies, to comply on their own as well.  
2591 So thank you very much.

2592 Mr. {Pallone.} Thank you. Mr. Green.

2593 Mr. {Green.} Thank you, Mr. Chairman, and again, Dr.  
2594 Hamburg, appreciate your patience today in--but if you think  
2595 this is tough, you have FDA to work on, which is--and I laugh  
2596 because in '07 we spent a great deal of our time, both in the  
2597 subcommittee and the full committee, in reforming FDA. And

2598 then last year with all the food safety issues that came up,  
2599 it seemed like we are back at it again, and I am glad you are  
2600 there.

2601 In my opening statement, I mentioned my concerns about  
2602 the location and number of FDA labs, and I know my colleague  
2603 from southern California, Congressman Harman, mentioned the  
2604 same thing. Texas does have the longest running border with  
2605 Mexico, and the port of Houston is right behind the port of  
2606 LA/Long Beach in imported tons of food, yet we don't have an  
2607 FDA lab. And I have had the honor of meeting my FDA  
2608 inspectors on the docks of the port of Houston, but they are  
2609 detailed out of Laredo, Texas.

2610 And I guess because it is such a large state and the  
2611 need for a lab somewhere, I am glad the bill does include the  
2612 ability to contract with labs because we want the inspections  
2613 done as quick as possible. Does the FDA tend to evaluate the  
2614 current locations of the 13 labs and whether these locations  
2615 are meeting the inspections demands? But also in the  
2616 President's budget, talks about three high-volume FDA labs,  
2617 and how would the FDA decide where to place these labs? And  
2618 what consideration would be placing in a place like Texas or  
2619 even southern California? I didn't know southern California  
2620 didn't have a lab with LA/Long Beach. And that is my only  
2621 question. So thank you, Mr. Chairman.

2622 Dr. {Hamburg.} Well, you know, I am fascinated that the  
2623 laboratory issue comes up so much here because it is such a  
2624 key issue. And in my past experience as a public health  
2625 official, it is often the laboratory that is the  
2626 underappreciated component of public health needs. So this  
2627 is very encouraging to me.

2628 At the present time, we don't have any plans to expand  
2629 that basic, you know, network--

2630 Mr. {Green.} Thirteen labs.

2631 Dr. {Hamburg.} --of laboratories that you mentioned.  
2632 Although, as I said to Congresswoman Harman, you know, with  
2633 additional resources and expanding need, that might be a  
2634 possibility. We will be creating some additional high  
2635 throughput laboratories. And in all honesty, I am not  
2636 certain about the process by which those laboratories are  
2637 being developed and cited. It is something I need to go back  
2638 as a very new FDA commissioner and learn more about. But the  
2639 laboratory issue is one that is essential as we have  
2640 discussed.

2641 Mr. {Green.} I guess the reason it comes up so often is  
2642 it, over the last three years actually, our committee has  
2643 spent so much time on, you know, pharmaceutical safety, food  
2644 safety, and the concern is that we are importing so much of  
2645 our food. Like I said, Laredo, Texas is probably the biggest

2646 land-based port in the world. And so much food comes from  
2647 Mexico we need the inspections as timely as possible to move  
2648 the produce or whatever the products, the foodstuffs  
2649 particularly. But we also need to make sure that it is--and  
2650 the problem is it is not paid for. But with this fee that is  
2651 going to be assessed, hopefully that will generate the  
2652 resources, both for the personnel and also for the  
2653 facilities.

2654         And I guess if you are having to contract with private  
2655 labs, that may be great, but there are times that a public  
2656 lab would be faster and ultimately cheaper to the folks who  
2657 pay the bills. And so that is why I just ask FDA to look at  
2658 that. I am glad we are going to contract because we want the  
2659 commerce to flow. But if there is a need to have a lab that  
2660 would be more economical and just as fast to contract with  
2661 the private labs, then I would hope this funding source--I  
2662 guess over the last three years, our hearings have said FDA  
2663 is--the staff, we don't have the staff, we don't have the  
2664 resources. Well, we are going to try to give you the  
2665 resources in this bill and hopefully to hire the staff and to  
2666 have the facilities.

2667         Dr. {Hamburg.} And let me just assure you that your  
2668 constituents are not being compromised in terms of the  
2669 laboratory testing that is needed to protect their food

2670 supply because samples can be shipped to labs. In the modern  
2671 era, it can be done in a timely and safe way. So the  
2672 coverage in terms of laboratory testing is still available,  
2673 but I hear and understand your concern about the gap in terms  
2674 of an onsite facility in your region.

2675 Mr. {Green.} Well, and I think the fear that some of us  
2676 had is that we don't want to play favorites. These ports  
2677 compete for cargo, and we don't want it to be based on that  
2678 there is not an FDA lab or it is slower to get this through  
2679 one port as compared to the other port. And I know I have  
2680 run out of time but appreciate the responsibility you are  
2681 taking on. And hopefully we will provide you with the tools  
2682 that you need. Thank you, Mr. Chairman.

2683 Mr. {Pallone.} Thank you, Mr. Green. Mr. Stupak.

2684 Mr. {Stupak.} Thank you, Mr. Chairman, and thank you,  
2685 Commissioner, for being here. As chair of Oversight and  
2686 Investigations and one of the authors of the Food Safety  
2687 Enhancement Act, I have done about nine hearings in the last  
2688 two years just on food safety and certainly is a major  
2689 problem. One of the problems I found every time we had a  
2690 hearing, there is always lack of information that the FDA did  
2691 not have from either the manufacturer of the food or the  
2692 producer of that food. And it was always difficult to get  
2693 information.

2694           In the Safety Enhancement Act authorizes the FDA to  
2695   issue subpoenas for records and other things relevant to any  
2696   hearing investigation or proceeding or relative to any other  
2697   matter within the FDA's jurisdiction, including matters under  
2698   the Public Health Service Act and the Federal Anti-Tampering  
2699   Act.

2700           Do you believe subpoena power would be beneficial to the  
2701   FDA?

2702           Dr. {Hamburg.} It is very important for us to get  
2703   access in a timely way to the information that we need, and I  
2704   think that that authority will enable us to act more swiftly  
2705   and effectively, yes.

2706           Mr. {Stupak.} Well, I hope you would because I think we  
2707   are still waiting for information from the 2007 salmonella  
2708   outbreak and peanut butter and from the Georgia plant,  
2709   Blakely, Georgia. I don't think we got all that information  
2710   yet.

2711           Some in the food industry though appear to be concerned  
2712   that the FDA will abuse its subpoena power. Their concerns  
2713   center around the subpoena provision that authorizes the FDA  
2714   to issue subpoenas in matters under FDA's jurisdiction that  
2715   are not part of a particular hearing or investigation of a  
2716   specific violation of the act.

2717           There seems to be a fear that FDA will go on fishing

2718 expeditions, constantly sending out burdensome unnecessary  
2719 requests for documents. How would you address these  
2720 concerns?

2721 Dr. {Hamburg.} Well, I think that we have enough work  
2722 to do without going on fishing expeditions. We would be  
2723 seeking information that would be of vital importance to  
2724 addressing the tasks at hand. It would be of great value to  
2725 have the ability to access critical information, to inform  
2726 the inspection process as well as to inform outbreak  
2727 investigations. And I think that if we are going to be able  
2728 to really move forward to ensure the safety of the food  
2729 supply, this is one of a number of tools that will enable us  
2730 to really do what needs to be done.

2731 Mr. {Stupak.} That is refreshing to hear because I have  
2732 been pushing subpoena power for the FDA for 10 years, and get  
2733 a witness to agree from the FDA. But by the time I got back  
2734 to my office, the FDA had called me and say that is not the  
2735 official position of the FDA. We are against subpoenas. So  
2736 it is refreshing to hear that, and I am sure you won't use it  
2737 for a fishing expedition.

2738 Let me ask you this. Chairman Waxman and I wrote to you  
2739 to review this phenyl A BPA. While previous FDA commissioner  
2740 found no problem with it, FDA's own science review found says  
2741 there was room for concern. And we wrote to you, and you

2742 wrote back indicating that you have agreed to review the  
2743 safety of BPA. So let me just say thank you on that point.

2744 I think it is important that we look at all the  
2745 documents and all the evidence and all the studies, not just  
2746 two studies when there are over 100 other studies that raise  
2747 concern on this phenyl A.

2748 Also on food safety, on the lab situation, it has been  
2749 my concern the last FDA commissioner thought food safety was  
2750 to close six or seven of the 13 field labs, which I thought  
2751 was the wrong idea. So we have always fought reorganization  
2752 or closing of these labs. And we actually had to put in  
2753 legislation to make sure these field people, critical work  
2754 for the FDA and for the safety of the American people, stay  
2755 on their jobs.

2756 And you recently wrote back to me, myself and Chairman  
2757 Waxman, indicating that there are no current or future plans  
2758 to close or consolidate any of these 13 field laboratories.  
2759 And you also went on and said that you are actually hoping  
2760 you will be able to hire at least 70 new analysts for the 13  
2761 labs to replace staff losses over the last few fiscal years.  
2762 So thank you for that, and without objection, I would like to  
2763 place the record from the commissioner in the record, this  
2764 letter in the record.

2765 Mr. {Pallone.} Without objection, so ordered.

2766 [The statement follows:]

2767 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

|  
2768 Mr. {Stupak.} Let me ask you one more question if I  
2769 may. Risk-based inspection schedule. One of the important  
2770 new requirements in the new food safety bill will be to put  
2771 in place is a risk-based inspection schedule for food  
2772 facilities. Under current law, even risky facilities can go  
2773 years between FDA inspections, but our legislation has strict  
2774 requirements to make sure FDA inspectors actually get into  
2775 the riskiest facilities as frequently as possible. The  
2776 riskiest facilities must be inspected at least every 6 to 18  
2777 months. No food production or storage facility will go more  
2778 than four years between inspections.

2779 Under current law, there is not any requirement  
2780 regarding how frequently these facilities must be inspected,  
2781 is there?

2782 Dr. {Hamburg.} There is not, and I think that your  
2783 desire to see a risk-based strategy be put in place is  
2784 absolutely key so that we can target resources on the highest  
2785 risk.

2786 Mr. {Stupak.} Does this bill give you the flexibility  
2787 you need to modify the inspection goals based on available  
2788 resources and the best available evidence on risk?

2789 Dr. {Hamburg.} Well, as I said in my testimony, I am  
2790 concerned about the requirements for inspection outstripping

2791 available resources, and that has been a chronic problem for  
2792 the FDA in terms of being able to fulfill its important  
2793 mission.

2794 I think that the inspectional strategy outlined in the  
2795 draft legislation is a wonderful aspirational goal. I would  
2796 love to be able to sit here and say that FDA could take it on  
2797 and fully achieve it, but there is a reality of limited  
2798 resources, both dollar and human. And I think that is where  
2799 we need some flexibility to really look at the numbers and  
2800 really also begin to move swiftly in the direction outlined  
2801 in this bill but also try to learn as we go so that we can  
2802 find ways to do our inspections in a more efficient targeted  
2803 way and really focus on the highest risk and really try to  
2804 leverage other resources to achieve the goals as well through  
2805 partnership with state and locals, partnership with foreign  
2806 governments and potentially with third parties that are  
2807 certified and overseen by the FDA to help us particularly  
2808 with respect to the burgeoning number of foreign sites for  
2809 inspection.

2810 Mr. {Stupak.} Well, the--

2811 Mr. {Pallone.} I am sorry, Mr. Stupak, but we are--

2812 Mr. {Stupak.} I just want to mention about the  
2813 registration fee for--

2814 Mr. {Pallone.} I am sorry. No more questions though.

2815 We are done with questions. Go ahead. You had a comment?

2816 Mr. {Stupak.} Yeah, I was just going to say hopefully  
2817 the registration fee that we would be putting in place with  
2818 up to 400,000 facilities would provide enough resources to do  
2819 the inspection and other work that the FDA sorely needs to  
2820 the resources and the personnel to do it. We understand  
2821 that. Hopefully that will be part of the bill.

2822 And thank you, Mr. Chairman, and thanks for your help on  
2823 this bill.

2824 Mr. {Pallone.} Thank you. Mr. Deal.

2825 Mr. {Deal.} Yield briefly to Mr. Shimkus for a follow  
2826 up.

2827 Mr. {Shimkus.} And I thank my ranking member, and I am  
2828 glad my colleagues here because I want to follow up on this  
2829 wordsmithing that we talked about on the may cause. That is  
2830 why we still have the same problem on the subpoena power  
2831 issue because in the subsection three, it says ``any other  
2832 matter relative to the commissioner's jurisdiction under this  
2833 act.'' I would like there to be a ``may cause.''

2834 I have a problem with the ``may cause'' in the other  
2835 part of the bill or the draft. We should at least have a  
2836 ``may cause'' for offering a subpoena to someone. And so I  
2837 would hope that that would be something else we would look  
2838 at. So I think there is some issues.

2839           We want subpoena power, but we want it for a reason. We  
2840 just don't want it to be at the whim, with all due respect,  
2841 Dr. Hamburg. And I will yield back to the ranking member.

2842           Mr. {Deal.} Let me ask you a question with regard to  
2843 another area, and that is the registration and fees collected  
2844 from commercial importers, and there has been a change in  
2845 this draft from previous drafts that we have seen.

2846 Specifically, why should drug and device manufacturers who  
2847 currently already pay an annual establishment fee be required  
2848 to pay a duplicative fee? And what entities are really  
2849 encompassed within this commercial importation fee schedule?

2850           Dr. {Hamburg.} Well, the importer fee refers to fees on  
2851 the individuals or the companies that are serving as the link  
2852 between foods that are grown, processed, manufactured  
2853 overseas and being brought into the United States to be  
2854 distributed to consumers here. And so they are not  
2855 necessarily representing a given manufacturer, but it is a  
2856 very important function because it is that bridge between  
2857 what is happening on the international scene and what is  
2858 coming into this country for use.

2859           Mr. {Deal.} Specifically with regard to the drug and  
2860 device manufacturers who currently already register and  
2861 already pay a fee, would you envision that they are going to  
2862 have to pay an additional registration fee in addition to

2863 what FDA already collects from? And if so, why?

2864 Dr. {Hamburg.} In terms of the importer function, I  
2865 need to go back and look at this issue with respect to  
2866 devices because I don't know how that system is set up,  
2867 whether it is the manufacturer that is serving in that role  
2868 or not. So I will go back and learn more about that.

2869 Mr. {Deal.} Would you take a look at that? I think  
2870 that is one that we really seriously need to look at. I  
2871 don't think we ought to be duplicating what you are already  
2872 doing because you have jurisdiction there. I think that  
2873 would be unfair.

2874 Let me ask you also quickly with regard to the tracing  
2875 of food, the tracing system that is put in place for you to  
2876 issue regulations. It appears that that would include the  
2877 restaurants to be able to have traceability, and I am told  
2878 that 7 out of every 10 eating establishments are not part of  
2879 chain operations. They are just independent, separate food  
2880 operations. I am just curious as to whether or not you think  
2881 that this would have a serious impact on these small business  
2882 owners. And do you think we ought to do a cost/benefit  
2883 analysis before we impose that kind of cost on these  
2884 individuals?

2885 Dr. {Hamburg.} Well, I think clearly we want to work  
2886 with restaurant owners and small businesses in order to make

2887 sure that the systems are not too cumbersome, but it is very  
2888 important that they keep records because if there is a  
2889 tainted food that is in their facility, the implications for  
2890 the health of their business as well as for the health of  
2891 their consumers is very significant indeed. And I think that  
2892 they would want to be able to assist in sharing their  
2893 information about where the foods came from so that the  
2894 traceback can occur and we can identify the source of an  
2895 outbreak and control it.

2896         So I think they are a very important link in the food  
2897 supply chain and, you know, protecting health really depends  
2898 on them keeping records.

2899         Mr. {Deal.} Let me ask you what has FDA done to  
2900 implement the current, what I think is called the one-up-one-  
2901 back traceability requirements? What has been done to  
2902 implement that?

2903         Dr. {Hamburg.} Well, the one-up-one-back has been in  
2904 place, as I understand it, for a while now. But it has  
2905 proven not to be adequate to really capture the full  
2906 lifecycle of a product and that we really need, as we  
2907 mentioned earlier, the full supply chain to be documented and  
2908 integrated. Interoperability, not just fragments, you know,  
2909 is really key to a successful and swift investigation of  
2910 outbreaks and the ability to control a problem and prevent

2911 future exposures to a contaminated food product.

2912 Mr. {Pallone.} Thank you. Just the way we are  
2913 proceeding, Mr. Markey is going to go now, and he is our  
2914 last--

2915 Dr. {Hamburg.} Okay.

2916 Mr. {Pallone.} --questioner for you, Dr. Hamburg. We  
2917 have one vote, but we will be right back after that. And  
2918 then we will start with the second panel. So, Mr. Markey.

2919 Mr. {Markey.} Thank you, Mr. Chairman, very much.  
2920 Congratulations, Dr. Hamburg.

2921 Dr. {Hamburg.} Thank you.

2922 Mr. {Markey.} You may know that I have a bill that  
2923 calls for BPA to be banned from being used in food and  
2924 beverage containers because of the risks that have been  
2925 identified. We have also recently learned the food and  
2926 chemical industries have launched a public relations campaign  
2927 opposing any efforts to deal with this issue.

2928 Is the FDA concerned about BPA? And what does the FDA  
2929 plan to do about those concerns?

2930 Dr. {Hamburg.} Well, we are concerned. Certainly I am  
2931 aware of, you know, some of the studies that have raised  
2932 issues in animal populations and some of the information  
2933 about BPA. In many components of the food supply, we are  
2934 starting to see activities at the local and the state level

2935 in terms of action with respect to BPA. And I would hope  
2936 that FDA could really be providing leadership on some of  
2937 these issues of assessing and analyzing risk.

2938 We are taking another look at the BPA issue. The acting  
2939 chief scientist at the FDA has been asked to take the lead on  
2940 this because, of course, this is a decision where we have to  
2941 bring the best available scientific data to bear. We need to  
2942 look at all of the studies and examine them. But it is an  
2943 issue of great consequence for Americans. As a mother as  
2944 well as a physician, it is an issue that I think we need to  
2945 look at seriously.

2946 And I look forward to being able to come back with some  
2947 report from this serious look that is being taken. And we  
2948 expect that it is going to be task for him over the summer to  
2949 lead this review, and by the end of the summer, beginning of  
2950 fall, we hope to be able to put forward a fresh look at the  
2951 BPA issue.

2952 Mr. {Markey.} Do you have any advice for parents who  
2953 are concerned about their children ingesting this chemical?

2954 Dr. {Hamburg.} Well, I think of course parents that are  
2955 concerned can find alternatives that don't have BPA, and I  
2956 think that for the most part, I think that those alternatives  
2957 are pretty clearly labeled and pretty available. And I think  
2958 anyone with concerns, you know, should do so.

2959 Mr. {Markey.} Okay, thank you for your work on this.  
2960 If you could keep us posted on the progress you are making  
2961 on--

2962 Dr. {Hamburg.} Absolutely.

2963 Mr. {Markey.} --the evaluation of it. Thank you so  
2964 much. Thank you, Mr. Chairman.

2965 Mr. {Pallone.} Thank you, and thank you very much, Dr.  
2966 Hamburg. As we have said, you know, we do intend to move  
2967 forward on this bill next week, and we appreciate your input  
2968 and whatever else comments you may give us by next Monday.  
2969 We have one vote. We will come back, and then we will hear  
2970 from our second panel. Thank you.

2971 Dr. {Hamburg.} Thank you. Thank you for your  
2972 leadership on this important issue.

2973 [Recess.]

2974 Mr. {Pallone.} The subcommittee will reconvene, and I  
2975 see our second panel is already seated. Let me introduce  
2976 each of you. On my left is Mr. Michael Ambrosio, who is  
2977 representing the Food Marketing Institute, and he is the vice  
2978 president for Quality Assurance Division at Wakefern Food  
2979 Corporation. Next we have Ms. Pamela G. Bailey, who is  
2980 president and chief executive officer of the Grocery  
2981 Manufacturers Association. And then we have Ms. Caroline  
2982 Smith DeWaal, who is the Safe Food Coalition food safety

2983 director of the Center for Science in the Public Interest.  
2984 Dr. Tim F. Jones, who is a state epidemiologist from the  
2985 Tennessee Department of Health. And last is Mr. Thomas E.  
2986 Stenzel who is president and CEO of United Fresh Produce  
2987 Association.

2988           Welcome. You know it is five minutes, and obviously  
2989 your statements become part of the record if you want to  
2990 include material more than the five minutes. And we all  
2991 heard before--I know some of you are wondering if you can  
2992 meet the deadline, but since we do intend to go to markup  
2993 next week, I agreed with what Mr. Shimkus said about we will  
2994 give you any additional written questions by the end of  
2995 business tomorrow, and we would like them back by Monday at  
2996 the end of business.

2997           So we will start with Mike Ambrosio. Thank you for  
2998 being here again.

|  
2999 ^STATEMENTS OF MICHAEL AMBROSIO, FOOD MARKETING INSTITUTE,  
3000 VICE PRESIDENT, QUALITY ASSURANCE DIVISION, WAKEFERN FOOD  
3001 CORPORATION; PAMELA G. BAILEY, PRESIDENT AND CHIEF EXECUTIVE  
3002 OFFICER, GROCERY MANUFACTURERS ASSOCIATION; CAROLINE SMITH  
3003 DEWAAL, SAFE FOOD COALITION, FOOD SAFETY DIRECTOR, CENTER FOR  
3004 SCIENCE IN THE PUBLIC INTEREST; TIM F. JONES, STATE  
3005 EPIDEMIOLOGIST, TENNESSEE DEPARTMENT OF HEALTH; AND THOMAS E.  
3006 STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION

|  
3007 ^STATEMENT OF MICHAEL AMBROSIO

3008 } Mr. {Ambrosio.} Thank you. Chairman Pallone, Ranking  
3009 Member Deal, and members of the Health Subcommittee, I am  
3010 honored to appear before you today on behalf of the Food  
3011 Marketing Institute to present our views and suggestions on  
3012 the Food Safety Enhancement Act Discussion Draft.

3013 FMI and its member company share the common goal of  
3014 enacting legislation this year that would genuinely improve  
3015 the safety of the food supply. Steps that actually prevent  
3016 the presence of adulterance in the food supply are the only  
3017 true way to improve the safety of our food.

3018 I am Mike Ambrosio, vice president of quality assurance,  
3019 Wakefern Food Corporation. I have been in charge of food

3020 safety programs at Wakefern for 30 years. Founded in 1946,  
3021 Wakefern has grown from a small struggling cooperative into  
3022 the Nation's largest retailer-owned, non-farm cooperative in  
3023 the United States. We are headquartered in Keasbey, New  
3024 Jersey. Wakefern, along with its Shop Rite Stores, employs  
3025 over 47,000 individuals in New Jersey, New York,  
3026 Pennsylvania, Delaware, Connecticut, Massachusetts, Rhode  
3027 Island, and Maryland.

3028 Today I am also representing FMI, a national trade  
3029 association that has 1,500 member companies made up of food  
3030 retailers and wholesalers in the United States and around the  
3031 world.

3032 FMI members operate approximately 26,000 retail food  
3033 stores with combined annual sales of roughly \$400 billion  
3034 representing three-quarters of all retail food store sales in  
3035 the United States. FMI's retail membership is composed of  
3036 national and regional chains as well as independent grocery  
3037 stores.

3038 This morning I will present several of FMI's  
3039 recommendations for revising the bill, but I ask that my  
3040 entire statement be included in the record.

3041 In April of 2008, I testified before this subcommittee  
3042 on legislation that would have modernized and overhauled the  
3043 food safety systems at the Food and Drug Administration.

3044 Since that time, high-profile food safety outbreaks and  
3045 recalls involving tomatoes, jalapenos, peanuts, and  
3046 pistachios have not only made headlines but regrettably have  
3047 caused illness and in some cases even death.

3048 Many of the themes and ideas that I share today will be  
3049 similar to those that I shared in 2008, but there are  
3050 differences that reflect lessons learned and new weaknesses  
3051 in the existing food safety system identified from these  
3052 latest recalls.

3053 As the purchasing agent for the consumer and the final  
3054 link in the supply chain, our industry understands that it is  
3055 vital to ensure that the FDA has the necessary authority,  
3056 credibility, and resources to meet the challenges of today's  
3057 global marketplace.

3058 Consumer confidence remains an essential factor in this  
3059 debate. Food safety issues can be extremely complex and  
3060 consumer vary greatly in their knowledge of the science and  
3061 other issues affecting the safety of our food supply.  
3062 However as food safety issues draw national headlines,  
3063 consumer awareness has a well concern about the safety of  
3064 commercially prepared food and products purchased at the  
3065 supermarket heightens.

3066 Mr. Chairman, I applaud you, Mr. Dingell, Chairman  
3067 Waxman, and all members of the committee for your efforts to

3068 address changes that are needed to improve our food safety  
3069 system. We support many of the proposals in the draft by  
3070 emphasizing the need to have preventative measures be the  
3071 foundation on which the food safety system should be built.  
3072 The draft also recognizes that we need to focus on the  
3073 majority of resources on facilities and products that pose  
3074 the greatest risk of contamination that could result in food  
3075 borne illness or injury. We must continue to be sure that  
3076 any changes meet certain criteria, be supported by science,  
3077 have measurable benefits, be affordable, be realistic and be  
3078 implemented without unintended consequences.

3079 First we applaud you for not only designating an entire  
3080 section of the bill solely to prevention, but also putting  
3081 this first in the most extensive section of the bill. From  
3082 our perspective, this is the appropriate emphasis.

3083 In addition, I would like to specifically comment on  
3084 certain sections of the draft. FMI recognizes that a strong  
3085 public/private partnership is needed to help ensure safety of  
3086 the food supply. Although every penny counts in this tough  
3087 economic times, there is nothing more important than  
3088 improving and ensuring the safety of our food supply. We are  
3089 willing to support a fair registration or user fee provided  
3090 that it is utilized by the FDA in a transparent and  
3091 accountable manner to improve the safety of our food supply

3092 through means such as conducting research and consumer  
3093 education programs.

3094         We look forward to working with the committee to address  
3095 our concerns about how the FDA may utilize any fees  
3096 collected. We support the requirement that every registered  
3097 food facility conduct a risk assessment and implement and  
3098 maintain a validated food safety plan and identify potential  
3099 resources of contamination and appropriate food safety  
3100 controls and document those controls that would prevent,  
3101 eliminate, and reduce potential hazards.

3102         Adherence to food safety plans goes a long towards  
3103 developing a culture within a company that is critical to  
3104 ensuring food safety. Mr. Chairman, thank you for the  
3105 opportunity to testify. We appreciate the work that has gone  
3106 into the development of the Food Safety Enhancement Act  
3107 discussion draft with the goal of improving food safety and  
3108 the food supply and helping to restore consumer confidence in  
3109 the food safety system. I look forward to your questions and  
3110 remain available to the subcommittee. Thank you.

3111         [The prepared statement of Mr. Ambrosio follows:]

3112 \*\*\*\*\* INSERT 2 \*\*\*\*\*

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3113

Mr. {Pallone.} Thank you. Ms. Bailey.

|  
3114 ^STATEMENT OF PAMELA BAILEY

3115 } Ms. {Bailey.} Thank you, Mr. Chairman. Good afternoon.

3116 Mr. {Pallone.} I don't know if that is on, the mike.

3117 You don't have a mike.

3118 Ms. {Bailey.} Thank you. I am Pam Bailey, and I am  
3119 president and CEO of the Grocery Manufacturers Association  
3120 which represents more than 300 food, beverage, and consumer  
3121 products companies.

3122 Americans enjoy one of the safest food supplies in the  
3123 world, but we recognize that steps can and must be taken to  
3124 make our food supplies even safer. We applaud Chairman  
3125 Waxman, Chairman Emeritus Dingell, Chairman Stupak, and  
3126 Chairman Pallone for developing the discussion draft of the  
3127 Food Safety Enhancement Act of 2009.

3128 Product safety is the foundation of consumer trust. We  
3129 look forward to working with the committee to quickly enact  
3130 food safety reforms that will restore consumer confidence and  
3131 will continually improve the safety of our food supply.

3132 Although the food industry is ultimately responsible for  
3133 the safety of our products, strong government oversight is a  
3134 critical part of our foods safety system. That is why GMA  
3135 supports much in the discussion draft, including your

3136 proposal to set safety standards for fruit and vegetables,  
3137 your proposals to improve the safety of imported food and  
3138 food ingredients and your proposals to give FDA strong  
3139 enforcement powers to deal with bad actors, including  
3140 mandatory recall authority.

3141         In particular, we strongly support proposals to require  
3142 all food manufacturers to conduct a hazard analysis to  
3143 identify potential sources of contamination, identify  
3144 appropriate preventive controls and to document those  
3145 preventive controls in a food safety plan.

3146         We believe that food safety plans are the cornerstone of  
3147 prevention and that they will help ensure that safety is  
3148 built in from the very beginning. We have proposed certain  
3149 modifications to some of these provisions to your staff, and  
3150 we look forward to working with you.

3151         In particular, we look forward to working with you to  
3152 address your concerns about traceability. We recognize that  
3153 the discussion draft instructs FDA to assess the costs,  
3154 benefits, and feasibility of traceability technologies and  
3155 gives FDA the power to exempt certain foods. Furthermore, we  
3156 recognize that the discussion draft instructs FDA to conduct  
3157 pilot projects and public meetings. However, we believe  
3158 these studies, meetings, and pilot projects should be  
3159 completed before FDA decides whether and how to assign the

3160 food industry the responsibility for tracking a food product  
3161 and which coding and identification systems may be best  
3162 suited to this task.

3163         As you anticipate in the draft, the cost and feasibility  
3164 of requiring every manufacturer to maintain the full pedigree  
3165 of every ingredient in every food may outweigh the public  
3166 health benefits. To address concerns raised during the  
3167 peanut product recall, we urge you to consider whether  
3168 intermediate distributors and brokers should include on the  
3169 labeling of their bulk ingredients the identity of the  
3170 ingredient supplier.

3171         In general, we support proposals to give FDA stronger  
3172 enforcement powers, including the power to order a recall.  
3173 We believe that certain enforcement provisions of the  
3174 discussion draft, such as mandatory recall and suspension of  
3175 registration, should only be exercised by senior agency  
3176 officials when there is a risk of serious adverse health  
3177 consequences and should ensure that companies are afforded  
3178 certain due process protections, such as an administrative  
3179 hearing.

3180         As we saw during the recent recalls of tomatoes and  
3181 jalapeno peppers, recalls can have a devastating financial  
3182 impact, and they need to reflect the best science and wisest  
3183 agency judgment.

3184           Finally, we strongly support efforts to provide FDA with  
3185 additional resources. GMA helped create the alliance for a  
3186 stronger FDA, and we have worked with other consumer and  
3187 industry groups to increase FDA spending. If Congress enacts  
3188 the FY 2010 request of the FDA and the Obama administration,  
3189 we will have seen food safety spending at FDA increase by  
3190 nearly 80 percent since F& 2006.

3191           More funding is needed. We look forward to working with  
3192 the committee to identifying appropriate role for industry.  
3193 Our industry is significantly increasing our own investments  
3194 in food safety, and we are prepared to make additional  
3195 investments to continually improve the safety of our food  
3196 supply and to comply with many of the new mandates that are  
3197 envisioned in the discussion draft. We are not opposed to  
3198 all fees, and I am confident that the committee can reach a  
3199 bipartisan consensus on the agency's resource needs and an  
3200 appropriate role for industry.

3201           Let me close by saying again that the food and beverage  
3202 industry is committed to working with you to quickly enact  
3203 food safety legislation which makes the prevention of  
3204 contamination the foundation of our food safety system.  
3205 Thank you.

3206           [The prepared statement of Ms. Bailey follows:]

3207 \*\*\*\*\* INSERT 3 \*\*\*\*\*

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3208

Mr. {Pallone.} Thank you. Ms. DeWaal.

|  
3209 ^STATEMENT OF CAROLINE SMITH DeWAAL

3210 } Ms. {DeWaal.} Thank you very much. Thank you for your  
3211 leadership, Chairman Pallone, and also the leadership from  
3212 many other members of this subcommittee and committee. And  
3213 also thank you to you, Ranking Member Deal, for the many  
3214 hearings that we have sat through. We have listened to the  
3215 witnesses. This work has been going on before this committee  
3216 for a long time, and I think hopefully we are nearing an end.

3217 My name is Caroline Smith DeWaal, director of food  
3218 safety for the Center for Science in the Public Interest, but  
3219 today I am representing 10 consumer, public health, and  
3220 victims' advocacy organizations that are members of the Safe  
3221 Food Coalition.

3222 Let me begin by saying that we believe this is a strong  
3223 bill that will improve food safety. It requires food  
3224 companies to build into their processes the conduct of  
3225 regular hazard analysis, and they have the institute  
3226 preventive controls to prevent problems from occurring. It  
3227 provides a modern framework for food safety oversight to  
3228 replace the antiquated food safety laws that have hamstrung  
3229 the Food and Drug Administration. It gives FDA essential new  
3230 authority to carry out the mission of preventing illnesses

3231 and outbreaks and to inspect food plants much more  
3232 frequently, and it addresses the funding issues urgently  
3233 needed to institute the program improvements, doing this with  
3234 a modest registration fee.

3235         The heart of any effective reform effort lies in  
3236 prevention, which is in the bill's hazard analysis and  
3237 preventive control section. The bill provides FDA with new  
3238 tools like written plans and access to processing records  
3239 that will allow government inspectors to review the  
3240 conditions in plants over time, not just when inspectors are  
3241 in the facility.

3242         We recommend additional strengthening of the bill by  
3243 requiring companies or labs to report pathogen on final  
3244 product samples to FDA whenever they are encountered in a  
3245 facility. This would give FDA an early warning of problems  
3246 and might prevent another tragedy, like the outbreak linked  
3247 to the Peanut Corporation of America.

3248         It is a common adage that you cannot detect what you  
3249 don't inspect. Random and frequent inspection by public  
3250 officials is a necessary component of an effective food  
3251 safety system. This legislation divides food companies into  
3252 three categories based on risk and directs FDA to inspect the  
3253 facilities every six months to four years.

3254         While this is a vast improvement over FDA's existing

3255 program, we continue to believe that more frequent  
3256 inspections are needed, particularly of high risk facilities.  
3257 Risk-based inspection is a concept that expands across the  
3258 entire spectrum of food products not just those regulated by  
3259 FDA.

3260         The registration fee, as proposed, is quite modest. And  
3261 at \$1,000 per facility, it should provide somewhere between  
3262 \$300 and \$400 million in new revenue for food safety  
3263 activities. Let us put this fee into context. In the Peter  
3264 Pan outbreak, the average cost per victim reporting an  
3265 illness was \$2,650. And this is based on an estimate using  
3266 the Economic Research Service Cost calculator. So when there  
3267 is an outbreak, consumers who are affected may pay over  
3268 \$2,500 or more. These are individuals. So clearly \$1,000  
3269 fee on each facility to avoid these problems is more than  
3270 reasonable, especially when compared to the cost of  
3271 individuals and families that you have had here before this  
3272 committee, testifying on the severe impact of food borne  
3273 illness.

3274         In addition, I would just like to note that companies  
3275 themselves can run advertising campaigns to promote their  
3276 products that run into the tens and even hundreds of millions  
3277 of dollars.

3278         To conclude, I just want to say that polling has shown

3279 that the public has lost confidence in the safety of food.  
3280 The percentage of consumers confident in food safety fell to  
3281 about 22 percent according to the University of Minnesota's  
3282 Food Industry Center. This legislation provides a modern  
3283 framework for FDA's regulation of the food supply that will  
3284 deliver many benefits to consumers though it does stop short  
3285 of structural reforms that we also think are essential.

3286 We appreciate your leadership, and we believe that these  
3287 new authorities that you are proposing will over time prevent  
3288 the outbreaks and illnesses and help restore consumer  
3289 confidence.

3290 Earlier this year, members of the Energy and Commerce  
3291 Committee made commitments to the victims of the Peanut  
3292 Corporation of America outbreak that change would come to  
3293 FDA. President Obama said at a bare minimum, we should be  
3294 able to count on our government, keeping our kids safe when  
3295 they eat peanut butter.

3296 We urge you, Chairman, to act swiftly to finalize this  
3297 legislation and to enact it. Thank you.

3298 [The prepared statement of Ms. DeWaal follows:]

3299 \*\*\*\*\* INSERT 4 \*\*\*\*\*

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3300

Mr. {Pallone.} Thank you. Dr. Jones.

|  
3301 ^STATEMENT OF TIM F. JONES

3302 } Dr. {Jones.} Mr. Chairman, members of the subcommittee,  
3303 thank you for the opportunity to be here today. Recent high  
3304 profile outbreaks demonstrate the huge challenges and  
3305 opportunities for improvement in the Nation's food supply and  
3306 food safety infrastructure. Laws, policies, and, to be  
3307 frank, philosophies developed decades ago no longer suffice  
3308 to successfully meet these new demands.

3309 The legislation we are discussing today is therefore a  
3310 critical step in reviving the food safety capacities of the  
3311 FDA. I work in a state health department as a epidemiologist  
3312 responsible for investigating food borne diseases and in  
3313 effect cleaning up the mess left when things go awry in the  
3314 food safety chain.

3315 I am excited to see that this proposed legislation  
3316 addresses many of the problems that I experience firsthand in  
3317 my role both investigating and helping prevent food borne  
3318 disease.

3319 Improving the traceability of food as called for in this  
3320 legislation is fundamental to successfully achieving many of  
3321 the other tasks described. If traceback information had been  
3322 more promptly available and shared faster, I think that many

3323 of the problems associated with the recent tomato/jalapeno  
3324 incident could have been mitigated. And likewise tracing  
3325 peanut butter from one plant to 4,000 different commercial  
3326 products would have been utterly impossible with many other  
3327 types of foods.

3328       Ensuring that all foods are traceable efficiently and  
3329 accurately is critical to maintaining food safety.  
3330 Contamination of produce and foods which are eaten uncooked  
3331 are of particular concern because consumers have less control  
3332 over the safety of those foods in their own kitchens.

3333 Setting standards for pre-harvest food production starts to  
3334 close a major current gap in the Nation's food safety system.

3335       Suspected produce-associated illnesses are particularly  
3336 difficult to investigate from both the public health and  
3337 regulatory perspectives. While large food service  
3338 corporations and the suppliers often have excellent quality  
3339 control programs with impeccable records, many other  
3340 companies don't.

3341       The portions of this bill requiring country of origin  
3342 labeling, improved distribution records, and plans to  
3343 regulate the safe production and harvesting of fruits and  
3344 vegetables are important to help address these problems.

3345       I am pleased to see that the agency is being encouraged  
3346 to markedly increase the scrutiny of food-handling entities.

3347 I would like to emphasize the importance of basing  
3348 inspections and product testing and any other interventions  
3349 by the agency on sound science. The bill does have important  
3350 directives to improve testing in the science base of the  
3351 agency's activities.

3352         It is critical that from top to bottom activities are  
3353 more efficient and effective and not just more frequent.  
3354 This bill's requirement that the agency's activities are  
3355 risk-based is particularly critical. It is likely that as  
3356 technology improves, the value of traditionally defined  
3357 inspections will change dramatically. And I urge that the  
3358 agency retain sufficient flexibility and authority to adapt  
3359 to changes rapidly and with as few barriers as possible.

3360         I think it is important that in any discussion of the  
3361 food safety system to emphasize the importance of interaction  
3362 between FDA and CDC along with state and local partners and  
3363 meeting the directive to enhance the science of food safety  
3364 and develop risk-based approaches. Data from CDC and its  
3365 partners on things like outbreaks, disease surveillance, and  
3366 attribution of human disease to specific foods will be  
3367 critical. It is imperative that such data are developed and  
3368 shared cooperatively to meet the needs of all the partners  
3369 involved in the system.

3370         In every discussion that I have been in pertaining to

3371 food safety, the importance and current inadequacy of  
3372 effective information sharing is probably the most common  
3373 single topic that is raised. I am pleased to see that issue  
3374 addressed in this bill. Improving the technological capacity  
3375 to share information will be important in accomplishing this,  
3376 but perhaps even more important is changing the engrained  
3377 policies of not sharing information among partner agencies  
3378 far beyond any logical limit, even when the failure to do so  
3379 threatens the public health.

3380         To meet the mandates of this bill, FDA will have to  
3381 increase interaction and coordination with state and local  
3382 agencies, which will require funding and focused attention.  
3383 Federal regulatory agencies frequently are prohibited from  
3384 sharing proprietary information obtained during  
3385 investigations. The flow of information in both directions  
3386 between FDA and CDC as well as state public health partners  
3387 is critical.

3388         Examples of this include such things as distribution  
3389 lists during recalls, information on suspected products or  
3390 producers, and information on potentially exposed people.

3391         The FDA, CDC, and other partner agencies must have both  
3392 the authority and expectation to share actionable information  
3393 with the public health partners to the extent necessary to  
3394 protect the public's health.

3395           And I will conclude with a final comment about the  
3396 importance of ensuring FDA and its state and local partners  
3397 have adequate resources to meet the responsibilities with  
3398 which they are charged in this bill. No one would argue that  
3399 the FDA is currently underfunded, overworked and essentially  
3400 overwhelmed. State and local food safety capacity must also  
3401 be robust in order to maintain an effective food safety  
3402 system.

3403           Adequate and consistent funding and resources must be  
3404 dedicated explicitly to sustain the food safety programs at  
3405 FDA as well as the state and local partners who work with  
3406 them to keep the food supply safe. Americans will eat a  
3407 billion meals today, and I can't think of a better investment  
3408 than one that will keep every one of those meals safe.

3409           [The prepared statement of Dr. Jones follows:]

3410 \*\*\*\*\* INSERT 5 \*\*\*\*\*

3411 | Mr. {Pallone.} Thank you, Dr. Jones. Mr. Stenzel.

|  
3412 ^STATEMENT OF THOMAS E. STENZEL

3413 } Mr. {Stenzel.} Good afternoon, Chairman Pallone,  
3414 Ranking Member Deal, and members of the subcommittee. I am  
3415 pleased to be with you. As you know, the fresh produce  
3416 industry has been a leading proponent of strong federal  
3417 government oversight of food safety. My name is Tom Stenzel.  
3418 I am president and CEO of the United Fresh Produce  
3419 Association. Our organization has been privileged to testify  
3420 10 times in the last two years before this committee or other  
3421 members of Congress, perhaps only runner up to Caroline on  
3422 this panel.

3423 Our board of directors in January of 2007 adopted a  
3424 series of policy principles calling for mandatory, science-  
3425 based regulation by the federal government. Today we  
3426 congratulate you and the leadership of the full committee in  
3427 presenting the draft of the Food Safety Enhancement Act of  
3428 2009 for consideration.

3429 While my written statement contains a number of  
3430 suggestions for strengthening the bill, I will focus just now  
3431 on three key areas of concern. Let me start by repeating  
3432 those policy principles I mentioned. To protect public  
3433 health and ensure consumer confidence, produce safety

3434 standards must allow for a commodity-specific approach based  
3435 on the best available science, must be consistent and  
3436 applicable to the identified commodity, no matter whether it  
3437 was grown in the United States or imported, and it must be  
3438 federally mandated with sufficient federal oversight of  
3439 compliance in order to be credible to consumers.

3440         We are pleased that these principles are recognized in  
3441 the draft Food Safety Enhancement Act. In looking  
3442 specifically at the draft, we strongly support the bill's  
3443 intent in Section 104 for FDA to focus on maximizing public  
3444 health by implementing regulatory standards for those  
3445 specific raw agricultural commodities that it believes are  
3446 most critical. The FDA has estimated that only five  
3447 commodities have been associated with 80 percent of all  
3448 produce-related food borne disease outbreaks in the past 10  
3449 years, and that is where we must direct our resources.

3450         In a highly diverse industry that is more aptly  
3451 described as hundreds of different commodity industries, one  
3452 size does not fit all. We support Congress specifying that  
3453 FDA have broad authority to regulate any produce commodities  
3454 it determines necessary. But with a clear mandate to develop  
3455 rule making that focuses resources for maximum public health  
3456 benefit on those specific types of commodities for which the  
3457 secretary determines that such standards are necessary to

3458 minimize the risk of serious adverse health consequences.

3459           We also recommend that Section 104 strengthen the  
3460 support for collaboration between HHS and the U.S. Department  
3461 of Agriculture and all state agencies in all areas of  
3462 education, research, and enforcement with regard to produce.  
3463 It is important that we bring the broadest knowledge and  
3464 resource base possible to assist all stakeholders in  
3465 understanding and complying with FDA set public health  
3466 standards.

3467           Dealing with Section 107 on traceability, I want to  
3468 assure the committee that fresh produce industry is committed  
3469 to farm to fork traceability of our products. As I presented  
3470 in detailed testimony before the House Committee on  
3471 Appropriations, Chairwoman Delaro's Ag Subcommittee earlier  
3472 this year, we have underway a produce traceability initiative  
3473 to provide electronic traceability for 6 billion cases of  
3474 fresh produce that move annually within the United States.  
3475 This is a massive and extremely expensive long-term  
3476 undertaking, but it is a commitment that we have made.

3477           However we are concerned that the prescriptive nature of  
3478 Section 107 could actually derail these important efforts to  
3479 bring the most cost efficient and cost effective technology  
3480 to bear on this challenge. As you weigh various traceability  
3481 provisions, we urge that Congress set the goal to mandate for

3482 food traceability but not overly prescriptive requirements  
3483 such as those in this bill.

3484         Rather we believe Congress would be more effective in  
3485 mandating an intensive evaluation of technologies, systems,  
3486 and pilot tests that will truly lead to the end result we all  
3487 desire. To that point, this legislation should set a goal  
3488 for total supply chain traceability across the food industry,  
3489 not single out individual food categories for traceability.

3490         Finally on the question of imports, I believe the  
3491 committee should carefully examine all of the provisions  
3492 regulating imported foods to assure equal treatment and fair  
3493 standards for imported and domestically produced foods. This  
3494 should be a principle maintained throughout all provisions.

3495         In Section 201, we support the bill's intent to require  
3496 importers to register with FDA and comply with good importer  
3497 practices. The committee should make clear that this is the  
3498 standard protocol for importing foods, and that the  
3499 limitations and restrictions envisioned in Section 109  
3500 provide very extreme authorities to be used by FDA only in  
3501 worst case scenarios when required to minimize the risk of  
3502 severe adverse health consequences.

3503         With regard to imports, we also strongly support the  
3504 concept of the safe and secure food importation program in  
3505 Section 113 and urge that the bill require FDA to implement

3506 such a program with clear direction that it shall be  
3507 implemented rather than may be implemented.

3508         Finally, let me mention 143 and country of origin  
3509 labeling. The fresh produce industry is already required  
3510 under the 2008 Farm Bill to provide mandatory country of  
3511 origin labeling at retail point of sale. Our industry has  
3512 moved rapidly to ensure compliance with this law and urges  
3513 that those products which are already covered be specifically  
3514 exempted from any new duplicative coverage under the FDNC  
3515 Act.

3516         Let me conclude with a comment about public health. The  
3517 very Department of Health and Human Services that regulates  
3518 our safety has the dual responsibility to promote public  
3519 health but consider the fact that we need, as Americans, to  
3520 double our consumption of fruits and vegetables to meet the  
3521 very simply U.S. dietary guidelines.

3522         With that public health imperative, fears of food safety  
3523 have no place in the fresh produce department. Thank you for  
3524 your leadership on this effort.

3525         [The prepared statement of Mr. Stenzel follows:]

3526 \*\*\*\*\* INSERT 6 \*\*\*\*\*

|  
3527 Mr. {Pallone.} Thank you, and thank all of you. We  
3528 will now take questions from the panel, five minutes each,  
3529 and I will start.

3530 I wanted to start with Ms. DeWaal. Many in the industry  
3531 have called for prevention, or I should say a stronger  
3532 emphasis on prevention. And many feel that we need to share  
3533 the responsibility for making food safe. The FDA obviously  
3534 does an important job, but manufacturers must also be  
3535 responsible for the foods that they make.

3536 Now, one of the ways that the draft before us proposes  
3537 to do this is through a new emphasis on prevention. It  
3538 requires companies to conduct hazard analysis to identify  
3539 potential safety risks for the food they handle. It then  
3540 requires that the facility owner adopt preventive measures to  
3541 reduce or eliminate these risks.

3542 So, Ms. DeWaal, can you elaborate on how preventive  
3543 controls, such as those put forth by the bill, will help make  
3544 food safer? And could you give us some examples of  
3545 preventive controls and how they might be implemented or  
3546 applied?

3547 Ms. {DeWaal.} Thank you, Chairman Pallone. The systems  
3548 that are going to be applied in this bill are well tested.  
3549 We have watched the implementation of what are called HACCP

3550 or hazard analysis critical control point systems in the  
3551 seafood industry, in the beef and poultry industries, and in  
3552 the--also in fresh juice and several other industries.

3553         The problem would be the approach that FDA has been  
3554 taking up until now and the solution that your bill will  
3555 bring to the agency is that they have been trying to apply  
3556 these systems one by one, industry by industry. And I think  
3557 what you see here is a unitary view, among industry and  
3558 consumer organizations, that these systems are needed across  
3559 the board. They are developed by the industry. They are  
3560 driven by the industry. They design the programs, but the  
3561 government can use them to actually go in and conduct  
3562 inspections, which are much more meaningful than the ones  
3563 they do today.

3564         Mr. {Pallone.} Well, let me ask each of you. I will  
3565 ask Ms. Bailey and then go to the others quickly if you would  
3566 respond, whether you support these preventive approaches to  
3567 food safety.

3568         Ms. {Bailey.} Absolutely. Yes, sir.

3569         Mr. {Pallone.} Okay, Mike?

3570         Mr. {Ambrosio.} Yes.

3571         Mr. {Pallone.} Dr. Jones?

3572         Dr. {Jones.} Yes, sir, we do.

3573         Mr. {Pallone.} All right, great. I mean obviously a

3574 consensus on the preventive approach being the critical part  
3575 of the bill. I wanted to ask about access to records though  
3576 too. One of the new requirements in the bill references  
3577 access to records. Section 106 requires that food  
3578 manufacturers and producers retain records relating to the  
3579 foods they produce, and upon request, provide these records  
3580 to the FDA. FDA would, in the event of a food borne disease  
3581 outbreak or during an inspection, have access to information  
3582 on how foods were produced, manufactured, transported or  
3583 stored. And I will initially ask Dr. Jones. Can you  
3584 describe for us how this type of records access would be  
3585 helpful to the FDA in the event of a food borne disease  
3586 outbreak?

3587 Dr. {Jones.} Well, I mean I think access to those  
3588 records are critical in order for them to sort of pinpoint  
3589 their interventions, but I also think the ability for FDA to  
3590 share that data with other agencies that assist them in those  
3591 investigations is critical. And that has been a huge barrier  
3592 for us. I mean I worked on outbreaks where FDA had the names  
3593 and phone numbers of people that had consumed contaminated  
3594 product and would not or thought that they could not share  
3595 that information with public health departments that are  
3596 responsible for calling those people and telling them not to  
3597 eat the stuff. And that is just mind-boggling to me. I mean

3598 I think it is subtle, but there is some addressing that issue  
3599 in this bill.

3600 Mr. {Pallone.} You want to comment also, Ms. DeWaal on  
3601 whether you believe that this access to records provision  
3602 will help protect public health?

3603 Ms. {DeWaal.} The access to records provision gives the  
3604 agency the ability to look at plants. When they visit them,  
3605 they can look at them as they are operating over time. Today  
3606 when an FDA inspector goes into a plant, they just see the  
3607 four walls of the plant. They may not even get access to any  
3608 records in that facility. They can look at production  
3609 practices as they are happening on that day.

3610 But with the access to records provision together with  
3611 this preventive control system and this written food safety  
3612 plan, the inspector will be able to go and look back and  
3613 where the company has faced perhaps challenges in its  
3614 operation and how they have addressed them.

3615 Mr. {Pallone.} Okay, thank you. I mean I don't know if  
3616 anybody else wanted to address that, but I think that is  
3617 fine. Thank you. Mr. Deal.

3618 Mr. {Deal.} Thank you. Mr. Stenzel, I guess I am going  
3619 to start with you from the producer side of it. First of  
3620 all, in a general context, do you see any problem or  
3621 potential of this legislation creating overlaps with FDA

3622 jurisdiction and requirements to do things versus current  
3623 USDA requirements to do things in our food supply?

3624       Mr. {Stenzel.} We don't see any jurisdictional issues  
3625 in public health in that sense. FDA has the statutory  
3626 authority now to regulate the fresh produce industry. We do  
3627 suggest strongly that there be a good coordination with the  
3628 U.S. Department of Agriculture in education, enforcement.  
3629 Certainly one of the keys to implementing this bill is going  
3630 to be an effective structure with FDA working with USDA and  
3631 state and local agencies in compliance, enforcement,  
3632 inspections. That needs to be strengthened, but there is not  
3633 a jurisdictional issue of competing authorities.

3634       Mr. {Deal.} My understanding is that at the production  
3635 level that good agricultural practices are the primary  
3636 preventive tool and mechanism for dealing with it at the  
3637 production level. Do you see perhaps that an updating or  
3638 improvement on those agricultural practices standards as they  
3639 apply to fruits and vegetables is important? And is there  
3640 anything here that would prevent that from taking place?

3641       Mr. {Stenzel.} Yes, sir, Mr. Deal, that is an extremely  
3642 important part. The FDA's good agricultural practices are  
3643 called to be updated in this draft legislation. We strongly  
3644 support that as the baseline guidance for all fruit and  
3645 vegetables. For those specific commodities in which FDA has

3646 determined a significant level of risk, then you move into  
3647 the rule making procedure. But that is one of the key  
3648 things. It is the way we can best focus our public health  
3649 resources on the greatest risk.

3650 I said in my testimony that 80 percent of all the  
3651 outbreaks have been associated with just five commodities.  
3652 So the basic good agricultural practices are very appropriate  
3653 for all fruits and vegetables, but let us focus the rule  
3654 making on those specific commodities that require it.

3655 Mr. {Deal.} And, Ms. Bailey, I believe you made the  
3656 point that since we have mandated studies and pilot projects,  
3657 et cetera, that those be completed before we start trying to  
3658 write the rules and regulations. Is that one of the points  
3659 you were making?

3660 Ms. {Bailey.} On traceability, yes.

3661 Mr. {Deal.} Yes. It seems to me that if we are going  
3662 to do the studies and the pilot projects, we ought to do that  
3663 before we write the regulations because presumably they will  
3664 give us the information to guide us in the rule making  
3665 process. So I think your point is well made. In that  
3666 regard, Mr. Stenzel, your industry has already put in place  
3667 some traceability standards. How do you see your current  
3668 efforts in traceability? How do they correspond with what is  
3669 in this legislation?

3670 Mr. {Stenzel.} I tell you this is proving to be a  
3671 massive, massive undertaking, and, you know, we are committed  
3672 to doing it even on a voluntary basis before any type of  
3673 requirement. But extremely complex system of creating that  
3674 interoperable system that can see the life cycle all the way  
3675 through of our products. But some of the specific language  
3676 in this bill, the full pedigree of each product, gives us  
3677 great cause for concern.

3678 Even though we are moving down a path of hundreds of  
3679 millions of dollars being invested in interoperable  
3680 traceability systems, we don't think they might meet exactly  
3681 the terms of this bill. So we would also strongly advise  
3682 that FDA be mandated to get involved in the technology, in  
3683 the pilot test, learn about each industry, and then write the  
3684 regulation.

3685 It is premature to tell every industry exactly how it  
3686 should be done until we have this greater learning.

3687 Mr. {Deal.} One of the scares that we have alluded to  
3688 here was the Mexican pepper scare that adversely impacted the  
3689 tomato industry. And I guess I would ask you again how do we  
3690 ensure that foreign producers meet the kind of standards that  
3691 we would need? Would it require, in your opinion, some kind  
3692 of foreign producer verification system of some sort?

3693 Mr. {Stenzel.} Well, I think the requirements in the

3694 import section are appropriate. That importers will now be  
3695 required to register with the FDA, and as part of good  
3696 importer practices, they will have to assure that their  
3697 products have been grown in accordance with these standards.  
3698 We believe that is an appropriate step to be taken.

3699 I don't think anyone envisions going, searching around  
3700 on every farm around the world, nor every farm in America to  
3701 be honest with that. That is simply not going to be the  
3702 case. The authority should be there for FDA if they need to  
3703 investigate an issue, but the basic responsibility is going  
3704 to lie with the importer or the food manufacturer.

3705 Mr. {Deal.} Does your organization represent the  
3706 organics producers?

3707 Mr. {Stenzel.} Yes, sir, we have a number of organic  
3708 suppliers in our group.

3709 Mr. {Deal.} Thank you. I have a statement, and I think  
3710 we have cleared it with your staff from the Frozen Food  
3711 Institute to be inserted in the record?

3712 Mr. {Pallone.} Without objection, so ordered. Chairman  
3713 Dingell.

3714 Mr. {Dingell.} Mr. Chairman, thank you. I would like  
3715 to commend the panel for their very helpful testimony and  
3716 thank you all. I would particularly like to address my  
3717 questions, however, to Ms. Bailey from GMA. I would like to

3718 first begin by welcoming you. I would like to follow up by  
3719 thanking you for the cooperative way in which you and GMA  
3720 have been working with the staff to try and resolve the  
3721 difficulties which we confront. And I would like to also  
3722 express my particular thanks to you for the most helpful way  
3723 in which you have behaved and the remarkable change that has  
3724 occurred under your leadership. So I thank you.

3725 First of all, am I fair in stating that FDA has been so  
3726 underfunded that they have not been able to provide the  
3727 necessary services to protect either the industry or the  
3728 consumers for a number of years?

3729 Ms. {Bailey.} That is right.

3730 Mr. {Dingell.} And as a result, they have been unable  
3731 to adequately fulfill their role in ensuring the safety of  
3732 the Nation's food supply?

3733 Ms. {Bailey.} Yes, we would agree.

3734 Mr. {Dingell.} Unfortunately our reporter doesn't have  
3735 a nod. You have to say yes or no.

3736 Ms. {Bailey.} I am sorry. I said yes, and if I could  
3737 give an example, FDA has not been able to update good  
3738 manufacturing practices since 1986, and that is just one  
3739 example of something they have not been able to do without  
3740 adequate resources.

3741 Mr. {Dingell.} That sounds like a very serious matter.

3742 Tell us what that means.

3743 Ms. {Bailey.} Well, good manufacturing practices serve  
3744 the basis--

3745 Mr. {Dingell.} Those are required both in food and  
3746 drugs, cosmetics and also--

3747 Ms. {Bailey.} That is right.

3748 Mr. {Dingell.} --in pharmaceuticals.

3749 Ms. {Bailey.} That is right, and so the preventive  
3750 controls that we are talking about, in HACCP for example, are  
3751 one step up from good manufacturing practices. You want to  
3752 have them updated, and as we all know, there have been  
3753 enormous advances in manufacturing and food processing since  
3754 1986 relating to pathogen control, environmental testing, all  
3755 of the advancements. And FDA has not been able to  
3756 incorporate them into updated good manufacturing practices  
3757 guidance for industry.

3758 Mr. {Dingell.} Would you also agree that FDA's science  
3759 base has eroded?

3760 Ms. {Bailey.} Absolutely yes.

3761 Mr. {Dingell.} And that the FDA's information  
3762 technology systems are inadequate?

3763 Ms. {Bailey.} Yes.

3764 Mr. {Dingell.} And that FDA has not been doing an  
3765 acceptable level of surveillance and research?

3766 Ms. {Bailey.} That is right.

3767 Mr. {Dingell.} Would you agree that they have not  
3768 conducted a satisfactory number of inspections over the  
3769 years? This figure I got, which seems interesting. FDA  
3770 conducted 6,562 domestic food facility inspections in 2008,  
3771 152 foreign food facility inspections in 2008. The total  
3772 number of registered facilities is 378,000, but there are  
3773 many more out there in the world who are shipping stuff to  
3774 us. Is that a fair statement?

3775 Ms. {Bailey.} That is an accurate statement, yes.

3776 Mr. {Dingell.} Thank you. And I am sure that you  
3777 agree, as you have said in your statement, that FDA needs  
3778 additional resources to do their job?

3779 Ms. {Bailey.} Yes.

3780 Mr. {Dingell.} And I want to commend you very much for  
3781 the way that you have been working with us on the  
3782 registration and the fee question. And I want you to know  
3783 that we are going to try very hard to see to it that we come  
3784 up with something that enables industry to work, prosper,  
3785 have a satisfactory Food and Drug Administration, one which  
3786 protects the consumers but also which doesn't overburden the  
3787 industry. And we look forward to continuing our efforts on  
3788 that, and I hope that you will continue to give us those  
3789 assistances.

3790           And again the reporter has no nod but--

3791           Ms. {Bailey.} Yes, we look forward to that. I thought  
3792 that Dr. Hamburg this morning laid a good basis for those  
3793 discussions going forward.

3794           Mr. {Dingell.} I am troubled about foreign people who  
3795 deliver food into the United States. Food and Drug doesn't  
3796 have the right number of inspections and inspectors at the  
3797 border, do they?

3798           Ms. {Bailey.} No, that is right. They do not.

3799           Mr. {Dingell.} I am told they only inspect about one  
3800 percent of foods coming into the United States. And the  
3801 games are played oftentimes where they are turned back,  
3802 rather where food shipments are turned with the result that  
3803 they go out and come in another port. Are you troubled about  
3804 that?

3805           Ms. {Bailey.} Yes, we need strong inspections at the  
3806 border.

3807           Mr. {Dingell.} Now, I am also troubled about the fact  
3808 that Food and Drug has no understandings with their sister  
3809 agencies, with customs, with immigration. So as a result a  
3810 lot of times, their inspectors will be at the ports, and  
3811 there is no Food and Drug folk. We ought to see to it that  
3812 there is a cooperative agreement there to make that possible  
3813 so that they would work together instead of ignoring each

3814 other's business. Isn't that right?

3815 Ms. {Bailey.} I think that sounds like a good idea,  
3816 yes.

3817 Mr. {Dingell.} Now, I note that I am three seconds  
3818 overtime. Pleasure to have you before us. Thank you. Thank  
3819 you, Mr. Chairman.

3820 Ms. {Bailey.} Thank you, Mr. Dingell.

3821 Mr. {Pallone.} Thank you, Chairman Dingell. Mr.  
3822 Shimkus.

3823 Mr. {Shimkus.} Thank you, Mr. Chairman. I have a lot of  
3824 questions. I am going to try to be quick. You all sat in  
3825 the first testimony. Can any of you tell me what ``may  
3826 cause'' means? Mr. Ambrosio, do you know what ``may cause''  
3827 means?

3828 Mr. {Ambrosio.} It is a very vague term.

3829 Mr. {Shimkus.} Okay, Ms. Bailey, ``may cause''?

3830 Ms. {Bailey.} I am not certain, no.

3831 Mr. {Shimkus.} Okay, Ms. DeWaal?

3832 Ms. {DeWaal.} Thank you. The actual subsection says  
3833 ``if the secretary has reason to believe that the use or  
3834 consumption of or exposure to an article of food may cause  
3835 adverse health consequences.'' So the actual standard, sir,  
3836 is ``reason to believe'' and the ``may cause'' is in there,  
3837 but it really is a standard which is very protective of

3838 public health. Thank you.

3839 Mr. {Shimkus.} Dr. Jones?

3840 Dr. {Jones.} I agree with those comments.

3841 Mr. {Shimkus.} And Mr. Stenzel?

3842 Mr. {Stenzel.} I believe that it is a much more vague  
3843 standard than that.

3844 Mr. {Shimkus.} And I hope we can work to clean up that  
3845 language, and I think there is an opportunity to do that.

3846 Let me ask this subpoena question again to those who may want  
3847 to talk about that. There are three criteria in Section 311

3848 which I didn't allude to the first. First, ``does any

3849 hearing, investigation, and other proceeding, respecting a

3850 violation of the act''? I think most people agree subpoena.

3851 ``Any hearing, investigation or other proceeding to

3852 determine if a person is in violation of a specific provision

3853 of this act''? I think an average person would say okay,

3854 subpoena these babies.

3855 The third one, ``any other matter relative to the

3856 commissioner's jurisdiction under this act, the Public Health

3857 Service Act, and the Federal Anti-Tampering Act.'' Any other

3858 matter, vague or not? Mr. Ambrosio?

3859 Mr. {Ambrosio.} It is vague.

3860 Mr. {Shimkus.} Thank you. Ms. Bailey?

3861 Ms. {Bailey.} Yes, that--it is vague.

3862 Mr. {Shimkus.} Ms. DeWaal?

3863 Ms. {DeWaal.} Actually these acts are important to  
3864 protect us against swine flu, against bioterrorism. So in  
3865 fact, these acts, if you understand the relationship between  
3866 the Food, Drug, and Cosmetic Act, and these other legal  
3867 statutes, I think the language may be appropriate but--

3868 Mr. {Shimkus.} It may be. It may not be. It may be.

3869 Ms. {DeWaal.} --we will go back and look at it.

3870 Mr. {Shimkus.} Okay, thanks. Dr. Jones?

3871 Dr. {Jones.} I am a physician, not a lawyer.

3872 Mr. {Shimkus.} Okay, either am I, but I pretend to be  
3873 one here.

3874 Dr. {Jones.} You know, so my tendency is to err on the  
3875 side of protecting the public's health, but I agree it is  
3876 somewhat vague.

3877 Mr. {Shimkus.} My tendency is to question the legal  
3878 language of the law that may harm folks by the--I found the  
3879 language of the law is very important. And interesting  
3880 things can be done as this gets crafted. Mr. Stenzel, I  
3881 think it is also quit a general standard and do suggest it is  
3882 an area to look at throughout the bill. Thank you.

3883 Mr. Stenzel, I want to ask specifically on Section 104,  
3884 which calls for the secretary to issue regulation on produce  
3885 safety standards. The language in the bill says the standard

3886 may include minimum standards for safety. This is a lot of  
3887 the language stuff that I have been focusing on today. Why  
3888 would we want the agency to issue minimum standards instead  
3889 of the appropriate standards for safety?

3890 Mr. {Stenzel.} Mr. Shimkus, thank you for raising that.  
3891 That is actually a subject I addressed in my written  
3892 testimony. I don't think we should be using such terms as  
3893 minimum or expecting minimum standards. We should have the  
3894 agency write the standards that are most appropriate that all  
3895 producers should follow. I can tell you this: that as soon as  
3896 we have minimum standards, the first thing that is going to  
3897 happen is someone is going to say that is not good enough.

3898 So if we are going to go down this path, let us make  
3899 sure the agency writes the most appropriate standards.

3900 Mr. {Shimkus.} And that is that whole debate that we  
3901 always have appear about some certainty. Industry needs  
3902 certainty. If we have vague language, there is uncertainty,  
3903 and with uncertainty comes higher risk because of trying to  
3904 comply. I appreciate that. Ms. Bailey, what was surprising  
3905 in the draft is--and I was on the ONI last Congress. I can't  
3906 talk about what was the hearings in previous Congresses or  
3907 what is going on this time.

3908 But baby formula has popped into this debate, and I know  
3909 of no hearings on baby formula in the last Congress when I

3910 was ranking on ONI. Have there been any reported problems  
3911 that would suggest that there needs to be a reason to change  
3912 the way infant formula is regulated? In the premises, it is  
3913 highly regulated already. Do you want to comment on that?

3914 Ms. {Bailey.} Yes, we are not familiar either with the  
3915 origin of that provision. We noticed it in this draft, and  
3916 we are, of course, aware of how high the regulated baby  
3917 formula is. And we are interested in receiving further  
3918 information, but it obviously is very important, as is the  
3919 safety of the product and the availability to mothers and  
3920 children.

3921 Mr. {Shimkus.} And thank you, Chairman. My time  
3922 expired. I would have gone on with a pilot program. I think  
3923 that has been discussed a little bit. I know Mr. Ambrosio  
3924 has some comments, and I think a pilot program might be  
3925 important. And I yield back.

3926 Mr. {Pallone.} The problem that we have is there is an  
3927 important vote on our other subcommittee. So I would like to  
3928 adjourn for just five minutes so that the members can go and  
3929 vote in the other subcommittee, and we will come right back.  
3930 So the subcommittee, if you bear with us, is just in recess  
3931 for five minutes.

3932 [Recess.]

3933 Mr. {Pallone.} Ms. DeGette.

3934 Ms. {DeGette.} Thank you very much, Mr. Chairman. I  
3935 want to echo Mr. Dingell's thanks to every single witness  
3936 here for working with us on this legislation. All of your  
3937 input has been very, very important, and none of you will be  
3938 surprised to know I want to talk about the mandatory recall  
3939 provisions of the bill, and I want to start with Ms. DeWaal.

3940 First of all, do you think, Ms. DeWaal, that the current  
3941 provisions of the Bioterrorism Act are sufficient to give us  
3942 the mandatory recall that we need in a robust food safety  
3943 system?

3944 Ms. {DeWaal.} No, I don't.

3945 Ms. {DeGette.} And why is that?

3946 Ms. {DeWaal.} Well, the Bioterrorism Act actually  
3947 didn't really give them mandatory recall, but it does give  
3948 them the authority to take certain actions like  
3949 administrative detention and some other actions when they  
3950 meet a very high--

3951 Ms. {DeGette.} But to interrupt you, it really has the  
3952 one step back and one step up. Is that sufficient to give us  
3953 the whole traceability?

3954 Ms. {DeWaal.} I am sorry.

3955 Ms. {DeGette.} I said mandatory recall, and I meant  
3956 traceability.

3957 Ms. {DeWaal.} Okay, I am sorry. Traceability--

3958 Ms. {DeGette.} That is what happens when you break my  
3959 train of thought.

3960 Ms. {DeWaal.} Thank you for that clarification. The  
3961 one step up and one step back traceability was a good first  
3962 step into this area, but I think the provisions in this bill  
3963 are much improved on that. What we have seen over the years,  
3964 since that law was passed, is that the FDA itself has had  
3965 trouble with identifying food products involved in major  
3966 recalls and outbreaks.

3967 Ms. {DeGette.} Because it just doesn't go far enough  
3968 forward or backward, correct?

3969 Ms. {DeWaal.} Right.

3970 Ms. {DeGette.} And, Dr. Jones, you are nodding your  
3971 head yes as well.

3972 Dr. {Jones.} Yeah, I mean I think there is such a huge  
3973 food production chain that if there is one point in the chain  
3974 where records aren't good--

3975 Ms. {DeGette.} You lose the whole thing.

3976 Dr. {Jones.} I mean if Bruno's produce doesn't know  
3977 where it came from, you could have the rest of the industry  
3978 known, and you can't get anywhere.

3979 Ms. {DeGette.} Right, thank you. Now, I want to ask  
3980 you, Mr. Amobrosio, Ms. Bailey, and Mr. Stenzel, I have read  
3981 all of your testimony and listened to you here today. You

3982 don't object in general to the concept of traceability, do  
3983 you, Mr. Ambrosio?

3984 Mr. {Ambrosio.} No.

3985 Ms. {DeGette.} Ms. Bailey?

3986 Ms. {Bailey.} No.

3987 Ms. {DeGette.} And Mr. Stenzel?

3988 Mr. {Stenzel.} No, ma'am.

3989 Ms. {DeGette.} And in fact, Mr. Ambrosio, in your  
3990 testimony, you recommended that the secretary be allowed to  
3991 design systems based on information gathered and not be  
3992 mandated to develop a specific type of system prior to those  
3993 efforts, correct? And, Ms. Bailey, in your testimony, your  
3994 written testimony, you talked about the concept of including  
3995 intermediate distributors and brokers in the labeling of bulk  
3996 ingredients to the supplier so that we could get that  
3997 traceability, correct?

3998 Ms. {Bailey.} That is right, yes.

3999 Ms. {DeGette.} And, Mr. Stenzel, I have to say the  
4000 produce industry in this country was really--maybe I  
4001 shouldn't say this in front of everybody else, but you folks  
4002 were the ones that gave me courage to believe that we could  
4003 do traceability because you are doing such a great job. So I  
4004 want to commend you. I guess the issue, as I heard in all of  
4005 your testimony today, is some concerns with the specific

4006 language of Section 7 of the committee draft. Would that be  
4007 accurate to say, Ms. Bailey?

4008 Ms. {Bailey.} That is right.

4009 Ms. {DeGette.} And I just want to--you know you talk in  
4010 your verbal testimony today about the tomato recall, and you  
4011 were talking about mandatory versus voluntary recalls. But  
4012 that made me think about traceability too because it doesn't  
4013 really matter if the recall is mandatory or voluntary. If it  
4014 is overbroad, it is still--I guess I should ask you, Mr.  
4015 Stenzel, since it is produce. If it is overbroad, it still  
4016 devastates the entire market, correct?

4017 Mr. {Stenzel.} Yes, that is absolutely correct.

4018 Ms. {DeGette.} So really what you want to have is the  
4019 ability to quickly trace where contamination came from foods,  
4020 correct? And, you know, what we have been seeing lately, I  
4021 was thinking about the latest, the pistachios, where they  
4022 were saying just don't eat any pistachios. Then I thought  
4023 well, what if you had pistachios that were incorporated in  
4024 granola or something like that that went a long way. You  
4025 could really devastate a food agency. Ms. Bailey, I wonder  
4026 if you want to comment on that.

4027 Ms. {Bailey.} I think first of all we are absolutely  
4028 sympathetic with your goal and the importance of improving  
4029 our traceability systems. I think it is a matter of

4030 prioritizing how we go about it. That is why we recommended  
4031 --first of all, there is a difference between a single  
4032 product like a strawberry that is ready to eat versus  
4033 ingredients that may be co-mingled and--

4034 Ms. {DeGette.} Right.

4035 Ms. {Bailey.} --and put into additional products.

4036 Ms. {DeGette.} Exactly, right.

4037 Ms. {Bailey.} And we saw in the peanut paste problem  
4038 that when there are brokers involved, PCA would sell the  
4039 paste to a broker who would then sell it to an end  
4040 manufacturer. And that is why we included the recommendation  
4041 that the distributor label it.

4042 Now, going forward, what we have learned working with  
4043 our member companies and other areas of the food industry, it  
4044 can be enormously expensive when you start to deal with co-  
4045 mingled ingredient commodity products, and that is where we  
4046 caution. And we think the legislation has it absolutely  
4047 right. Let us ask FDA to first identify cost/benefit because  
4048 in the end resources are finite.

4049 Ms. {DeGette.} Right, let me just say, because my time  
4050 has expired, that I really hope all of you will come in and  
4051 work with us on this particular traceability language because  
4052 from the very early days of my working on this issue, what  
4053 you are saying is exactly my view, which is we need to have

4054 traceability throughout the industry but that we can't have a  
4055 one-size-fits-all traceability system or technology. The key  
4056 is those things be interoperable.

4057         So if you have tomatoes and peppers mixed in a salsa,  
4058 that is one level of complexity. If you have that salsa  
4059 incorporated in a processed food, that is another layer of  
4060 complexity. And then if you have that put into something at  
4061 a restaurant or any place, that is another layer. So we have  
4062 to really work on that.

4063         What I am amazed about though is that we do have the  
4064 technology, and we just need to work on it. So I hope you  
4065 will all work with us in the next week to improve this  
4066 language. Thank you for your indulgence, Mr. Chairman.

4067         Mr. {Pallone.} Mr. Buyer.

4068         Mr. {Buyer.} I had to take a deep breath because Mr.  
4069 Matheson and I and I guess now Chairman Dingell and Gene  
4070 Green, you know, we have taken this trying to educate the  
4071 committee here on electronic pedigree with regard to drugs.  
4072 Yet now all of a sudden, there is this great interest to do  
4073 something expansive on pedigree with food.

4074         So I just want you to stop and ponder and think about  
4075 this, Mr. Chairman, because as we move to the Drug Safety  
4076 Bill, it is the reason I went right at the FDA Commissioner.  
4077 You can't say I have this level of interest in making sure

4078 that they go after tainted food but with regard to drugs  
4079 well, maybe that is a little bit different. We are not going  
4080 to send this message to the country that tainted food, bad  
4081 lettuce, that is really awful, but we can have a different  
4082 standard when it comes to bad Lipitor. I am uncomfortable.

4083 Let me ask some questions because I don't think I  
4084 completely understand. When I look at Section 106 and  
4085 Section 107, we have sort of an all-in, and then under  
4086 traceability, we have some exemptions. So you know I come  
4087 from a very small town. I grew up on the Tippecanoe River,  
4088 Buffalo, Indiana. We have two stops signs on either side of  
4089 a bridge. That is the size of the town I come from. So I  
4090 think about small businesses, and I worry.

4091 So when we think about access to records, and we are  
4092 going to say requirement with regard to restaurants. Are we  
4093 going to include concessionaires? Does anybody anticipate  
4094 that, that we would include concessionaires? So that when  
4095 you go to MCI Arena, how about when you go to the college  
4096 football game? How about high school? How about little  
4097 league? You know we make deer chili at our little league  
4098 games. I mean what all is going to be included?

4099 How about convenience stores? How about when you pull  
4100 into that mom-and-pop gas station and they have created  
4101 something? You can get elk sausage. I mean what kind of

4102 requirements are we going to be placing, and where do we  
4103 stop? Has anybody thought about do we as a committee need to  
4104 have better definition as to who is in and who is out? Total  
4105 silence. Yes?

4106 Mr. {Stenzel.} Congressman, at the risk of your wrath,  
4107 I just don't think that food safety is something that is  
4108 determined by scale or size of company. I run a trade  
4109 association that has many very small members who are going to  
4110 be extremely challenged to comply with this regulation. We  
4111 also have very many big members, but in last summer's  
4112 outbreak, we also found that some of the issues and some of  
4113 the issues where people were getting sick were the very  
4114 smallest restaurants. And we have to be able to have a  
4115 system that takes care of--

4116 Mr. {Buyer.} Well, there is food handling. There is a  
4117 different between food processing and food handling, right?

4118 Mr. {Stenzel.} Yes, sir.

4119 Mr. {Buyer.} So the people up here on this dais love to  
4120 talk about all these food borne pathogens and all these  
4121 sicknesses that everybody comes down to predominantly deals  
4122 with the handling of food, right, not so much always the  
4123 processing of food at a manufactured facility? I almost feel  
4124 like they are being used as a scapegoat when, in fact, it is  
4125 other handling. And probably everybody here in the audience

4126 and around the country, we have all gotten sick because  
4127 somebody left the mayonnaise out overnight or something.

4128 Well, when I look at the traceability requirement, we  
4129 decide, I guess, farms, for example, they got to keep their  
4130 records or, I guess, little league has to keep their records  
4131 or everybody that is going to be involved with food is going  
4132 to have to keep their records, but we are going to exempt now  
4133 restaurants and farms would be required to maintain the  
4134 safety records. But direct sales by farms are exempt.

4135 What about seafood? So if we are going to exempt on the  
4136 farm, are we going to exempt seafood? How about that trawler  
4137 that goes right out there, gets the seafood and he owns the  
4138 restaurant and the trawler and processes the food? Should  
4139 they be exempted just like we are going to exempt on the  
4140 farm? Total silence. See those are the same kind of  
4141 questions I have. When we start picking and choosing where  
4142 we draw the line. Ms. Bailey?

4143 Ms. {Bailey.} If I could, the language in that section  
4144 at the end is very important and I think goes to the heart of  
4145 our concerns. There are a number of questions. There has to  
4146 be a sense of what is feasible technologically, what the  
4147 cost/benefit is, and what the relation is to food safety.

4148 Mr. {Buyer.} If we are going to exempt farms, should we  
4149 exempt trout farms, catfish farms? How about fish caught on

4150 the Great Lakes? What about seafood?

4151 Ms. {Bailey.} I think those are all questions that need  
4152 to be answered, and if I could offer, the analogy might be--  
4153 this is very similar to electronic medical records in that it  
4154 is a concept that makes good sense. But it is not easy to  
4155 achieve and there are many reasons why it is not easy to  
4156 achieve both technologically and--

4157 Mr. {Buyer.} Well, see it is easier for me to be able  
4158 to achieve electronic pedigree in the drug industry when I  
4159 have specific companies, yet I can't get cooperation here to  
4160 do this. But they say that what I am trying to do is too  
4161 complex? What the heck is this? This is a decentralized  
4162 model of the umpteenth degree. I would love to work with  
4163 you, Mr. Chairman. I yield back.

4164 Mr. {Pallone.} Thank you. Okay, we are done with our  
4165 questioning, and just a reminder again. You heard us earlier  
4166 about that you may get written questions by the close of  
4167 business tomorrow, and we would like you to answer them by  
4168 the close of business on Monday. And again I want to thank  
4169 you all. This was very helpful. I can't emphasis enough  
4170 that even though, you know, our plan is to go to markup next  
4171 week, that we would very much like and we intend to, you  
4172 know, consider a lot of the statements that were made today  
4173 as we move forward over the next week. And several members

4174 have commented on how valuable, you know, your testimony is  
4175 going to be as we move forward.

4176           Without objection, the meeting of the subcommittee is  
4177 adjourned. Thank you.

4178           [Whereupon, at 2:30 p.m., the subcommittee was  
4179 adjourned.]