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2 HIF070.140

3 HEARING ON ``HOW DO WE FIX OUR AILING FOOD SAFETY SYSTEM?''

4 WEDNESDAY, MARCH 11, 2009

5 House of Representatives,

6 Subcommittee on Health

7 Committee on Energy and Commerce

8 Washington, D.C.

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

12 Members present: Representatives Pallone, Dingell,
13 Eshoo, Engel, Green, DeGette, Schakowsky, Gonzalez, Barrow,
14 Christensen, Castor, Sarbanes, Space, Sutton, Waxman (ex
15 officio), Stupak, Deal, Shimkus, Buyer, Pitts, Murphy,
16 Blackburn, Gingrey, and Barton (ex officio).

17 Staff present: Phil Barnett, Staff Director; Karen
18 Nelson, Deputy Staff Director for Health; Karen Lightfoot,

19 Communications Director; Rachel Sher, Counsel; Steve Cha,
20 Professional Staff Member; Virgil Miller, Legislative
21 Assistant; Jennifer Berenholz, Deputy Clerk; Lindsay Vidal,
22 Press Assistant; Alli Corr, Special Assistant; Alvin Banks,
23 Special Assistant; Caitlin Sanders, Staff Assistant; Clay
24 Alspach, Counsel; Ryan Long, Counsel; and Chad Grant,
25 Legislative Analyst.

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26 Mr. {Pallone.} The subcommittee is called to order.
27 Today the subcommittee is meeting to discuss the topic of
28 food safety. Unfortunately, news of unsafe food products has
29 continued to make front-page headlines. The outbreak of
30 E.coli in spinach a few years ago, the outbreak of salmonella
31 in peppers this past summer, and the most recent outbreak of
32 salmonella in peanut butter all emphasize that now in the
33 time for us to act. Nine people have died as a result of
34 this most recent peanut butter outbreak, and hundreds more
35 have gotten sick. And millions of dollars have been lost in
36 sales due to products being recalled.

37 Food safety, or perhaps more accurately the lack
38 thereof, continues to be one of my top priorities. In every
39 Congress for the last 12 years, I have introduced food safety
40 legislation that aims to bolster the FDA's enforcement and
41 regulatory authority over the food industry.

42 This year, I have collaborated with my colleagues Mr.
43 Dingell and Mr. Stupak to introduce a comprehensive FDA
44 reform bill. Many of the food provisions within the FDA
45 Globalization Act built upon concepts and provisions I have
46 put forth in my previous bills, and they emphasize prevention
47 and shifting the responsibility of safe food from the FDA to
48 the manufacturers.

49 What it all comes down to is that it is not the
50 government's duty to make food safe. The companies, in my
51 opinion, should be responsible for the products they make and
52 must be held accountable for that responsibility. It is
53 their job to make their food safe and to implement a plan
54 that will ensure that they achieve that goal.

55 It is the government's job, on the other hand, to set
56 standards for food safety and hold the food industry
57 accountable for meeting those standards through regulatory
58 and enforcement authorities. We must empower the FDA with
59 those authorities so that the agency can effectively prevent
60 problems from ever occurring rather than simply reacting when
61 something bad has happened. And we must also require
62 manufacturers to put in place the food safety plans to ensure
63 that their products and production lines are safe.

64 But there are other mechanisms aside from food safety
65 plans that companies can implement to ensure the safety of
66 their products. And we will hear testimony this morning from
67 industry experts on the various safety mechanisms companies
68 can implement in order to product their product lines and
69 keep our Nation's food supply safe.

70 We will also hear about some of the regulatory
71 authorities that the FDA needs in order to ensure that
72 companies are actually implementing and following these

73 preventative mechanisms.

74 And finally we will hear from witnesses about the
75 enforcement tools the FDA needs to fulfill its mission of
76 protecting the public health and protecting Americans from
77 harmful products both in the United States and abroad.

78 I am looking forward to the discussion today and the
79 information we will glean. We do want to pass food safety
80 legislation rather quickly this year if we can, and so
81 obviously today's hearing will be very helpful in that
82 regard.

83 And I do want to mention--I don't see him--but
84 Congressman Stupak has done an excellent job in the ONI
85 Subcommittee in bringing attention to this issue over the
86 last, actually over the last three years. He and I and
87 Congressman Dingell have this legislation, but he has
88 repeatedly had hearings addressing some of the concerns that
89 have led to the legislation.

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

91 ***** COMMITTEE INSERT *****

|
92 Mr. {Pallone.} And I now recognize my colleague, Mr.
93 Deal.

94 Mr. {Deal.} I want to thank the Chairman Pallone for
95 holding this hearing as we evaluate concepts that we as
96 policymakers should consider in approaching reform of the
97 Nation's food supply as a food safety issue at the Food and
98 Drug Administration. I appreciate the timeliness of this
99 hearing, particularly since my home state of Georgia has
100 itself been under a lot of attention as a consequence of a
101 rogue peanut processing operation in the state, as you
102 indicated, contributed to nine deaths and several hundred
103 Americans being sickened all across our country.

104 But let me be clear. I support giving FDA to resources
105 it needs to ensure our Nation's food supply remains safe and
106 reliable for American dinner tables across the country. I
107 believe a modernized approach to risk identification and
108 prevention, particularly through hazard analysis and critical
109 control point plans and similar prevention-minded procedures
110 is a realistic and evidence-based solution to mitigating the
111 hazards in the Nation's food supply chain.

112 We must focus on pursuing reforms with public safety
113 protection as a top priority. However, we must do so
114 diligently and methodically to ensure our actions do not

115 cripple small businesses in the food industry across the
116 country.

117 Our Nation's food supply needs a great deal of
118 improvement in terms of the safeguards and fallback measures
119 expected of a 21st century food supply chain in the United
120 States. Recognizing the need for a risk-based approach to
121 food safety reform, I have joined Representatives Jim Costa
122 and Adam Putnam in cosponsoring H.R. 1332, The Safe Food
123 Enforcement Assessment Standards and Targeting Act of 2009,
124 Safe FEAST Act as it is referred to. This act takes an
125 aggressive yet realistic effort to improve food safety by
126 granting FDA enhanced statutory authority to do its job as
127 well as require implementation of safety measures to prevent
128 food borne problems before they even manifest themselves.

129 It is my hope that any legislation that we pass out of
130 this committee is similar to the provisions contained in H.R.
131 1332. Look forward to continuing to work with my colleagues
132 on both sides of the aisle as we look at concepts that are
133 aimed to improve the safety of America's food supply. Thank
134 you for holding this hearing today. I look forward to the
135 testimony of our witnesses, and I welcome them to this
136 hearing today. Thank you. I yield back my time.

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

138 ***** COMMITTEE INSERT *****

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139 Mr. {Pallone.} Thank you, Mr. Deal. Next is Chairman
140 Waxman. I forgot to mention the work that you did on your
141 previous committee on government oversight on the food safety
142 issues as well. Thank you.

143 The {Chairman.} Thank you very much, Mr. Chairman.
144 America does not need another deadly outbreak to understand
145 that our food safety system is in desperate straits. We have
146 ample proof of that. This is a bad situation not just for
147 the American public but for the food industry itself. We
148 must act now to address the problem, and this hearing today
149 is the first step on that legislative path.

150 Today we will hear about some of the major concepts that
151 our witnesses believe must be included in a model food safety
152 bill. The FDA Globalization Act of 2009 provides an ideal
153 starting point, and I commend Chairman Emeritus Dingell,
154 Chairman Pallone, Chairman Stupak for their work on this
155 bill. Using this bill as a foundation, this committee will
156 work with the President's FDA to implement some common sense
157 food safety measures that are long overdue.

158 As we move forward, we will also draw upon the work of
159 Chairman Stupak and Ranking Member Walden who lead our
160 subcommittee on Oversight and Investigations. It is clear we
161 need to give FDA some basic authorities that will enable it

162 to do its job.

163 As the Oversight and Investigation hearing illustrated,
164 FDA does not have the authority to routinely access records
165 documenting the steps that manufacturers take to assure
166 safety. FDA also lacks modern and flexible enforcement tools
167 like administrative civil monetary penalties. It is our job
168 to get FDA the resources and authorities it needs to get the
169 job done and to do it well.

170 But with over 300,000 registered food facilities
171 throughout the U.S. and abroad, it is clear we can't rely on
172 FDA alone to prevent food-borne illness outbreaks.
173 Manufacturers must implement preventive systems to stop
174 outbreaks before they occur, and we need to hold them
175 accountable when they fail.

176 Dr. Stephen Sundlof, FDA's director of food safety and
177 applied nutrition, agreed at our hearing last month that each
178 company in the chain of manufacturing has an obligation to
179 ensure that the ingredients they are using as well as their
180 final products are safe for Americans to consume.

181 Related to this, I would like to announce now that next
182 Thursday, on March 19, we will hold another investigative
183 hearing that focuses on the companies that purchased these
184 tainted peanuts and why their food safety systems failed to
185 prevent these deaths and illnesses.

186 We have a challenging job ahead of us, but we also have
187 many reasons to be optimistic. In his budget, President
188 Obama called for over \$1 billion for FDA's efforts to
189 increase and improve inspections, domestic surveillance,
190 laboratory capacity, and domestic response to prevent and
191 control food-borne illnesses.

192 I also know that President Obama is committed to naming
193 an FDA commissioner soon, and I look forward to his
194 announcement. The food safety crisis calls for strong
195 leadership at that agency, and we need it now.

196 Let me say a few words about the notion of a so-called
197 single food agency. A lot of good points have been made
198 about the need to improve our fragmented system and ensure
199 that food safety is given appropriate attention by our
200 regulatory agencies, but reorganizing large federal
201 bureaucracies takes a great deal of time. And this is time
202 we do not have when it comes to food safety. We have to act
203 now. We have to concentrate the additional resources we can
204 get at this point on the job at hand.

205 Our first goal should be to address the problems that
206 plague this program where it currently sits. After we finish
207 that job, we can consider whether a reorganization is
208 necessary, and if so, how to go about it.

209 I look forward to hearing from our witnesses about what

210 steps we can take to begin this process. Thank you, Mr.

211 Chairman. Yield back my time.

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

213 ***** INSERT 8 *****

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214 Mr. {Pallone.} Thank you, Chairman Waxman. Our ranking
215 member of the full committee, Mr. Barton.

216 Mr. {Barton.} Thank you, Chairman Pallone and Chairman
217 Waxman. As we all know, there are differences between the
218 political parties in Congress, but there are also many
219 similarities. On food safety, there is no daylight between
220 Henry Waxman and Joe Barton, between the Republican minority
221 and the Democratic majority. We both agree it is important.
222 We both agree we need to take a look at the problem in a
223 serious fashion, and we both agree that if necessary we need
224 to work together to move legislation to fix that problem.

225 This committee in the last Congress through the
226 Oversight and Investigation Subcommittee held nine hearings
227 on food safety, and just this past month, as has already been
228 mentioned, we held another hearing on the most recent food
229 safety outbreak, the peanut butter salmonella outbreak.

230 This committee and the various subcommittees have been
231 active on food safety and we are going to continue to be
232 active. The food safety debate in the past few years has
233 centered on funding additional money for the Food and Drug
234 Administration. Unfortunately, in my opinion, instead of
235 asking the appropriators to give the FDA additional funding,
236 some have wanted to raise the additional money through a pay-

237 to-play fee on food companies.

238 Last Congress, Nathan Deal of Georgia, ranking member on
239 this subcommittee, and myself wrote the appropriators and
240 asked them to give the FDA additional funds through the
241 appropriation process. The appropriators responded
242 positively, increased the appropriation for the FDA by \$150
243 million in last year's supplemental appropriation bill.

244 We are the authorizing committee, and it is our job to
245 give the FDA the authority to have the tools that it needs to
246 make sure that our food is safe to eat. We must then get
247 industry, consumers, the Food and Drug Administration, and
248 the Congress together to strengthen the food safety system.

249 Last week, I cosponsored the bipartisan Safe Food
250 Enforcement Assessment Standards and Targeting Act. That
251 takes up a page just the name of the thing. Which was
252 introduced by Congressman Costa, Congressman Putnam,
253 Congressman Deal, among others, because I think that it is
254 the right approach to food safety. It takes a risk-based,
255 prevention-based approach to fixing the problem.

256 We need to focus on preventing food problems before they
257 occur. One way the legislation I just enunciated does that
258 is by requiring that companies create and properly execute
259 food safety plans. Expert say that if the peanut corporation
260 of America had had one, the salmonella outbreak never would

261 have happened in the first place. The Costa Putnam bill also
262 take a risk-based approach to food safety. It requires the
263 FDA to focus the resources on high-risk facilities first
264 where we get the most bang for our regulatory buck.

265 Mr. Chairman, this is an issue that unites consumers and
266 producers. Consumers want to be confident the food they eat
267 is safe. Producers rely on that confidence because without
268 it, their brand means nothing. In fact, it is a negative.
269 There seems to also be a bipartisan and a bicameral support
270 for moving food safety legislation.

271 Again I say that on the Republican side, we stand united
272 with our friends on the Democrat majority side. We want to
273 outline the problems in hearings like the one we are having
274 today. And if we need a legislative solution, we are
275 prepared to cooperate in preparing that solution. Thank you,
276 Chairman Pallone, again for holding this hearing.

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

278 ***** COMMITTEE INSERT *****

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279 Mr. {Pallone.} Thank you. Next is the gentleman from
280 Texas, Mr. Gonzalez. Thank you. The gentlewoman from the
281 Virgin Islands, Ms. Christensen.

282 Ms. {Christensen.} Thank you, Mr. Chairman. Mr.
283 Chairman, when the Subcommittee on Oversight met last month
284 to take testimony on the salmonella outbreak, Chairman
285 Pallone, you promised that you would hold this hearing. So I
286 want to thank you and Ranking Member Deal for following up so
287 quickly.

288 In listening to the tragic stories of the families who
289 were here that day and hearing the callousness of the peanut
290 corporation executives from the emails that the subcommittee
291 had uncovered, it was clear that there were gaping holes in
292 the food safety system, which needed to be closed.

293 In reviewing the testimony, several themes emerge with
294 which I agree. One, the health and well being of the
295 American public could not wait any longer for solutions to
296 address our broken food safety system. Two, that the system
297 must be completely overhauled in a manner that prioritizes
298 coordination, resources, prevention, surveillance,
299 accountability, transparency, and response and that empowers
300 the FDA. And third, that we paid the price for our Nation's
301 broken food system, and we paid in human lives and health,

302 direct and indirect economic costs in the way that citizens
303 both here and abroad view products coming from the U.S.

304 So I look forward to the testimony of our outstanding
305 panel and to working to make bills like H.R. 759 law. Thank
306 you, Mr. Chairman.

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

308 ***** COMMITTEE INSERT *****

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309 Mr. {Pallone.} Thank you. Mr. Gingrey.

310 Mr. {Gingrey.} Thank you, Mr. Chairman. Mr. Chairman,
311 public health officials estimate that each year 76 million
312 people become sick, 325,000 are hospitalized, and 5,000 die
313 from food-borne illnesses caused by contamination. And of
314 course, the most recent of these incidents in my home state
315 of Georgia sickened more than 677 people in 45 states and
316 caused at least nine deaths due, in part, to a breakdown at
317 FDA Oversight.

318 We therefore have an important oversight and legislative
319 role in ensuring confidence in the safety of our food supply.
320 And I do commend the chairman for holding these hearings.
321 While I am pleased to see this committee engaged on such a
322 critical issue as food safety, we must avoid sending mixed
323 signals.

324 If we are trying to build a consensus that the FDA is
325 overworked and lax on food safety oversight, adding things
326 like tobacco to FDA's responsibilities, I hope, will not take
327 away from the very thing we are advocating here today.
328 People understand the dangers of tobacco. There is no safe
329 cigarette, but what they don't understand and they don't
330 expect is a spinach salad or a scoop of peanut butter to kill
331 them or their loved ones.

332 So, Mr. Chairman, I hope that these hearings will help
333 us reach a greater understanding of the breakdowns in the
334 current system as well as the appropriate solutions to
335 safeguard the health and the welfare of all Americans. And I
336 do look forward to working with you in a bipartisan way. And
337 I thank you, Mr. Chairman. I yield back.

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

339 ***** COMMITTEE INSERT *****

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340 Mr. {Pallone.} Thank you. The gentleman from Maryland,
341 Mr. Sarbanes.

342 Mr. {Sarbanes.} Thank you, Mr. Chairman, for holding
343 the hearing and for the work you have been doing on food
344 safety and also want to salute Chairman Stupak, Chairman
345 Waxman for their work as well as so many others who have been
346 part of this effort.

347 There are so many obvious negative consequences to not
348 having good oversight of our food supply. Among them, of
349 course, are when there is a severe contamination, which can
350 lead to harm and to death, and we have seen that recently
351 once again.

352 A little less obvious is the low level contamination
353 that can be broadly distributed across the food supply, but
354 it is also certainly the province of those who are supposed
355 to guard our food safety.

356 The third that I am particularly intrigued with, and I
357 have read some of the testimony and look forward to the
358 witnesses today, is the effect that occurs when there is an
359 outbreak and a crisis and alarm in the public that then
360 causes people to turn away from healthy food, which, of
361 course, undermines our overall objective of getting people to
362 eat right in this country. So we have got to make sure we

363 protect the food supply so that we can advance our overall
364 goal.

365 I look forward to the hearing today. Thank you. I
366 yield back.

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

368 ***** COMMITTEE INSERT *****

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369 Mr. {Pallone.} Thank you. Mr. Pitts.

370 Mr. {Pitts.} Thank you, Mr. Chairman. Like to thank
371 you for convening this hearing on a topic that we read about
372 in the newspapers every day, food safety. The ongoing
373 salmonella outbreak linked to the consumption of products
374 containing peanut ingredients from a single firm, Peanut
375 Corporation of America, is only the latest in a string of
376 high profile food safety related incidents.

377 The U.S. food supply is widely regarded as among the
378 safest in the world. Nonetheless, as we have just heard,
379 public health officials estimate that each year 76 million
380 people become sick, 325,000 are hospitalized, and 5,000
381 people die from food-borne illnesses caused by contamination
382 from any one of a number of microbial pathogens.

383 Recent scares about spinach and peppers and peanut
384 butter and other products, both imported and domestic, have
385 lead to public confusion about which products are safe and
386 whether the food items they have in their refrigerators and
387 pantries could be contaminated.

388 These instances have also lead to a lack of confidence
389 among many Americans in the government's ability to keep them
390 and their families safe from food-borne illnesses. Our
391 constituents must have confidence that when they go to their

392 local grocery store or convenience store, the food they buy
393 is safe and it has met the highest standards and safeguards
394 of our food safety system.

395 The U.S. food safety system, which includes as many as
396 15 different federal agencies collectively administering at
397 least 30 different laws related to food safety must be
398 modernized to meet the conditions of the 21st century.

399 I look forward to hearing from our witnesses today,
400 specifically on the role FDA plays in food safety on what
401 must be done to prevent or mitigate future food-borne
402 illnesses and outbreaks, what changes must be made to FDA's
403 current practices, and whether FDA's current resources are
404 adequate to accomplish these goals.

405 And I would like to thank all of our witnesses for
406 testifying today. I look forward to your statements. I
407 yield back my time.

408 [The prepared statement of Mr. Pitts follows:]

409 ***** COMMITTEE INSERT *****

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410 Mr. {Pallone.} Thank you, Chairman Dingell, and thank
411 you for introducing this bill and all your efforts on this
412 issue.

413 Mr. {Dingell.} Thank you, Mr. Chairman, and thank you
414 for holding today's hearing on the adequacy of our food
415 safety system.

416 I want to say that this is a most timely and necessary
417 hearing because we have before us one of the finest messes in
418 history. Everybody is busily blaming Food and Drug for the
419 inadequacy of the protection of American consumers. The
420 blame for that lies right here in the Congress and downtown
421 in the executive branch because of the failure of the
422 agencies in the federal government and this Congress to see
423 to it that FDA has, first of all, a good and adequate basic
424 fundamental statute on which they may work, and our failure
425 to see to it that they have an adequate and reliable revenue
426 stream to enable them to do what has to be done.

427 Food safety is long a concern of mine, and today's
428 hearing is very timely and necessary. You have mentioned,
429 and it has been mentioned already, that we have a fine piece
430 of legislation before this committee, which I will mention
431 later. We do, and its enactment could do much to resolve the
432 problems at Food and Drug.

433 There are not only problems with regard to food, but
434 there are problems with regard to pharmaceuticals and
435 devices. And there are severe problems in an uncooperative
436 food processing industry that has done everything it can to
437 obfuscate the matters and to see to it that we don't get
438 legislation.

439 As you know, Mr. Stupak and his sister subcommittee has
440 had some fine hearings, and he has brought folks in here to
441 explain what is going on out there and to have Food and Drug
442 tell us whether we have the resources. And we have had
443 hell's own time prying the truth out of them.

444 We have a major problem on our hands relating to the
445 safety of the food supply. It is killing Americans. The
446 government accountability offices recognize this when they
447 designated federal oversight of food safety as a high risk
448 area for the first time in 2007. The Congress has done
449 nothing about this except to talk and to come forward with a
450 lot of wondrous plans like setting up a single agency to
451 administer the business.

452 Now, we have given them some more money, and that has
453 been useful, but we have a lot more that has to be done. FDA
454 is responsible for 80 percent of the food supply in the
455 United States, but it is receiving only 24 percent of the
456 expenditures. And I repeat, as a result of this, people are

457 getting sick and dying.

458 Every year, 76 million people contract a food-borne
459 illness in the United States. About 325,000 of these require
460 hospitalization, and about 5,000 die according to the Center
461 for Disease Control. So we have that on our backs and upon
462 our hands.

463 More specifically, in the last two years, we can cite
464 just a few events which have occurred. Melamine in infant
465 formula and in milk products coming in from China. Nothing
466 done to stop it. Tainted peppers from Mexico, harmful
467 seafood and harmful fish from China, E.coli in spinach. That
468 is just a little, and every year we get new information about
469 the Food and Drug's inability to protect the American people.

470 Unfortunately the theme of a failed food supply system
471 has not receded. We currently find ourselves in the middle
472 of what is possibly the largest food recall in history, and
473 it is costing billions of dollars to consumers and to
474 innocent food processors because Food and Drug could not and
475 did not do its job. And we have had hearings, by the way, on
476 that which read like a joke book.

477 We currently find ourselves with FDA wrestling with a
478 food-borne illness outbreak associated with salmonella which
479 has been found in peanut products produced by the Peanut
480 Corporation of America, PCA. And because of the outright

481 negligence of this company, more than 2,100 products from ice
482 cream to dog food have been recalled. And by the Department
483 of Agriculture can investigate and can inspect dog food
484 manufacturers every year. Food and Drug can't do the same
485 thing for food processors for human beings.

486 Because of the outright negligence of this company then,
487 more than 680 people in 46 states have been sickened, and so
488 far, we know of nine who have died from these events. And I
489 think we can assume, given the way things have been going,
490 that this is not yet over.

491 What we have found in this instance and in many others
492 is that FDA funding is woefully inadequate and their
493 authorities are outdated. They have proven to be incapable
494 of protecting our food supply. I commend the President for
495 recognizing the inadequacy of FDA's resources and for
496 proposing increased funding for food safety activities in his
497 budget package.

498 However, my experience in the Congress has shown me that
499 the only way to adequately address the problem of resources
500 is by ensuring a steady predictable revenue stream for FDA.
501 I propose to do this by establish a registration fee for
502 manufacturers so that we can look and see what is coming into
503 this company.

504 And I would note to you because of Food and Drug's

505 inability to address this problem that we are finding
506 controlled substances are coming into this country right
507 alongside of other commodities uninspected by Food and Drug
508 or anybody else.

509 This is the only way we can make sure that Food and Drug
510 is able to carry out its responsibilities. In addition to
511 the shortage of resources, we must address the issue of
512 authorities. It is shameful that FDA does not have authority
513 to mandate recalls, to require manufacturers to identify and
514 develop plans to mitigate hazards before they occur rather
515 than after people are sick and die. And to identify safety
516 questions by having full access to safety records without
517 delay and to appropriately trace the ability and not only
518 their own ability, but the origin of tainted products.

519 Mr. Chairman, you and I, along with Chairman Stupak,
520 have an appropriate safety solution to our food problems,
521 H.R. 759, and I urge and invite our colleagues to join us in
522 this particular undertaking. As a result of the failure to
523 have Food and Drug given the authority it needs and the
524 resources, people, I repeat, are dying.

525 The Congress is working to address a mess left behind by
526 another industry that has been left to self-regulate. I
527 refer to the banks and the securities industry. And there,
528 they are destituting people all across the United States in

529 all kinds of way from their 401(k)s to their retirements to
530 their saving account and to their hopes of the future and
531 their homes and their mortgages.

532 I look forward to our witnesses' testimony today. I
533 apologize for taking so much time, but I hope that this
534 process will shake some folks up so that we will get some
535 progress that we need in making the American people safe. I
536 thank you, and I commend you, Mr. Chairman.

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

538 ***** COMMITTEE INSERT *****

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539 Mr. {Pallone.} Thank you. The gentleman from Illinois,
540 Mr. Shimkus.

541 Mr. {Shimkus.} Thank you, Mr. Chairman, and I will be
542 brief. I want to thank the Chairman Emeritus. He is
543 passionate about this. I see my friend Bart Stupak here, and
544 I got to serve on ONI, had numerous of these hearings. We
545 know the need, and we know we need to move rapidly.

546 I have always been supportive of a risk-based approach
547 in making sure that the money that is needed goes to where it
548 is needed. And I think we need to focus on that. There are
549 a lot of preventive aspects that we can do like irradiation
550 in a lot of those areas that doesn't food quality. I think
551 we identified that, and we ought to help and incentivize
552 movement in that direction. And funding is always going to
553 be an issue. Make sure we fund appropriately so the money is
554 going to where it is needed.

555 That is why I am excited about being back on this
556 committee. Mr. Chairman, I think serving with Bart has
557 helped me get up to speed on this issue, and I look forward
558 to being helpful. I yield back.

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

560 ***** COMMITTEE INSERT *****

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561 Mr. {Pallone.} Thank you. The gentleman from Georgia,
562 Mr. Barrow.

563 Mr. {Barrow.} Thank you, Mr. Chairman, and thank you
564 for keeping your promise to stay on this issue until we get
565 something done about it. I can add nothing to the
566 comprehensive statement of the Chairman Emeritus. But as
567 befits my diminutive stature in the picture, I will focus on
568 something smaller.

569 I know that colleagues of mine are working on more
570 comprehensive legislation from subjects like increasing the
571 resources and increasing the amount of FDA inspections to
572 creating a system of traceability to creating mandatory
573 recall authority. There are a whole bunch of major elements
574 that need to be put in place.

575 I want to focus on something that I think ought to be a
576 part of any comprehensive bill or can stand alone as a
577 genuine contribution to this. And that is a measure to
578 increase the effectiveness of both the sampling and the
579 testing that is done of food. What we need in this country
580 is a system that doesn't give manufacturers the option of
581 knowing what they need to know and when they need to know it,
582 but requires them to know what they need to know when they
583 need to know it, and that provides real-time information,

584 reporting that information at the very same time to an
585 effective regulator of the public interest so that the public
586 knows what we need to know when we need to know it.

587 I think that would go a long way toward cleaning up what
588 is broke in this system, but we cannot continue to rely on a
589 system that is essentially the honor system that allows folks
590 to use the American people as a population of lab rats to
591 test the food on them first to find out what is wrong with
592 it. That won't work. We have to be proactive about it, and
593 that is what I hope the witnesses will be able to share with
594 us about today. Thank you, Mr. Chairman. I yield back.

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

596 ***** COMMITTEE INSERT *****

|
597 Mr. {Pallone.} Thank you. The gentlewoman from
598 Tennessee, Ms. Blackburn.

599 Ms. {Blackburn.} Thank you, Mr. Chairman, and welcome
600 to our witnesses. We are ready to hear from you today, and I
601 have just a couple of thoughts to add to the comments that
602 have been made. The hearings on food safety are not new. I
603 will also say that as we have worked through this process
604 over the last several years, one of the things that we have
605 repeatedly asked you all for is clarification on your
606 internal communications. How you communicate with one
607 agency, one division knowing what work is being done in
608 another one. It seems as if you continually have stumbles
609 that do harm to the work that you are trying to do.

610 Also, best practices. You seem reticent to talk about
611 best practices and how you address some of the problems that
612 face you all with food safety and with other parts. We know
613 that you have to change the way you deal with quality
614 control, that that something for the suppliers as well as for
615 you all internally. And we know that you need a reformed
616 review system, that you also need some organizational changes
617 to take place.

618 Now, with the Chairman Emeritus in his remarks, which we
619 all agree with much of that. I will differ on one point. I

620 think before you start spending more money, what you need to
621 do is show how you are going to reorganize and how you are
622 going to address the problems that are before us.

623 And thank you, and I yield back.

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

625 ***** COMMITTEE INSERT *****

|
626 Mr. {Pallone.} Thank you. The gentlewoman from
627 Colorado, Ms. DeGette.

628 Ms. {DeGette.} Thank you very much, Mr. Chairman, and I
629 want to thank my compadre, Bart Stupak, for all the work we
630 have been doing in ONI over the last 10 years on these food
631 safety issues. I think that the bill that the chairman and
632 the Chairman Emeritus and Mr. Stupak introduced is excellent,
633 especially since it includes several issues I have been
634 working on for many years, which is mandatory recall
635 authority for the FDA and also traceability because we had
636 the ability to do mandatory recall right now.

637 Most people think we have it, and if we had had it,
638 perhaps some of those people in this latest peanut butter
639 outbreak would not have died because the FDA would have been
640 able to recall that peanut butter sooner.

641 Two things I will say. The first thing is I think we
642 need to improve the traceability provisions in the bill, and
643 I look forward to working with the chairman on that. The
644 technology exists, and there is no reason we shouldn't be
645 doing it.

646 The second thing is, as well as more resources, we need
647 to give the FDA more authority to obtain the information that
648 they need through subpoena authority and other kinds of

649 authority.

650 And finally, I agree completely with Chairman Waxman
651 when he says that we need to do all of this now, and then
652 after we do it, we need to look at structural changes in the
653 way we oversee our food safety in this country.
654 Congresswoman DeLauro and I have worked for many years on a
655 unity food safety agency, but that will take time. And time
656 is certainly something we don't have right now, given what is
657 happening with all these outbreaks. Thank you, Mr. Chairman.

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

659 ***** COMMITTEE INSERT *****

|
660 Mr. {Pallone.} Thank you. The gentlewoman from
661 Florida, Ms. Castor.

662 Ms. {Castor.} Thank you, Mr. Chairman, and I want to
663 thank my colleague, Mr. Stupak, as well. Food safety is
664 vital to the health of all Americans. And many of you know,
665 the Government Accountability Office keeps a very short list
666 of major government problems that require significant reform.
667 It is called the high risk series, and it includes notorious
668 governmental failures such as the Financial Regulatory
669 System, maintenance of our roads and bridges. Food safety
670 also is on this high-risk list, and reform is vital.

671 Let me give you one example. Tomatoes from my home
672 state of Florida last year were blamed for a nationwide
673 salmonella outbreak that was eventually traced to jalapeno
674 and Serrano peppers from Mexico. In the meantime, the FDA's
675 warning not to consume tomatoes from Florida cost tomato
676 producers at least \$100 million. All of the time and effort
677 spent warning consumers about Florida tomatoes only served to
678 delay the solution to the real problem and allow more
679 Americans to get sick.

680 We have to address a lack of resources, the labyrinth
681 regulatory regime, the lack of federal authority. The
682 problems facing the food safety and oversight are legion, and

683 they are difficult, but they are not insurmountable. So I
684 look forward to the witnesses' thoughtful recommendations
685 today. Thank you.

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

687 ***** COMMITTEE INSERT *****

|
688 Mr. {Pallone.} Thank you. The gentleman from Ohio, Mr.
689 Space.

690 Mr. {Space.} Thank you, Mr. Chairman. In yielding
691 back, I would just like to thank you and Chairman Stupak and
692 Chairman Dingell for your good work in this area. I look
693 forward to the testimony.

694 [The prepared statement of Mr. Space follows:]

695 ***** COMMITTEE INSERT *****

|
696 Mr. {Pallone.} Thank you. The gentlewoman from Ohio,
697 Ms. Sutton.

698 Ms. {Sutton.} Thank you, Mr. Chairman, for having this
699 hearing and, you know, it was only a month ago today that
700 under the tremendous leadership of Chairman Stupak that we
701 had a hearing in the Oversight Subcommittee on the recent
702 salmonella outbreak associated with peanut products. And at
703 that hearing, I told the tragic story of an elderly woman
704 from my district who died of salmonella poisoning.

705 Sadly, Mr. Chairman, since then, another elderly woman
706 from northeast Ohio by the name of Nellie Napier has died
707 from salmonella. In fact, her death was announced that day.
708 There have been over 99 cases of salmonella reported in Ohio
709 and 680 nationwide.

710 Now, I know, Mr. Chairman, that you and others have long
711 been working to fix our broken food safety system, and I
712 thank you. I thank Chairman Waxman and Chairman Emeritus
713 Dingell and Ms. DeGette and others.

714 The bottom line, Mr. Chairman, is that Congress needs to
715 act quickly and comprehensively to address the food safety in
716 our country. It is clear that the FDA does not have the
717 current authority or capacity to properly oversee the safety
718 of our food supply. That is why I reintroduced the Protect

719 Consumers Act, to give FDA mandatory recall authority. It is
720 a very simple measure. Certainly should be part of a
721 comprehensive overhaul, but frankly I would love to see it
722 moved quickly in its own right if we cannot move the
723 comprehensive bill as quickly as we would like.

724 We cannot sit back and let any more people become ill
725 from food they eat. I look forward to hearing from our
726 panelists today and working with my colleagues to fix our
727 broken food system, and I yield back.

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

729 ***** COMMITTEE INSERT *****

|
730 Mr. {Pallone.} Thank you. The gentleman from New York,
731 Mr. Engel.

732 Mr. {Engel.} Mr. Chairman, I would like unanimous
733 consent to have Mr. Green's remarks entered into the record.

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

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

736 ***** INSERT 9 *****

|
737 Mr. {Engel.} Thank you, Mr. Chairman. Thank you for
738 holding this important hearing today. If there is any good
739 that may come of the Peanut Corporation of America salmonella
740 crisis, it is now clearly than ever that our food safety
741 system is broken and in need of critical reforms.

742 An AP poll last year found that 46 percent of people
743 were scared that they would get sick from tainted, and there
744 is a reason for this fear: U.S. food-borne illnesses result
745 in 76 million illnesses, hundreds of thousands of
746 hospitalizations, and up to 5,000 deaths each year.

747 As one of our witnesses astutely pointed out in his
748 testimony, our Nation is sustaining deaths equivalent to
749 those that perished in the World Trade Center attack in New
750 York every six months. When you think about it in those
751 terms, it just takes your breath away. And yet, we have set
752 up the FDA to fail here. We expect the FDA to ensure the
753 safety of our Nation's food supply, but we haven't given it
754 the resources or authority to get the job done.

755 Sure there are many food companies and facilities that
756 are employing best practices to preserve their own food
757 products, but unfortunately it is those that don't that cause
758 crippling problems for our public health and economy. This
759 is why it is so important to grant FDA the ability to mandate

760 clear preventative controls, strong traceability, and
761 mandatory recalls within their food safety authority.

762 Mr. Chairman, the costs are clear. I look forward to
763 working with you on a comprehensive food safety reform bill
764 this year. I yield back.

765 [The prepared statement of Mr. Engel follows:]

766 ***** COMMITTEE INSERT *****

|
767 Mr. {Pallone.} Thank you. Gentlewoman from California,
768 Ms. Eshoo.

769 Ms. {Eshoo.} Thank you, Mr. Chairman, for holding this
770 very important hearing on the issue of food safety, which is
771 so needed. The American people should be able to trust their
772 government to protect them from food-borne illnesses, and
773 right now, to put it mildly, we are not even doing an
774 adequate job.

775 When people are dying or becoming seriously ill as a
776 result of what they ingest in the United States of America
777 that has always has the highest standards, we are really in
778 trouble. And it is an area that most frankly the Congress
779 has neglected for a long time.

780 So I think that now is the time to address it because
781 the FDA really should be the world's premier food inspection
782 authority. It is an issue that affects everyone. Doesn't
783 matter whether you are rich or poor, where you live in the
784 country, whether you are a youngster or an oldster, God help
785 you if you have ingested something that has not been
786 reviewed.

787 And we live in a global economy, and we have things
788 pouring into our country, and unless it is inspected, then
789 our citizens are placed at risk. I have cosponsored

790 legislation that Congresswoman DeLauro has offered. I think
791 it is a very good bill. I think that there are good ideas,
792 both in this committee and from outside the committee. I
793 think that the system has to obviously be modernized, and I
794 really think that we should separate out food from the FDA.

795 I think we should have a food safety administration. I,
796 for one, am a little tired of running the FDA on user fees.
797 I think we are doing it on the cheap, and as long as we do
798 that, we are going to be plagued with the problems that we
799 are here to discuss today.

800 So I look forward to working with all of my colleagues
801 on this issue. I don't think anyone has a corner on the
802 market of wisdom on it, but I do think that the committee
803 should take into consideration all of the bills that are
804 being introduced on this because there are very good ideas
805 that are contained in each one.

806 So thanks again, Mr. Chairman, and to the witnesses that
807 are going to testify today, thank you. We know that you will
808 be instructive. We will learn from you, and hopefully we
809 will pay close attention to you. Thank you.

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

811 ***** COMMITTEE INSERT *****

|
812 Mr. {Pallone.} Thank you. I think that concludes
813 opening statements by the members. So we will now turn to
814 our panel. I want to welcome you, and I ask you to come
815 forward. We only have one panel today, but they are
816 distinguished. And they are actually quite--let them sit
817 down first.

818 I will start on my left with Ms. Caroline Smith DeWaal,
819 who is the food safety director for the Center for Science in
820 the Public Interest, and she has been dealing and calling
821 attention and been a watchdog on this issue for a number of
822 years. Many of your ideas have been incorporated in my bill
823 and then into the larger bill sponsored by Mr. Dingell and
824 Mr. Stupak and myself.

825 Mr. William Hubbard, who is former associate
826 commissioner for policy and planning at the Food and Drug
827 Administration and an advisor for the Alliance for a Stronger
828 FDA. Good to see you again.

829 Dr. Martin Cole, who is research professor of biology
830 and director of the National Center for Food Safety and
831 Technology at the Illinois Institute of Technology.

832 Mr. Thomas Stenzel who is president and CEO of United
833 Fresh Produce Association.

834 And finally Jim Lugg who is former executive vice-

835 president, Food Safety and Quality, Fresh Express, and
836 consultant for Chiquita Brands. Thank you all for being
837 here, and we have 5-minute opening statements, and we will
838 start with Ms. DeWaal.

|
839 ^STATEMENTS OF CAROLINE SMITH DEWAAL, FOOD SAFETY DIRECTOR,
840 CENTER FOR SCIENCE IN THE PUBLIC INTEREST; WILLIAM HUBBARD,
841 ADVISOR, ALLIANCE FOR A STRONGER FDA, FORMER ASSOCIATE
842 COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG
843 ADMINISTRATION; MARTIN COLE, PH.D., RESEARCH PROFESSOR OF
844 BIOLOGY AND DIRECTOR, NATIONAL CENTER FOR FOOD SAFETY AND
845 TECHNOLOGY, ILLINOIS INSTITUTE OF TECHNOLOGY; THOMAS E.
846 STENZEL, PRESIDENT AND CEO, UNITED FRESH PRODUCE ASSOCIATION;
847 AND JIM LUGG, CONSULTANT, CHIQUITA BRANDS, FORMER EXECUTIVE
848 VICE PRESIDENT, FOOD SAFETY AND QUALITY, FRESH EXPRESS

|
849 ^STATEMENT OF CAROLINE SMITH DEWAAL

850 } Ms. {DeWaal.} Thank you very much, Chairman Pallone and
851 also Chairman Deal for having this hearing. I do want to
852 recognize just the tremendous food safety leadership that is
853 in this room from you, Chairman Pallone, to former Chairman
854 Dingell, Mr. Stupak, and Representatives DeGette and Eshoo.
855 You have all been tremendous leaders, and we are thankful to
856 be hopefully at this point of having legislation poised to
857 really address these problems.

858 I am the director of food safety for the Center for
859 Science in the Public Interest. And we represent over

860 900,000 consumers both in the U.S. and Canada. We are
861 focused on food safety, nutrition and even alcohol issues.
862 Pretty much anything you put in your mouth we worry about.

863 The impact of the Peanut Corporation of America outbreak
864 and recall are still reverberating through the food supply.
865 It has caused nearly 700 confirmed illnesses and nine deaths
866 and the recall of over 3,200 separate products. Despite its
867 size and scope, this event is neither rare nor unexpected.
868 Congress has held nearly 20 hearings in the last two years
869 focused on similar failures of FDA's food program linked to
870 everything from spinach tainted with E.coli, pet food
871 containing an intentionally added melamine, which sickened
872 and killed many, many animals, and even a previous peanut
873 butter salmonella outbreak, which was thoroughly investigated
874 in this committee.

875 These events are causing steep declines in consumer
876 confidence, both in the overall safety of the food supply and
877 in FDA's ability to protect the public. Nearly half of those
878 questioned by Consumers Union in November said their
879 confidence in food safety had declined.

880 Also last fall, a poll conducted by Ipsos McClatchy
881 reported that 28 percent of those polled believe food safety
882 had gotten worse, and 46 gave food safety controls a failing
883 grade. In July 2008, in the midst of the salmonella outbreak

884 linked first to tomatoes and then to peppers, an Associated
885 Press Ipsos poll found that 46 percent of people were worried
886 that they might get sick from eating tainted products.

887 Clearly it is time for Congress to take action to
888 fundamentally reform and fully fund our food safety system.

889 I will now outline a couple of the essential elements
890 that CSPI thinks need to be in any legislation moving forward
891 to begin the process of reforming FDA's food safety program.

892 The heart of any effective reform effort lies in
893 prevention, not response. Legislation should include at
894 least the following three components for preventing food
895 safety problems at food processors. First, Congress should
896 require every food plant regulated by FDA to have a food
897 safety plan detailing that it has analyzed its operations,
898 identified potential hazards, and is taking steps to minimize
899 or prevent contamination. These requirements are already in
900 place for all meat and poultry processors today but not in
901 plants regulated by FDA.

902 Legislation should set risk-based inspection frequencies
903 for food plants and establish clear auditing parameters when
904 states are conducting inspections on behalf of the federal
905 government.

906 And finally specific authority should allow the agency
907 to set testing frequencies and require food processors to

908 report adverse reports to government inspectors. Without
909 these checks on the plants, companies can follow the
910 practices of PCA, which instead of fixing its salmonella
911 problems, it fixed the tests.

912 Consumer concerns extend up and down the food chain from
913 the farm to the table. So legislation also needs to provide
914 on-farm food safety plans that will give farmers tools to
915 manage risks like raw manure, unsafe water, and worker
916 hygiene.

917 Imported foods also pose special challenges as they
918 enter the U.S. from all over the world including many
919 countries where they are essentially unregulated. CSPI
920 supports the use of certification systems operated by foreign
921 governments and some third parties if they are subject to
922 appropriate oversight by FDA. Certifiers of imported product
923 can give FDA boots on the ground and greatly increase the
924 agency's capacity to enforce our food safety requirements
925 among the foreign facilities from 175 different countries
926 that export to the U.S.

927 President Barack Obama has promised a government that
928 works. These new authorities, together with increased
929 funding will certainly help FDA improve. But to deal with
930 the root of the problem, Congress and the Obama
931 administration will need to go beyond making a few

932 improvements. Structural reforms are also essential.

933 FDA is responsible for 80 percent of the food supply,
934 and yet the commissioner's attention is frequently on drugs,
935 medical devices, and cosmetics, animal feed, many other
936 issues that FDA regulates. Food issues frequently
937 unfortunately fall to the bottom of the pile. Today there is
938 no single expert in charge of the policies budget and
939 enforcement staff and no credible voice communicating to the
940 public and the industry what needs to be done to prevent
941 outbreaks.

942 It is time to elevate food monitoring functions within
943 the Department of Health and Human Services. With both the
944 public and the regulated industries clamoring for change, we
945 are very happy to be here today and to have the tremendous
946 leadership on this committee. Thank you.

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

948 ***** INSERT 1 *****

949

|

Mr. {Pallone.} Thank you. Mr. Hubbard.

|
950 ^STATEMENT OF WILLIAM HUBBARD

951 } Mr. {Hubbard.} Thank you, Mr. Chairman. I have a
952 written statement for the record. I will just make a few
953 brief remarks if I may.

954 As you know, the public is confused and even frightened
955 by what is going on. Imagine a fully loaded 737 crashing
956 every other week. That is the type of toll we are talking
957 about here, but yet we continue to tolerate the intolerable.
958 And the public health costs have been mentioned by many of
959 the members today, and they are very real.

960 Suffering out there is very real, and also I don't think
961 we should disregard economy costs that companies and the
962 health care system are being burdened by food-borne disease
963 outbreaks that are largely preventable. So we are allowing
964 things to happen that we can stop, and I would like to make
965 two main points about the problem.

966 First is the issue of FDA resources. I believe I have a
967 slide if we could put it up, and I think really in a way it
968 captures the problem that FDA has gone through. Do we have
969 that slide? When I came to the FDA in the 1970s, there were
970 70,000 food processors in the United States. FDA had the
971 resources to inspect 35,000 times a year, which meant

972 everybody could get a visit every other year. There were
973 very few imports at the time.

974 [Slide.]

975 As you can see from this slide, we are now doing about
976 6,000 or 7,000 a year, but if you plotted the increase in the
977 industry, that has gone from the 70,000 domestic firms at
978 that period to 150,000 today and another 216,000 farm firms.
979 So we have gone from inspecting about 50 percent of the food
980 supply at any time to five percent of the domestic processors
981 and about two percent of all processors. And that has
982 largely been a function of resources. FDA's budget has been
983 cut and cut and cut for 30 years, and we simply need to find
984 a way to reverse that.

985 And you can also plot, as those numbers go the direction
986 they go, recalls have gone up. FDA's adverse findings when
987 they do do inspections have gone up, and you have a general
988 lack of overall quality in many of these firms.

989 I will say, however, as I say in my testimony, I think
990 the food supply is generally safe. We have gaps though that
991 are willing to cause the problem. Unless everybody does it
992 right, no one can get it right.

993 And then the other main point I wanted to make is
994 authorities. FDA has authorities dated to 1906. It is
995 essentially a relic of the 19th century. It doesn't work.

996 It requires an inspector to perhaps catch a problem the day
997 he happens to get there if he gets there at all. FDA needs
998 the kind of preventive controls many of you have mentioned
999 and Ms. DeWaal mentioned, in which they can require a firm to
1000 examine how they make their food and control hazards so the
1001 food never gets contaminated to begin with.

1002 And those are practices that the leading food firm use
1003 now, so we are not talking about imposing on the food
1004 industry some strange new regulatory regime. We are talking
1005 about adopting industry-developed preventive control
1006 technology that has been proven to work.

1007 And then lastly there are some other provisions that I
1008 think are very important. Trace back has been mentioned. We
1009 saw with the tomatoes last year and the spinach earlier how
1010 these outbreaks drag on for weeks or even months because FDA
1011 doesn't have adequate trace back authority.

1012 They need access to the records of these firms so they
1013 know where the food has come from and where it is going.
1014 They need mandatory recall authority. Clearly some firms
1015 simply stall for a few days, and during those few days while
1016 FDA is begging them to do a recall, the food is moving and
1017 being consumed.

1018 And we also need to accredit these labs that are doing a
1019 lot of the work because you need to know you have a high

1020 level of quality in the laboratories.

1021 There are some other things in my testimony; however, in
1022 the interest of time, I will stop there. But I certainly do
1023 urge you to act this year on food safety legislation.

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

1025 ***** INSERTS 2, 3 *****

1026 | Mr. {Pallone.} Thank you. Dr. Cole.

|
1027 ^STATEMENT OF MARTIN COLE

1028 } Mr. {Cole.} Chairman Pallone, Ranking Member Deal, good
1029 morning. I guess what I would like to try and do, I have
1030 written testimony. I would like to make a few remarks to try
1031 and help this committee wrestle with the complexities of the
1032 food safety systems and what approaches they should take.

1033 I really do applaud the important work and the urgency
1034 and the opening remarks that have been made this morning.
1035 Certainly we have seen, I think we are all acknowledging, the
1036 complexity of the supply chain. The food business is global
1037 now. Go to the supermarket, the products can be from
1038 anywhere in the world. Global sourcing of ingredients.

1039 Look at consumer trends now. You know we want people to
1040 eat healthy food. There is a trend toward more natural,
1041 fresher products, less preserved, more convenient products,
1042 longer shelf life. All of those, as a food microbiologist,
1043 they go against traditionally what you would like to see in
1044 the marketplace. So we want food to be healthy, but we want
1045 it to be safe.

1046 And we certainly need to, I think as the opening remarks
1047 have mentioned, we have new issues, and we need a new
1048 approach, okay. We need to have a modern food safety system

1049 here in the U.S. I think really in simple terms, I look at
1050 that in terms of four main components to a modern food safety
1051 system.

1052 First of all, risk-based preventative measures. You
1053 need programs to monitor progress. That can be trend
1054 analysis. That can be testing, inspection, even
1055 Epidemiology, but you need programs to be able to monitor
1056 progress.

1057 You need appropriate government oversight. Without
1058 government oversight, you get the issues that we have in
1059 peanut butter and salmonella.

1060 And then lastly you need a strong research program
1061 because things are changing so fast. If you don't have a
1062 world class research program, you can't deal with issues
1063 proactively and deal with them swiftly.

1064 Dealing with microorganisms--and I am a microbiologist
1065 by trade--dealing with microorganisms is even more
1066 complicated because they are alive, okay. So bacteria have
1067 the ability to grow and survive and adapt throughout the food
1068 chain. So when we are designing food safety systems, we need
1069 to be cognizant of the ability of bacteria to change and to
1070 grow and adapt. So that adds another complexity with what we
1071 are dealing with.

1072 Now, in response to these issues, I mean this is not

1073 just a U.S. issue. Internationally, the food safety
1074 community has responded by developing new tools, risk-based
1075 tools, to try and ensure the safety of the food supply. And
1076 it now possible through modeling and risk assessment to be
1077 able to link the level of hazard or the prevalence of a
1078 hazard in the food supply to the likely illness that it is
1079 likely to cause. And that has allowed us to develop new risk
1080 management frameworks that will provide for scientific
1081 underpinning to the develop or risk-management options, the
1082 science behind the frequency of inspections, et cetera. So
1083 these new developments we need to be using.

1084 It is ironic that, you know, in the U.S. much of these
1085 developments have been led by U.S. scientists, and yet we
1086 need to start walking the talk here. So we have done a good
1087 job, I think, in tracking sporadic cases of food-borne
1088 illness through new tools, food safety net, Wholesfield, del
1089 electrophoresis fingerprinting if you like, of organisms.
1090 But we are really falling behind in the prevention side, and
1091 that is really where we need to up our game.

1092 A quick word about oversight testing and inspection. I
1093 think the short answer is you can't test and inspect safety
1094 into food. Okay you need that oversight because without
1095 that, you get the PCA issue. But testing alone, think of the
1096 issue with salmonella where a very low infective dose can

1097 give you an illness. It is like looking for a needle in a
1098 haystack. The statistics of sampling are such that you can't
1099 test safety into food.

1100 Think also of the volume of foods that are coming into
1101 the U.S. now. What is it? Over 60 percent of fresh produce,
1102 fruit and vegetables, coming to the U.S. from overseas, over
1103 80 percent of seafood coming from overseas. You know we need
1104 to be practical about the percentage of foods we can
1105 realistically inspect. We need the inspection there as a
1106 deterrent, but we need to be smart about where we use those
1107 resources. And we need to use them where the highest risks
1108 are.

1109 Now, in industry, there are two main tools for really
1110 applying and implementing risk-based measures, and as was
1111 mentioned before, these are standards tools that have been
1112 adopted through Codex. The two main tools are good
1113 manufacturing practice, or GMP, and hazard analysis critical
1114 control point, or HACCP. And you can think of GMP as like
1115 the building blocks, the standard operating procedures for
1116 sanitary design, equipment, people, labeling, recall
1117 procedures, et cetera.

1118 Many of the recall issues that we see from FDA actually,
1119 if you look at whether GMP would deal with them or whether
1120 HACCP would, many of them actually would deal with GMP, and

1121 it is an oversight issue that we have. So we need to think
1122 about where we should be using GMP and also where we should
1123 be using HACCP.

1124 HACCP is a more systematic approach identifying,
1125 evaluating the food safety hazards. It is usually more
1126 quantitative in nature, usually defining a critical control
1127 point in the food chain that you must control to reduce,
1128 eliminate, and prevent hazards. Typically in a value chain,
1129 you would be looking at a performance standard for HACCP as
1130 well.

1131 Now, I also have one slide to share with the committee
1132 this morning. I could take that. I think it is a good lead
1133 in to some other testimony relating to fresh produce. You
1134 can go to slide three please. That is great. So really I
1135 think it kind of illustrates a good lead in to the next
1136 witness. If you look at the complexity of the supply chain
1137 for fresh produce, you can't pasteurize lettuce, okay. You
1138 would have lettuce soup if you were to do that.

1139 Okay, so there isn't one kill step in the chain. So you
1140 have to take a through chain approach. You have to take good
1141 agricultural practice. You have to look at what you are
1142 doing in terms of washing of the produce, and you have to
1143 look at what you are doing in terms of the distribution.

1144 So I just wanted to share with you this is a complex

1145 business. There is research going on at the moment between
1146 industry and government to really try and come up with the
1147 risk management options that would build some robustness into
1148 the value chain for fresh produce. This is a category of
1149 food we want people to eat more of, okay. Hugely impactful
1150 in terms of nutrition, and yet we need to build more
1151 robustness in terms of safety.

1152 My final comment, Mr. Chairman, is around research. You
1153 know the U.S., I think, should be really at the forefront of
1154 research in terms of the safety and health of food. It is
1155 such an important driver of public health, but also very
1156 important in terms of trade for the U.S. With that, thank
1157 you very much.

1158 [The prepared statement of Mr. Cole follows:]

1159 ***** INSERTS 4, 5 *****

1160

|

Mr. {Pallone.} Thank you, Dr. Cole. Mr. Stenzel.

|
1161 ^STATEMENT OF THOMAS STENZEL

1162 } Mr. {Stenzel.} Thank you very much, Mr. Chairman. I
1163 don't have a slide, but I will thank Dr. Cole for sharing on
1164 behalf of the fresh produce industry. And I will affiliate
1165 myself with his remarks.

1166 In my written testimony, I have provided a number of
1167 specific policy provisions that I will call to the
1168 committee's attention, but I would like to spend just a few
1169 minutes this morning talking a bit more personally about some
1170 of these issues.

1171 First, I would encourage all of you to eat more fresh
1172 fruits and vegetables. At a time when Congress is debating
1173 health care reform, all public health authorities agree that
1174 one of the most important things we can do to improve health
1175 is to eat more fruits and vegetables. But achieving that
1176 goal is dependent upon the main issue that we are talking
1177 about today, and that is the critical challenge to modernize
1178 and reform food safety law.

1179 Now, I personally am confident in my produce choices
1180 today. We consume over a billion servings of fresh produce
1181 every day in the United States, over five million bags of
1182 salad every day. And out of the hundreds of different

1183 produce items in the supermarket, a very small number, only
1184 five, have been related to any type of food-borne disease in
1185 recent years in quantity.

1186 But we also know that we have issues. Consumers know
1187 it, and consumers are fearful of fresh produce at the moment.
1188 And that is something we have to address. Now, our industry
1189 has been working in this area for many, many years, but the
1190 spinach crisis almost three years ago now was a watershed
1191 moment for us.

1192 Remember the unprecedented national response. We pulled
1193 spinach off of the shelves of every grocery store in America
1194 for weeks. In fact, we now know the only contaminated
1195 product came from one farm through one processing plant on
1196 one day's production, even one afternoon shift. It wasn't
1197 even the whole day. There has been no contamination from
1198 that processing plant or from spinach in the last two and a
1199 half years. And yet today, spinach consumption is still down
1200 in the United States, one of the healthiest vegetables that
1201 we should all be consuming.

1202 Following that outbreak, we undertook a mission. First,
1203 to look at a comprehensive reevaluation of all our leafy
1204 greens production. Mr. Lugg will talk about that, and his
1205 leadership in that area of our industry has been tremendous.
1206 We looked at every possible step and have adopted the most

1207 rigorous good agricultural practices with strong compliance
1208 measures and audits, some conducted by the California
1209 Department of Food and Agriculture, but also other states and
1210 private sector auditors.

1211 But our industry also had to address the broader
1212 question of federal regulation. In January of 2007, our
1213 board of directors adopted a series of policy principles for
1214 mandatory federal oversight of our business. Let me explain
1215 the three principles briefly.

1216 First, we believe produce safety standards must allow
1217 for commodity specific food safety practices based on the
1218 best available science. In a highly diverse industry that is
1219 more aptly described as hundreds of little industries, one
1220 size clearly does not fit all. For example, food safety
1221 requirements applicable to products grown close to the ground
1222 would be very different from food safety practices for fruit
1223 grown on trees.

1224 Secondly, we believe produce safety standards must be
1225 consistent for any individual commodity wherever it was grown
1226 or processed anywhere in the United States or imported into
1227 the country. Consumers must have confidence that the same
1228 safety standards were applied no matter whether the produce
1229 is grown in California, New Jersey, or Mexico.

1230 Finally we believe achieving consistent produce safety

1231 standards across the industry does require strong federal
1232 government oversight and responsibility. That is going to
1233 take credibility for consumers, and it is also going to
1234 create equity for producers across all of our industry. The
1235 FDA must determine the most appropriate nationwide safety
1236 standards in an open and transparent process with full input
1237 from the states, industry, academia, consumer groups, and all
1238 stakeholders.

1239 Most of my testimony this morning has been about
1240 prevention. Preventive controls are where it is at. That is
1241 what we have to do. As Dr. Cole said, we are not going to
1242 test food safety into our products. But I do have to take
1243 just one moment to talk about outbreak investigations as
1244 well.

1245 When I testified before the ONI subcommittee last summer
1246 in the midst of the jalapeno outbreak, I raised several
1247 issues that were critical, and I think the peanut paste
1248 fiasco of the last several months continues to reinforce
1249 those. It is clear that no one is in charge of these
1250 outbreak investigations. There is no chain of command.
1251 There is no command and control procedure, and American
1252 consumers and industry alike are left to be whipsawed back
1253 and forth from momentary change to change.

1254 Crisis planning is not done in advance. It seems to be

1255 learned on the job. The government's failure to use industry
1256 expertise, at least in our case, to help reduce and end the
1257 outbreak last summer was a tragedy.

1258 Now, let me say that this needs to be transparent. It
1259 has to be supported by consumer groups, and it has to be a
1260 squeaky clean system. But there is expertise in industry
1261 that can help reduce, moderate, and end outbreaks even in the
1262 tragic situations when they occur. And we have to find a way
1263 for CDC and FDA to take advantage of that expertise.

1264 Finally risk communication is critical. The principle
1265 of timely and rapid communication with the press and public
1266 cannot be underestimated. But it is also critical that any
1267 risk communication expert would advise precision and care in
1268 communicating exactly what needs to be said and not
1269 speculating. One single office at FDA needs to have the
1270 authority and accountability for public communications with
1271 one single officer designated as the media spokesperson.

1272 Let me conclude. There is a public health imperative
1273 that we consume more fresh produce. We as an industry are
1274 doing everything we possibly can to make sure that we are
1275 delivering safe and healthy products. But because science
1276 tells us there is no such thing as zero risk, government must
1277 also be able to assure the public that our food safety
1278 systems are based on the best available science and are

1279 enforced by strong and appropriate oversight. Thank you.

1280 [The prepared statement of Mr. Stenzel follows:]

1281 ***** INSERT 6 *****

1282 | Mr. {Pallone.} Thank you, Mr. Stenzel. Mr. Lugg.

|
1283 ^STATEMENT OF JIM LUGG

1284 } Mr. {Lugg.} Thank you, Mr. Chairman and members of the
1285 subcommittee. My name is Jim Lugg. I am former executive
1286 vice-president of food safety and quality at Fresh Express
1287 and today a consultant to Chiquita Brands International.

1288 The strategy or food safety plan is a requirement for
1289 any company that is in the food business. And it must be a
1290 solid one, and it must be adhered to. Regular reviews of
1291 that food safety plan are required so that we are constantly
1292 updating it for new risks that we have become aware of.

1293 In our business in Fresh Express, we have to look at
1294 really three areas. One is the production area. Second is
1295 harvesting, and third is processing. Each of those areas are
1296 unique unto themselves and require specialized plans. But
1297 these reviews that we do of these three areas are what help
1298 us identify risks and prevent contamination from occurring.

1299 More importantly, I think the overall lesson we have
1300 learned from these plans are that we have to do a very good
1301 job at focusing on preventive efforts. That means that in
1302 our case we have really four things that we look at: where
1303 are we planting the crop, what is the environment surrounding
1304 the crop along with its creatures, third, what kind of water

1305 will we use to irrigate with and then process it with, and
1306 finally, all along that supply chain we have the worker
1307 issue, worker hygiene.

1308 But again I stress the fact that even though we have a
1309 robust plan and we have been doing fresh cut lettuce since
1310 1978, we constantly must update that plan so as we can
1311 identify new risks that we didn't realize because of new
1312 science or whatever the case may be.

1313 But I can point out a simple case that you can all
1314 identify with, I think. If we have a lot of lettuce that we
1315 are ready to harvest and one of our people can identify what
1316 seems to be an animal incursion into that field of product,
1317 we have two choices. If we can clearly identify where the
1318 incursion occurred, we can avoid harvesting that product. If
1319 we can't clearly identify that risk, we abandon the field
1320 completely.

1321 But I emphasize that this issue of risk evaluation is a
1322 never ending process in the food industry. And that is true
1323 whether it is fresh, whether it is frozen, or whether it is
1324 canned. Almost without fail, these risk evaluation lead to
1325 more effective preventive steps, and that is the bottom line.

1326 And I also would emphasize that these food safety plans,
1327 at least at our company where we handle a number of different
1328 vegetables, are not transferable. Lettuce is different from

1329 tomato, so they must be commodity specific.

1330 And then I want to go on and just mention that in our
1331 company when we do identify a risk, we focus intently on how
1332 to manage that risk and how to evaluate whether our
1333 management practices are safe. This requires a lot of record
1334 keeping, what has been measured, when it was measured, and
1335 all those sorts of details. But the important point I want
1336 to make is that once the risks are identified, the preventive
1337 process controls must be put in place and then measured for
1338 their effectiveness.

1339 I also want to conclude actually by saying that we have
1340 a lot of tools that we can use to measure our effectiveness
1341 such as third party audits, testing, inspections, and so
1342 forth. And these tools are very effective in helping us
1343 evaluate how well we are doing.

1344 But the one thing I just want to give you a simple
1345 example of in closing is an acre of spinach has more or less
1346 three million plants in it. The typical practice for
1347 sampling a spinach field to measure, see if a pathogen is
1348 present, is to collect something less than 100 plants from
1349 that acre of three million plants. You can calculate for
1350 yourself how challenging the odds are of finding a pathogen
1351 in that sort of a regime.

1352 Finally and just to summarize, I believe the FDA should

1353 insist on every food company having a very current food
1354 safety plan. Secondly, the FDA should satisfy itself that
1355 regular risk evaluations are being done. Third, FDA should
1356 have access to preventive action steps that have been taken
1357 to manage the risk. And finally, my message is it is all
1358 about prevention. Thank you.

1359 [The prepared statement of Mr. Lugg follows:]

1360 ***** INSERT 7 *****

|
1361 Mr. {Pallone.} Thank you, Mr. Lugg, and thanks to all
1362 the panel. We will have 5 minutes questions from each member
1363 who desires, and I will start with myself.

1364 I wanted to ask Dr. Cole. You explained the difference
1365 between the hazard analysis and critical control points or
1366 HACCP and good manufacturing processes. But I am not sure I
1367 understand how that relates to many of the bills that are
1368 now--you know, they are calling them preventive safety plans
1369 which you flashed up in your chart or preventive controls.

1370 Just describe to me a little better maybe the
1371 differences between the HACCP and many of the bills, the
1372 language in the bills preventive safety plans or preventive
1373 controls if you could a little better. I know you flashed
1374 one of those up, but I don't necessarily understand the
1375 difference.

1376 I understand that the GMPs are like the basic
1377 fundamentals but--

1378 Mr. {Cole.} Yeah, I think the best way to think about
1379 it is the term preventative food safety plan is a broad term
1380 which could include a whole range of different preventative
1381 measures. The way that those preventative measures could be
1382 implemented within industry and then inspected are things
1383 like GMP which is the, as you said, are the basic kind of

1384 building blocks. You can't do HACCP unless you have the
1385 building blocks in place, unless you have the basic sanitary
1386 conditions in place.

1387 Mr. {Pallone.} But then these preventative control
1388 systems can vary widely. So if that is the case, is it
1389 sufficient to just require that all manufacturers or
1390 producers simply have a food safety plan in place, or do we
1391 have to--if it has to be a need for FDA to have ability to be
1392 more specific than that?

1393 Mr. {Cole.} I think the trick there is, because even
1394 with the additional resources, there is always going to be
1395 finite kind of resources we can bring to bear on a public
1396 health burden. So we have to be smart about the way that we
1397 apply these tools. And so we have to use either GMP or HACCP
1398 or both appropriately to the hazard that we are trying to
1399 control and the risk that we are trying to manage.

1400 So, you know, let us take a fresh produce example. I
1401 think the comments from one of the testimonies here relating
1402 the products--is it product specific. If we were to look at
1403 the safety of potatoes, okay. Potatoes usually end up being
1404 cooked and prepared, and we are not really that concerned
1405 about the safety of potatoes.

1406 Mr. {Pallone.} So it is going to vary from product to
1407 product?

1408 Mr. {Cole.} It is going to vary depending on the level
1409 of risk that we are trying to control, yes.

1410 Mr. {Pallone.} Now, let me go to Ms. DeWaal then. I
1411 mean you can comment on this as well, but if there was a
1412 system of mandatory preventive controls in place prior to the
1413 PCA outbreak, would that have helped to prevent it from ever
1414 occurring in the first place? And if you want to comment on
1415 what Dr. Cole mentioned.

1416 Ms. {DeWaal.} Well, thank you, and I do agree with Dr.
1417 Cole that the preventive control plan covers your underlying
1418 GMPs, sanitation plans, as well as your HACCP plan if you
1419 have one, and your testing.

1420 The key element for the PCA recall and outbreak is that
1421 the company, because of the absence of a plan and the records
1422 to support that plan, they were not compelled during the
1423 inspections to actually show what they knew to the
1424 inspectors, which meant that when the State of Georgia went
1425 in and did inspections, they were just doing a spot check.
1426 Conditions on that day were what they could inspect. If a
1427 bill passes that contains this kind of requirement, when an
1428 inspector arrives, they will not only to get to inspect the
1429 plants and the products that are there, they will be able to
1430 go back and look through the records. And hopefully in that
1431 case, they would have found and acted on the causative

1432 salmonella test result findings that PCA had.

1433 Mr. {Pallone.} Because they basically have a plan in
1434 place about what they have to check for is what you are
1435 saying?

1436 Ms. {DeWaal.} That is right. It gives the inspectors
1437 the access to the information on food safety that the plant
1438 itself maintains, which today FDA doesn't have it and the
1439 states don't have it.

1440 Mr. {Pallone.} Well, just give me a little more.
1441 Maybe, Mr. Stenzel, you know, talk about how a plan might be
1442 different, you know, like tomatoes versus spinach. And are
1443 there certain things that you would require, you know, for
1444 both versus things that would be different?

1445 Mr. {Stenzel.} There are. You are seeing the full
1446 chain here in this panel discussion. We actually start at
1447 the farm level with good agricultural practices, which are
1448 kind of the GMPs of the farm level I might say. That is the
1449 basics that all farms should be following. There are also
1450 then commodity specific standards and practices that we
1451 believe are appropriate, we have called for FDA to implement.
1452 Particularly for those products that have been associated
1453 with a pathogen in the past, even rarely. So for tomatoes,
1454 there would be different sets of standards and practices,
1455 commodity-specific guidelines.

1456 Today that exists. The industry has worked hard in
1457 different sectors, tomato industry, the leafy greens. In
1458 fact, we have done a pretty good job, but we need FDA to be
1459 the holder of that standard so that it is applied across the
1460 industry and is not left just to individuals to follow it on
1461 our own.

1462 Mr. {Pallone.} Okay, thank you. Mr. Deal.

1463 Mr. {Deal.} I think there seems to be general agreement
1464 that a food safety plan needs to be in place, and they will
1465 vary depending on what level of production you are in. Mr.
1466 Lugg, though, if we do make these plans mandatory and FDA
1467 comes in to inspect, in your opinion, what records should be
1468 disclosed to the FDA inspector in terms of those safety
1469 plans?

1470 Mr. {Lugg.} We would really like to have happen is when
1471 the plans are being developed, we would like to have FDA
1472 input along with our own so that the plan has all of the
1473 steps that the FDA would like to see included in it so that
1474 when the inspector arrives, he has been a part of that
1475 architecture, and he can easily see what he wants to see.

1476 Mr. {Deal.} So he would, by having access to the plan,
1477 know what they have done from a preventive standpoint?

1478 Mr. {Lugg.} Exactly. I think the owner of the food
1479 needs to own the food safety plan, but certainly there are

1480 very good advisors within CFSAN, for example, that can assist
1481 in making that plan even better.

1482 Mr. {Deal.} Let us go to the next step on this in a
1483 logical sequence, and any of you that would like to respond,
1484 please do so. The next logical step is what do you do with
1485 regard to laboratory testing? Now, I would imagine that many
1486 firms have internal labs that do internal testing, and they
1487 would, of course, I presume, maintain records of their own
1488 internal testing. Others would rely on external labs to
1489 provide testing and test results back for them. The one big
1490 question that I still have is to what extent do we require
1491 those lab tests to be disclosed to FDA?

1492 And the reason I have some concern about it is that you
1493 may have tests being done for a variety of different reasons.
1494 One might be someone who is going to process a product, but
1495 they want to find out what the status of the raw product is.
1496 Let us say peanuts for example. In its raw stage, they may
1497 get a result that may have some salmonella contamination.

1498 But if they are intending to follow through with the
1499 kill cycle, then obviously that should eliminate that
1500 particular problem. My concern is that I don't think we
1501 ought to necessarily overburden FDA with every lab report
1502 given under every circumstance and for every purpose.

1503 So how do we differentiate what lab report should be

1504 disclosed? And do you have any thoughts on that?

1505 Mr. {Hubbard.} I will take a shot at that if I may.

1506 The FDA's concern is that if you require these lab tests to
1507 be routinely submitted, people may just stop doing them.

1508 Mr. {Deal.} That is right.

1509 Mr. {Hubbard.} Firms often do them as part of their
1510 quality control process at the end to make sure that their
1511 systems are working. I think the state of Georgia was
1512 considering legislation that would require notification. But
1513 the theory is if you require it and the firm just stops doing
1514 the lab testing, you have not improved things.

1515 Mr. {Deal.} Right.

1516 Mr. {Hubbard.} But it would be important if FDA finds a
1517 connected problem, say, in a PCA example, is in their
1518 inspection and says to them do you have any laboratory
1519 findings that would help us understand if you are the source
1520 of the problem. And if they say yes, then, of course, FDA
1521 should be able to access those records.

1522 Mr. {Deal.} So you are saying then that should be a
1523 part of the maintain records subject to inspection when the
1524 FDA inspector comes in, not that the lab, upon receiving a
1525 negative or positive, as the case may be, report that the lab
1526 has to directly report at that point to FDA.

1527 Mr. {Hubbard.} I understand that that is the FDA

1528 position, yes.

1529 Mr. {Deal.} Okay. All right, anybody else want to
1530 comment on that? Ms. DeWaal?

1531 Ms. {DeWaal.} Thank you. I just want to note that
1532 today most of the bills that you are looking at do have some
1533 lab reporting, but the different bills are different in their
1534 strengths. And we really want to get, first of all, this
1535 access that Mr. Hubbard is talking about. Any time an
1536 inspection is done, the inspectors should be able to see the
1537 full range of what the plant is looking at.

1538 But there are times, for example, where, if testing is
1539 compulsory for an industry or where there is some kind of
1540 public health alert, that you might want to compel some kind
1541 of reporting to the agency. So I think you need to leave the
1542 door open in some of those circumstances for testing direct
1543 reporting. But the reporting really should go from the plant
1544 to the agency, not necessarily from the lab.

1545 Mr. {Deal.} Dr. Cole?

1546 Mr. {Cole.} Yeah, I think that is a pretty good answer.
1547 Again it comes back to based on risk. So if we are looking
1548 at the testing results as part of an ongoing food safety plan,
1549 I think the agency should have access to those records as
1550 part of that. They should have access as to what follow-up
1551 actions were taken as a result of those results. And then

1552 for certain products, you might want to make it compulsory
1553 that a positive salmonella, for example, is a notified
1554 situation. If I am making infant formula, for example, and I
1555 get a positive salmonella, that should be a notifiable
1556 instance, and that should go directly to the agency.

1557 So again unfortunately the devil is in the detail with
1558 the risk, managing the risk versus the resources.

1559 Mr. {Deal.} Well, just a quick comment. That is where
1560 we need your help, in fleshing out the devil because we can
1561 get the broad principles. I think it is the fleshing out of
1562 that I would appreciate hearing from you if you have any
1563 further thoughts about how we do that. Thank you, Mr.
1564 Chairman.

1565 Mr. {Pallone.} Thank you, Mr. Deal. Mr. Gonzalez is
1566 next.

1567 Mr. {Gonzalez.} Thank you very much, Mr. Chairman.
1568 First question, and I need to get the pronunciation. Is it
1569 Ms. DeWaal? Is that correct?

1570 Ms. {DeWaal.} DeWaal, that is correct.

1571 Mr. {Gonzalez.} DeWaal. Thank you. We have DeWaals in
1572 San Antonio that came from Minnesota, but they spell their
1573 name a little different, but it is DeWaal.

1574 Page three of your written testimony, ``the absence of
1575 federal inspection, inadequate state inspection have let

1576 problems at PCA fester.' ' No matter how much we, I guess,
1577 empower the FDA, it is just going to be overwhelming. We are
1578 never going to have all of the assets and resources truly
1579 because of just the expanse of the issues. And we are going
1580 to have to form partnerships obviously with state authorities
1581 and, of course, private enterprise.

1582 With the Peanut Corporation of America, my understanding
1583 is that they had an operation in Texas. You are probably
1584 very familiar. It may have been Georgia-based, but we had
1585 peanut butter, a lot of it obviously out of the state of
1586 Texas.

1587 Mr. {Deal.} Virginia-based.

1588 Mr. {Gonzalez.} It is Virginia-based? Well, then we
1589 are a subsidiary and happy to have been a subsidiary. But
1590 the question comes down to is that they did have private
1591 testing. And I am just wondering. I don't know what we have
1592 out there now as far as certification of the labs that are
1593 actually hired. The question always is that the closeness of
1594 the relationship generally will lead to whatever conclusion
1595 the person that is requesting the testing.

1596 Do you have concerns about that particular aspect going
1597 forward?

1598 Ms. {DeWaal.} Yes, I think it is critically important
1599 that the legislation should contain a lab accreditation

1600 provision. Now, that won't apply to every in-house lab that
1601 a company may have. But lab accreditation will raise the
1602 confidence that both inspectors at the state level, federal
1603 level, can have in the results of those tests.

1604 But getting to your question on the complexity and how
1605 will FDA actually manage its job, I mean they have a huge job
1606 of regulating both the domestic industry and the imports.
1607 And the reality is the agency has been starved for resources.
1608 There are certainly management structures that could work
1609 that would allow for FDA to have very consistent programs
1610 working with the states to do inspection, but I don't believe
1611 those programs have been designed at the agency.

1612 And unfortunately the public is really losing confidence
1613 in the ability of this agency to do those tasks. So it is
1614 important to get the funding in place, to get the new
1615 legislation and these new authorities in place where there is
1616 common agreement on so much of this.

1617 But I am not sure that even with those elements we are
1618 going to be able to restore consumer confidence in the
1619 functioning of this agency. So I was very glad today to hear
1620 Chairman Waxman say that the question of structure, which was
1621 also raised by Representative Eshoo, would be one that they
1622 would leave open for further consideration because it is very
1623 important that consumers trust the agency to manage this huge

1624 responsibility.

1625 Mr. {Gonzalez.} And I think the authors of the bills
1626 recognize that, and we are going to be moving forward, and
1627 hopefully we will do as complete a job as possible under the
1628 circumstances and the competing bills.

1629 This is going to be to Mr. Stenzel and Mr. Lugg. And
1630 that is what really establishes accountability? In my view,
1631 it is liability. Not that this may have an application, one
1632 concern I have is that the FDA is, in essence, not just the
1633 floor of the standard of care but represents the standard,
1634 which we all agree today is totally inadequate in form and in
1635 practice.

1636 And yet many people will look to that as what would
1637 govern the behavior of individuals out there in this
1638 particular chain as we say from the farm to the retailer. Do
1639 you all have any views on the liability of individuals out
1640 there and how important that aspect in this whole, what I
1641 say, the accountability established by liability?

1642 Mr. {Stenzel.} Mr. Gonzalez, you raise an important
1643 point. I think the chairman mentioned it in the beginning.
1644 It is the responsibility of food companies and food purveyors
1645 to ensure that we have safe foods. It is government's
1646 responsibility, we believe, to make sure that there is a
1647 system of oversight and integrity and set the standards that

1648 we have to comply with. But ultimately that liability on the
1649 individual food company is a pretty darn important motivator.
1650 Look at PCA, you know, for the example of when you do
1651 something wrong, I think they were called a rogue operator,
1652 Mr. Deal, look at what that penalty is going to be.

1653 I would also like to comment on your earlier question if
1654 I may about partnerships particularly on farm. This is very
1655 important. We don't anticipate a reality of FDA hiring 3,000
1656 inspectors to go across farms in the United States or abroad.
1657 The partnership there we would recommend is with USDA who
1658 knows agriculture in the United States, knows it abroad as
1659 well, in partnership with state department of agriculture.

1660 FDA needs to set the public health standard. That is
1661 for the integrity and confidence. But then in terms of
1662 actual outreach education auditing on farm, a strong
1663 partnership with agriculture would make sense.

1664 Mr. {Gonzalez.} And Mr. Lugg, I apologize but my time
1665 is up. And I yield back to the chairman.

1666 Mr. {Pallone.} Thank you. The gentleman from Illinois,
1667 Mr. Shimkus.

1668 Mr. {Shimkus.} Thank you, Mr. Chairman. I want to
1669 start with Mr. Lugg, and like the comments that were just
1670 addressed by my colleague from Texas, I understand that the
1671 heavy hand of a liability process will also punish the bad

1672 actors, and it is in the best interest of everyone to have a
1673 safe and efficient operation.

1674 Mr. Lugg, is it safe to say that sometimes the
1675 inspections conducted by you all are maybe more specific than
1676 you might get from an FDA inspection?

1677 Mr. {Lugg.} Yes, our inspections particularly with
1678 respect to good agricultural practices in the field are very
1679 detailed.

1680 Mr. {Shimkus.} Can you give us an example--

1681 Mr. {Lugg.} Sure.

1682 Mr. {Shimkus.} --of something that you may have spotted
1683 that FDA may not have?

1684 Mr. {Lugg.} Yes, in the agricultural production sector,
1685 which the FDA really doesn't spend a lot of time with, we
1686 have our own staff that will go and select a piece of ground
1687 that we are going to plant on, and that piece of ground is
1688 chosen based on the environment that surrounds it, and the
1689 quality of the water that we could use to irrigate with.
1690 That is something that the FDA wouldn't normally be concerned
1691 with.

1692 Now, we have a new group in California called the leafy
1693 greens marketing agreement, and they do get concerned with
1694 the good agricultural practices. But the FDA folks generally
1695 come into our manufacturing facilities.

1696 Mr. {Shimkus.} And I think, Mr. Stenzel, I think that
1697 is kind of your point you were making as far as having USDA
1698 deal kind of with the agricultural end of this process. I
1699 think a lot of us, depending upon the, you know, what your
1700 life experiences are. I used to be in the active military,
1701 and we feared the inspector general coming down. And the
1702 inspector general would have--we knew the list, right. We
1703 knew the standards, and by golly, by knowing they were coming
1704 down, it made us clean up. Really we want to be careful. I
1705 mean we really want to go after the bad actors.

1706 I mean we want to go after the people who would take a
1707 report, falsify the records, inspect them, and nail them
1708 versus those who have a proven track record of having--or, I
1709 think you testified once before or when we were doing the
1710 Oversight Investigation, if you talk about leafy greens. And
1711 if the processing facility has irradiation and salmonella is--
1712 --you may want to inspect to make sure that the irradiation
1713 machine is working. But if that is killing salmonella, then
1714 you have addressed that need versus maybe the multitude of
1715 other things that you might have to do.

1716 Ms. DeWaal, I have talked about this because I really
1717 want to focus, and I have talked about the risk-based
1718 approach. And that talked about the food safety plan, but
1719 then identifying for particular crops. I mean you can have a

1720 generic system, but you do have to identify for the specific
1721 crop. But what about the debate of the inspection regime?
1722 If you have a successful manufacturing facility, has good
1723 manufacturing process, has a food safety plan, has
1724 historically been graded at 100 percent, A plus, super duper,
1725 five star quality. Do you think it is a good use of our
1726 resources to be in their twice a year versus--my issue is if
1727 they are a good actor, we ought to incentivize them. And we
1728 ought to take the time for the second investigation and go
1729 after the bad actors. Could you comment on that?

1730 Ms. {DeWaal.} Certainly. The question of trying to
1731 create a risk-based inspection system but one that also gives
1732 the agency the flexibility to identify the best performers
1733 and spend less time and less resource there is one that we
1734 have really spent a lot of time looking at. I wish we were
1735 dealing with legislation that required six-month inspections.
1736 Most of the bills actually are looking at, you know, maybe
1737 one year, maybe two years, maybe four years, depending on the
1738 type of facility. So there is a broad range of inspection.

1739 But there is one bill that actually provides strict
1740 inspection, a risk-based inspection system, but then gives a
1741 lot of flexibility to FDA to set alternative inspection
1742 frequencies when plants show that they deserve it. And that
1743 type of language is contained in Representative DeLauro's

1744 bill, the Food Safety Modernization Act.

1745 So the bills range from very general language also to
1746 very specific language. Her bill has more frequent
1747 inspection frequencies, and maybe, I don't know how the
1748 committee would feel about the affordability of some of the
1749 inspection frequencies in the bill. But it is a very good
1750 model to look at it because it really defines what is risk-
1751 based inspection for the agency and then sets these
1752 alternative inspection frequencies based on criteria.

1753 Mr. {Pallone.} Thank you. Ms. Christensen.

1754 Ms. {Christensen.} Thank you, Mr. Chairman, and I want
1755 to thank the panelists for their testimonies and particular
1756 for their recommendations.

1757 Some of you have recommended a separate agency, and I
1758 will ask. Anyone can answer or all can answer. For those
1759 who think we should have a separate agency or for those who
1760 don't, do you think it would be just as effective to have
1761 just a specific office under FDA with a single head? Would
1762 that equate well enough for you?

1763 Ms. {DeWaal.} I think I will start this answer. You
1764 all are welcome to join in. We have looked at the question
1765 of a single agency ranging from a unified agency with all of
1766 meat and poultry inspection combined with all of FDA
1767 inspection to one that is more narrow.

1768 The approach that we are looking at right now is one
1769 which just separates out the food functions at FDA under a
1770 separate food standards administration, similar to what they
1771 have done in many European countries and in other developed
1772 countries around the world.

1773 The food standards agency would be headed by a food
1774 safety expert, and we don't have that in place today at FDA.
1775 There is no line authority for food safety. The policy
1776 issues are handled at CFSAN, the Center for Food Safety and
1777 Applied Nutrition. The inspection force is managed by the
1778 Office of Regulatory Affairs. The budget comes out of the
1779 commissioner's office.

1780 There is really no line authority here, and really there
1781 is no risk communicator. When something bad happens, I mean
1782 who is going to be on the call? Right now, we hear from
1783 CFSAN. We hear from ORA and CDC. So I think there is a
1784 structural problem that needs to be addressed at FDA. It is
1785 possible that you could have a deputy commissioner for food
1786 issues, for example, that might play that role, but it is
1787 very important to us that you have someone with direct line
1788 authority to the secretary of agriculture.

1789 Just looking at the sister food safety agency for a
1790 moment, at the U.S. Department of Agriculture, they did about
1791 10 years ago pass a law that required food safety to be

1792 headed by an undersecretary of food safety, and that person
1793 does have direct line authority to the secretary of
1794 agriculture.

1795 So our concern about some kind of deputy commissioner
1796 model is that you would still have everything going through
1797 the commissioner who has just an incredibly large job for
1798 consumer protection today.

1799 Mr. {Hubbard.} I will give it a shot too. I have spent
1800 some time over the years thinking about that. It may be
1801 necessary to do that at some point, but if we could wave a
1802 magic wand right now and create a single food agency,
1803 tomorrow nothing would be any different because you would
1804 still have an under-resourced, under-authorized agency that
1805 couldn't solve these problems. So I think you are doing the
1806 right way which is fix the underlying problem. Then go back
1807 and see if the structure can work with that and be effective.
1808 And if it is not, then I think the next step would be to look
1809 at a single agency.

1810 Mr. {Stenzel.} If I may, I think I am going to agree
1811 with Caroline on this, that I do think that there is a
1812 fundamental problem in the lack of direct food authority
1813 within the agency at this point. So I would urge you to
1814 think about at least that narrow issue in the current food
1815 safety legislation.

1816 Whether is the equivalent of undersecretary of FSIS at
1817 USDA I think is a good one. We have to untangle food
1818 authority from everything else within FDA.

1819 Ms. {Christensen.} Thank you. I came from the
1820 Committee on Homeland Security, and, of course, there as
1821 well, food security is also a major concern. And the way the
1822 system is today, I don't have any degree of comfort that if
1823 the terrorists wanted to do something to our food system that
1824 they would have any problem. I was noting that then
1825 Secretary Tommy Thompson had raised that concern, and he
1826 remarked that he couldn't understand why terrorists had not
1827 attacked our food supply because it was so easy to do.

1828 But your recommendations talks about preventing
1829 contamination at the production, at the storage and
1830 transportation lines. Do you feel that the recommendations
1831 that you are giving us around the food safety system now are
1832 adequate also for protecting from an attack either from a
1833 homegrown or outside terrorist?

1834 Mr. {Hubbard.} Well, the principles are the same
1835 because you would analyze the risk and how easy it would be,
1836 say, to introduce a microbial agent into food and then have
1837 it, you know, be shipped around to a lot of different places
1838 and injure a lot of different people. So you still would be
1839 looking at well, how accessible is my facility? Might be as

1840 simple as making sure there is a security guard every night
1841 and the doors are locked. And of course, in other areas, it
1842 might need to be more sophisticated than that.

1843 Mr. {Pallone.} Mr. Gingrey.

1844 Mr. {Gingrey.} Thank you, Mr. Chairman. A couple of
1845 weeks ago when we were having a hearing about the salmonella
1846 outbreak, unfortunately from the processing plant in my home
1847 state of Georgia down in southwest Georgia. The testimony
1848 told us that the labs, these private labs that the processing
1849 plant contracted with to check for salmonella, apparently
1850 there were several positive results, and then finally one
1851 negative. And you know the rest of that story.

1852 But the question I want to ask of the entire panel is
1853 what came up during that hearing. The fact that the labs
1854 were not required, maybe even prohibited, as I understood it,
1855 from sending that positive information to anybody else except
1856 from whence it came, from who they were contracted with to do
1857 the laboratory testing, and it just seemed to me that it
1858 would be fairly easy to get that information to the FDA.
1859 Computers allow us to do that.

1860 I would like to ask the entire panel in fact what your
1861 thoughts are in regard to these positive results from the
1862 private labs actually being required to submit those to the
1863 FDA. And we will start from my left, your right.

1864 Ms. {DeWaal.} Thank you. The facts situation that was
1865 outlined in that committee hearing was just tragic, and I
1866 think the committee did a tremendous service to get those
1867 facts out. The mandatory requirement for labs to report
1868 would--it looks like an appealing solution because they are
1869 the ones doing the test. But we have real concerns that if
1870 you don't couple any mandatory testing reporting with a
1871 requirement to test, then the result will be, as Mr. Hubbard
1872 said, that companies just won't test.

1873 So you need to have in the legislation the ability for
1874 FDA to say for peanut processors, you might have to test for
1875 this pathogen or that indicator organism, and then determine
1876 when those test results would be appropriate. I do think
1877 that there are some pathogens--botulism is an example--where
1878 mandatory reporting by a lab might be appropriate.

1879 But I think the legislation should be clear that FDA has
1880 the authority to require companies to test. They should be
1881 able to test their test records when they inspect the plants,
1882 and that means anybody, the Agricultural Department of
1883 Georgia or the FDA. And then on certain pathogen
1884 combinations that, in fact, it would be open to mandatory
1885 testing either by the plant or by the lab.

1886 Mr. {Hubbard.} Mr. Deal touched upon that earlier.
1887 Certainly it would be important if FDA went to a facility

1888 like PCA and was doing an inspection and identified PCA as a
1889 source of a problem, that they should be able to say as part
1890 of their inspection process have you done any lab testing?
1891 And if the answer is yes, could we see that so we could see
1892 what you knew and when you knew it?

1893 But to require all labs to automatically send
1894 information to the FDA could actually cause people to stop
1895 doing the testing, which would not be an outcome that I think
1896 most people would want. I think Ms. DeWaal sort of--

1897 Mr. {Gingrey.} But as Ms. DeWaal said, FDA certainly
1898 could require in certain commodities at--

1899 Mr. {Hubbard.} In certain commodities.

1900 Mr. {Gingrey.} --certain steps in the process--

1901 Mr. {Hubbard.} Yeah.

1902 Mr. {Gingrey.} --that the testing be done for
1903 particular pathogens, and that could be a requirement.

1904 Mr. {Hubbard.} And that might be necessary in some
1905 cases. That is right.

1906 Mr. {Cole.} I would agree with those comments. I think
1907 this is a situation where given, you know, this is not the
1908 first outbreak we have had with peanut butter. We had one
1909 two years ago. There have been outbreaks overseas. I think
1910 we should be viewing this product as a high-risk product. We
1911 should have a requirement to test and a requirement to report

1912 those tests. I think also we need to have preventative
1913 controls in place to prevent contamination. Once salmonella
1914 is in that product, it is very resistant, okay, to heat
1915 processing et cetera. So we need suppliers or companies
1916 buying that product too should have, you know, really done a
1917 better job in supplier assurance of that product rather than
1918 just looking at test results as well.

1919 Mr. {Stenzel.} I think we share a pretty common view on
1920 the panel, particularly the access to those test records is
1921 the most critical aspect. I share the same concern in terms
1922 of required every single test to be automatically forwarded
1923 to FDA. I am not sure that that is the most effective answer
1924 for a company that deliberately retested and retested until
1925 they found something they wanted.

1926 That is criminal behavior, and no matter what standard
1927 we would put in place, I am not sure we are going to prevent
1928 someone who does that. They would not send the results--

1929 Mr. {Gingrey.} Yeah, agreed. In that situation, it
1930 wouldn't have made a difference.

1931 Mr. {Stenzel.} But the access to the records I think is
1932 absolutely critical.

1933 Mr. {Gingrey.} Thank you, Mr. Stenzel. Mr. Lugg? Your
1934 microphone is not on.

1935 Mr. {Lugg.} I am sorry. Because we are in the fresh

1936 business, and the difficulty we have in collecting a
1937 representative sample, we rely so heavily on prevention that
1938 we just have a lot of lab results from our agricultural
1939 fields. We do have a program of what we call intelligent
1940 testing, and we do share those results routinely with
1941 researchers and our California Department of Public Health.

1942 As far as a requirement to furnish test results, I think
1943 that might discourage people from actually getting tests done
1944 and might in the end result in not the result that you would
1945 like.

1946 Mr. {Pallone.} We have to move on. Mr. Waxman.

1947 The {Chairman.} Thank you, Mr. Chairman. I want to
1948 elaborate on some of the points Mr. Gonzalez raised. We have
1949 learned at numerous hearings the foods program at FDA has
1950 been starved for resources over the years and, Mr. Hubbard,
1951 in your testimony, you state there are currently 150,000
1952 registered facilities in the U.S. And the charts you
1953 provided us today on the plummeting numbers of inspections in
1954 the U.S. paint a stark picture of the effects of this loss of
1955 resources, and that has a real impact on food safety.

1956 But the problem doesn't stop there. We are all acutely
1957 aware of the fact that we now have an increasingly globalized
1958 food market. We import foods from all over the world,
1959 apparently more than 200,000 registered foreign food

1960 facilities. How much does each inspection cost? Do you have
1961 any kind of estimate you can give?

1962 Mr. {Hubbard.} Domestic inspection or HACCP inspection
1963 can be around \$3,000 and regular sanitation GMP inspection
1964 can be around \$2,000. So they are not cheap.

1965 The {Chairman.} Well, if we are talking about having
1966 FDA inspect over 360,000 facilities with some regularity,
1967 that is an overwhelming task in terms of the workload, and it
1968 will obviously cost a great deal.

1969 I have heard many suggest that the answers to extend
1970 FDA's workforce by supplementing it with private inspectors
1971 working on behalf of FDA, but I want to raise some concerns
1972 about that. There was a recent article in ``The New York
1973 Times'' that raised problems with these private inspectors.
1974 They say that food company being inspected often hires and
1975 pays for its own private inspector creating a conflict of
1976 interest, how those private inspectors frequently did not
1977 catch the problems at plants, whose products later sickened
1978 consumers.

1979 And some of those companies who later were found to have
1980 contaminated products were even given excellent or superior
1981 or ratings. That was the case with both PCA peanut outbreak
1982 and with the children's snack Veggie Booty in 2007.

1983 So in some ways, I am even more concerned about the

1984 notion of relying on private inspectors in foreign countries.
1985 Obviously the primary reason domestic companies want to
1986 import from other countries is that these products are less
1987 expensive. And the reason they are less expensive is usually
1988 that they are not produced under strong food safety
1989 protection. So relying on third parties in those countries
1990 raises some serious questions.

1991 My fundamental concern with a third-party system for
1992 imported foods governed by FDA is that it still puts a huge
1993 burden and responsibility on FDA. I think that a company
1994 benefiting from the importation of cheaper products and
1995 ingredients should have a duty to check up on these foreign
1996 companies and be held accountable when there are failures.

1997 Indeed, some companies are already doing very thorough
1998 inspections of their foreign suppliers on their own. Do you
1999 agree that a company should have a responsibility to check on
2000 its own suppliers? And if we are forced to rely on third-
2001 party private inspectors, what sort of protections do you
2002 think can be put into place to address some of these
2003 concerns?

2004 Mr. {Hubbard.} Yes, Mr. Chairman. You have touched
2005 upon a very important issue, and it may be your single
2006 hardest policy choice in this debate because you are
2007 absolutely right. The third-party system has not proven

2008 itself to be working properly now. It clearly is not
2009 working. FDA does believe that there are ways of beefing up
2010 that system--

2011 The {Chairman.} Don't pay attention to that.

2012 Mr. {Hubbard.} --with prohibitions against conflict of
2013 interest, with better training, with FDA audits behind them.
2014 The fundamental dilemma is you can never have enough
2015 inspectors to go to 316,000 facilities of FDA inspectors.
2016 But on the other hand, these third-party folks need to be
2017 under a very serious regimen of oversight, and I do think
2018 that your question about having the importers, the U.S.
2019 importer bear more responsibility for the quality of the
2020 product they are buying from, say, China is an important
2021 piece of it.

2022 And, in fact, the major food companies are beginning to
2023 acknowledge that they need to do that, that they need to know
2024 who they are buying from and what their quality is. And if
2025 they don't know that, they should not be buying from that
2026 foreign firm.

2027 Ms. {DeWaal.} Thank you.

2028 The {Chairman.} Do you want to add anything to that?

2029 Ms. {DeWaal.} I do. The concept you have laid out in
2030 terms of having the company take more responsibility works
2031 well when you are dealing with ingredients. But, sir, it

2032 doesn't work so well when you are dealing with whole foods.
2033 There are a lot of foods that come in a port of entry and go
2034 directly into retail. And who is going to be that importer
2035 of record becomes a real issue because it is defined today in
2036 regulations. But it could give rise to some fly-by-night
2037 situations.

2038 The {Chairman.} Well, we have to look at these concepts
2039 carefully because we can't afford all the inspectors that we
2040 think we are going to need, and I don't know that we can rely
2041 on all those third-party inspectors either to feel that we
2042 are being protected.

2043 I see my time has expired, and other members are waiting
2044 for their turn. So I will yield back the time I have
2045 overdone.

2046 Mr. {Pallone.} Thank you, Chairman Waxman. I am going
2047 to ask Mr. Sarbanes to ask questions, and then that will be
2048 it before the votes. We have three votes, a 15, a 5, and a
2049 5. So we will ask you to stay so we can continue with
2050 questions. So we will do Mr. Sarbanes, and then we will come
2051 back for the rest of the members.

2052 Mr. {Sarbanes.} Thank you very much, Mr. Chairman.
2053 Thank you all for your testimony. I was particularly
2054 interested in the discussion about consumer confidence and
2055 how difficult it is going to be to restore consumer

2056 confidence. And I take it that, if I am hearing the
2057 discussion properly, even with the best food safety regime in
2058 place, there is still going to be outbreaks, right? So if
2059 you link your bid to boost consumer confidence to the notion
2060 that you would prevent outbreaks, that is sort of a dead-end
2061 aspiration.

2062 So it really comes then, I would imagine, the thing that
2063 is going to bolster consumer confidence the most effectively
2064 is a rapid response when there is--because that is the high
2065 profile incidences, right, that occur? Otherwise it is like
2066 oxygen. You are not going to notice it, right, if things are
2067 working well. So it is when there is an outbreak that you
2068 have a rapid response, that you have the traceability
2069 opportunities and so forth. And you show the public that you
2070 can quickly isolate it, you know, within hours, within days,
2071 whatever is feasible to do with a good safety regime. And
2072 then they come away from the experience saying, you know, the
2073 cop is on the beat. This is being handled, and, you know, we
2074 are protected.

2075 And I would just like to get your reaction to that. And
2076 maybe there is other leverage points to help with this
2077 consumer confidence question, but it seems to me that is
2078 probably one of the most obvious. Yeah, Ms. DeWaal.

2079 Ms. {DeWaal.} Thank you. You are right that we are

2080 always going to have outbreaks. The issue is how many and
2081 how big are they. The bills that you are considering address
2082 both ends. If we can prevent the problems from occurring,
2083 then the number of outbreaks will be reduced. If we can
2084 increase the traceability, the ability to find the
2085 contaminated product, then we are going to reduce the size of
2086 those outbreaks.

2087 So I think there are components that address both of
2088 those issues, but I think they are both essential.

2089 Mr. {Sarbanes.} Any other comments? Yes?

2090 Mr. {Hubbard.} I would like to make the point, Mr.
2091 Sarbanes, most of my career at the FDA, Roper and Washington
2092 Post and Harris polls showed FDA with the second highest
2093 consumer confidence in the entire--among all civilian
2094 agencies, next to the National Park Service. But since,
2095 2000, that has reversed.

2096 Mr. {Sarbanes.} Um-hum.

2097 Mr. {Hubbard.} It used to be around 70 percent
2098 confidence level. Now it is around 30 percent. That is a
2099 tremendous reversal that I think reflects the kind of concern
2100 you are talking about because when FDA can't find the source
2101 of these things quickly and then stamp them out, get the food
2102 out of the commerce, then I think the public just feels their
2103 government is not serving them well.

2104 So the speed at which outbreaks can be responded to and
2105 stopped is absolutely important. But that will require more
2106 than FDA.

2107 Mr. {Sarbanes.} Right.

2108 Mr. {Hubbard.} You have the CDC component, and then the
2109 state health departments are a big piece of that.

2110 Mr. {Sarbanes.} Let me ask a question about the
2111 deterrent effect because you all have alluded to this. And I
2112 am just curious now where the number of inspections relative
2113 to the number of facilities and so forth is so low. I mean
2114 is there an operative deterrent effect at the current time,
2115 or not really?

2116 Mr. {Hubbard.} I actually tracked that a few years
2117 back. As the inspections went down, the recalls went up.
2118 And the adverse findings from the FDA inspections that did
2119 get done went up. So in other words, as inspectors
2120 disappeared, the vigilance in the firms disappeared with
2121 them.

2122 Mr. {Sarbanes.} Right.

2123 Mr. {Hubbard.} So I think the fact that they think FDA
2124 might come helps, and the fact that, you know, FDA won't come
2125 now is clearly not helpful.

2126 Mr. {Sarbanes.} Well, and I imagine there is a sort of
2127 tipping point that you have to get past to create an

2128 effective deterrent in this process. I have no further
2129 questions. Thank you, Mr. Chairman. I yield back.

2130 Mr. {Pallone.} Thank you. So we are going to break.
2131 We have three votes. Should be back in about half an hour,
2132 but we will come right back and finish with the rest of the
2133 members. Committee stands in recess.

2134 [Recess.]

2135 Mr. {Pallone.} If I could ask the panel to take their
2136 seats again, and thank you. And our next member for
2137 questions is the gentlewoman from Florida, Ms. Castor.

2138 Ms. {Castor.} Thank you, Mr. Chairman. To the panel,
2139 just as folks all across the country would be surprised that
2140 FDA does not have mandatory recall authority, I think they
2141 would also be quite surprised that the FDA does not have the
2142 authority to fine bad actors.

2143 Has this always been the case? Compare that to other
2144 agencies that have that authority to institute civil monetary
2145 penalties and then if you would provide a recommendation on
2146 what you think an FDA reform food safety bill should contain.

2147 Mr. {Hubbard.} I will give that a shot if I may. If
2148 you line up the various authorities of agencies all across
2149 government, the newer agencies tend to have a much broader
2150 range of authorities, such as civil money penalty and
2151 subpoena authority.

2152 FDA is one of the oldest agencies, and it was created in
2153 1906. And at the time, it was believed that the way to
2154 enforce the law is to put the owner in jail if he sold a bad
2155 food. But, you know, you are not going to put the Kraft CEO
2156 in jail because one of his firms made a little mistake. And
2157 to enjoin the company that is making the food, which is a
2158 good thing, and seize the food if it was considered
2159 adulterated.

2160 But it did not give FDA these more modern tools that
2161 provide them more leverage. So, for instance, civil money
2162 penalties, the industry won't like, but it is a nice
2163 intermediate tool to say okay, tomorrow it is going to cost
2164 you \$1,000. And if you don't fix it, it might cost you
2165 \$2,000. And finally they will fix it.

2166 And those kind of flexible tools have been shown to be
2167 very helpful for FDA in other contexts such as medical
2168 devices where it does have that authority.

2169 So I absolutely encourage you to look at the modern
2170 toolbox that regulatory agencies have and consider giving FDA
2171 those tools as well.

2172 Ms. {DeWaal.} We strongly agree. There are a whole set
2173 of tools, including things like even citizen sue provisions
2174 which are used in statutes that have been developed in the
2175 last 20 or 30 years. FDA doesn't have any of this capacity.

2176 So I think the bill should include updating both the criminal
2177 penalty section but also giving this new authority for civil
2178 monetary penalties, traceability, and mandatory recall.

2179 Thank you.

2180 Mr. {Stenzel.} Honestly, Ms. Castor, I really don't
2181 have the experience to answer the question historically or
2182 related to other agencies. I do think some of the civil
2183 penalty areas can make sense in this area as well.

2184 Ms. {Castor.} Anyone else? Are any states that you
2185 know of, have they adopted their own civil penalties under
2186 their state inspection regulatory authority? Do you know?
2187 Okay, thank you very much, and I will yield back.

2188 Mr. {Pallone.} Thank you. The gentlewoman from Ohio,
2189 Ms. Sutton.

2190 Ms. {Sutton.} Thank you, Mr. Chairman, and thank you
2191 for the witnesses for waiting for us. A couple of things
2192 very quickly. Mr. Lugg, you made an observation that has
2193 been made here in the past in our oversight hearing in which
2194 when discussing the concept of required reporting of test
2195 results to the FDA, you indicated that that may result in the
2196 failure to test and have an opposite effect.

2197 But I have to tell you that after we heard that sort of
2198 proffered at the last hearing, I received a lot of feedback,
2199 and it was certainly running through my mind, from my

2200 constituents who all well, we will fix that. We will just
2201 make them test. And so I mean I just have to tell you that
2202 in the realm of America, people are like that seems
2203 ridiculous to this congresswoman and to the people at least
2204 who I heard back from.

2205 So I think we can correct that problem if we need to by
2206 mandating the test. And I just appreciate having the
2207 opportunity though to address that. The other questions that
2208 I have, a lot of you have talked about imports and the
2209 complex sort of questions that it creates in ensuring the
2210 safety of the process and the food that results on our dinner
2211 tables.

2212 Ms. DeWaal and I think, Dr. Cole, you also addressed
2213 this issue. And, Dr. Cole, I think, if I am not mistaken--
2214 let us see if I can find it--you explained the way that this
2215 works under the WTO. And I think that that is really, really
2216 helpful because I am not sure that people out and about
2217 really understand our limitations on ensuring the safety of
2218 imports into this country. That in many ways--and perhaps
2219 this is a simplification, and I certainly ask you to explain
2220 in more detail--but in summary, when I read your statement
2221 about this, in essence we rely on the standards of other
2222 countries. Is that sort of an accurate assessment, or would
2223 you like to expand on that?

2224 Mr. {Cole.} I think through WTO, appropriate level of
2225 protection is defined by the member, in this case a country,
2226 and the regulations are set up to provide a shield, not a
2227 sword. So if a country can decide that it is going to have a
2228 more stringent standard than the default CODEX standard, it
2229 needs to have evidence that its own safety system can meet
2230 that standard as well. That is kind of how it works in a
2231 nutshell.

2232 So there are frameworks there from CODEX that we can
2233 borrow from. There are default criteria that we can use. It
2234 doesn't stop us setting our own standard, but we need to be
2235 able to show actually that we are meeting that standard for
2236 our own public health benefit, if you know what I mean.

2237 Ms. {Sutton.} But with respect to the WTO and as things
2238 currently exist, you mentioned that the idea of what is
2239 considered ``reasonable'' differs from country to country,
2240 and acceptable risk is culturally defined.

2241 And I think that those are important things for the
2242 American people to understand when we talk about certainly
2243 another subject that is related to this, and that is the way
2244 our trade system is working and what kind of exposures we
2245 have as a result of some of the policies that we follow. So
2246 I appreciate that assessment.

2247 Now, there are so many things that I would to explore

2248 more. But, Ms. DeWaal, as you noted in your testimony and we
2249 have heard some conversation here today about, the ability to
2250 access records from food manufacturers is now currently found
2251 in the Bioterrorism Act of 2002. And, of course, the FDA
2252 cannot demand access to food company's records unless they
2253 believe that an article of food is adulterated and presents a
2254 threat of serious adverse health consequences or death to
2255 humans or animals.

2256 And if you could just take this moment to explain how
2257 the limitations of working under that framework have resulted
2258 in adverse results.

2259 Ms. {DeWaal.} Thank you for the question. Probably one
2260 of the best examples if the failing of records access when it
2261 was needed by FDA was in an inspection of another peanut
2262 butter processor. That company, and it was disclosed
2263 actually in this committee's investigations, that company
2264 found that they had an inspection going on, and the inspector
2265 wanted to see the salmonella testing records. But the
2266 company itself said well, you have to submit the request in
2267 writing. FDA never circled back with that written request,
2268 and the company never disclosed those records. Another major
2269 multistate recall resulted from peanut butter linked to that
2270 company.

2271 It is clear that FDA does not have the record access

2272 that it needs under the Bioterrorism Act. So I think it is
2273 essential that in any legislation that should emerge from
2274 this process that that be fixed. And records access should
2275 be tied into this food safety plant. It should be broad. It
2276 should go to testing. It should go to processing records and
2277 corrective actions. Thank you.

2278 Mr. {Pallone.} Thank you. Ms. Eshoo.

2279 Ms. {Eshoo.} Thanks again, Mr. Chairman, and thank you
2280 to the witnesses for your patience and waiting and for the
2281 testimony that you have given.

2282 I wanted to highlight something that appeared in the
2283 ``New York Times'' last week, and Chairman Waxman made
2284 reference to it. But I want to read this, and with your
2285 permission, Mr. Chairman, I would like to place the full
2286 article in the record of the hearing.

2287 Mr. {Pallone.} Without objection, so ordered.

2288 [The information follows:]

2289 ***** COMMITTEE INSERT *****

|
2290 Ms. {Eshoo.} Thank you. The story starts out ``when
2291 food industry giants like Kellogg want to ensure that
2292 American consumers are being protected from contaminated
2293 products, they rely on private inspectors like Eugene A.
2294 Hatfield. So last spring, Mr. Hatfield headed to the Peanut
2295 Corporation of America plant in southwest Georgia to make
2296 sure its chopped nuts, paste, and peanut butter were safe to
2297 use in things as diverse as granola bars and ice cream. The
2298 peanut company though knew in advance that Mr. Hatfield was
2299 coming.

2300 He had less than a day to check the entire plant, which
2301 processed several million pounds of peanuts a month. Mr.
2302 Hatfield, 66, an expert in fresh produce, was not aware that
2303 peanuts were readily susceptible to salmonella, which he was
2304 not required to test for anyway. And while he was inspecting
2305 the plant to reassure Kellogg and other food companies of its
2306 suitability as a supplier, the Peanut Corporation was paying
2307 for his efforts.'

2308 You can tell where I am going with this. Now, here is a
2309 quote. ``The overall food safety level of this facility was
2310 considered to be SUPERIOR''--that is in capital letters--``he
2311 concluded in his March 27, 2008 report for his employer, the
2312 American Institute of Baking, which performs audits for major

2313 food companies. A copy of the audit was obtained by the
2314 ``New York Times.''

2315 Now, it seems to me we have a big problem here. We
2316 know, according to your testimony, what it costs to do
2317 inspections. It is not cheap, but it seems to me that
2318 outside of national security, there are two major functions
2319 the government has--and I have always kept this with me, from
2320 local government to the Congress--public health and public
2321 safety.

2322 And this issue bears both responsibilities. We are now
2323 not only talking about preventing. We are talking about life
2324 and death in our system, the American system, that should be
2325 the gold standard of the world. So for the record, what I
2326 would like to know is do you think that this third-party,
2327 these private inspectors are really the best way to go? I
2328 mean it said in this article that the contributions of third-
2329 party audits to food safety are the same as the contribution
2330 of mail order diploma mills to education.

2331 Why don't we start over here? I heard your comments
2332 earlier. Why don't we start over here with Mr. Lugg?

2333 Mr. {Lugg.} Thank you for the question. That is a very
2334 good subject that you raise, and that is--

2335 Ms. {Eshoo.} I know it is, but I want to know what you
2336 think of these private inspectors. Do you think they should

2337 be retained? Do you think they have a place in the system?
2338 Do you think that we can reform it so that private inspectors
2339 have to exercise more responsibility? Tell me what you think
2340 representing you--who are you representing?

2341 Mr. {Lugg.} Chiquita Brands--

2342 Ms. {Eshoo.} Chiquita.

2343 Mr. {Lugg.} --International.

2344 Ms. {Eshoo.} Right.

2345 Mr. {Lugg.} Our philosophy has been from day one we
2346 cannot rely on third-party inspectors.

2347 Ms. {Eshoo.} Um-hum.

2348 Mr. {Lugg.} We do believe that there should be in place
2349 a system for licensing third-party inspectors, and they
2350 should be regularly brought in to keep their licenses in
2351 force. And--

2352 Ms. {Eshoo.} So they are not paid by the very people
2353 that they are inspecting? Is that what you are saying?

2354 Mr. {Lugg.} Whoever pays, I didn't address the payment
2355 issue.

2356 Ms. {Eshoo.} I see.

2357 Mr. {Lugg.} But I just am--

2358 Ms. {Eshoo.} Well, how is what you just said, how does
2359 it differ from what we have today?

2360 Mr. {Lugg.} Well, we are very concerned that standards

2361 are different depending on the audit firms that do the audit.

2362 Ms. {Eshoo.} I see.

2363 Mr. {Lugg.} And if we always go back to the CODEX
2364 Almontarius, which is a fundamental document and auditors are
2365 licensed based on their knowledge and so forth of how to
2366 conduct inspections, there should be an improvement in the
2367 third-party audit, regardless of who pays for it.

2368 Ms. {Eshoo.} Good. Mr. Stenzel?

2369 Mr. {Stenzel.} Congresswoman, I would say that private
2370 inspectors are an essential and important part of our food
2371 safety system today.

2372 Ms. {Eshoo.} But what I just read--

2373 Mr. {Stenzel.} Because we have one example where it
2374 didn't work--

2375 Ms. {Eshoo.} But this is--so you think it is the only
2376 one?

2377 Mr. {Stenzel.} I didn't say it is the only one, nor
2378 that it is the end of the solution. But private inspection
2379 is one way that private sector companies do audit each other,
2380 and that is an important part. No one is more concerned than
2381 Kellogg in that story that the people they hired to do
2382 inspections didn't do an adequate job.

2383 Ms. {Eshoo.} But where is the safety valve in this, in
2384 what you are saying?

2385 Mr. {Stenzel.} But here is where I think is important
2386 when we get to this legislation. Should FDA incorporate
2387 third-party private inspectors? And if that becomes the
2388 case, then there has to be much more rigorous certification
2389 of inspectors.

2390 Ms. {Eshoo.} So you are acknowledging that there are
2391 holes in what the system does now?

2392 Mr. {Stenzel.} Absolutely.

2393 Ms. {Eshoo.} Good. All right. Well, at least you are
2394 doing that. I am glad. And, Mr. Chairman, I think that when
2395 we do a bill, we have to pay a lot of attention to this area.
2396 And I think that it is important to have a stand-alone NHHS.

2397 I worry a great deal that what Congress is going to fall
2398 back on is what we have done with so many other areas of FDA
2399 and fund it through some kind of user fee. And I don't think
2400 that is the way to approach this. I think we are skating on
2401 very, very thin ice.

2402 I also think that Congress should be taking a look at an
2403 overlapping term for the FDA commissioner so that it is never
2404 politicized. I think it should be a six-year term and not be
2405 subject to the whims of politics that we have seen. That
2406 hasn't come up today, but I think there is a lot of work to
2407 be done relative to the FDA.

2408 And if we come up with all kinds of reforms but we don't

2409 fund what needs to be funded, we are going to be right back
2410 here with these good people hearing testimony all over again.
2411 So thank you. I was glad to return from the floor. I did
2412 want to ask the questions, and I thank the witnesses and the
2413 chairman. This is a big issue for us in the country.

2414 Mr. {Pallone.} Thank you. Ms. DeGette.

2415 Ms. {DeGette.} Thank you very much, Mr. Chairman. Mr.
2416 Stenzel, I wanted to ask you. With produce in particular,
2417 the industry now has the ability to trace produce not just
2418 from the field but from the exact part of the field it was
2419 planted all the way to the end wherever it is, the grocery
2420 store or the restaurant. Correct?

2421 Mr. {Stenzel.} That possibility exists. It is
2422 certainly not in place across the whole industry.

2423 Ms. {DeGette.} But it is done in parts of the industry?

2424 Mr. {Stenzel.} In some cases, yes.

2425 Ms. {DeGette.} Some companies have instituted voluntary
2426 traceability within their companies, correct?

2427 Mr. {Stenzel.} Absolutely. Many companies are doing
2428 that.

2429 Ms. {DeGette.} And, in fact, California has enacted
2430 standards that involve traceability, correct?

2431 Mr. {Stenzel.} Yes, ma'am.

2432 Ms. {DeGette.} And so I guess I am wondering what your

2433 industry's view would be if we enacted traceability laws as
2434 part of comprehensive food safety legislation?

2435 Mr. {Stenzel.} I would comment on the whole area.

2436 Traceability is an essential part of food safety. I think it
2437 is something that we have to look at. I would first ask in
2438 the Bioterrorism Act in the one up, one down, I am not aware
2439 of any case where FDA has ever cited a company for failure to
2440 produce records in an adequate time. So a lot of what we
2441 talk about in produce traceability, even last summer's
2442 episode was chasing the wrong commodity.

2443 Ms. {DeGette.} Right.

2444 Mr. {Stenzel.} Not the fact they couldn't trace the
2445 tomatoes.

2446 Ms. {DeGette.} Right. Well, we need to fix the one up
2447 one down too.

2448 Mr. {Stenzel.} Right.

2449 Ms. {DeGette.} I think everybody agrees with that. But
2450 if we did fix that, we could do traceability.

2451 Mr. {Stenzel.} On traceability for produce, about 18
2452 months ago, our industry launched an industry-wide initiative
2453 to handle bulk produce. If it is in a bag or if it is in a
2454 package, you have a UPC code, and it is much more easily
2455 tracked. But for bulk produce in cartons--

2456 Ms. {DeGette.} I hope you don't mind if I interrupt

2457 you.

2458 Mr. {Stenzel.} Please.

2459 Ms. {DeGette.} I only have 5 minutes, and the question
2460 I asked you was does your industry support traceability?

2461 Mr. {Stenzel.} We are doing everything we can to
2462 implement traceability across the--

2463 Ms. {DeGette.} And would you support it as part of a
2464 comprehensive--

2465 Mr. {Stenzel.} Certainly as part of comprehensive food
2466 safety.

2467 Ms. {DeGette.} --legislation. Thank you very much.

2468 And, Mr. Lugg, what is your view on traceability? Would you
2469 be supportive as well?

2470 Mr. {Lugg.} We certainly are 100 percent supportive,
2471 and if you look at any of our packaged salads, you can trace
2472 them immediately.

2473 Ms. {DeGette.} Now, Mr. Hubbard, I want to ask you a
2474 question about traceability because, as you know, we have
2475 discussed this in my legislation. And I have also talked
2476 about it with Ms. DeWaal. So you might actually have some
2477 input too.

2478 What my traceability legislation says is that the FDA
2479 shall develop guidelines for each different industry. Do we
2480 have the technology to do that in the different parts of the

2481 food industry?

2482 Mr. {Hubbard.} I think we do, and in fact, I think the
2483 tomato folks showed some of that technology to you last
2484 summer. And clearly there is bar code and radio frequency
2485 identification technology and others that allow you to track
2486 a product all the way back to its origin. And the Defense
2487 Department is using it for everything from tanks to nuts and
2488 bolts. And so it is becoming widely used anyway. And I
2489 would hope that that might be one avenue for a solution here.

2490 Ms. {DeGette.} This is an issue we started talking
2491 about some years ago. And people in the industry didn't
2492 think that they could do it. And so they opposed it, but now
2493 I call it the salsa fiasco of last year where first we
2494 thought it was tomatoes, then jalapenos. And it took months
2495 and months. It not only hurt the consumers, it devastated
2496 the tomato industry. I think people are now realizing not
2497 just the health benefits but the commercial benefits.

2498 Ms. DeWaal, I wanted to ask you a question. I think you
2499 talked about this before, and I just wanted to put a little
2500 fine point on it. With the peanut problems we have had this
2501 year, it seems to me that the types of records production,
2502 you would both need to have mandatory inspections of some
2503 kind in every industry. And you would also have to have
2504 mandatory production of those documents because if you just

2505 had mandatory production of the documents without the
2506 mandatory inspections, then people might not do the
2507 inspections. Is that what you were saying?

2508 Ms. {DeWaal.} That is correct. The inspections are an
2509 essential part of the enforcement program. This is to
2510 prevent outbreaks from occurring. The records production
2511 should be part of that, and also mandatory testing for
2512 certain pathogens that might be linked to those products. So
2513 all of this goes into a preventive approach.

2514 Ms. {DeGette.} Right, because you don't want people to
2515 get sick in the first place if possible. I just have one
2516 last question for all the witnesses if you can just answer
2517 yes or no. Would you support mandatory recall authority for
2518 the FDA as part of comprehensive food safety legislation?

2519 Ms. {DeWaal.} Yes.

2520 Mr. {Hubbard.} Yes.

2521 Mr. {Cole.} Yes.

2522 Mr. {Stenzel.} Yes.

2523 Mr. {Lugg.} And yes.

2524 Ms. {DeGette.} Thank you very much, Mr. Chairman.

2525 Mr. {Pallone.} Thank you. Mr. Stupak.

2526 Mr. {Stupak.} Thank you, Mr. Chairman, and thanks for
2527 allowing me to sit in even though I am not part of the
2528 subcommittee. You know my interest in this and in our

2529 legislation. The hearing focused today a lot on inspection
2530 fees, certifications, even brought up the 6-year term for the
2531 FDA commissioner. But no matter what we do in this field,
2532 whether it is inspection fees or whatever we are doing, we
2533 still have to change the culture of the FDA.

2534 You can have all the laws and all the money in the
2535 world, but if we don't have a culture at the FDA that is
2536 willing to be aggressive in this area, we are still going to
2537 have food-borne illnesses. For instance, we talked a lot
2538 about the tomato industry. The tomato industry and members
2539 of our Committee on Oversight Investigations repeatedly told
2540 the FDA because of the time of the outbreak, the only place
2541 that tomatoes could have possibly affected it were from south
2542 Florida. South Florida has a very good trace back and
2543 certification of their product. So it couldn't have come
2544 from the United States.

2545 But what did the FDA do? They still--and if you go to
2546 their website today--still insist it is tomatoes. They have
2547 killed the tomato industry. Last year, \$125 million they
2548 lost because the FDA wouldn't listen to anybody. And we find
2549 out it is jalapenos out of Mexico. But go to website, the
2550 tomato industry is still being associated with this outbreak.
2551 So I think we need leadership at the FDA, and we haven't had
2552 that.

2553 Mr. Hubbard, you said that we can never make food 100
2554 percent safe, and I guess I would tend to agree with you
2555 somewhat. And then you said that there are gaps in our food
2556 safety system. What are those gaps?

2557 Mr. {Hubbard.} Well, principally, it is that the system
2558 relies upon this infrequent inspection process and forces FDA
2559 to pay got-you or state inspectors, instead of putting the
2560 burden on the producer to demonstrate at all times that they
2561 are producing a safe food. That is the paradigm shift that
2562 needs to occur.

2563 Mr. {Stupak.} Okay, let me ask you this. Our
2564 committee's research has found that more than 10 years ago,
2565 recommendations to develop a national food protection
2566 training center have been repeated made, yet no action has
2567 been taken to date.

2568 More than 8 years ago, the Department of Health and
2569 Human Services office of inspector general concluded that an
2570 effective food safety system depends on the collective effort
2571 and coordination among federal, state, and local levels on
2572 government. Yet that same report noted the FDA provides
2573 limited training for state food protection professionals, and
2574 that states themselves cannot afford the cost of such
2575 training.

2576 Nearly 2 years ago, the FDA issued program standards,

2577 which requires states to have training plans that ensure all
2578 inspectors receive training required to adequately perform
2579 their work assignments. Still only a few states have done
2580 it. So let me ask do we need a national food protection
2581 training center to train state and local inspectors to
2582 federal standards, and maybe even these private inspectors we
2583 have heard so much about today?

2584 Mr. {Hubbard.} I think we do, and in fact, I would urge
2585 you to consider in your legislation authorizing or mandating
2586 that FDA creates such a thing. I think the Georgia example
2587 showed that states were not perhaps up to snuff, and these
2588 third-party inspectors, as several members have raised,
2589 clearly are not up to snuff either. So that sort of a
2590 training academy would, in my view, raise standards for
2591 everyone.

2592 Mr. {Stupak.} Okay, there is some limited training, I
2593 know, through University of Maryland, but it is very limited.
2594 You don't have to go through it, so we are almost looking
2595 like a college curriculum. That is being developed through
2596 some legislation. That is why I wanted to ask you that
2597 question.

2598 But let me ask you this, and if you know this. What is
2599 the current practice? Like take the PCA, Peanut Corporation
2600 of America. Georgia and Texas state inspectors inspected it.

2601 What happened to those reports? Do they go to the FDA and
2602 sit on a shelf or in someone's computer program? Is there an
2603 internal audit about what is being done in these inspections?

2604 We heard about Mr. Hatfield from Ms. Eshoo about never
2605 inspecting or gave a superior rating. The one in Texas
2606 received a very good rating. Is there an internal audit
2607 conducted by the FDA then of these reports that come in? Or
2608 do they just sit until something happens? Do you know?

2609 Mr. {Hubbard.} Well, there is the paper process that
2610 says how it should work, and there is a way it apparently
2611 really works. What should have happened in that case is that
2612 state inspector should have been trained to an FDA standard,
2613 which I gathered didn't happen.

2614 Mr. {Stupak.} Right.

2615 Mr. {Hubbard.} Then they should have presented the FDA
2616 with the findings, but, of course as you know, the state
2617 inspector didn't find any problems. So, you know, I suppose
2618 you could argue there was nothing for FDA to follow up on.

2619 Mr. {Stupak.} But wouldn't the FDA at least have some
2620 standards like especially since you had the 97 ConAgra peanut
2621 butter outbreak? Wouldn't they at least inspect for
2622 salmonella?

2623 Mr. {Hubbard.} They did do guidance after that ConAgra
2624 example, and the way it works is the FDA actually commissions

2625 state officials. So when they go in, they carry two badges,
2626 the Georgia badge and the FDA badge. And they are supposed
2627 to do the equivalent of an FDA inspection, but that
2628 apparently did not happen in this case.

2629 Mr. {Stupak.} Correct, because a true FDA inspection
2630 takes a little bit of time. I think you indicated \$2,000 up
2631 to \$5,000 for an inspection and more than 8 hours.

2632 Mr. {Hubbard.} Yeah, on average, an FDA inspection of
2633 that nature would take a day to a day and a half, whereas
2634 state inspections are often done in a couple of hours.

2635 Mr. {Stupak.} So even if these inspectors are trained,
2636 certified, everything, you still need an internal audit of
2637 what they are doing, or someone at the FDA looking at this to
2638 make sure it is being done properly, do we not?

2639 Mr. {Hubbard.} I think you are right.

2640 Mr. {Stupak.} Okay, was there ever internal audits like
2641 that of state inspectors on foods? Do you know in your time
2642 there?

2643 Mr. {Hubbard.} You know, I am sorry. I don't know, but
2644 I would hope so.

2645 Mr. {Stupak.} Well, I think that is one of the
2646 questions in our follow up period that we are having next
2647 week is, you know, were there internal audits and what was
2648 going on with these things? One more if I may, Mr. Chairman.

2649 Mr. Lugg, you indicated that I think your first
2650 priority, you said, when you come to work on food is you
2651 select the land and then you watch the water and that. Is
2652 that in this country or other countries too? Chiquita
2653 bananas come from all over, right? Costa Rica, everywhere?

2654 Mr. {Lugg.} Yes, our company operates in approximately
2655 70 countries around the world, but particularly in the Fresh
2656 Express packaged salads, whether the product is coming from
2657 Guatemala, which we have to get our snow peas from in winter
2658 months, or down in Chile where get in the winter months. We
2659 send our own inspecting staff down to locate the land, and
2660 then we use special, global, geospatial technology to make
2661 sure that those lots are actually being harvested when they
2662 say they were.

2663 Mr. {Stupak.} Okay, what about the chemicals that they
2664 use during the process? Is that all approved by your
2665 company?

2666 Mr. {Lugg.} Those are chemicals that we approve, and
2667 then there are samples taken to make sure that they are
2668 within the residue limits.

2669 Mr. {Stupak.} Thank you, Mr. Chairman.

2670 Mr. {Pallone.} Thank you, Mr. Stupak. Let me thank the
2671 whole panel. I mean we are done with our questions, but, you
2672 know, we really do appreciate your input not only today but

2673 throughout the process. Mr. Stupak has had hearings and
2674 hearings in the full Government Reform Committee with Mr.
2675 Waxman. We do intend to move a bill. You know, I this
2676 subcommittee, probably our next hearing will be a legislative
2677 hearing on legislation that we would move. We are still
2678 waiting for the new FDA. I mean there isn't a commissioner.
2679 So we would still like to get that input. But, you know, it
2680 is our intention to move fairly quickly.

2681 So thank you very much. We appreciate all your input.
2682 Without objection, this meeting of the subcommittee is
2683 adjourned.

2684 [Whereupon, at 1:25 p.m., the subcommittee was
2685 adjourned.]