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1 {York Stenographic Services, Inc.}

2 HIF042.020

3 HEARING ON ``THE SALMONELLA OUTBREAK: THE CONTINUED FAILURE

4 TO PROTECT THE FOOD SUPPLY''

5 WEDNESDAY, FEBRUARY 11, 2009

6 House of Representatives,

7 Subcommittee on Oversight and Investigation

8 Committee on Energy and Commerce

9 Washington, D.C.

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

13 Members present: Representatives Stupak, Braley,
14 Markey, DeGette, Schakowsky, Christensen, Welch, Green,
15 Sutton, Barrow, Inslee, Pallone, Dingell, Waxman (ex
16 officio), Walden, Deal, Radanovich, Sullivan, Burgess,
17 Blackburn, Gingrey and Barton (ex officio).

18 Also present: Representative Bishop.

19 Mr. {Stupak.} This meeting will come to order.

20 First I want to take the opportunity to welcome all of
21 our new and returning members to the subcommittee. I am
22 honored to be able to serve as chairman for another term. I
23 want to welcome our new ranking member, Mr. Walden of Oregon,
24 and also Mr. Braley, the vice chair of this subcommittee.
25 You have been on the subcommittee for some time, Mr. Walden.
26 I look forward to working with you in a good, bipartisan
27 working relationship in the 111th Congress like we had in the
28 110th Congress.

29 I welcome Chairman Waxman in his new role as chairman of
30 the full committee. Mr. Chairman, I know you will serve us
31 well and will continue the tradition of aggressive and fair
32 oversight that this committee has become known for. I also
33 look forward to working with your staff along with Mr. Kevin
34 Barstow, who in this case here traveled once again to Georgia
35 to look at the peanut plants in Georgia as he did in 2007. I
36 think Kevin is going to be in every peanut plant in Georgia
37 if this keeps up, so I want to thank Kevin and Scott
38 Schloegel and the whole staff for all their hard work in
39 preparation for today's hearing.

40 I want to thank Chairman emeritus, John Dingell, the
41 gentleman from my home State of Michigan, for his long and

42 distinguished career in the House and here in the Energy and
43 Commerce Committee. I must note today in fact the first
44 resolution on the Floor today, so members will be moving back
45 and forth in and out of this committee to pay tribute to Mr.
46 Dingell as being the longest-serving Member in the history of
47 the U.S. House of representatives. He served more than 53
48 years and 2 months. As was noted in the ceremony honoring
49 Chairman Dingell last night, we will honor him for the time
50 he has served and we honor him more for what he has done
51 while serving. It is truly a pleasure and a privilege to
52 serve with Mr. Dingell and have him on this committee.

53 Now the business before us today. This hearing today
54 that we have is ``The Salmonella Outbreak: the Continued
55 Failure to Protect the Food Supply.'' We will begin with
56 opening statements. The chairman, the ranking member, the
57 chairman emeritus will be recognized for 5 minutes for an
58 opening statement, and other members will be recognized for 3
59 minutes for their opening statements. I should note, there
60 is a lot of interest in this hearing. We already have a
61 statement submitted by the record with unanimous consent.
62 Representative Sanford Bishop is here. He is from Georgia.
63 He has an interest in this. And also Mr. Barrow is here,
64 again not part of the subcommittee but he is a member of the
65 full committee. Mr. Green is here, so a lot of interest in

66 this hearing. So I will begin with the opening statement.

67 Since late 2008, the United States has been in the grips
68 of a nationwide outbreak of salmonella infections that to
69 this date is believed to have caused 550 illnesses and eight
70 deaths in 43 States. In January, public health officials in
71 Minnesota and Connecticut connected the outbreak to peanut
72 butter produced by the Peanut Corporation of America, PCA, at
73 its plant in Blakely, Georgia. This finding triggered a
74 series of recalls that have included all peanut butter and
75 other peanut products produced at the facility for the past 2
76 years and recalls by over 54 companies of more than 1,900
77 products containing the ingredients from the Blakely,
78 Georgia, and Plainview, Texas, facilities of PCA. The
79 recalls have cost business and government millions of
80 dollars. The psychological cost has been widespread concern
81 among parents of the millions of children nationwide who
82 daily enjoy peanut butter sandwiches, cookies, crackers and
83 other snacks. The President of the United States has
84 expressed the view of parents across America when he said
85 that his 7-year-old daughter eats peanut butter probably
86 three times a week and that, ``I don't want to have to worry
87 about whether she is going to get sick as a consequence to
88 having her lunch.''

89 Today's hearing will examine how this contamination was

90 allowed to grow unchecked and the collective failure of
91 multiple players--the peanut butter manufacturer, the Food
92 and Drug Administration, State regulators and private
93 industry--to take steps that might have prevented the
94 outbreak. This subcommittee is well versed on the issues we
95 address today. In the last Congress we held eight hearings
96 to examine the safety and security of the Nation's food
97 supply including one in April of 2007 in which we
98 specifically examined a similar outbreak arising from
99 salmonella contamination of peanut butter manufactured by
100 ConAgra.

101 Although we continue to learn new facts about the
102 outbreak in the Georgia facility at which it all started, the
103 facts we already know paint a very disturbing picture. When
104 the FDA inspectors entered the plant in Georgia, they found a
105 facility riddled with unsanitary and unsafe conditions
106 according to the inspector's preliminary report. Mold was
107 observed growing on the ceiling and walls in the cooler used
108 to store peanut butter products. A live roach and several
109 dead roaches were observed in the washroom adjacent to the
110 production/packaging area. Most importantly, salmonella was
111 found in two separate locations in the plant including the
112 one that was only 3 feet from finished peanut butter
113 products. Even more disturbing is the fact that Peanut

114 Corporation of America knew about salmonella contamination
115 for over a year and a half but did nothing to address it.
116 Internal company records reveal that since June 2007, PCA's
117 products tested positive for salmonella on 12 different
118 occasions but that the company continued to produce and
119 distribute its peanut butter products without consequence.

120 And we know that the multiple players had opportunities
121 to report or detect the contamination but failed to do so.
122 The FDA had the authority to conduct inspections at the PCA
123 facility and to test for salmonella, but when the FDA sent
124 state inspectors to the plant on its behalf in 2007 and 2008,
125 it did not test for salmonella, even though both visits
126 occurred after the 2007 salmonella outbreak traced to the
127 ConAgra plant just 70 miles down the road from the PCA plant.
128 One of these inspections occurred just one day after PCA-
129 manufactured product had tested positive for the presence of
130 salmonella. The Georgia Department of Agriculture conducted
131 two inspections of the Blakely plant in 2008 but did not
132 conduct tests for salmonella on either occasion despite an
133 internal goal to conduct such tests once a year. Private
134 laboratories that conducted the tests when PCA had firsthand
135 knowledge of the positive findings of salmonella failed to
136 report those results to anyone but the company. Neither the
137 FDA nor the State of Georgia requested access to those

138 records until after the salmonella outbreak. PCA's largest
139 customers such as Kellogg's engaged contractors to conduct
140 audit of the Blakely plant but they did not conduct their own
141 salmonella test and did not require PCA to show them their
142 internal test results, which would have revealed a consistent
143 pattern of salmonella contamination.

144 So we appear to have a total systemic breakdown with
145 severe consequences for hundreds of victims for which we need
146 explanation. That is why we have asked representatives from
147 each of these players, the manufacturer, the FDA, the State
148 regulator, the private laboratories as well as victims of
149 this outbreak to testify today. At this hearing we will seek
150 answers to the following questions. What has been the human
151 impact of this outbreak? How could the company, regulators,
152 laboratories and industry let the salmonella contamination
153 remain hidden for over a year before the outbreak? What
154 legislative or regulatory changes can be implemented to
155 prevent such catastrophic failures in the future? On this
156 last question, it bears noting that we already have a vehicle
157 for change in this area, H.R. 759, the FDA Globalization Act
158 of 2009, which I am sponsoring along with Congressmen Dingell
159 and Pallone.

160 I look forward to today's testimony as an opportunity to
161 gather additional information with which to shape this

162 legislation to address the public health impact of this and
163 similar outbreaks. If there any good that can come from this
164 tragic outbreak, it could come from long-overdue legislative
165 change to protect the American people from dangers in the
166 Nation's food supply.

167 [The prepared statement of Mr. Stupak follows:]

168 ***** COMMITTEE INSERT *****

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169 Mr. {Stupak.} Next I would turn to my ranking member,
170 Mr. Walden, for his opening statement, please.

171 Mr. {Walden.} Thank you very much, Mr. Stupak, and Mr.
172 Chairman, I look forward to working with you in my new role
173 as the ranking Republican on the Oversight and Investigation
174 Subcommittee. We have worked together on issues before for
175 many years to protect the safety of Americans in many
176 different ways and to improve security and other things in
177 agencies. So I look forward to our work together.

178 Ladies and gentlemen, I remember our previous food
179 safety investigations into E. coli in spinach, E. coli in
180 meat, salmonella in peanut butter, salmonella in jalapenos,
181 now salmonella in a variety of peanut-containing products.
182 This container is full of products that less than a month ago
183 people were consuming thinking it was fine to eat, and one of
184 the things I am going to do today is ask Mr. Parnell from
185 Peanut Corporation of America if he would like to open this
186 and sample some of the products that he didn't think were a
187 problem in sending out to the rest of us to eat. Now, there
188 are some recalled products in here and there are some that
189 are probably okay now. Lives were lost and people were
190 sickened because they took a chance and I believe knowingly
191 shipping product that was contaminated.

192 Yesterday we learned there is another plant in Texas
193 that the FDA didn't even know existed that apparently has
194 never been inspected and now we learn there was salmonella in
195 that plant as well. This is simply outrageous.

196 The latest outbreak of salmonella has sickened 11 people
197 in my home State of Oregon. It has touched the lives of
198 teenagers in Baker County and toddlers all the way the other
199 side of the State in Medford and in Wilsonville. Pets have
200 now been added to the list of those falling ill from
201 salmonella-tainted products. A dog in Oakland, Oregon,
202 apparently is the first animal illness in the Nation linked
203 to recalled products.

204 Today we will hear from a witness from one of these
205 affected families, Peter Hurley. Mr. Hurley, I welcome you
206 and your wife and your three children today. Jacob is here.
207 Three-year-old Jacob, do you want to stand up and give a wave
208 there? You are going to hear about Jacob's story. Jacob
209 became sick in January. For about 2 weeks Peter and his wife
210 watched as poor Jacob got sicker and sicker and they
211 consulted their pediatrician and sought counsel and advice
212 and poor Jacob apparently couldn't keep anything down. The
213 pediatrician said well, what does Jacob like to eat because
214 at least maybe we can get him to eat what he likes to eat and
215 help him along. Austin peanut butter crackers is his

216 favorite. So he continued to peanut butter crackers, and
217 eventually as the news came forward that those crackers and
218 other products like those in this container may well be
219 containing salmonella, a State epidemiologist showed up at
220 their house on a Saturday night, took the crackers, and from
221 what I understand, every other package was contaminated with
222 salmonella. Can you imagine the tragedy as a parent of
223 knowing that in effect you have been poisoning your 3-year-
224 old child with the help of your pediatrician, none of whom
225 knew this was the problem until the damage was done?

226 Salmonella is a naturally occurring microorganism. It
227 is usually transmitted to humans by eating contaminated
228 foods. To reduce the risk of contamination, we require food-
229 processing firms to follow the Food and Drug Administration's
230 current Good Manufacturing Practices that serve as the
231 minimum sanitary processing requirements for producing safe
232 food. Failure to comply with the Good Manufacturing
233 Practices is a violation of law, and if noncompliance leads
234 to the distribution of adulterated or contaminated foods,
235 more severe penalties may be applicable. Good Manufacturing
236 Practices also serve as the basis for food-firm inspections
237 conducted by the FDA and by State government inspectors.

238 Now, the Peanut Corporation of America, whose president
239 and plant manager are invited witnesses today, has been

240 identified as the sole source of this salmonella outbreak.
241 Several of the company's products were tainted with
242 salmonella at the PCA plant in Blakely, Georgia, and shipped
243 to more than 100 consignee firms that serve as suppliers to
244 food producers large and small for use as an ingredient in
245 hundreds of different products such as cookies, crackers, ice
246 cream, cereal and candy. At least two Oregon companies I am
247 aware of have had to recall their products because they
248 included ingredients that were sourced back to PCA. The
249 health implications are all too clear, as our witnesses will
250 testify today. Additionally, there are economic consequences
251 for the food producers that use those ingredients and had to
252 conduct those recalls.

253 As FDA has reported and as indicated in documents
254 obtained by this committee, the Peanut Corporation of America
255 routinely violated numerous Good Manufacturing Practices and
256 knowingly shipped adulterated products to its customers. In
257 an internal e-mail chain between the plant manager, Sam
258 Lightsey, and the president, Steward Parnell, the two men
259 discussed microbial testing completed on finished product.
260 The e-mails state the company was notified of a confirmed
261 positive salmonella test on a sample conducted by an outside
262 lab. That sample was tested again and a negative reading
263 occurred. Then Peanut Corporation of America shipped

264 contaminated product to another outside lab and received a
265 negative result. In response to getting a negative result,
266 the company president gave instructions to his plant manager
267 to ship the salmonella-positive products, specifically
268 telling them ``turn them loose.'' Another e-mail from Mr.
269 Parnell, the president wants to discuss another positive test
270 of salmonella and the time lapse in the shipment of product
271 as a result. Mr. Parnell expresses his concern of losing
272 huge amounts of dollar sign, dollar sign, dollar sign, dollar
273 sign, dollar sign due to delays in shipment and costs of
274 testing. It appears Mr. Parnell was more concerned about his
275 company's bottom line than the food safety of Americans.

276 Expert witnesses will explain that a subsequent negative
277 test result for salmonella on a sample never, never negates
278 the initial finding of a confirmed positive. In response to
279 a confirm positive, PCA should have immediately destroyed the
280 entire lot of contaminated product, ceased production and
281 attempted to uncover the root cause of the contamination.
282 All these steps are part of the FDA's manufacturing
283 requirements that firms are forced to follow, required to
284 follow.

285 FDA must enhance the GMPs for food and get stronger
286 authority. Food firms should be required to give FDA access
287 to records that show compliance, prove that kill step for

288 pathogens actually works and confirm sanitation and
289 protection against cross-contamination. To help prevent
290 outbreaks in the future, FDA inspectors must have access to
291 internal documents. We must assure the public the food on
292 our grocery shelves is safe and what we put into our mouths
293 and those of our children, elderly parents and even our pets
294 is safe. While Congress moves on legislation, our food
295 safety agencies and food manufacturing firms can take
296 immediate action to improve the production of safe food, and
297 I suggest that we demand those actions now, Mr. Chairman.
298 Thank you.

299 [The prepared statement of Mr. Walden follows:]

300 ***** COMMITTEE INSERT *****

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301 Mr. {Stupak.} Thank you, Mr. Walden. I suggest you
302 keep your contaminated products on your side of the aisle.
303 That would be a new way to get back into the majority but we
304 will pass on that.

305 Mr. Waxman, opening statement, please, sir.

306 The {Chairman.} Thank you very much, Mr. Chairman. I
307 am pleased to see you continuing your aggressive oversight on
308 the issues of food safety and I am pleased also to see that
309 you are working with our counterparts on the Republican side,
310 especially Ranking Member Walden, to do this in a bipartisan
311 basis. There is no partisanship when it comes to questions
312 of food safety. We are shocked at what has been going on in
313 this country on food issues, and what this committee needs to
314 do is to find out the truth, hold people accountable and make
315 sure it doesn't happen again.

316 For too long, people have been worried about this and
317 they want to know what is happening, who is responsible.
318 Well, we are going to hear in this first panel that those who
319 most often pay the price are the young, the elderly and the
320 infirmed because these tainted products distributed by the
321 Peanut Corporation of America were sent to elementary
322 schools, nursing homes, hospitals and even FEMA meal kits
323 handed out in the wake of the Kentucky ice storms. We are

324 going to hear today the results of our subcommittee's
325 investigation and we have obtained documents that I would ask
326 unanimous consent be made part of the record.

327 Mr. {Stupak.} Without objection.

328 [The information follows:]

329 ***** COMMITTEE INSERT *****

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330 The {Chairman.} These documents obtained by our
331 subcommittee are very disturbing because what they show is
332 that this company cared more about its financial bottom line
333 than it did about the safety of its customers. Last
334 September, for example, PCA was notified by a private lab
335 that its products had testified positive for salmonella.
336 This wasn't the first positive test the company received and
337 it may not be the last. In response, the president of the
338 company sent an e-mail. Stewart Parnell was complaining that
339 the positive salmonella tests were costing them huge amounts
340 of money, and I see on the screen that we are flashing up
341 this e-mail. ``There is going to be a huge lapse in time
342 from the time we pick up peanuts until the time we can
343 invoice.'' Well, even after the FDA began investigating in
344 January and forced the company to recall some products, PCA's
345 first concerns were financial. On January 19, Mr. Parnell
346 sent an e-mail pleading with the FDA officials to allow the
347 company to keep doing business. He wrote that they
348 ``desperately at least need to turn the raw peanuts on our
349 floor into money.'' He assured the FDA that these peanuts
350 would be cooked and further processed by their Texas
351 facility. This Texas facility is the same one that was shut
352 down yesterday after salmonella was found there too.

353 The subcommittee also obtained documents that appear to
354 show that Mr. Parnell was not forthcoming about his company's
355 past. Despite multiple records showing positive salmonella
356 tests over 3 years, he wrote an e-mail to his company's
357 employees on January 12 asserting flatly that, ``We have
358 never found any salmonella at all,'' and he blamed the news
359 agencies. They are looking for news stories that are going
360 to scare people about the cause of this food sickness
361 outbreak. The subcommittee obtained a statement from an
362 official at one of the private labs used by PCA to test for
363 salmonella. The lab official reported that PCA's plant
364 manager in Georgia, Sam Lightsey, admitted to shipping
365 products before receiving lab results. The official stated,
366 ``When I called Mr. Lightsey in early October 2008 to give
367 him the serology reports that JLA obtained from the lab for
368 the confirmed salmonella, he paused and said uh-oh or
369 something to that effect and then told me he had released the
370 product for shipping. When I asked him if he could get it
371 back, he said it was on a truck heading to Utah.'' This lab
372 official also informed us that PCA stopped using its services
373 because it received too many positive tests. The official
374 stated, ``I called Mr. Lightsey to follow up on the recent
375 discussion regarding the confirmed positive and he confirmed
376 that because of the high coliform results, they are going to

377 send samples to a different lab.''

378 Mr. Chairman, I want all these documents in the record.
379 I want them to be made public. I hope that in this hearing,
380 we are going to be able to find out more about the actions of
381 these PCA officials. I look forward to hearing from the labs
382 that conducted these tests as well as the State and federal
383 officials in charge of overseeing this company, and I also
384 want to extend my condolences to the victims and family
385 member, the victims who are here today. We have got to find
386 out the truth. We have got to hold people accountable and we
387 have got to make sure that this doesn't continue in the
388 future.

389 Thanks for your hard work and the aggressive oversight
390 that I know you are committed to. I yield back the time.

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

392 ***** COMMITTEE INSERT *****

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

394 I next turn to Mr. Barton of Texas for an opening
395 statement.

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

397 Today you are going to see Congress at its best and at
398 its worst. This subcommittee hearing is Congress at its
399 best. We have an issue that affects the public health and
400 safety of American people. We have a chairman and a
401 subcommittee chairman who have quickly acted to bring it to
402 the country's attention, to bring witnesses forward both from
403 the victims' side and from the regulatory side and also give
404 an opportunity for the affected party, the company in this
405 case, to present their side of the story. That has been done
406 on a bipartisan basis with full cooperation including
407 yesterday a full committee meeting, business meeting, where
408 we unanimously voted to subpoena to compel some of the
409 witnesses that didn't want to voluntarily testify to come
410 before the Congress so that people would know. That is
411 Congress at its best. Mr. Waxman and Mr. Stupak are to be
412 commended for their leadership.

413 I also want to commend Mr. Walden, the new ranking
414 member on the Minority side, for the best opening statement I
415 have heard in 22 years in an oversight hearing, and that goes

416 back to John Dingell, Billy Tozan, Tom Bliley, Mr. Waxman and
417 others who have always specialized in aggressive oversight.
418 He put the case succinctly. He put the case in personal
419 terms. He did it in a way that we can understand. So that
420 is Congress at its best.

421 Unfortunately, today we are also going to see Congress
422 at its worst. We have the stimulus package that is in limbo
423 somewhere in conference between the Senate and the House of
424 Representatives, and the House conferees were appointed
425 yesterday. This committee, who has got jurisdiction for
426 approximately \$100 billion of that stimulus, including all
427 the healthcare issues, all the telecommunications issues, all
428 the energy issues, all the environmental issue has one
429 conferee, the chairman of the committee. Nobody on the
430 Minority side. It is a very small conference but the Speaker
431 has seen fit that the Minority doesn't count. Our voice
432 doesn't count. Well, I have a prediction to make. By the
433 end of the day or the end of the week, they are going to hear
434 the voice of the Minority on this issue. We need to do
435 something to help the economy for this country, we need to do
436 it cooperatively on a bipartisan basis, but when you shut one
437 side out, it makes it very difficult to work in a positive
438 fashion.

439 So on a positive note, this is an important hearing. We

440 are totally supportive. Whatever the results of the hearing
441 are, I am sure we will work together to implement those, but
442 on the other issue, it is not democracy when only one side
443 has a voice.

444 With that, Mr. Chairman, I yield back.

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

446 ***** COMMITTEE INSERT *****

|
447 Mr. {Stupak.} Thank you, Mr. Barton.

448 By order of appearance, members will be recognized for 3
449 minutes for an opening statement. Next would be Mr. Green
450 from Texas.

451 Mr. {Green.} Thank you, Mr. Chairman. I want to thank
452 you for holding the hearing today. Last year we had many
453 hearings on food safety, but unfortunately, the committee was
454 never able to pass a food safety bill. The recent salmonella
455 outbreak is yet another example of how the FDA and State
456 agencies are unable to protect the American food supply. The
457 committee's investigation has shown that Peanut Corporation
458 of America was operating with blatant disregard for safety
459 standards, which ultimately led to at least eight deaths and
460 sickened 600 individuals. Investigations by this committee
461 found the Peanut Corporation of America shopped for labs that
462 gave them negative salmonella results after originally
463 testing positive, that they would not wait for the results
464 and would ship the products out for consumption without
465 ensuring they were safe for consumption. Peanut Corporation
466 of America's plants are also in deplorable condition,
467 especially the plant in Georgia with cockroaches near the
468 peanuts, water leakage, mold and unsanitary production line.
469 On the 3rd we learned that the Peanut Corporation of

470 America was operating an unlicensed and uninspected plant in
471 Plainview, Texas. This plant was never inspected until the
472 FDA began investigating the salmonella outbreak, at least
473 never inspected by the FDA. Unfortunately, my home State of
474 Texas is one of the states where the FDA relies on our State
475 inspectors to oversee food safety. On Monday the Texas
476 Department of State Health Services shut down the Plainview
477 plant after it tested positive for possible salmonella. It
478 is unbelievable that a food-processing plant can deliver
479 possibly tainted products into our food supply without a
480 license and without ever being inspected. One thing is
481 clear: No plant should be able to operate in the manner in
482 which the Peanut Corporation of America has operated.

483 Congress, myself included, said for years that the FDA
484 is underfunded, and that is still true, but throwing money at
485 them will not solve the problem. We need to overhaul the way
486 the FDA reviews and inspects our food-processing plants and
487 food supply. This committee, Congress and the new
488 Administration must do all we can to shut down those unlawful
489 operators and find a new way to protect the American food
490 supply.

491 Again, I want to welcome our witnesses here,
492 particularly the children. I have a 4-year-old granddaughter
493 who loves peanut butter and crackers. In fact, as I sit here

494 today, my son, they are having a new baby this morning in
495 south Texas, a little boy, and all of them, all my
496 grandchildren eat peanut butter and I have a jar here, and I
497 didn't bring it to check it for salmonella, but anyway, it is
498 so important for the American people literally from our
499 smallest citizens to our oldest.

500 Thank you, Mr. Chairman.

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

502 ***** COMMITTEE INSERT *****

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503 Mr. {Stupak.} Thank you, Mr. Green.

504 Mr. Deal for an opening statement, please, 3 minutes.

505 Mr. {Deal.} Thank you, Mr. Chairman.

506 First of all, I would like to welcome the deputy
507 commissioner of agriculture from the State of Georgia, Mr.
508 Terry Coleman, who by the way is a former speaker of the
509 Georgia House of Representatives as a Democrat, Mr. Chairman,
510 and also Mr. Oscar Garrison, who is the assistant
511 commissioner of agriculture of the Georgia Department of
512 Agriculture, who is going to testify on one of our panels.

513 Mr. Chairman, our Nation has always prided itself on
514 having the safest food supply in the world. This confidence
515 is founded on the hard work of those who grow, process,
516 package and deliver our food coupled with the oversight and
517 inspections provided by the federal agencies such as FDA and
518 USDA working with their comparable State regulatory
519 authorities. Let no one misunderstand, however, we are all
520 outraged by the alleged violations of law and common
521 standards of safety which are the focus of this hearing, and
522 our sympathy goes out to those who were injured and to those
523 who have suffered losses. Although I am a resident of the
524 State of Georgia where the production of peanuts is a vital
525 part of our State's economy, there will be no statements of

526 provincial protectionism from me for it is those who are
527 closest to the problem that are the most infuriated by it for
528 we know that the vast majority of those who produce peanuts
529 and the resulting products are decent, law-abiding people.
530 Right now peanut farmers are poised to plant this year's
531 crop. The uncertainty created by the actions of Peanut
532 Corporation of America will cost them millions of dollars.
533 They and many more in the chain of production have done
534 nothing wrong but they are suffering the consequences of the
535 questionable actions of one company. These innocent
536 individuals and companies are more concerned than almost
537 anyone that the cloud of suspicion be removed from the peanut
538 industry.

539 As legislators, we should be asking how we can make the
540 system work better. I am sure we can learn from this
541 unfortunate experience how to reform our inspections system
542 at both the federal and state levels. In fact, the Georgia
543 General Assembly is in session right now and is considering
544 legislation to strengthen the role of our State inspections
545 and oversight. We have the responsibility to shake the
546 scales of justice as it relates to food safety but the
547 architect whose eyes are focused only on the actions of the
548 most egregious will design scales of justice that will not
549 work for it fails to account for the overwhelming weight of

550 the majority who are honest and law abiding. That is our
551 challenge as we go forward to ensure the safety of all
552 without destroying the underlying industry.

553 I am confident that the peanut industry of my State and
554 the Nation will work cooperatively with this committee, with
555 this Congress and the legislatures of the various States to
556 craft reforms that will restore the confidence of the
557 American people in the safety of peanut products. Toward
558 that end, I pledge my best efforts, for after all, the good
559 health of the American public and in fact the fate of the
560 peanut butter and jelly sandwich lie in the balance.

561 Thank you, Mr. Chairman.

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

563 ***** COMMITTEE INSERT *****

|
564 Mr. {Stupak.} Thank you, Mr. Deal.

565 Next we will hear from Mr. Braley, the vice chair of the
566 subcommittee, a new member of the committee. Welcome.

567 Mr. {Braley.} Thank you, Mr. Chairman. I just want to
568 tell you how honored I am to be serving as your vice
569 chairman. I look forward to working with you and Ranking
570 Member Walden on the important work of the committee.

571 As I was preparing for the hearing today, I thought of
572 Upton Sinclair and what he must be thinking as we sit hear
573 nearly 100 years after the publication of The Jungle facing
574 the very same food questions that dominated the discussion of
575 this Capitol over 100 years ago, and that was highlighted by
576 this advertisement that appeared in USA Today where we have
577 the unbelievable aspect of corporations paying thousands of
578 dollars to say ``it ain't me'', and as we focus on the
579 important topics we are here to talk about today, we need to
580 keep in mind the enormous economic consequences to people who
581 are not involved in this contamination as well.

582 This recent outbreak of salmonella in peanut products
583 has resulted in the recall of over 1,700 products, one of the
584 largest recalls ever under the jurisdiction of the FDA, but
585 this outbreak is not just disturbing because of its size. It
586 is particularly troubling because of its impact on Americans

587 most vulnerable to tainted food. As noted in the Monday
588 issue of USA Today, salmonella affects people who are most
589 vulnerable depending upon the strength of their immune system
590 and how old or young they are, and we all know that
591 salmonella is most dangerous to very young children. Given
592 that, I think it is outrageous that the contaminated King Nut
593 peanut butter, which was the product in which the source of
594 this salmonella outbreak was first located, was distributed
595 to nursing homes, hospitals and schools.

596 Yet the serious concerns I have about the severity of
597 the effects of salmonella on children are only compounded by
598 the sheer popularity of peanut butter and peanut butter
599 snacks among children. As President Obama noted recently,
600 peanut butter is very prevalent in the diets of young
601 children like his daughter Sasha. As a parent, I know this
602 firsthand. I am also concerned as a parent that three States
603 have had to remove tainted Peanut Corporation of America
604 products from their school lunch programs. These States
605 receive peanut butter or roasted peanuts from the Federal
606 Government, which bought them from the Peanut Corporation of
607 America. It is completely unacceptable that our Nation's
608 schools could be serving children products that could make
609 them severely ill or kill them and that the Federal
610 Government would be purchasing and distributing these

611 potentially dangerous products to our schools.

612 There are many questions that need to be answered today
613 about the practices of Peanut Corporation of America, about
614 the FDA and State inspections of their plants, and about the
615 general safety of our food supply. One thing that is clear
616 is that we need to be doing a much better job of protecting
617 Americans, particularly children and other vulnerable
618 populations, from unsafe food products. I look forward to
619 hearing the testimony of the witnesses and hope that this
620 hearing will help to determine what Congress needs to do to
621 prevent these outbreaks in the future and ensure the safety
622 of our Nation's food supply.

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

624 ***** COMMITTEE INSERT *****

|
625 Mr. {Stupak.} Thank you, Mr. Braley.

626 Mr. Gingrey for an opening statement, please. I guess
627 he is not there.

628 How about Mr. Burgess for an opening statement? Order
629 of appearance we have been going by. Mr. Burgess.

630 Mr. {Burgess.} Thank you, Mr. Chairman.

631 Mr. Chairman, it seems like we have been here before.
632 We have previously established that there are serious
633 problems within the FDA. In the last Congress we had 16 FDA-
634 related hearings. Now we begin a new session of Congress
635 with a hearing on the Food and Drug Administration and their
636 role in inspecting the Peanut Corporation of America, the
637 source of over 553 salmonella-related illnesses and at least
638 eight deaths. Mr. Chairman, this is like a bad movie and we
639 all have read the script before. In 2007, we investigated
640 the Food and Drug Administration's role with ConAgra and the
641 salmonella illness in their peanut-based products, and just
642 like today, in 2007 it was the State of Georgia which was the
643 source of the salmonella and peanut-based products, so it is
644 not just a bad movie script, it is a deadly one, and it has
645 got the same theme, salmonella, the same actors, the Food and
646 Drug Administration and the State of Georgia, but with one
647 crucial difference: this time there is the possibility of

648 criminal activity by the Peanut Corporation of America. And
649 we know that the Peanut Corporation of America engaged in
650 deliberate misconduct in this case. We know that the Peanut
651 Corporation of America not only retested salmonella-positive
652 batches of peanut products, they intentionally shipped the
653 products to their unsuspecting clients. At least 75
654 companies, 16 different food categories make over 1,000 types
655 of consumer foods with peanut products made by the Peanut
656 Corporation of America and then they put them in front of the
657 whole world for our consumption. It is no wonder in the past
658 month, it seems like almost on every newscast at the top of
659 every hour we are notified of yet another recall of yet
660 another product creating yet another crisis, a crisis in an
661 already troubled economy.

662 Mr. Chairman, this is a deliberate act that is almost
663 astonishing in its cruelty. It is a violation not only of
664 the trust of the American consumer but also of their business
665 partners. The president of the Peanut Corporation of America
666 could give us answers, should give us answers, but we won't
667 get them today because it is my understanding, that
668 individual is going to plead his Fifth Amendment rights.
669 Boy, I would love to ask, how did you think this was going to
670 work out for you.

671 I also continue to be troubled by how much the Food and

672 Drug Administration needs our attention and modernization.
673 They need more powers like the mandatory recall power, which
674 I had previously advocated, as well as the power to retrieve
675 all records for any food company being investigated. But no
676 matter how much demand greater action and accountability from
677 the Food and Drug Administration, we can only hold the Food
678 and Drug Administration accountable for the laws that are
679 there and then businesses like the Peanut Corporation of
680 America, they violate not just the law but the fundamental
681 tenets of their business practices. It is not any longer
682 about following the rules of the FDA. It is just about being
683 a good citizen of the world. So for me, yeah, it is time
684 again to focus on the Food and Drug Administration and how we
685 need to work on the Food and Drug Administration and help it
686 in its mission but we also should focus on punishing the bad
687 actors in this case.

688 Mr. Chairman, now it is a criminal matter, and although
689 we need to work to continue to modernize the FDA by giving
690 them the money and the power they need to continue to protect
691 our citizens, you know, there is not a night that goes by it
692 seems that Lou Dobbs doesn't end his newscast by saying,
693 ``Doesn't anyone deserve a government that works?'' and that
694 is not just a rhetorical question, Mr. Chairman.

695 Mr. Chairman, let me ask that this committee answer Mr.

696 Dobbs in the affirmative. Let us make it unambiguous. Let
697 us make it a bipartisan affirmative and let us also commit
698 that from this hearing forward we will make our actions match
699 our rhetoric, and I will yield back.

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

701 ***** COMMITTEE INSERT *****

|
702 Mr. {Stupak.} Thank you, Mr. Burgess.

703 Ms. Christensen for an opening statement. Welcome to
704 the committee.

705 Ms. {Christensen.} Thank you, Mr. Chairman, and good
706 morning, Chairman Waxman, Chairman Stupak, Ranking Members
707 Barton and Walden. This is my first hearing with the
708 Subcommittee on Oversight and Investigations and I am glad to
709 be here but I am really sickened by the reasons that we are
710 meeting this morning.

711 The recent salmonella outbreak demonstrated clear and
712 serious deficiencies in our country's food safety system,
713 some based on centuries-old legislation, and so this hearing
714 is very important to fixing the problems that cause so much
715 preventable illness and the eight deaths that should not have
716 happened, so thank you for holding it, and thank you also to
717 those who are here to testify, especially the families of
718 those who suffered because of the unscrupulous, likely
719 criminal business practices and the fact that our government
720 failed you. I extend condolences to the Almer and Tousignant
721 families, and to Mr. and Mr. Hurley, we are glad to see that
722 Jacob is well enough to be here with us today.

723 For the past several months we have heard countless
724 reports about the salmonella outbreaks, and with each story

725 and each investigation we learn a bit more about how many
726 gaps there are in our Nation's processes to ensure food
727 safety. We have also learned how key agencies such as FDA
728 lack the authority, resources and oversight that they clearly
729 should have to ensure the safety of our food and the health
730 of our families and our loved ones. Finally, we have learned
731 about the tragic consequences that these gaps in food safety
732 have on innocent lives, consequences that could have been
733 avoided, should have been avoided and consequences that I
734 look forward to working with you, my colleagues on this
735 committee, to avoid in the future.

736 Thanks to Mr. Dingell, Mr. Pallone and Mr. Stupak, who
737 have already launched an effort that is heading us in the
738 right direction with the introduction of H.R. 759, the Food
739 and Drug Administration Globalization Act of 2009, which I am
740 proud to cosponsor. Through provisions which empower the FDA
741 with additional resources and mandatory recall authority as
742 well as oversight over and access to the safety plans of food
743 service facility established as well as access to those tests
744 that are conducted to measure safety and inspection records,
745 we are finally on a better path to prevention. We know those
746 measures are too late for the precious lives that have been
747 lost and the others that were put in jeopardy, lives of some
748 of more vulnerable people, those in nursing homes, hospitals

749 and schools, all because we had to wait for a company to
750 initiate the recall of a product that they knew was tainted,
751 that they knew would make people sick just to protect their
752 profit margins.

753 There is plenty of blame to go around because many balls
754 were dropped. The only blameless ones in all of this are the
755 individuals who died, those who got sick and their families
756 and loved ones. If for no one else, let this hearing be
757 about them and let the lessons we learn and the next steps we
758 take to ensure that their suffering is not forgotten.

759 Thank you, Mr. Chairman. I yield back the balance of my
760 time.

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

762 ***** COMMITTEE INSERT *****

|
763 Mr. {Stupak.} Thank you.

764 Mr. Radanovich for an opening statement, please.

765 Mr. {Radanovich.} Thank you, Chairman Stupak and
766 Ranking Member Walden. Also I want to thank Mr. Waxman and
767 Mr. Barton for holding this important hearing on the outbreak
768 of salmonella in peanut products.

769 As a representative of one of the largest agriculture
770 producing districts in the Nation, I am keenly aware of the
771 importance of food safety as a public health hazard and also
772 as an issue of national security. However, what truly makes
773 me more concerned about food safety, it is not so much my
774 role as a Member of Congress but as a father of a 10-year-old
775 boy who happens to love peanut butter and jelly sandwiches.
776 Parents these days have so many things to worry about. It is
777 unfortunate that peanut products, which are often a staple in
778 the diet of a 10-year-old boy, have been added to this list.
779 Even with the best parenting in the world, there are some
780 things that are out of our control as parents. My wife and I
781 can choose to avoid packing my son peanut products in his
782 lunch but that doesn't stop him from trading his granola bar
783 for trail mix that has salmonella-tainted peanuts in it.

784 My condolences go out to those who have lost your loved
785 ones and to those who have been tragically affected by the

786 salmonella outbreak, it was an avoidable situation, and I am
787 looking forward to hearing the testimony from the witnesses
788 and learning how Congress can help prevent situations like
789 this from reoccurring.

790 So I look forward to the hearing and what we might learn
791 from it, and Mr. Chairman, I yield back.

792 [The prepared statement of Mr. Radanovich follows:]

793 ***** COMMITTEE INSERT *****

|
794 Mr. {Stupak.} Thank you.

795 Ms. Sutton for an opening statement, 3 minutes. Welcome
796 to the committee.

797 Ms. {Sutton.} Thank you, Mr. Chairman.

798 On Christmas Day, my local newspaper had a story about a
799 resident in a Summit County nursing home, that she was very
800 ill, and on top of many other medical conditions she suffered
801 from fever, abdominal cramps and diarrhea. Doctors diagnosed
802 this woman with a case of salmonella, and a few weeks later
803 she died. The woman I speak is one of the eight people who
804 died of salmonella and is among the 550 people nationwide who
805 became sick as a result of this bacteria. According to the
806 Ohio Department of Health, there have been 89 cases of
807 salmonella reported in Ohio in the past 4 months. This
808 figure is much higher compared to occurrences in other
809 States.

810 Mr. Chairman, this outbreak demonstrates yet again that
811 our food inspection system is broken. The source of the
812 salmonella was traced to a factory in Georgia, we have heard,
813 called the Peanut Corporation of America, or PCA, and on
814 multiple occasions PCA's peanut products have tested positive
815 for salmonella. PCA still shipped their products to schools,
816 nursing homes and stores, despite that. Now there is a

817 document on the FDA website with 288 pages worth of recalled
818 products that include peanuts. The negligent practices in
819 this food manufacturing plant are unacceptable and the
820 government must do more to protect Americans. Regulatory
821 agencies like the FDA, they need more power and they must
822 execute more power and oversight to prevent another
823 catastrophe like this. This is why I reintroduced the
824 Protect Consumers Act. This bill is very simple. It would
825 give the FDA mandatory recall authority over food products.
826 Mandatory recall authority is only one of the critical steps,
827 and there are other bills out there that are equally
828 important and more comprehensive but just taking this simple
829 step is a step that we should pursue with haste. Currently,
830 the FDA is forced to rely on the company at issue to do the
831 right thing, and we know that that isn't a good way to
832 operate.

833 I look forward to hearing from PCA to learn why they
834 continued to sell their contaminated products. I am also
835 eager to hear from government officials to learn about their
836 role in the recall and I look forward to working with my
837 colleagues here on the committee to fix our broken system so
838 that America's families can trust that the food they are
839 eating is safe. That is not too much to ask.

840 Thank you.

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

842 ***** COMMITTEE INSERT *****

|
843 Mr. {Stupak.} Thank you.

844 Ms. Blackburn for an opening statement, please.

845 Ms. {Blackburn.} Thank you, Mr. Chairman. Thank you
846 for the hearing, and I want to thank our witnesses for taking
847 their time to come before us today.

848 As you have heard, FDA review and oversight is not new
849 to this committee. This is something that we have gone over
850 and over and over during my 4 years on this committee, and
851 Mr. Chairman, I sit here and I am listening to the opening
852 statements and looking at our witnesses and I think, how many
853 more Americans are going to have to be affected by some type
854 of illness or worse before we get down to the basics on
855 review, reform and accountability that is lacking in the
856 system that is before us. I think it is unacceptable for the
857 American public's health, and indeed, their life in many
858 cases to be put at risk.

859 Now, peanuts, as you have heard, this is why we are
860 here. This is the latest of our contamination issues in our
861 food supply, and it is so unfortunate that contaminated
862 product was knowingly shipped to various locations, some in
863 my State of Tennessee, and indeed, we express our sympathies
864 to the families who have been injured, harmed or experienced
865 loss of life because of this. We have 11 cases that are in

866 Tennessee alone. Indeed, this is something that could have
867 been prevented. We all know the source. We have discussed
868 that with Peanut Corporation of America. We are going to
869 look more into that today. And one thing that I am really
870 going to want to know a bit more about is how there could
871 have been 12 known cases of salmonella between June of 2007
872 and September of 2008, how there could have been 12 times
873 that this was known and appropriate action was not taken.
874 And what the American people are wanting to see is not more
875 rhetoric, they want to see action, and Mr. Chairman, I think
876 that is where reforming this system comes forward as what our
877 next step should be to make certain that the American people
878 can trust us to do our job, to reform the system so that they
879 have trust in the food supply and the product that is placed
880 on their shelves, and I yield back the balance of my time.

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

882 ***** COMMITTEE INSERT *****

|
883 Mr. {Stupak.} Thank you.

884 Ms. DeGette for an opening statement. Ms. DeGette is
885 vice chair of the full committee.

886 Ms. {DeGette.} Thank you so much, Mr. Chairman. We
887 spend a lot of time together in these food safety hearings,
888 and I want to welcome our new members of the committee. I
889 have been on this subcommittee for 12 years now, and since I
890 have been on this subcommittee this is our 10th food safety
891 hearing at which the members of the Oversight and
892 Investigation Subcommittee spend quite a bit of time in a
893 bipartisan way wringing our hands.

894 Now, in the meantime, with the latest problem, over 500
895 people have been sickened, 15 of them are in my home State of
896 Colorado, half of the sickened people are children, and eight
897 people have died. This is the deadliest outbreak of
898 foodborne illness in decades but we have seen in the last few
899 years jalapenos, peanut butter again, meat, dog food and on
900 and on and on. I guess my question is to Congress in
901 general, how many sick kids does it really take for us to
902 finally act? How many workers need to get laid off before
903 private industry and Congress put resources into protecting
904 the integrity of our food distribution system? And I cannot
905 think of a case that better demonstrates the need for the FDA

906 and USDA to have mandatory recall authority than this case.
907 The Peanut Corporation of America sells in bulk to companies
908 and then those companies manufacture and distribute processed
909 foods. So even though people started getting sick last
910 summer, current federal law does not empower public health
911 officials to issue a recall in response to an emergency like
912 this. My constituents are shocked when they hear this, and
913 instead companies are left to voluntarily decide for
914 themselves if and when to recall their products. And so Mr.
915 Chairman I know this isn't a legislative hearing but I am
916 sure that the parents who are sitting here today would like
917 to know that there are actually legislators working on these
918 issues. I have introduced legislation again this year, which
919 I have introduced many times in the past, to finally give the
920 government mandatory recall authority, and the good news is,
921 finally this is supported not just by the regulators but also
922 by the industry, and so I think when we pass comprehensive
923 food safety legislation, finally the FDA and USDA will have
924 mandatory recall authority.

925 The second bill I have reintroduced this year, which I
926 have introduced many times in the past, is the TRACE Act, and
927 what this bill does is creates a comprehensive traceability
928 system so that we can trace from where the peanuts came from
929 to when they are in those little peanut butter crackers that

930 the children are eating, where that came from so that we can
931 recall that right away. That problem was a particular
932 problem last year with the jalapenos in the salsa. I am
933 happy to report that Mr. Dingell and Mr. Stupak have included
934 both my mandatory recall language and some traceability
935 language in their comprehensive bill and I am also happy to
936 report that the regulators support traceability and now again
937 the manufacturers are beginning to understand that situation.

938 Mr. Chairman, I am eager for this hearing today. We
939 need to shed light on this situation, but once we do that,
940 Mr. Chairman, I look forward to working with you and Mr.
941 Waxman so that we can move legislation and begin to solve
942 these problems.

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

944 ***** COMMITTEE INSERT *****

|
945 Mr. {Stupak.} Thank you.

946 Mr. Gingrey for an opening statement, please, 3 minutes.

947 Mr. {Gingrey.} Mr. Chairman, thank you for recognizing
948 me on this, my first hearing as a member of this
949 subcommittee, and I look forward to serving under your
950 leadership and that of Ranking Member Walden in the crucial
951 oversight role of the subcommittee. Let me welcome our
952 former Georgia Speaker of the House and now deputy commission
953 of agriculture, Terry Coleman, as well as Mr. Oscar Garrison,
954 the assistant commissioner, who I certainly look forward to
955 hearing his testimony on the third panel

956 Now, I first want to express my sincere condolences to
957 the families that are here today and those families across
958 the Nation who have either lost a loved one or have suffered
959 illness as a result of this salmonella outbreak. For those
960 testifying today, I appreciate your willingness to come
961 before this subcommittee and share your stories, as difficult
962 as it may be, with us. All of us have a responsibility to
963 learn from this tragedy and to take the necessary steps to
964 ensure that no other family has to ensure what you have
965 experienced.

966 Mr. Chairman, it is regrettable to see that the facility
967 under investigation today is located in my home State of

968 Georgia and it is also unfortunate that Mr. Parnell and Mr.
969 Lightsey from PCA, the Peanut Corporation of America, will
970 likely refrain from testifying in accordance with their Fifth
971 Amendment rights. And while they are within their
972 Constitutional rights, I would offer this admonition to them
973 and to anyone else who makes the products that our citizens
974 and their families consume: If you circumvent the law or
975 merely take advantage of lax oversight, don't think you have
976 gamed the system forever because justice will catch up to you
977 and you will pay. Further, if the circumstances as presented
978 and reported to this point bear out to be true, then it seems
979 the decision to achieve shortsighted profits has trumped
980 common sense and morality. For this, there will be an
981 accounting.

982 Mr. Chairman, as we in Congress move forward, we must
983 also recognize that no matter how high a regulatory wall we
984 erect, there will always be someone who is brazen enough or
985 stupid enough or greedy enough to try and climb over that
986 safety barrier, and though our gut reaction might be to build
987 an even higher wall, we have an obligation to thoroughly
988 evaluate and ensure that current law was properly enforced
989 first. The wall's integrity, after all, comes not from the
990 height, Mr. Chairman, but from its foundation.

991 So as we proceed with this hearing, I will listen

992 carefully to the witnesses and their statements and their
993 responses to the questions in the hope that we will get to
994 the bottom of this tragedy.

995 Mr. Chairman, with that I yield back.

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

997 ***** COMMITTEE INSERT *****

|
998 Mr. {Stupak.} Thank you, Mr. Gingrey.

999 Again, by order of appearance at the subcommittee, Mr.
1000 Welch from Vermont. Welcome to the committee, and you are
1001 always welcome to come sit up here on the top row too.

1002 Mr. {Welch.} I hear the air is pretty good up there.

1003 Thank you very much. I want to echo what Mr. Gingrey
1004 said and express my condolences, and believe me, it is very
1005 kind of you to come here and it makes a real difference that
1006 you are willing to share your story, painful as it is, and I
1007 apologize that we have added to your burden by making you sit
1008 through so many opening statements. But, you know, I have
1009 been listening to them too and there is something that I find
1010 quite heartening in this. We all agree that what Peanut
1011 Corporation of America did was despicable and outrageous and
1012 they should be held to account. But what you as parents, as
1013 sons have a right to expect from your government is that we
1014 have systems in place that give you the assurance that when
1015 you buy food, it is safe. It is as simple as that. And
1016 obviously there is nothing worse as a parent to see a child
1017 who is sick and we don't know what the outcome is going to be
1018 or to lose a parent before his or her time. And I am
1019 heartened by what I have heard today from the members of this
1020 committee and also I was earlier at the meeting of the whole

1021 committee when I heard our chairman, Mr. Towns, and our
1022 ranking member, Mr. Issa, both expressed the commitment to
1023 having vigorous oversight, and that doesn't change just
1024 because we have had a new change in Administration because
1025 there are unscrupulous folks out there who for a quick buck
1026 will put in peril people that you love, and it is our mutual
1027 responsibility to do every single thing we can to have
1028 systems in place that give you the assurance that the food
1029 you buy is safe, and what you are doing, and we so
1030 appreciate, is your coming forward with your personal story
1031 that makes it real, that makes it vivid, and that is at some
1032 personal inconvenience and pain to you, so I join my fellow
1033 committee members in thank you for your service.

1034 [The prepared statement of Mr. Welch follows:]

1035 ***** COMMITTEE INSERT *****

|
1036 Mr. {Stupak.} Thank you, Mr. Welch.

1037 Mr. Sullivan for an opening statement, 3 minutes, and
1038 welcome to the subcommittee.

1039 Mr. {Sullivan.} Thank you, Chairman. I appreciate it.

1040 As a new member of the Oversight and Investigation
1041 Subcommittee, I would like to thank Chairman Stupak and
1042 Ranking Member Walden for holding this hearing this morning.
1043 It is an honor to be named to this prestigious subcommittee.
1044 I am pleased to be part of this important discussion on food
1045 safety and look forward to working with each of you as we
1046 move forward in the 111th Congress. Unfortunately, the
1047 salmonella outbreak has hit my state of Oklahoma. According
1048 to the Oklahoma Department of Health, three adolescents
1049 contracted salmonella due to the tainted peanut butter. One
1050 of those adolescents was from Rogers County which borders my
1051 district. Fortunately, they are all recovered but this
1052 serves as a reminder that we must take every precaution
1053 necessary to keep our food safe.

1054 In late 2008, the Centers for Disease Control identified
1055 an outbreak of salmonella affecting 600 people in 43 States
1056 with the recent outbreak perhaps contributing to eight
1057 deaths. This is an issue that affects each and every one of
1058 us, our friends and our families. It is clear that the food

1059 companies and the FDA have a shared responsibility in keeping
1060 our food supply safe and secure, and I look forward to their
1061 recommendations on how to do that in light of the recent
1062 salmonella outbreak.

1063 Thank you in advance to our panels before us today, and
1064 my condolences to those who have lost loved ones in this
1065 unfortunate incident. I look forward to the hearing and
1066 testimony of our witnesses to get to the bottom of this
1067 incident, and I yield back the balance of my time.

1068 [The prepared statement of Mr. Sullivan follows:]

1069 ***** COMMITTEE INSERT *****

|
1070 Mr. {Stupak.} Thank you, Mr. Sullivan.

1071 Mr. Markey, a member of the subcommittee, for a
1072 statement, please.

1073 Mr. {Markey.} Thank you, Mr. Chairman, very much, and
1074 thank you so much for having this hearing.

1075 Peanut butter is a classic American food enjoyed by
1076 young and old alike, and when it is contaminated by a
1077 dangerous pathogen, it is something that sends chills through
1078 every family in America because there are few things more
1079 American than peanut butter, perhaps baseball of course, but
1080 this week we learned that there too was a positive test for
1081 steroids, and salmonella poses a serious health risk as well.
1082 So this requires an ongoing effort by this Congress to ensure
1083 that in all of these cases that there is no contamination of
1084 these things that Americans take for granted as being
1085 American. Peanut butter goes well with jelly but not with
1086 salmonella. Peanut butter was probably half of my diet as a
1087 child. It is one of those foods that is really good for you
1088 and tastes great too, but now mothers and fathers across
1089 America are worried about salmonella and don't know what to
1090 put in their kids' lunches. This is not good for our
1091 country. More than 1,800 food products have been recalled
1092 including crackers, snack bars, cookies and all sorts of

1093 other items made with peanut butter that may contain the
1094 disease-causing bacteria. Salmonella already has had an
1095 impact on hundreds of families.

1096 The FDA under the Bush Administration failed to take
1097 steps necessary to ensure the safety of our food supply. We
1098 learned once again with this recall that mandatory authority
1099 is required. When it comes to food safety recalls, we need
1100 mandates and not maybes. We cannot run the risk that we will
1101 see families across this country once again afflicted with
1102 this kind of a problem. The families who testify here today,
1103 and we thank you for that, represent millions of other
1104 frightened families across this country, and your story is
1105 their story. Your story represents this fear that a parent
1106 can be lost, that a child can be sickened by a product which
1107 they assume is safe because the Federal Government is
1108 ensuring that it is safe by putting the fear of the
1109 government into the hearts of those that produce products
1110 like peanut butter and peanut butter-related products. That
1111 did not exist and that is why you are here today. We thank
1112 you for your courage in testifying today. I can promise you
1113 that your testimony today will result in the changes that
1114 will protect millions of families in our country.

1115 I yield back the balance of my time.

1116 [The prepared statement of Mr. Markey follows:]

1117 ***** COMMITTEE INSERT *****

|
1118 Mr. {Stupak.} Thank you, Mr. Markey.

1119 Ms. Schakowsky for an opening statement, please.

1120 Ms. {Schakowsky.} Peanut butter. Peanut butter. Is
1121 there a kitchen that doesn't have peanut butter, is there a
1122 lunchbox that doesn't have peanut butter sandwiches at some
1123 point? It is actually more American than apple pie. But
1124 what I really find amazing is that it was known by the Peanut
1125 Corporation of America that their product was tainted with
1126 potentially life-threatening salmonella and yet released into
1127 the food stream anyway. How could that possibly happen? The
1128 only explanation is they thought based on some reality, given
1129 the lax regulation of the last Administration, that they
1130 would get away with it.

1131 I am so sorry to the testifiers and the families that
1132 are here today that were burdened by this, afflicted by this,
1133 tortured by this, that your government failed you, and I am
1134 grateful to the chairman for holding this hearing today so
1135 that we can set in motion those safeguards that will never
1136 let that happen again and to hold accountable the people that
1137 made the decisions that allowed it to happen. In one of the
1138 most developed nations in the world with access to
1139 unparalleled technologies and resources, there is simply no
1140 excuse that we can offer to you that contaminated or

1141 otherwise unsafe food made it all the way to consumers and to
1142 your tables.

1143 I have been a food safety advocate since 1969 when I a
1144 young group of housewives got together to get freshness dates
1145 on food. We led a little housewives' campaign that has
1146 resulted in dates, expiration dates, sell-by dates being on
1147 food throughout our marketplace, and yet today we find that
1148 this could happen. So I thank the panel before us right now
1149 for being here to testify.

1150 I want to just mention that one of the laboratories,
1151 Deibel, is in my district. I have been told by the committee
1152 that they were very cooperative with the committee. I
1153 appreciate that and look forward to their testimony as well
1154 and want to join with my other colleagues in assuring you
1155 that we will act to make your families safe from this kind of
1156 potential killer. Thank you.

1157 [The prepared statement of Ms. Schakowsky follows:]

1158 ***** COMMITTEE INSERT *****

|
1159 Mr. {Stupak.} Well, thank you. That concludes the
1160 opening statements of members of the subcommittee. I noted
1161 once for the record Mr. Barrow is here. He is a member of
1162 the full committee. Do you have an opening statement you
1163 would like to submit?

1164 Mr. {Barrow.} Well, first off, thank you, Mr. Chairman,
1165 for holding this hearing and for allowing me to audit these
1166 proceedings as though a member. I have very little to add to
1167 what has been said before but I will add very little.

1168 Mr. {Stupak.} Very quickly, because you are not allowed
1169 opening--

1170 Mr. {Barrow.} It seems to me that in addition to the
1171 provisions that have been talked about before that are part
1172 of a comprehensive reform, things like mandatory recall
1173 authority, one thing we very badly need is a testing regime
1174 in the industry in which folks are required to test and know
1175 what they need to know and a mandatory contemporaneous
1176 reporting requirement so that the regulators will know what
1177 the processors know when they know it. I think that would
1178 add great teeth and great effectiveness to any mandatory
1179 recall authority, and that is what I look forward to
1180 exploring with other members on the panels later on.

1181 [The prepared statement of Mr. Barrow follows:]

1182 ***** COMMITTEE INSERT *****

|
1183 Mr. {Stupak.} Well, thank you. We discussed that
1184 certification of labs and testing before and it is part of
1185 our global bill, and we would love to have you on the bill.
1186 You will be allowed to ask questions later as we move on.

1187 Mr. Bishop, we already have your opening statement. A
1188 valuable Member of the House, while not part of the
1189 committee, we appreciate you being here and monitoring the
1190 proceedings. Without objection, Mr. Bishop's statement will
1191 be made part of the record.

1192 [The prepared statement of Mr. Bishop follows:]

1193 ***** COMMITTEE INSERT *****

|

1194 Mr. {Stupak.} As I said, that concludes our opening
1195 statements by members. I would now like to have our first
1196 panel of witnesses to testify. First we have Mr. Jeffrey
1197 Almer of Savage, Minnesota, whose 72-year-old mother,
1198 Shirley, died after eating salmonella-contaminated peanut
1199 butter at a nursing home--I should also note he has a
1200 photograph of his mother that I am sure he will explain to us
1201 as we move on; Mr. Lou Tousignant of Minneapolis, Minnesota,
1202 whose 78-year-old father, Clifford, died after eating
1203 salmonella-contaminated peanut butter at a nursing home, and
1204 Mr. Peter K. Hurley, a police officer from Wilsonville,
1205 Oregon, whose 3-year-old son, Jacob, was severely sickened by
1206 salmonella after eating Austin crackers.

1207 It is the policy of this subcommittee to take all
1208 testimony under oath. Please be advised that you have the
1209 right under the rules of the House to be advised by counsel
1210 during your testimony. Do you wish to be represented by
1211 counsel, gentlemen? Okay. Everyone indicates no. I am
1212 going to ask you to rise and raise your right hand to take
1213 the oath.

1214 [Witnesses sworn.]

1215 Mr. {Stupak.} Let the record reflect that the witnesses
1216 replied in the affirmative. You are now under oath. We will

1217 begin with your opening statement. If you don't mind, Mr.
1218 Almer, would you begin, please, 5-minute opening statement,
1219 and we appreciate you all being here and coming here.

|
1220 ^TESTIMONY OF JEFFREY ALMER, SAVAGE, MINNESOTA; LOU
1221 TOUSIGNANT, MINNEAPOLIS, MINNESOTA; AND PETER K. HURLEY,
1222 WILSONVILLE, OREGON

|
1223 ^TESTIMONY OF JEFFREY ALMER

1224 } Mr. {Almer.} Thank you, Mr. Chairman and committee
1225 members for inviting me to testify today. My name is Jeff
1226 Almer and I am here today on behalf of the family of Shirley
1227 Almer, my mother, and as a member of S.T.O.P., Safe Tables
1228 Our Priority, a nonprofit organization that represents
1229 foodborne illness victims nationwide. My sisters, Vickie and
1230 Ginger, are also with me today.

1231 Shirley Almer had a lot of Sisu, which in her Finnish
1232 heritage describes a person with spunk, fortitude and
1233 determination. That is why her death on December 21 from all
1234 things salmonella-contaminated peanut butter came as such a
1235 shock to our family.

1236 In May of 2007, Mom had a couple of dime-sized spots of
1237 cancer diagnosed on her right lung. She decided to have it
1238 removed at the University of Minnesota and was subsequently
1239 diagnosed cancer-free. She took a family trip to Florida a
1240 year later to celebrate with her children and grandchildren,

1241 and it was such a joy to see her enjoying life after that
1242 terrible scare.

1243 Then in July 2008, she suffered a seizure and was
1244 diagnosed with a brain tumor. The prognosis was hopeful and
1245 she was determined to do whatever it took to beat cancer for
1246 a second time. A second seizure robbed her of movement and
1247 speech capabilities. She underwent brain radiation and a
1248 gamma knife procedure. She was required to stay at the
1249 University Hospital but fought back through rehab and
1250 regained the use of her limbs and her speech despite the
1251 diagnosis of some doctors. It was sheer determination and a
1252 can-do attitude she overcome all of that, never complaining.
1253 One of her wonderful rehab nurses told me she was a shining
1254 light and said she was absolutely amazed at the recovery.
1255 Mom was released in early October to recuperate with her
1256 family and was once again declared cancer free. She made
1257 plans. She bought Christmas presents. She wanted to get
1258 another puppy. She wanted to visit her sister Mary in
1259 Arizona and she was looking forward to being around to watch
1260 her grandchildren grow up.

1261 Unfortunately, she suffered a urinary tract infection
1262 around Thanksgiving and needed to check in short term to a
1263 rehab care facility for treatment. Her short stay was
1264 supposed to end the Monday prior to Christmas when she would

1265 then join the family for the holidays. She began to complain
1266 of stomach cramping and had diarrhea. There was a downward
1267 spiral from that point on. Our family was absolutely stunned
1268 to learn on the day before her scheduled release that doctors
1269 were giving her hours to live. It was very unexpected and
1270 equally hard to fathom how she could have gotten to this
1271 point. We were devastated as we ended up saying our tearful
1272 goodbyes and watching her last breaths on that Sunday.

1273 It was just after the New Year that my sister Ginger was
1274 informed by the Minnesota Department of Health about the
1275 positive test for salmonella. A week before her death she
1276 had unknowingly consumed salmonella-laced peanut butter while
1277 in her immune-compromised state of health. Cancer couldn't
1278 claim her but peanut butter did. Now that we understood the
1279 cause of her death, our grief was replaced by anger as we
1280 struggled to accept this preventable tragedy. Our family
1281 feels cheated. My mom should be here today.

1282 Her death and the deaths of seven others could have been
1283 so easily prevented if it were not for the greed and avarice
1284 of the Peanut Corporation of America. PCA appears to be more
1285 concerned with squeezing every dollar possible at the expense
1286 of sanitary conditions and sound food manufacturing
1287 processes. Every company needs to have a moral and ethical
1288 compass when producing the Nation's food supply. In this

1289 absence, we need a cohesive regulatory system to serve as our
1290 safety net; too often it is reactive, if at all.

1291 While they were not expecting to kill anyone, PCA now
1292 has the blood of eight victims on their hands along with the
1293 shattered health of a known 600 others, and they have
1294 devastating their own community with the unemployment. Their
1295 legacy is now that of a company that did what it could get
1296 away with until their shoddy practices has led to the
1297 Nation's largest recall. Their behavior is criminal, in my
1298 opinion. I want to see jail time and I want to see them
1299 served nothing but the putrid sludge they have been trotting
1300 out. I don't believe anyone in this country buys all the
1301 protests of innocence they have been saying.

1302 Shirley Almer loved this country but was terribly let
1303 down by a broken and ineffective food system with abysmal
1304 oversight. She was let down in the worst possible way by the
1305 very government whose responsibility it is to protect its
1306 citizens' health and safety. We cannot continue to ignore
1307 the public health threat caused by poorly regulated and
1308 contaminated foods. We cannot allow food safety to be
1309 continually underfunded and expose unsuspecting Americans to
1310 deadly pathogens.

1311 This brings up many important questions. How much time
1312 and money will end up being spent on the act of recalling

1313 over 1,000 food products? What about the lost productivity
1314 and medical expenses for the sickened? When we will have a
1315 proactive instead of a reactive system? And my last question
1316 would be, when will all these painful deaths and sickness
1317 stop being collateral damage?

1318 The government and the industry need to work together to
1319 correct a multitude of problems. I am proud to be asking for
1320 change on behalf of my mother, Shirley, and on behalf of
1321 S.T.O.P. Although this country has many important issues
1322 right now, I am urging President Obama and distinguished
1323 Members of Congress to make the safety of our Nation's food
1324 supply a priority. It is imperative that Americans trust
1325 that their health is not compromised by the food on their
1326 plate.

1327 We love you, Mom, and we miss you every day. Thank you
1328 very much.

1329 [The prepared statement of Mr. Almer follows:]

1330 ***** INSERT 1 *****

|
1331 Mr. {Stupak.} Thank you, Mr. Almer.

1332 Mr. Tousignant, your opening statement, please. If you
1333 want to submit a longer statement for the record, it will be
1334 included. If you would, please, Mr. Tousignant.

1335 Mr. {Tousignant.} Before I begin, Mr. Chairman, would
1336 you start the video, please?

1337 [Video]

|
1338 ^TESTIMONY OF LOU TOUSIGNANT

1339 } Mr. {Tousignant.} Mr. Chairman, members of the
1340 committee, my father was a highly decorated Korean War
1341 veteran. He fought in many difficult battles in his years in
1342 Korea and was awarded three Purple Hearts for his valor. He
1343 faithfully served his country for over 22 years and he loved
1344 every minute of it. The only thing that he loved more was
1345 his family.

1346 He was the proud father of six: Paul, with me here
1347 today, Marshall, Susan, Calvin, Jane and myself. As you can
1348 see by those photos, he loved spending time with his
1349 grandchildren and his great-grandchildren. He had 15
1350 grandchildren and 14 great-grandchildren.

1351 But he was a man that physically and psychologically
1352 scarred from Korea, and early on it was difficult for our
1353 family, but like most battles in his life, he overcame it, so
1354 much so that he became one of the most generous men that many
1355 had known. The night of his funeral, I was having a
1356 conversation with my brother-in-law, Dan Herrick, almost with
1357 me today, and he shared a story with me of when he and my
1358 sister were first married. Like most young married couples,
1359 times were tight back then and my father knew that, and he

1360 would invite them over, make up a story saying my car starter
1361 won't work right, something is wrong with the brake,
1362 something is wrong with the door, come on over and take a
1363 look at it. And he would always give Dan and my sister Jane
1364 a little something for the trouble of coming over. He helped
1365 a lot of through the years including his own parents when he
1366 joined the Army as a teenager. He sent money back home
1367 because times were tight then as well. As long as he had a
1368 few dollars in his pocket, he was more than willing to help
1369 anyone.

1370 His final battle occurred in December of 2008 when he
1371 ate some contaminated peanut butter from PCA. He suffered
1372 for weeks until he finally died on January 12, 2009. He had
1373 just entered a full-time healthcare facility in Brainerd,
1374 Minnesota, a month earlier. He had few goals left in life
1375 except for one: he wanted to live to be older than his
1376 father. He wanted to live to be 80 years old. He was 78
1377 when he died, a year and a half too early.

1378 We can't be certain of how many years Dad was robbed of,
1379 and because of the way he died, because of all the media
1380 attention, our grieving process has been different than most.
1381 We should not be sitting here in front of you today, any of
1382 us. We can no longer pick up the phone and ask him what game
1383 he is watching today. My nieces and nephews can no longer

1384 crawl over to Grandpa and have their photos taken with him.
1385 My brother Marshall and my sister-in-law Ann, who were
1386 fortunate enough to spend the last 3 1/2 years with him, can
1387 no longer go to his house daily and just check in and see how
1388 he is doing. My brother Paul, who spoke with him frequently,
1389 can no longer call him just when he feels like. He has
1390 trouble sleeping at night now, not just because we lost our
1391 father but the senseless way that this happened.

1392 What happened to our father, the seven other families
1393 like the Almers, the over 600 others sickened like the
1394 Hurleys is not new. Over the years there have been hundreds
1395 of similar outbreaks and other heartbreaking stories. Why
1396 has this been allowed to happen? Two years ago the Peter Pan
1397 outbreak affected more than 600 people in 47 States. Two
1398 years later, here we are again asking for change.

1399 I submit to you, ladies and gentlemen, how can we truly
1400 be leaders of the free world if we can't keep our own
1401 citizens safe from the food that we eat every single day? We
1402 have a blind faith that when we go to a grocery store, the
1403 food there is also safe. Clearly it is not.

1404 Do not let the death of my father, the seven others and
1405 hundreds sickened by in vain. Please do your job. Do not
1406 let us be back here next year or the year after experiencing
1407 the same thing. Companies like PCA and Mr. Parnell who make

1408 our food should have rules that they live by. Companies
1409 should be inspected more than once every 5 years. Companies
1410 should not be allowed to shop around for lab results.
1411 Companies like King Nut should not be allowed to slap a label
1412 on their product they received from a factory that they know
1413 nothing about, never visited nor even ever inspected once.
1414 The FDA should also have the right to recall contaminated
1415 food themselves and not wait for companies to do so on their
1416 own. We can't allow the number of FDA inspectors and
1417 inspections to continue to decline.

1418 My father was a good man. He faithfully served his
1419 country. The system that was set up to protect all of us
1420 here today has failed. My father died because he ate peanut
1421 butter.

1422 [The prepared statement of Mr. Tousignant follows:]

1423 ***** INSERT 2 *****

|

1424 Mr. {Stupak.} Thank you, Mr. Tousignant.

1425 Mr. Hurley, your testimony, please.

|
1426 ^TESTIMONY OF PETER K. HURLEY

1427 } Mr. {Hurley.} Good morning, Congressmen, Congresswomen
1428 and committee members. My name is Peter Hurley. My wife
1429 Brandy and I are parents of three children: Lauren, 5,
1430 Jacob, 3, and Alyssa, 8 months. I am a police officer in
1431 Portland, Oregon, and my wife is a marketing manager.

1432 Our whole family, baby and all, have traveled from
1433 Oregon to Washington, D.C., to testify before you regarding
1434 the salmonella outbreak that has affected us as well as
1435 hundreds, if not more likely, thousands, of fellow Americans.

1436 I want to take a moment to acknowledge the eight
1437 families who have lost loved ones. Eight people have died
1438 due to PCA's willful negligence. We were just lucky. It
1439 could have been very different for us.

1440 We made this journey to appear before you because we
1441 felt it important enough for you to hear our story of how the
1442 Peanut Corporation of America poisoned our son. We want you
1443 to hear how Jacob and a PCA-supplied product are genetically
1444 linked in the hopes that you will take action to protect our
1445 food supply.

1446 Jacob's story began with him becoming ill with diarrhea
1447 and vomiting in early January. He was sallow, lethargic and

1448 probably had a fever that we missed. In a few days he began
1449 to have blood in his diarrhea. We took him to the
1450 pediatrician. A few days later the pediatrician called to
1451 let us know that the lab results had come back and that Jacob
1452 had salmonella poisoning. At this point we did not know how
1453 Jacob got the poisoning, and because of that, we did not know
1454 how to protect the rest of the family. All we knew was that
1455 five or six people had already died in a new salmonella
1456 outbreak. At that time only King Nut peanut butter, a PCA
1457 product, was listed as a source, which we did not have. What
1458 had we unknowingly given him that had given him salmonella
1459 poisoning?

1460 As Jacob's diarrhea continued, my wife was given the
1461 okay from our pediatrician's office for Jacob to eat his
1462 favorite comfort food, Austin toasty crackers with peanut
1463 butter, the very food that we later found was the cause of
1464 his poisoning, so here we have a boy who is trying to get
1465 over food poisoning and one of the foods that was seen safe
1466 even to the people in the pediatric medical community is the
1467 exact product that is continuing to poison him.

1468 A week later, Dr. Bill Keene from Oregon's Office of
1469 Disease Prevention and Epidemiology came to our house at 5:00
1470 on a Saturday night. As a friend said, this is like having
1471 the head of the FBI coming out to take fingerprints. On that

1472 Saturday night, Dr. Keene took custody of our supply of
1473 Austin toasty crackers with peanut butter manufactured by
1474 Kellogg's with a PCA product. One week later, Dr. Keene
1475 called us to say that Jacob and the crackers he had taken
1476 from our house had an exact DNA subtype match for salmonella.
1477 Three out of the six packages of crackers he tested were
1478 positive, and that was all that we had left. The issue was
1479 no longer what had we done unknowingly but what had PCA done
1480 knowingly.

1481 Jacob continued to have diarrhea for 11 days. We had to
1482 be extremely vigilant to ensure that there was never any
1483 cross-contamination between Jacob and Alyssa, our 7-month-
1484 old. If Alyssa had come down with salmonella poisoning,
1485 there is a good chance that we would be one of the families
1486 who had lost a loved one due to PCA's willful negligence.

1487 I have read the FDA's most recent report. This was not
1488 an accident. It sickens me to know that a company and its
1489 employees could knowingly allow tainted product to go out the
1490 door and into the Nation's food supply. Does no one have a
1491 conscience anymore? People would be in utter outrage if they
1492 heard of a police officer putting a loaded gun to someone's
1493 head, pulling the trigger, and then in the horrific aftermath
1494 say it was just that the bullet in the chamber wouldn't fire.
1495 We, the United States, are the first world. Have we fallen

1496 to second world food status for our food safety? As the
1497 woman taking care of our dog while we are here in D.C. said,
1498 ``Even my dog is not safe. What is this, China?''

1499 Where do we go from here? We need to have a faster 911-
1500 oriented medical response for food contamination in order to
1501 prevent further innocent victims. We need FDA inspectors out
1502 there with the authority to stop production immediately when
1503 there is a problem. We need the FDA to have the ability to
1504 criminally prosecute quickly and effectively. Oregon has the
1505 dubious distinction of suffering the first-ever domestic
1506 terrorism in the United States. It was carried out by the
1507 Rajneeshees in the 1980s. They sprayed a salad bar in The
1508 Dalles, Oregon, with salmonella. If a small group of
1509 religious fanatics in Oregon could pull it off, who else
1510 could?

1511 None of us should be so naïve as to think that Al-Quaeda
1512 could not easily taint our food supply. If the very well-
1513 funded Al-Quaeda could put it mind to it, I shudder to think
1514 of what could happen to this country when people do not know
1515 where to turn to find safe, uncontaminated food. The panic,
1516 pandemonium and lawlessness would be horrific.

1517 I will leave you with my favorite quote by the 19th
1518 century author, poet and philosopher, Johann Wolfgang Goethe:
1519 ``Few men have imagination enough for reality.'' On behalf

1520 of all Americans, my whole family, Jake and I ask you to
1521 please have imagination enough to think of the worst-case
1522 scenario and to work to protect against it. Thank you.

1523 [The prepared statement of Mr. Hurley follows:]

1524 ***** INSERT 3 *****

|
1525 Mr. {Stupak.} Thank you, and thank you to this panel
1526 for not only being here but also sharing your story and your
1527 video to put a human face on this latest recall we have. I
1528 would like to express my condolences to you, Mr. Almer, and
1529 to you, Mr. Tousignant, and Mr. Hurley, we are glad that
1530 Jacob is doing better and it is good to have your whole
1531 family here. Thank you for being here.

1532 As family members and victims of this outbreak, I am
1533 sure that you have asked yourself the same questions I have
1534 asked myself: What was this company thinking releasing
1535 tainted product to the public. During our investigation, the
1536 committee requested and received internal e-mail from PCA
1537 relating to the outbreak and past testing for salmonella. I
1538 would like to ask you about some of these documents. Mr.
1539 Hurley, right in front of you is there book, the document
1540 book. Let me ask you this. On October 6, it is tab #43, if
1541 you want to open it up there. Tab #43, on October 6, 2008,
1542 Stewart Parnell, president of the Peanut Corporation of
1543 America, responded to news from Sam Lightsey, the manager of
1544 PCA's plant in Blakely, Georgia, as tab #43 says, Mr.
1545 Lightsey had informed Mr. Parnell, ``We received final lab
1546 results from Deibel this morning and we have a positive for
1547 salmonella.'' Mr. Parnell's response was as follows, and

1548 again, it is found there in tab #43: ``We need to discuss
1549 this, the time lapse. Besides the cost, it is costing us
1550 huge...'' and there are dollar signs ``and causing obviously
1551 a huge lapse in time from the time we pick up peanuts until
1552 the time we can invoice.'' And in there you see there are
1553 five dollar signs. Let me ask each of you, what is your
1554 reaction to this company responding to positive salmonella
1555 testing with concern about its own financial well-being? Mr.
1556 Hurley, do you want to start?

1557 Mr. {Hurley.} Not to sound trite or overly confident,
1558 but as a police officer, I can unequivocally say that it is
1559 criminal.

1560 Mr. {Stupak.} Mr. Tousignant?

1561 Mr. {Tousignant.} An act that is this egregious, I
1562 completely agree with Mr. Hurley. I mean, this is a
1563 completely criminal act that in essence he was really playing
1564 Russian roulette with children and the elderly when he sent
1565 this peanut butter out.

1566 Mr. {Stupak.} Mr. Almer, do you care to comment?

1567 Mr. {Almer.} When I came here today, I didn't think I
1568 could possibly get more outraged than I already am about how
1569 this happened, but I have to tell you, it has reached another
1570 level after seeing e-mails and comments from Mr. Parnell. No
1571 excuses.

1572 Mr. {Stupak.} On tab 46, there is another tab in there,
1573 another e-mail, and let me just--there are other faxes and e-
1574 mails the committee has uncovered but you indicated that it
1575 was criminal, Mr. Hurley. Being a former police officer
1576 myself, I am identifying with you. The Justice Department is
1577 doing their investigation. There are certain things that our
1578 committee could and could not bring out at this time, so I
1579 want to assure all of you that there still is a criminal
1580 investigation going on.

1581 You also mentioned about your dog and the sitter taking
1582 care of it saying, ``What are we, China?'' Well, in 2006
1583 some of those peanuts that were positive came from China, so
1584 it is a global problem.

1585 But let me ask you this, #46, tab 46, even after several
1586 weeks into this outbreak, Mr. Parnell was asking the FDA
1587 whether it could use peanuts from its plants. Here is what
1588 they wrote to the FDA, ``Obviously we are not shipping any
1589 peanut butter products affected by the recall but desperately
1590 at least need to turn the raw peanuts on our floor into
1591 money.'' So we have at least two e-mails here in which Mr.
1592 Parnell reacts to the outbreak by worrying about how money it
1593 is costing him. Any comments on that? Mr. Hurley.

1594 Mr. {Hurley.} Narcissistic, I would say, maybe.

1595 Mr. {Stupak.} Okay. Mr. Tousignant?

1596 Mr. {Tousignant.} I am at a loss, personally. I mean,
1597 I just can't see how anyone could run a business and be a
1598 member of a community and maybe even belong to a church in
1599 that community and be making decisions not only like this but
1600 also putting jobs in that community as well in a very, very
1601 tight environment like this too.

1602 Mr. {Stupak.} Mr. Almer?

1603 Mr. {Almer.} I would expect that if you are making
1604 food, you would want to eat that food that you are producing,
1605 and I don't believe that Mr. Parnell would actually want to
1606 eat this product if he is producing food in that manner.

1607 Mr. {Stupak.} Well, thank you, and again, let me thank
1608 you for coming here and sharing your stories. I know it is
1609 difficult, but we need to have the human face because people
1610 have to see. They just think we have these hearings but
1611 there is a reason for these hearings and that is so people
1612 see what happens when frankly a number of people let us down
1613 but including our own government. That concludes my 5
1614 minutes for questioning. Mr. Walden for questions, 5
1615 minutes, please.

1616 Mr. {Walden.} Thank you very much, Mr. Chairman. As we
1617 have sat here, I have been updated that now in Oregon we have
1618 12 lab-confirmed reports of salmonella, and also as I
1619 referenced in my comments, they now have confirmed the dog

1620 and the dog biscuits from the household were positive as
1621 well, so Mr. Hurley, I believe it was you who said somebody
1622 is watching your dog. We now know that it is there as well.

1623 I wonder if Mr. Parnell is in the audience. Is Mr.
1624 Parnell in the audience? You know, I would think that the
1625 least he could have done was be here to hear your comments
1626 and to hear about your loved ones, like a victim impact
1627 panel, because that is really what this is today.

1628 Mr. Almer, I will be asking Mr. Parnell, as I mentioned
1629 in my opening statements, and I appreciated the comment about
1630 Russian roulette because that is really what this is about
1631 is, which of these would he eat and his company because they
1632 sure put it out there for your mother and your father and,
1633 Mr. Hurley, your son, and all the rest of us to consume, and
1634 I wonder if he will take the top off. We are going to give
1635 him that opportunity.

1636 Mr. Hurley, from your written testimony it seems like
1637 you were pleased with the State of Oregon's response to your
1638 son's illness. Can you tell me what Oregon did that was
1639 helpful to you and may serve as a model for other States?
1640 What out of that experience can you share with us?

1641 Mr. {Hurley.} At the time when Dr. Keene came to our
1642 house, I was unfamiliar with his rank and status and--

1643 Mr. {Walden.} As the state epidemiologist.

1644 Mr. {Hurley.} As the state epidemiologist. Exactly.
1645 And since then I have learned, as my friend said, it is kind
1646 of in terms of rank like having, you know, the director of
1647 the FBI come by to take latent fingerprints. What he did
1648 though is unique for the whole country, and that is that Jake
1649 is the only person in the whole country where you have a DNA
1650 link between the product, the Austin peanut butter crackers,
1651 and his lab samples. Sorry for the crassness, but it was lab
1652 fecal samples. And it is an exact DNA match so that they
1653 know that the peanut butter crackers that he ate that went
1654 through his system is what made him sick, and Jake is the
1655 only one in the whole country and that is because Dr. Keene
1656 came to our house at 5 p.m. on a Saturday night on his own
1657 time while running errands because he was concerned enough
1658 about where this was going and what was happening that he
1659 then took those samples, sent them off to the lab and he said
1660 that the lab spent lots of time and lots of hours and money
1661 on it to find that link, and with that kind of a link, then
1662 they had a batch number and a processing number that they
1663 were able to contact Keebler with directly.

1664 Mr. {Walden.} And as far as you know, that wasn't done
1665 anywhere else in the country?

1666 Mr. {Hurley.} To this date when I--I spoke to him last
1667 on Friday, I believe it was, and at that time nobody else had

1668 any direct links, and as he said, most States don't have the
1669 manpower or money to do that, and also it seems as if most
1670 State epidemiologists, they know that people have gotten sick
1671 because they get that from the county health records and then
1672 they work on the other side looking at the lab results of
1673 product out there or voluntary lab results but they don't put
1674 the two and two together by looking for product at its
1675 location.

1676 Mr. {Walden.} I would say too as my staff was
1677 collecting this assortment of products that are on the recall
1678 list, we ran into even in some of their homes items that are
1679 on that list that frankly they thought had already been
1680 thrown out, destroyed, whatever, and sort of beyond this
1681 hearing but in real time, people may still have products at
1682 home that should be destroyed, and as we were chatting here,
1683 just the breadth, the scope of the items that are out there,
1684 what would you--Jacob suffered through this. Certainly as
1685 apparent, and I, like you, am a parent, but what should we be
1686 telling people across the country today about this?

1687 Mr. {Hurley.} I don't know what we should be telling
1688 them but I do know that one of the tough things in this has
1689 been getting all the products off the shelves. I know that
1690 locally in Oregon there was a story done where they went to
1691 some small local markets where people weren't getting their

1692 product directly from a supplier, they were going out and
1693 purchasing themselves, a small mini market kind of situation,
1694 with lots and lots and lots of products on the shelf, and,
1695 you know, how do you get that word out when it is voluntary.
1696 There is no system in place to get the word out to all these
1697 retailers of all these different products.

1698 Mr. {Walden.} Did you do searches online looking for
1699 products once you started down this process? I mean--

1700 Mr. {Hurley.} No. You know, we gave up our supply of
1701 peanut butter crackers to the doctor and after that, as he
1702 said, you know, just don't eat anything with peanuts in it or
1703 any peanut products until we know more down the road, and so,
1704 you know, we have got stuff still in our pantry but it is
1705 sitting there waiting to kind of see how this develops
1706 because I know it will be a little bit longer.

1707 Mr. {Walden.} I guess that is the concern is everything
1708 in the pantry, and it is amazing to me how much of what we
1709 consume has some peanut or peanut paste or something in it
1710 that may well be on this list.

1711 Thank you, Mr. Chairman. Thank you, Mr. Hurley.

1712 Mr. {Stupak.} Thank you. I just want to let you know,
1713 as of last night, the Republican cloakroom still had the
1714 Keebler peanut butter crackers in there. Mr. Shimkus brought
1715 it to our attention, and I think we got it out of your

1716 cloakroom.

1717 Mr. {Walden.} Yes, they are supplied by the Democrats
1718 in a conspiracy.

1719 Mr. {Stupak.} Just trying to help.

1720 Ms. Christensen for questions, please.

1721 Ms. {Christensen.} Thank you, Mr. Chairman, and again,
1722 thank you and your families for being here this morning and
1723 for sharing these painful stories with us.

1724 Do you have any concerns about the speed with which they
1725 outbreak was linked to peanut butter by public health
1726 officials? We have focused a lot on the company itself but I
1727 want to just turn the focus to our response as a government.

1728 Mr. {Almer.} I would like to add that my mom at the
1729 peanut butter some time in mid-December and the salmonella
1730 outbreak was known about in early September, so the time it
1731 took to find out the cause could have prevented a lot more of
1732 the problems that happened.

1733 Ms. {Christensen.} I just have another question that
1734 either of you could answer or all of you. I will preface it
1735 by saying that as a physician I used to do drug testing on
1736 ships coming into port and so forth, the people that worked
1737 there, and I had to ascertain by temperature that this person
1738 gave me the sample and I had to be responsible for the chain
1739 as it went from the ship to the lab. So I have a lot of

1740 concerns about the second lab test, whether the second
1741 samples were from the same batch, especially with positive
1742 tests going back to 2007. Do you think it is good enough for
1743 the company themselves to be the ones collecting, contracting
1744 for the testing and reporting the results? Shouldn't that be
1745 fixed?

1746 Mr. {Tousignant.} Well, I think clearly in this case
1747 that is definitely the key. I mean, clearly the company
1748 could not be trusted to do it on their own. Now, I know that
1749 there are probably a lot of companies that are running an
1750 ethical business, but unfortunately, we have to worry about
1751 the ones that are not, and we have to have a process in place
1752 that allows us to be in charge of that.

1753 Ms. {Christensen.} Thank you. I don't have any other
1754 questions for this panel, Mr. Chair.

1755 Mr. {Stupak.} Thank you, Ms. Christensen.

1756 Mr. Deal for questions, please, 5 minutes.

1757 Mr. {Deal.} Well, I too express my sympathy to all of
1758 you for the loss of your family members and certainly the
1759 trouble that your young son has undergone. We have heard Mr.
1760 Hurley talk about his interaction with his State
1761 epidemiologist. Would the other two of you elaborate on any
1762 contact you may have had with health authorities? For
1763 example, did any of you get contacted by the CDC, et cetera?

1764 Mr. {Tousignant.} My brother, actually Marshall, was
1765 contacted by the State of Minnesota and we found out, I wan
1766 to say about a week after the fact after my father died or
1767 maybe a few days after he died that indeed he did have
1768 salmonella and they actually found it in his blood.

1769 Mr. {Almer.} It was about 2 weeks after my mother died
1770 that my sister Ginger received a call from the Minnesota
1771 Department of Health if we had brought in any kind of food
1772 from the outside, had she eaten chicken, had she eaten peanut
1773 butter, and it was my sister who remembered she had served my
1774 mother peanut butter toast two times. That really became a
1775 huge key to finding out--actually I have heard the Minnesota
1776 Department of Health was very instrumental in finding the
1777 very source of this outbreak, and we were told by them that
1778 my mother's death was key to the whole thing.

1779 Mr. {Deal.} Well, I think the reason for this oversight
1780 and investigation hearing is to find out how we can best plug
1781 the loopholes and close the gap so that hopefully we will not
1782 see a repeat of this kind of situation in the future, and we
1783 thank you all for taking the time and going to the expense of
1784 being here today, and with our assurances that I am sure our
1785 chairman and other members of this committee will follow
1786 through to try to make sure we can do the best we can from
1787 our end to make sure it doesn't repeat itself.

1788 Thank you all for being here. I yield back.

1789 Mr. {Stupak.} Ms. Sutton for questions, please.

1790 Ms. {Sutton.} Thank you, Mr. Chairman, and thank you
1791 all so much for your testimony, for coming here to dispel any
1792 notion that your loved ones are acceptable collateral damage
1793 or some sort of statistic as opposed to real people with real
1794 families who are suffering because of actions that have been
1795 taking place.

1796 If I may, I would like to show you some new information
1797 that the subcommittee received and get your response to it.
1798 I have a statement from Michelle Pronto, and I believe it is
1799 at tab 10. Ms. Pronto works for J. Leek Associates, which is
1800 one of the private labs PCA used to test salmonella. She
1801 manages the microbiology lab there. The subcommittee spoke
1802 with Ms. Pronto and she agreed to provide a written
1803 statement, which I ask to be placed into the record.

1804 Mr. {Stupak.} Without objection.

1805 [The information follows:]

1806 ***** COMMITTEE INSERT *****

|
1807 Ms. {Sutton.} Ms. Pronto explains in her statement that
1808 in October of last year her lab found salmonella in PCA's
1809 peanut products. She reported this positive finding to Sam
1810 Lightsey, who is the plant manager, as we know, in Georgia,
1811 and this is how she described their conversation. She
1812 stated, ``When I called Mr. Lightsey in early October 2008 to
1813 give the serology reports that JLA had obtained from Deibel
1814 Lab for the confirmed salmonella, he paused and said uh-oh or
1815 something to that effect and then told me he had released the
1816 product for shipping. When I asked if he could get it back,
1817 he said it was on a truck heading to Utah.'' Now, you guys
1818 saw that earlier, and let me ask you, any of you, is there
1819 anything you would like to say in response when you hear this
1820 statement from the plant manager and that he shipped the
1821 product without even waiting to get the results of the
1822 salmonella test?

1823 Mr. {Almer.} I would like to add, I know that trucks
1824 can be stopped, doors can be opened, product can be taken
1825 out, or the truck can be just turned right around. It costs
1826 more money, sure, but it is easy to do.

1827 Ms. {Sutton.} Anybody else?

1828 Mr. {Hurley.} I would concur. That is absolutely
1829 ludicrous.

1830 Ms. {Sutton.} And let me share something else that Ms.
1831 Pronto had to say. She said, ``During a phone conversation
1832 in August 2008, Sammy Lightsey of PCA informed me that the
1833 Albany, Georgia, JLA lab was reporting higher aerobic plate
1834 counts--those are APC results--and higher coliform results
1835 than another lab he apparently used.'' Then she said this:
1836 ``I received an e-mail on 9/10/08``--September 10 of 2008--
1837 ``from JLA employee Stephanie Fletcher stating that she was
1838 told by QC manager''--quality control manager--``of PCA that
1839 PCA was no longer going to send us samples.'' Finally, she
1840 said this: ``I called Mr. Lightsey to follow up on the
1841 recent discussion regarding the confirmed positive and he
1842 confirmed that because of the high coliform results, they
1843 were going to send samples to a different lab.'' So this lab
1844 official certainly seems to be saying that when PCA didn't
1845 like the positive test results, it just took its business
1846 elsewhere.

1847 So what is your opinion, and I could guess but I don't
1848 think anyone could say it better than you. What is your
1849 opinion of a business that engages in activity like this?

1850 Mr. {Tousignant.} I think unfortunately that is an
1851 example of why we can't trust self-checking or self-
1852 regulation, and I think this is an example of why our food
1853 supply is not safe.

1854 Mr. {Hurley.} You can't have lab shopping. You can't
1855 have lab shopping going on to find your best results.

1856 Mr. {Almer.} It is just a complete conflict of
1857 interest. They are the ones who do not benefit by the
1858 negative results or positive results, whatever they may be.
1859 They can't shop around.

1860 Ms. {Sutton.} Again, I thank you very much for your
1861 testimony and I am so very sorry for your loss.

1862 Mr. {Stupak.} Following up that last question, if I
1863 may, with your 30 seconds, do you think any lab results from
1864 any food producer should automatically be sent not only to
1865 the producer of that food but also to the FDA simultaneously?
1866 Any objection to that?

1867 Mr. {Hurley.} No objection, and I actually would have
1868 just been under the assumption that that is how the process
1869 already was.

1870 Mr. {Stupak.} That is not the way it goes. It is part
1871 of our legislation. Thank you.

1872 Mr. Gingrey for questions, please, 5 minutes.

1873 Mr. {Gingrey.} Mr. Chairman, thank you, and I have
1874 already expressed my condolences to the families and I will
1875 repeat that now. I know this is a painful experience for all
1876 the family members as we can see in your faces as you give
1877 your testimony.

1878 I guess the main question that I want to ask you because
1879 we will have the two subsequent panels, hopefully the second
1880 panel will respond to our questions but it is likely, as I
1881 said in my opening statement, that they will not, but of
1882 course, the third panel is a very important panel, so I guess
1883 my question to each of you is, what would you want us to ask
1884 them? And when I say ``them'' I am talking about the FDA, I
1885 am talking about the CDC, I am talking about USDA, United
1886 States Department of Agriculture, and I am talking about the
1887 department of agriculture in the respective States, all 50
1888 have one, and the health departments. And so if you could
1889 maybe tell me ahead of time what to ask, I will be glad to do
1890 that when we have that opportunity.

1891 Mr. {Almer.} I would like to respond and ask them why
1892 anyone would not want to have mandatory recalls. Why do we
1893 leave it up to the companies to decide when they are going to
1894 recall their product? That is an important part. I guess
1895 that would be my main question.

1896 Mr. {Tousignant.} I am not sure that you are asking the
1897 question maybe down this line but the question that I have
1898 is, why does the FDA not already have this authority? Why do
1899 they not have the ability to recall these items themselves?
1900 And secondly is a budgetary issue. Why are there inspectors
1901 and number of inspections continuing to decline? Who is in

1902 charge of the budget? Because if you think about people's
1903 main concern, it is safety of food foremost. We have to be
1904 able to eat. This is just as important as the economy is
1905 right now.

1906 Mr. {Hurley.} No comment.

1907 Mr. {Gingrey.} Well, I thank you gentlemen, and again,
1908 I think that we on the committee are very appreciative of you
1909 coming and testifying as painful as it is. I don't know if
1910 you are aware but on this committee, on both sides of the
1911 aisle, we probably have three M.D.'s, we have a registered
1912 nurse, we have a clinical psychologist, and we have some
1913 experts that have been on the committee for a long time, the
1914 chairman and ranking member, in regard to these healthcare
1915 issues. So it is something that certainly has got our
1916 attention and obviously we plan to do everything we can to
1917 try to close that weak link in the chain because, as I said,
1918 it is only as strong as the weakest link and obviously there
1919 is a problem, and we thank you so much for being here.

1920 Mr. {Walden.} Would the gentleman yield?

1921 Mr. {Gingrey.} I will be glad to the yield to the
1922 ranking member.

1923 Mr. {Walden.} I think it is important to point out that
1924 it is already against the Food, Drug and Cosmetic Act law to
1925 knowingly ship product that tests positive. That is the

1926 amazing thing here. Out of everything we have, it would
1927 appear they knew it was positive. If you get a positive hit
1928 on a salmonella test, you are supposed to destroy the
1929 product. They may test again to figure out in their process
1930 where they are having this contamination. That is a
1931 different deal. But you are not supposed to ship it out for
1932 consumption, and that is what is outrageous here. So that
1933 piece is already in the law. Obviously the inspection piece
1934 and some of these other things need to be dealt with, but it
1935 is just stunning.

1936 I yield back.

1937 Mr. {Gingrey.} Mr. Chairman, if I have any remaining
1938 time, I yield back.

1939 Mr. {Stupak.} The chair will use 45 seconds of your
1940 remaining time. Even subpoena power, I have been trying to
1941 get the FDA to have subpoena power for 12 years. They keep
1942 denying us saying they don't need it, a great example where
1943 you need subpoena power.

1944 Ms. DeGette.

1945 Ms. {DeGette.} [Presiding] Thank you. Well, okay, let
1946 us talk about subpoena power. Let us talk about the criminal
1947 laws. But these companies don't even have to produce their
1948 records to the FDA if they have these tests for salmonella,
1949 and in the previous peanut contamination hearing we had with

1950 ConAgra, what happened was, they had--it wasn't as blatantly
1951 criminal as this case, but what happened in that case was,
1952 they had water dripping down and they had all kinds of
1953 records that showed this, and they had the FDA inspectors
1954 come to the factory but the company made this decision not to
1955 produce the records because the records showed that there was
1956 a problem, and so while it is true that it is criminal
1957 activity and while it is also true that the FDA could use
1958 subpoena authority, it would be pretty simple for Congress to
1959 pass a law, and in fact, I think it is in Mr. Dingell's bill,
1960 to say that it is also a requirement that they produce this
1961 information when they have a test that shows negative, that
1962 they produce it to the FDA and put some criminal penalties in
1963 place, and I am sure all of you gentlemen would agree with
1964 that too.

1965 I don't really have any questions. I just sit here and
1966 I feel sick at heart when I hear you talk about your
1967 families, and Mr. Hurley, when I see your little kids, you
1968 know, I have two girls myself, so I feel sickened hearing
1969 about your parents, and what makes me so sick, as I said in
1970 my opening statement is, I have been sitting here for 12
1971 years listening to this. So I guess what I will say is, I
1972 want to echo what all of you said. It shouldn't be that hard
1973 for the most sophisticated country in the world to put a

1974 system in place that requires them to provide the documents
1975 when they see a problem, that gives the FDA mandatory recall
1976 authority, which by the way would act, I think, to light a
1977 fire under these companies if they knew that there was
1978 mandatory recall authority and they couldn't mess around.
1979 And then as I mentioned in my opening statement, traceability
1980 so that what happened in Oregon could happen in all the
1981 States where if you had mechanisms in place that were
1982 interoperable, then if you found salmonella in a little kid
1983 in Oregon, you could rapidly work throughout the United
1984 States to figure out the source of that salmonella and to
1985 recall all those food products. And if that happened, I
1986 don't think we would have lost Mr. Almer's and Mr.
1987 Tousignant's parents because we knew about that salmonella
1988 several months in advance.

1989 So I will make a commitment to you as someone who has
1990 worked on this for years along with Mr. Stupak, Mr. Dingell,
1991 Mr. Waxman, our friends on the other side of the aisle. We
1992 are going to do this, and I hope we will do it this year
1993 because I don't want to be back here in 6 months. Neither do
1994 you, Mr. Walden or Mr. Gingrey, any of you guys. We have
1995 just sat here too long listening to this and we can fix it.
1996 I have got some legislation. We have comprehensive
1997 legislation. We need to figure out, should we move this one

1998 bill at a time. We could do my mandatory-recall bill on the
1999 suspension calendar next week. Mr. Walden would agree. I
2000 will bet you Mr. Barton would agree. And we could do
2001 comprehensive food safety. We have been working on it for a
2002 long time. So I will just make the commitment to you. We
2003 are going to do this and we are going to do this in one your
2004 loved ones' memories. I will yield back.

2005 I recognize Mr. Burgess for 5 minutes.

2006 Mr. {Burgess.} I thank you. And it does seem like déjà
2007 vu all over again to quote a great American. Mr. Walden is
2008 exactly correct in the way we have dealt with a lot of these
2009 things repetitively and all the issues with notification, all
2010 the issues with recall, all of the issues with the failure of
2011 the kill step to take the bacteria off the exterior of the
2012 peanut. Those are all very important. If you have a
2013 criminal mind at the back of it running the operation, it is
2014 just hard to know how you deal with that asymmetric threat.
2015 We know that through multiple hearings, as I referenced in my
2016 opening statement, we beat on the FDA until it is a wonder
2017 there is anything left of them. They need better systems in
2018 place. We need to fund them better. We recognized that
2019 through hearing after hearing after hearing last Congress.
2020 We haven't even done our appropriations from last year yet.
2021 Those are due to come up in an omnibus bill in March so they

2022 need more money and we know that. We have been slow to
2023 respond. But still, the baseline, if you have got that
2024 asymmetric threat of a criminal mind, all of these things are
2025 very, very difficult to prevent if you have got someone who
2026 is willfully ignoring the rules and not just ignoring the
2027 rules, purposely working against you.

2028 Dr. Gingrey is correct. You do have three physicians on
2029 this subcommittee. You have got a clinical psychologist and
2030 a nurse. After today's hearing, we may need the clinical
2031 psychologist as well as the nurse. I am not sure if the
2032 doctors are going to do you any good.

2033 But let me just ask you, being a physician myself, I
2034 would like to ask each of you the same question generally,
2035 and Mr. Deal got to it a little bit, but this can be a
2036 difficult diagnosis, even though the clinical symptoms
2037 present themselves, and we are talking about salmonella and
2038 it seems very obvious to link the clinical symptoms with the
2039 ultimate diagnosis, but Mr. Almer, in your situation, was the
2040 correct diagnosis, did the doctors have that in order to
2041 timely offer treatment or was this something that was
2042 established after the fact?

2043 Mr. {Almer.} We actually though she had died from
2044 pneumonia, and we found out 2 weeks later that that wasn't
2045 even on the death certificate, and we were given notice by

2046 the department of health of the salmonella positive test.

2047 That was our first notice of it.

2048 Mr. {Burgess.} And there is some time lag in normal
2049 clinical circumstances between submitting a sample and
2050 getting a test result back, whether it is positive or
2051 negative. So is that in fact what occurred during that time
2052 interval or was this something in fact that was discovered
2053 completely after the fact?

2054 Mr. {Almer.} From what I am told, somebody was doing
2055 their due diligence at the facility and they noticed they had
2056 some patients with diarrhea and sent the stool samples for
2057 testing and my mother's was one of those.

2058 Mr. {Burgess.} So there were actually more people in
2059 the facility who were affected?

2060 Mr. {Almer.} There were actually--my sister lives up in
2061 the Brainerd community where three of the people have died.
2062 There actually are two others that may also die of salmonella
2063 at this time.

2064 Mr. {Burgess.} Just for my curiosity, were any
2065 diagnoses made in time to offer treatment? Salmonella is
2066 treatable. Oftentimes the other underlying conditions can
2067 make it impossible but the organism itself is one that we can
2068 generally get if we have got the knowledge.

2069 Mr. {Almer.} There was some treatment, possible sepsis,

2070 blood infection, which is common, I guess, with salmonella,
2071 but I don't think any of us knew or the facility knew that my
2072 mother had salmonella at that time, so she was already gone
2073 before anyone knew.

2074 Mr. {Burgess.} So to the best of your knowledge, no one
2075 received lab results in a timely fashion that would have
2076 allowed treatment to stop the disease?

2077 Mr. {Almer.} No, to my knowledge, no.

2078 Mr. {Burgess.} Yes, sir, and in your case with your
2079 dad?

2080 Mr. {Tousignant.} I am sorry?

2081 Mr. {Burgess.} I am going to mess up your name anyway
2082 but I can't see your name plate. Tousignant?

2083 Mr. {Tousignant.} Mr. Tousignant, yes.

2084 Mr. {Burgess.} Yes, sir. Okay. I am sorry. In your
2085 situation, was the diagnosis established before your dad
2086 died?

2087 Mr. {Tousignant.} To the best of my knowledge, no. I
2088 believe it was, like I mentioned earlier, a few days to a
2089 week later.

2090 Mr. {Burgess.} And again, very, very difficult for the
2091 caregivers involved because they are doing their best, and in
2092 your dad's situation, a bloodborne infection which obviously
2093 would be a good deal more aggressive.

2094 And then Mr. Hurley in your situation, the
2095 epidemiologist came to the house, but prior to that level of
2096 involvement, did your son's caregivers have an idea, did your
2097 son's physicians have an idea, that his symptoms clinically
2098 might tip off the diagnosis of salmonella?

2099 Mr. {Hurley.} Nothing was mentioned to us in the
2100 beginning, and actually the samples were given on a
2101 Wednesday. On Friday the pediatric nurse called and said so
2102 far things look good, and then it was the next day on
2103 Saturday or Sunday that the doctor called from home to let us
2104 know.

2105 Mr. {Burgess.} And then it was that result that led the
2106 epidemiologist to come to your home to collect samples?

2107 Mr. {Hurley.} Correct. First it went to the county. A
2108 couple days later I got a call from the county health, and
2109 then a couple days later got a call from the state
2110 epidemiology office, answered some questions over the phone
2111 because then things were really starting to move along
2112 nationally in terms of PCA, and so then when he found out
2113 that even while he was sick that he was eating the peanut
2114 butter crackers, he said can I come over in a couple of
2115 hours.

2116 Mr. {Burgess.} But of course, your son was under active
2117 care from a pediatrician or infectious disease specialist

2118 during the course of his illness?

2119 Mr. {Hurley.} No. I mean, they told us what the
2120 illness was. Basically we just treated for--I mean, just
2121 made sure he had plenty of fluids and--

2122 Mr. {Burgess.} So it was symptomatic treatment?

2123 Mr. {Hurley.} Right, symptomatic treatment, but no, he
2124 was not in a hospital.

2125 Mr. {Burgess.} Well, again, this underscores it. It is
2126 a difficult diagnosis in a clinical setting and then
2127 obviously made more much difficult by the criminal minds
2128 behind this enterprise. So again, just like every other
2129 member of the committee, our condolences on your loss and
2130 thank you for spending so much time with us this morning.

2131 I yield back, Mr. Chairman.

2132 Mr. {Stupak.} Ms. Schakowsky for questions, please.

2133 Ms. {Schakowsky.} It is not so much a question, unless
2134 you want to respond to it, but I do want to be sure and get
2135 on the record, and I am wondering, is Mr. Parnell here yet?
2136 He is to be on the next panel, I guess. There is on tab 4 a
2137 couple of e-mails that I just can't get over. On June 6,
2138 2008, a PCA employee sent an e-mail to Steward Parnell
2139 alerting him that their product may have salmonella. If you
2140 look at that, you see it says ``lot number put on hold,''
2141 exclamation points, ``I just spoke with Stephanie, with

2142 JLA,' ' the private laboratory. ``This lot is presumptive
2143 salmonella,' ' in caps, and a total of 15 exclamation points
2144 in these two sentences alone. Now, to any normal person,
2145 this would be a red flag and the alarms would go off and you
2146 would realize this is serious. I am sure everyone would
2147 agree with that.

2148 So here is the e-mail that Mr. Parnell sent in response.
2149 Later in the day he wrote, ``I go through this about once a
2150 week. I will hold my breath again.' ' So how is anyone to
2151 react to the incredible disregard of this urgent e-mail? It
2152 is just absolutely beyond me. I don't know if any of you can
2153 put this into words, and certainly we would welcome your
2154 words on the record. Mr. Tousignant, did you want to--

2155 Mr. {Tousignant.} When this first happened, I think for
2156 a couple of my brothers and sisters and I, we wanted to
2157 believe that this somehow was really just an accident, that
2158 something happened with one of the companies, that somehow
2159 this got into the food. And as we have gone along in this
2160 process of discovery and learning more information as each
2161 day goes on, it just baffles me and I know it probably
2162 baffles every single one of us up here today and our families
2163 and the others in the country, that this is affected, that
2164 any one person can make a decision like this so consistently
2165 and so blatant.

2166 Ms. {Schakowsky.} I also want to say that I understand
2167 if you feel angry at us as well because as Congresswoman
2168 DeGette said, we have been here before, and again, as others
2169 have, I just want to make a commitment that we are definitely
2170 going to create the systems, act quickly so that hopefully we
2171 put in place the assurances that you are the last panel of
2172 people suffering from this that have to come before us.
2173 Thank you.

2174 Mr. {Stupak.} Thank you, Ms. Schakowsky.

2175 Let me thank this panel again. I think that concludes
2176 everybody's questions. So Mr. Hurley, your family asked when
2177 we were going to let you go. You are free to go if you want
2178 or stay for the rest of this hearing, you can, Mr. Tousignant
2179 and Mr. Almer, if you would like to, you can, but thank you
2180 for being here and thank you for putting a face on the
2181 tragedy that families are feeling across this country. Thank
2182 you very much for your testimony.

2183 Once the clerk clears that table, we will start with our
2184 second panel of witnesses. Our second panel of witnesses
2185 will come forward. On our second panel, we have Mr. Stewart
2186 Parnell, who is president of Peanut Corporation of America,
2187 and Mr. Sammy Lightsey, plant manager of that Peanut
2188 Corporation of America's Blakely, Georgia, facility.

2189 It is the policy of this subcommittee to take all

2190 testimony under oath. Please be advised, gentlemen, that
2191 witnesses have the right under the rules of the House to be
2192 advised by counsel during their testimony. Do you wish to be
2193 represented or advised by counsel, Mr. Lightsey?

2194 Mr. {Lightsey.} No.

2195 Mr. {Stupak.} Mr. Parnell?

2196 Mr. {Parnell.} Yes, sir.

2197 Mr. {Stupak.} I would ask you to state the name of your
2198 counsel who will be advising you. Counsel cannot testify but
2199 can advise you, and before you answer a question if you want
2200 to consult with them before you answer it, you are allowed to
2201 under the rules of the House. So who would your counsel be,
2202 sir?

2203 Mr. {Parnell.} Bill O'Reilly.

2204 Mr. {Stupak.} Okay, and Mr. O'Reilly, you are right
2205 here then, right? Okay. Mr. Lightsey?

2206 Mr. {Lightsey.} I am sorry. I misunderstood the
2207 question.

2208 Mr. {Stupak.} Hit your mic, right there, a little
2209 button there. Is Mr. O'Reilly going to be your counsel too?

2210 Mr. {Lightsey.} No, Jim Parkman.

2211 Mr. {Stupak.} Jim?

2212 Mr. {Lightsey.} Parkman.

2213 Mr. {Stupak.} Parkman. Okay. Mr. Parkman, raise your

2214 hand just so we know who you are. Okay. Very good. The
2215 sample applies to you. If you want before you any questions
2216 you want to consult with your counsel, you have a right to do
2217 so. So I am going to ask you both to rise and raise your
2218 right hand to take the oath.

2219 [Witnesses sworn.]

2220 Mr. {Stupak.} Let the record reflect that the witnesses
2221 replied in the affirmative. You are now under oath. You
2222 will 5 minutes for an opening statement or you may submit a
2223 longer statement for inclusion in the hearing record.

|
2224 ^TESTIMONY OF STEWART PARNELL, PRESIDENT, PEANUT CORPORATION
2225 OF AMERICA; AND SAMMY LIGHTSEY, PLANT MANAGER, PEANUT
2226 CORPORATION OF AMERICA

2227 Mr. {Stupak.} Mr. Lightsey, do you have an opening
2228 statement?

2229 Mr. {Lightsey.} No, I do not.

2230 Mr. {Stupak.} Mr. Parnell?

2231 Mr. {Parnell.} No, sir.

2232 Mr. {Stupak.} Then we are going to go right to
2233 questions, and members have 5 minutes for questions, and I
2234 will begin.

2235 Mr. Parnell, I want to ask you about an e-mail you sent
2236 to your employees at the Peanut Corporation on January 12,
2237 2009, after public health officials found salmonella in
2238 peanut butter from your plant in Georgia. Right in front of
2239 you right there is our binder tab. It is tab #44, if you
2240 care to look at it. In particular, I want to ask you about
2241 the following statement you made in that e-mail. You said,
2242 ``We do not believe the salmonella came from our facility.
2243 As you probably know, we send hourly PB samples to an
2244 independent lab to test for salmonella during production of
2245 peanut butter and we have never found any salmonella at

2246 all.'' Mr. Parnell, during its investigation FDA found on 12
2247 separate occasions between June 2007 and September 2008
2248 peanut products produced by PCA and tested by private labs
2249 were found to be contaminated with salmonella. On six of
2250 these occasions the FDA found that you had already shipped
2251 the product and that you conducted no subsequent testing. So
2252 your statement that you ``never found any salmonella at all''
2253 does not appear to be true. So here is my question then, and
2254 I remind you, you are under oath: Mr. Parnell, did you or
2255 any officials at the Peanut Corporation of America ever place
2256 food products into the interstate commerce that you knew to
2257 be contaminated with salmonella?

2258 Mr. {Parnell.} Mr. Chairman and members of the
2259 committee, on the advice of my counsel, I respectfully
2260 decline to answer questions based on the protection afforded
2261 me under the United States Constitution.

2262 Mr. {Stupak.} Mr. Parnell, let me ask you this. In the
2263 last panel, and you heard the last panel testify, did you
2264 not?

2265 Mr. {Parnell.} Mr. Chairman and members of the
2266 committee, on the advice of my counsel, I respectfully
2267 decline to answer your question based on the protection
2268 afforded me under the United States Constitution.

2269 Mr. {Stupak.} I just asked you if you heard the other

2270 panel.

2271 Mr. {Parnell.} Mr. Chairman and members of the
2272 committee, on the advice of my counsel, I respectfully
2273 decline to answer your question based on the protection
2274 afforded me under the United States Constitution.

2275 Mr. {Stupak.} Okay. Well, let me ask you this
2276 question, Mr. Parnell. The earlier panel, we talked a little
2277 bit about money and some of the e-mails and statements
2278 attributed to you about cost of business, how not moving
2279 product was hurting you, hurting your business, and that
2280 actually you deal with salmonella, again from the e-mails,
2281 once a week. So the food poisoning of people, is that just a
2282 cost of doing business for your company?

2283 Mr. {Parnell.} Mr. Chairman and members of the
2284 committee, on the advice of my counsel, I respectfully
2285 decline to answer your question based on the protection
2286 afforded me under the United States Constitution.

2287 Mr. {Stupak.} Mr. Walden, I believe you had a question
2288 you had alluded to earlier. Would you like to ask that
2289 question?

2290 Mr. {Walden.} I would, Mr. Chairman.

2291 Mr. Parnell, Mr. Lightsey, let me just cut to the chase
2292 then. In this container are products that have your
2293 ingredients in them, some of which were on the recall list,

2294 some of which are probably contaminated. It seems like from
2295 what we read you are willing to send out that peanut base
2296 with these ingredients, and I just wonder, would either of
2297 you be willing to take the lid off and eat any of these
2298 products now like the people on the panel ahead of you, their
2299 relatives, their loved ones did?

2300 Mr. {Parnell.} Mr. Chairman and members of the
2301 committee, on the advice of my counsel, I respectfully
2302 decline to answer your question based on the protection
2303 afforded me under the United States Constitution.

2304 Mr. {Walden.} Mr. Lightsey?

2305 Mr. {Lightsey.} At this time on advice of counsel, I
2306 exercise my rights under the Fifth Amendment of the
2307 Constitution.

2308 Mr. {Stupak.} Mr. Parnell, is it your intent to refuse
2309 to answer all of our questions today based on your right
2310 against self-incrimination afforded to you under the Fifth
2311 Amendment of the Constitution?

2312 Mr. {Parnell.} Yes.

2313 Mr. {Stupak.} Mr. Lightsey, is it your intention to
2314 refuse to answer all our questions today based on the right
2315 against self-incrimination afforded to you under the Fifth
2316 Amendment of the Constitution?

2317 Mr. {Lightsey.} Yes.

2318 Mr. {Stupak.} All right. Then I have no choice but
2319 that both of you are dismissed at this time. You are subject
2320 to the right of the subcommittee to recall you at a later
2321 time and date if necessary.

2322 I would now like to call our third panel of witnesses to
2323 come forward. On our third panel we have Dr. Stephen
2324 Sundlof, who is the director of the Center for Food Safety
2325 and Applied Nutrition at the Food and Drug Administration;
2326 Mr. Oscar Garrison, who is the assistant commissioner of the
2327 Consumer Protection Division at the Georgia Department of
2328 Agriculture; Ms. Darlene Cowart, who is the president of J.
2329 Leek Associates Incorporated, JLA, and Mr. Charles Deibel,
2330 who is president of Deibel Laboratories.

2331 It is the policy of this subcommittee to take all
2332 testimony under oath. Please be advised that you have the
2333 right under the rules of the House to be advised by counsel
2334 during your testimony. Do any of you wish to be advised by
2335 counsel during your testimony? Ms. Cowart?

2336 Ms. {Cowart.} Yes, Mr. Chairman, I have counsel present
2337 today, and I do wish to be represented.

2338 Mr. {Stupak.} Counsel's name is?

2339 Ms. {Cowart.} Mr. Evans Plowden and his associates.

2340 Mr. {Stupak.} Okay. If you want to consult with them
2341 before you answer a question, please do.

2342 Ms. {Coward.} Thank you.

2343 Mr. {Stupak.} Mr. Deibel?

2344 Mr. {Deibel.} Yes, sir, I have counsel present but they
2345 are sitting in back of me.

2346 Mr. {Stupak.} Just identify their name for the record.

2347 Mr. {Deibel.} Charles Deibel.

2348 Mr. {Stupak.} Mr. Deibel, your lawyer's name. You
2349 stated your name.

2350 Mr. {Deibel.} Richard Chapman.

2351 Mr. {Stupak.} Mr. Garrison, do you wish to have counsel
2352 present?

2353 Mr. {Garrison.} Yes, sir, I am being represented by Mr.
2354 Ted Hester of King and Spaulding at the request of our
2355 Georgia Attorney General, Thurbert Baker.

2356 Mr. {Stupak.} Very good. Mr. Chappell?

2357 Mr. {Chappell.} Mr. Chairman, no, sir.

2358 Mr. {Stupak.} Dr. Sundlof?

2359 Dr. {Sundlof.} No, sir, Mr. Chairman.

2360 Mr. {Stupak.} Okay. As I said, it is the policy to
2361 take all testimony under oath. I am going to ask you now to
2362 rise and raise your right hand to take the oath.

2363 [Witnesses sworn.]

2364 Mr. {Stupak.} Let the record reflect that the witnesses
2365 replied in the affirmative. You are now under oath. We will

2366 begin with opening statements for 5 minutes. If you wish to
2367 submit a longer statement for inclusion in the record, that
2368 will be allowed. Dr. Sundlof, let us start with you, please,
2369 sir.

|
2370 ^TESTIMONY OF STEPHEN SUNDLOF, D.V.M., PH.D., DIRECTOR OF THE
2371 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG
2372 ADMINISTRATION, ACCOMPANIED BY MICHAEL CHAPPELL, ACTING
2373 ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG
2374 ADMINISTRATION; OSCAR GARRISON, ASSISTANT COMMISSIONER,
2375 CONSUMER PROTECTION DIVISION, GEORGIA DEPARTMENT OF
2376 AGRICULTURE; DARLENE COWART, PRESIDENT, J. LEEK ASSOCIATES,
2377 INC.; AND CHARLES DEIBEL, PRESIDENT, DEIBEL LABORATORIES

|
2378 ^TESTIMONY OF STEPHEN SUNDLOF

2379 } Dr. {Sundlof.} Thank you, Mr. Chairman and members of
2380 the committee. I am Dr. Stephen Sundlof, director of the
2381 Center for Food Safety and Applied Nutrition at the U.S. Food
2382 and Drug Administration, which is part of the Department of
2383 Health and Human Services. I am accompanied today by Mr.
2384 Michael Chappell, FDA's acting associate commissioner for
2385 regulatory affairs. FDA appreciates the opportunity to
2386 discuss our ongoing investigation of the foodborne illness
2387 outbreak associated with salmonella typhimurium, which has
2388 been found in peanut products produced by the Peanut
2389 Corporation of America, or PCA.

2390 Let me begin by expressing my personal and the agency's

2391 concern for people harmed in this outbreak of foodborne
2392 illness. FDA can and will learn from this outbreak what we
2393 can do to better assure the safety of our food supply moving
2394 forward. And it is important to note that the manufacturers
2395 play a critical role in ensuring the safety of the foods that
2396 they introduce into commerce. Strong food safety programs
2397 begin with a commitment and the strong oversight of the
2398 managers and the promotion of strong food safety culture
2399 throughout the company.

2400 In the typical traceback process employed by FDA and our
2401 partners at the Centers for Disease Control and Prevention,
2402 CDC notifies FDA when it identifies the possible foods
2403 associated with foodborne illness through its epidemiological
2404 investigation. At that point the FDA starts its
2405 investigation to identify the source of contamination. In
2406 the current case, FDA started its tracing process before CDC
2407 notified us of a strong epidemiological link to both help
2408 inform the epidemiological study and to shorten the time
2409 required to remove potentially contaminated foods from the
2410 market. Since early December of 2008, FDA has collaborated
2411 with the CDC, U.S. Department of Agriculture and state public
2412 health departments to investigate the multi-State outbreak of
2413 human infections due to salmonella typhimurium.

2414 Peanut butter was first identified as a possible source

2415 in mid-December, and on January 7 and 8, based on preliminary
2416 epidemiological data, the FDA decided to investigate
2417 institutional food sources of peanut butter rather than wait
2418 for more-conclusive data. On January 7, FDA made its initial
2419 contact with the King Nut Company, which distributes peanut
2420 butter manufactured by PCA to institutional facilities, food
2421 service industries and private label companies. Two days
2422 later on January 9, FDA initiated our inspection of the PCA
2423 manufacturing plant in Blakely, Georgia. As part of its
2424 epidemiological investigation, the Minnesota Department of
2425 Health tested an open 5-pound container of King Nut peanut
2426 butter obtained at a nursing home where three patients were
2427 sickened by the outbreak strain of salmonella typhimurium.
2428 By January 10, Minnesota health officials had found that
2429 peanut butter contained the same strain of salmonella
2430 typhimurium. However, because it was an open container which
2431 could have been contaminated by someone or something else in
2432 the environment, these results did not confirm the Blakely
2433 plant as the source.

2434 So FDA expanded the testing of unopened containers of
2435 the same strain of peanut butter, and on January 19, the
2436 Connecticut Department of Health tested an unopened container
2437 of King Nut peanut butter and found that it contained the
2438 same strain of salmonella typhimurium associated with the

2439 illness linked to the outbreak. The fact that salmonella
2440 typhimurium was confirmed in an unopened container of peanut
2441 butter indicated that the peanut butter was contaminated when
2442 it left the Blakely processing plant.

2443 As I noted earlier, FDA had already initiated the
2444 inspection of PCA's Blakely plant on January 9. We completed
2445 our inspection on January 27. FDA's environmental sampling
2446 at the plant found two salmonella strains, neither of which
2447 was associated with the outbreak. We are confident, however,
2448 that based on the investigations by the States, CDC and FDA
2449 that the Blakely plant is the source of contamination related
2450 to the salmonella typhimurium outbreak. Further, FDA's
2451 review of the testing records revealed that there were
2452 instances in 2007 and 2008 where the firm distributed product
2453 in commerce which had tested positive for salmonella.

2454 The first recalls began on January 10 by the King Nut
2455 Company, and on January 13 by PCA. Expanded recalls followed
2456 on January 28 and on January 28 the firm voluntarily recalled
2457 all peanut products processed in its Blakely facility since
2458 January 1, 2007, and these included dry and oil-roasted
2459 peanuts, granulated peanuts, peanut meal, peanut butter and
2460 peanut paste. Many companies that received the peanuts and
2461 peanut products manufactured by PCA's Blakely facility have
2462 in turn conducted their own voluntary recalls. FDA is

2463 continuing to work with the purchasers of PCA's peanuts and
2464 peanut products to identify affected products and facilitate
2465 their removal from the market. FDA initiated inspections at
2466 the direct consignees of PCA and King Nut and continues to
2467 follow the distribution points of the products. FDA has
2468 established a web page to provide constantly updated
2469 information on the contamination and recall. It includes a
2470 searchable databases to assist consumers in quickly
2471 identifying recalled products, and we encourage consumers to
2472 check this website frequently.

2473 FDA is reviewing with Health and Human Services our
2474 prior legislative requests to strengthen the agency's ability
2475 to protect Americans from foodborne illness to determine
2476 whether those requests should be updated in light of our
2477 experience with this outbreak. At this time we want to
2478 highlight the need for enhanced authorities in several areas.
2479 Number one, authority for FDA to issue preventive controls
2480 for high-risk foods; two, authority for enhanced access to
2481 food records during routine inspections; three, the authority
2482 for FDA to require food facilities to renew their
2483 registrations every 2 years and for FDA to modify the
2484 registration categories. In addition, we note that mandatory
2485 recall authority would be a useful tool that in some
2486 circumstances could result in faster removal of implicated

2487 products from commerce.

2488 In closing, Mr. Chairman, let me assure you that the FDA
2489 is working hard to ensure the safety of the food supply in
2490 collaboration with our federal, State, local and
2491 international food safety partners. Although the salmonella
2492 typhimurium foodborne illness outbreak underscores the
2493 challenges that we face, the American food supply continues
2494 to be among the safest in the world and food safety is a
2495 priority of the new Administration. Please be aware that FDA
2496 is actively conducting both criminal and regulatory
2497 investigations related to this matter. To protect the
2498 integrity of these ongoing investigations and any related
2499 actions that might be pursued in the future, FDA must
2500 necessarily keep certain information confidential. It is
2501 also premature for FDA to draw conclusions about our
2502 preliminary observations or how the FDA's legal authorities
2503 might apply to those observations, but that said, we will do
2504 our best to respond to any questions that you may have.

2505 Thank you again for the opportunity to discuss these
2506 important public health matters.

2507 [The prepared statement of Dr. Sundlof follows:]

2508 ***** INSERT 4 *****

|
2509 Mr. {Stupak.} Thank you.

2510 Mr. Chappell?

2511 Mr. {Chappell.} I don't have an opening statement.

2512 Mr. {Stupak.} Okay. Mr. Garrison, opening statement,
2513 please, sir, 5 minutes. If you have a longer statement, we
2514 will submit it to the record.

|
2515 ^TESTIMONY OF OSCAR GARRISON

2516 } Mr. {Garrison.} Chairmen Waxman, Stupak, Ranking
2517 Members Barton and Walden, and distinguished members of the
2518 subcommittee, I would like to thank you for the opportunity
2519 to offer this testimony today. I am here on behalf of
2520 Georgia's Commissioner of Agriculture, Tommy Irvin. I am
2521 Oscar Garrison, the assistant commissioner responsible for
2522 Georgia Department of Agriculture's Consumer Protection
2523 Division. I have been directly involved with food safety at
2524 various levels for more than 15 years. I want to express my
2525 sympathy to the victims of the salmonella outbreak that were
2526 here today and also to the victims of foodborne illness in
2527 this country.

2528 The Georgia Department of Agriculture takes its
2529 commitment to food safety very seriously. We are more
2530 concerned about food safety and food being sold and processed
2531 in Georgia than anyone. To more effectively carry out our
2532 mission, the Department is working with our State legislature
2533 on an amendment to the Georgia Food Act that would require
2534 regular testing by the food manufacturers in Georgia. This
2535 legislation would require processing plants to promptly
2536 report to the Department the presence of any suspected

2537 contamination that would render food injurious to health or
2538 otherwise unfit for consumption. We encourage this committee
2539 to consider federal legislation that would require similar
2540 testing and reporting nationwide.

2541 We would like to have additional resources that would
2542 permit us to perform more inspections more frequently and
2543 comprehensively along with product testing, but with
2544 tightening budgets, FDA, Georgia and other States are
2545 stretching their resources about as effectively as we are
2546 able to. The Department has requested and our governor has
2547 recommended \$24 million to help fund a new laboratory to be
2548 located in south Georgia that would increase the product
2549 testing that our Department is currently capable of
2550 performing. Currently, we can test about 4,500 food samples
2551 per year in our State laboratories. The Georgia Department
2552 of Agriculture is required through the Georgia Food Act to
2553 license and inspect food sales establishments and processing
2554 plants. We inspect approximately 16,000 facilities ranging
2555 from processing plants to food storage warehouses to retail
2556 grocery stores. These inspections are conducted by a field
2557 force of approximately 60 inspectors.

2558 For many years the Department of Agriculture, like
2559 agencies in other States, has had a contractual relationship
2560 with the Food and Drug Administration that requires us to

2561 conduct inspections at various food-processing plants in
2562 Georgia that ship products into interstate commerce.
2563 Including the two inspections we conducted for FDA, our
2564 Department conducted a total of nine inspections at the plant
2565 between 2006 and 2008. During these inspections, our
2566 inspectors did not see any conditions that would raise a red
2567 flag indicating an imminent health hazard.

2568 An inspection is simply a snapshot in time. An
2569 inspector can only see what is there at that particular time
2570 that they are conducting the inspection. The Department
2571 utilizes all the resources available to us to verify that
2572 food processors are operating responsibly. However, it is
2573 important to recognize that if processors do not act
2574 responsibly and most certainly if they engage in criminal
2575 activity designed to avoid detection, the most rigorous and
2576 regular inspections would not readily detect a problem. We
2577 do not have all the facts, but once the Peanut Corporation of
2578 America had test results disclosing the presence of
2579 salmonella, it was unconscionable for that company to ship
2580 the product, fail to recall the product or fail to notify us
2581 or FDA.

2582 In closing, let me thank you for joining with us in an
2583 effort to improve the safety of this country's food supply.
2584 This tragic situation must serve as a wakeup call leading to

2585 reforms in the United States food safety network and through
2586 additional funding that will permit food safety agencies at
2587 the federal, State and local levels to more effectively
2588 perform their jobs. Thank you.

2589 [The prepared statement of Mr. Garrison follows:]

2590 ***** INSERT 5 *****

|
2591 Mr. {Stupak.} Thank you, Mr. Garrison.

2592 Ms. Cowart, your opening statement, please, for 5
2593 minutes. If you have a longer statement, we will insert it
2594 in the record.

2595 Ms. {Cowart.} Thank you.

2596 Mr. {Stupak.} Thank you.

|
2597 ^TESTIMONY OF DARLENE COWART

2598 } Ms. {Cowart.} Mr. Chairman, my name is Darlene Cowart,
2599 and you have my biographical information, I believe, in the
2600 record. My education has been in biology and food science,
2601 and I have worked in the agricultural commodity and food-
2602 related quality control area since completing my education.
2603 I am currently president of JLA USA. Our company is one of
2604 several under the umbrella of JLA Global, which has
2605 facilities in the United States and abroad. JLA USA has
2606 testing facilities in seven locations in the United States.
2607 While the majority of our work is related to the peanut
2608 industry, we also provide services and testing to the almond
2609 industry and to some degree other food businesses. JLA USA
2610 maintains microbiology laboratories in Albany, Georgia, and
2611 Edenton, North Carolina. We provide a broad range of testing
2612 services to the agricultural commodity and food business. I
2613 understand the committee's concerns today relate to the
2614 recent salmonella outbreak and therefore involve our
2615 microbiology testing.

2616 Mr. Chairman, when we test for salmonella, we receive
2617 from the customer samples of the product to be tested
2618 together with the notification of the test that the customer

2619 wants us to perform. Specifically, we receive a request for
2620 analysis which details the battery of tests desired by the
2621 customer and includes the customer's description of the
2622 product to be tested, and I believe you have copies of these
2623 also in the record. I have also furnished the committee
2624 staff a detailed description of the method we use to test for
2625 salmonella, and I will simply summarize that here.

2626 First we pull a representative sample from the
2627 customer's containers to get a composite sample of 375 grams.
2628 That composite sample is then put into a sterile bag with
2629 other substances and incubated. We remove some of the
2630 mixture into the test tubes and for other procedures and
2631 eventually we put the resulting substance into what is called
2632 a VIDAS instrument. This machine's computer will
2633 automatically give us the result either positive or negative
2634 for salmonella. If the result is not negative from the
2635 instrument, the negative certificate of analysis is sent to
2636 the customer. If the result is positive, it is what we call
2637 in our laboratory a presumptive positive, which must be
2638 confirmed, because at this point several organisms can look
2639 like salmonella but are not. However, since the test
2640 necessary to confirm the presumptive positive can take up to
2641 5 days, we notify the customer of the presumptive positive by
2642 e-mail and a telephone call. The confirmation process is

2643 quite technical and is also described in the paper that we
2644 furnished the committee staff. If after the confirmation we
2645 find that salmonella is ruled out, we prepare a negative
2646 certificate of analysis for immediate release to the
2647 customer. If we do confirm that the presumptive positive is
2648 salmonella, then we prepare and issue a positive certificate
2649 of analysis and again we notify the customer via a telephone
2650 call and an e-mail alert. Mr. Chairman, all these procedures
2651 confirm to the appropriate FDA and accepted laboratory
2652 standards.

2653 From January 1, 2007, through September of 2008, we
2654 tested approximately 1,000 samples of product from Peanut
2655 Corporation of America. Of these in 2007, six samples were
2656 confirmed positive for salmonella, and all the rest were
2657 negative. In 2008 we issued a total of four confirmed
2658 salmonella positive certificate of analysis. I wish to
2659 emphasize, Mr. Chairman, that we at JLA do not take the
2660 samples from the product nor do we have knowledge of the
2661 sampling procedure used by PCA for the samples we receive.
2662 With respect to the PCA samples on each occasion that JLA
2663 received samples, the product samples would have been sent by
2664 mail to a JLA laboratory together with this request for
2665 analysis. The information provided on the request for
2666 analysis is the only information about the sample that JLA

2667 receives. Following a confirmed salmonella positive issued
2668 to PCA in August of 2008, PCA discontinued sending product
2669 samples to JLA with one exception. We did receive a few test
2670 samples under the name PP Sales, and it is my understanding
2671 that this name is an internal designation within PCA and
2672 possibly refers to a different product line. JLA did test
2673 and obtain a confirmed salmonella positive on a PP Sales
2674 sample sent to JLA in late September 2008. A positive COA
2675 was issued to PCA in early October 2008. In every instance
2676 when we found presumptive positives or confirmed positives,
2677 we reported the results to PCA by e-mail and telephone as I
2678 described earlier.

2679 Salmonella can occur in raw agricultural commodities and
2680 the accepted procedure for killing salmonella in raw
2681 agricultural products is to heat the product to a necessary
2682 temperature for the appropriate period of time, and that
2683 procedure is commonly referred to as the kill step. It is
2684 possible for salmonella to be reintroduced into a product
2685 after the kill step. This can occur if the product comes in
2686 contact with contaminated raw ingredients, equipment or
2687 personnel. Therefore, it is extremely important that all
2688 food manufacturing facilities maintain proper procedures and
2689 processes to ensure that recontamination does not occur.
2690 Salmonella in processed foods is preventable and the

2691 application of an appropriate kill step combined with good
2692 manufacturing processes that eliminate the possibility of
2693 recontamination should result in a salmonella-free product.
2694 Microbiological testing for salmonella and other pathogens is
2695 an important evaluative tool that manufacturers can and
2696 should employ to ensure that their manufacturing processes
2697 are safe.

2698 Mr. Chairman, we are cooperating fully with the
2699 committee and your staff and JLA pledges to continue working
2700 with the committee to make certain the food supply is safe
2701 for all consumers. Thank you, Mr. Chairman.

2702 [The prepared statement of Ms. Cowart follows:]

2703 ***** INSERT 6 *****

|

2704 Mr. {Stupak.} Thank you.

2705 Mr. Deibel, your opening statement, please.

|
2706 ^TESTIMONY OF CHARLES DEIBEL

2707 } Mr. {Deibel.} Good morning, Chairman Stupak and members
2708 of the subcommittee. I would like to thank you for giving me
2709 this opportunity to speak with you today. My name is Charles
2710 Deibel and I am the president of Deibel Laboratories, a firm
2711 that specializes in microtesting food and personal care
2712 products and food safety consulting. We have 10 labs in
2713 North America with our headquarters in Illinois. For more
2714 than 40 years Deibel Labs has provided scientific consulting
2715 services to food manufacturers around the country. My
2716 father, who remains active in the company today, started
2717 Deibel Labs when he was the dean of the University of
2718 Wisconsin's bacteriology program in the late 1960s. He is
2719 widely recognized as one of the most knowledgeable scientists
2720 in the food industry, pioneering test methods still in use
2721 today and helping to shape food safety systems in America.
2722 In addition to microtesting food products and their
2723 ingredients, we work with many manufacturers to help evaluate
2724 their existing food safety programs, conduct risk
2725 assessments, perform plant audits and offer training in food
2726 safety procedures.

2727 I would like to give you a brief summary of Deibel Lab's

2728 dealings with Peanut Corporation of America, or PCA. My
2729 company did not provide day-to-day testing services for PCA
2730 as we did for many of our clients. Instead, during 2007 and
2731 2008, PCA's Plainview, Texas, and Blakely, Georgia,
2732 facilities sporadically submitted samples containing peanuts
2733 to Deibel Labs to test. We have voluntarily cooperated with
2734 the Centers for Disease Control, the Food and Drug
2735 Administration and this subcommittee to provide detailed
2736 records of the tests we performed for PCA's facilities
2737 including samples from PCA's Blakely facility that tested
2738 positive for salmonella in late September 2008 and our
2739 records of the immediate communications of those results to
2740 PCA's Blakely facility personnel. We also provided records
2741 detailing the requests that personnel at the Blakely facility
2742 made to us to retest existing samples and the negative
2743 results of those tests.

2744 Mr. Chairman, may I briefly supplement the written
2745 statement that is in the record?

2746 Mr. {Stupak.} Without objection, yes.

2747 Mr. {Deibel.} As you know, the story about PCA's
2748 actions becomes clearer almost by the hour. I have learned
2749 more in reading the FDA's website publications, the results
2750 of the investigation recorded, readings in newspapers and in
2751 sitting today. I am horrified in seeing the projections of

2752 the very damning e-mails in the screens to our left and
2753 right.

2754 In late January the FDA and CDC requested that our labs
2755 provide them with cultures of ingredients we tested, and
2756 based on provisions of the 2002 Bioterrorism Act we
2757 voluntarily submitted this work. In late January counsel for
2758 this committee came to us as part of the subcommittee's
2759 investigation. We voluntarily and promptly provided staff
2760 counsel with all relevant documents and access to witnesses
2761 and myself within minutes of any request. On February 5,
2762 2009, we first saw and learned of the willful and gross
2763 negligence in sanitary manufacturing and Good Manufacturing
2764 Practices contained in FDA's amended investigation report.
2765 At about that same time we received samples from the PCA
2766 Texas facility and found them to be positive for salmonella.
2767 We promptly provided that information to your committee and
2768 FDA.

2769 It is not unusual for Deibel Labs or for other food
2770 testing laboratories to find that samples clients submit do
2771 test positive for salmonella and other pathogens. What is
2772 virtually unheard of is for an entity to disregard those
2773 results and place potentially contaminated products into the
2774 stream of commerce. I commend the subcommittee for examining
2775 what can be done to prevent an incident like this from

2776 happening again.

2777 As discussions progress on how best to reform our
2778 national food safety program, I urge you to look at the
2779 entire model used today. Our current food safety system
2780 relies heavily on inspections conducted by the FDA and the
2781 State agencies with which it contracts. This is a reactive
2782 response rather than the comprehensive, systemic process
2783 needed to safeguard our food. The FDA should focus on
2784 quality control systems that minimize the potential for
2785 contamination to occur in the first place and develop
2786 mitigating strategies for correcting a potential issue before
2787 it impacts food safety.

2788 The FDA has a great deal of knowledge and understanding
2789 of how manufacturers can improve our food safety practices.
2790 Our Nation's small and medium-sized companies in particular
2791 could greatly benefit from guidance documents from FDA yet
2792 their job is to inspect, not to provide guidance and so they
2793 don't. Yet the USDA routinely issues guidance documents to
2794 the food processors under its jurisdiction. FDA staff are
2795 reluctant to point manufacturers to the information and
2796 resources they need or provide direct guidance on how an
2797 observation can be corrected. As a result, opportunities to
2798 improve food production practices are missed. Testing, much
2799 like inspection, is only one piece of an overall food safety

2800 policy. It is the last chance to catch a problem.

2801 The larger piece, however, is on the front end, quality
2802 control systems that minimize the potential for the
2803 contamination to occur in the first place. Every year
2804 millions of pounds of food products end up in landfills
2805 because of positive test results for harmful organisms. The
2806 problem here is not in finding a positive test result. The
2807 issue we are discussing here is a firm that found a positive,
2808 tried to contest the compliancy and released the product
2809 anyway. The attention to this issue of food safety is
2810 important. It is an opportunity to build stronger bridges
2811 between FDA and the food manufacturers. By taking a
2812 preventative, systemic approach, we can implement reforms
2813 that will go a long way towards ensuring that consumers have
2814 access to safe and wholesome foods. Thank you.

2815 [The prepared statement of Mr. Deibel follows:]

2816 ***** INSERT 7 *****

|
2817 Mr. {Stupak.} Thank you. That concludes the opening
2818 statements. I ask unanimous consent that Chairman Dingell,
2819 his full statement be made part of the record. Without
2820 objection.

2821 [The prepared statement of Mr. Dingell follows:]

2822 ***** INSERT 8 *****

|
2823 Mr. {Stupak.} I will also note for the record that Mr.
2824 Inslee was here. I guess he is going to be back, and as a
2825 member of the full committee would be allowed to ask
2826 questions of this panel.

2827 And we have three different parts of this panel, if you
2828 will. We will probably go more than one round of questions
2829 so we will try to go 5 minutes and we will come back if we
2830 have to.

2831 Ms. Cowart, let me ask you a couple questions if I may.
2832 On tab 38 is the first tab I sort of see in here in the
2833 binder. It is a November 2, 2006, letter to Mr. Parnell of
2834 PCA, Peanut Corporation of America. In 2006 were you
2835 consulting with them as to their plant and salmonella? In
2836 looking at this, it looks like you were acting more as a
2837 consultant as opposed to lab testing, right?

2838 Ms. {Cowart.} At this point I received a phone call,
2839 our JLA received a phone call, and they had a problem or they
2840 reported a problem with some salmonella in some peanut
2841 granules and they needed someone to do a walk-through of the
2842 facility, and so by proximity, based in Albany, Georgia, and
2843 I have that background, I did go through and do a walk-
2844 through and tried to help them understand where the
2845 salmonella was coming from on that particular issue.

2846 Mr. {Stupak.} So in 2006 JLA was not testing, you sort
2847 of did a walk-through to try to figure out where the
2848 salmonella was coming from?

2849 Ms. {Coward.} Right. I didn't pull any samples at that
2850 point. Our company has a microbiology department that does
2851 testing, and then there is another piece that will help, as
2852 you just--

2853 Mr. {Stupak.} Sure. And in this tab 38, in this
2854 letter, you sort of indicated three sources, right? It could
2855 have come from the organic Chinese peanuts?

2856 Ms. {Coward.} That was what they told me when I arrived
2857 there, that that was the source of the granules.

2858 Mr. {Stupak.} Okay. Or I think you identified it come
2859 have come from production because there was some question
2860 about not cooking it long enough, high enough temperatures to
2861 kill the salmonella, right?

2862 Ms. {Coward.} What I asked for was the documents for
2863 the time and temperature of the roaster, and that could not
2864 be provided at the time.

2865 Mr. {Stupak.} And then of course there was also in the
2866 packaging because they were using water in the packaging area
2867 and we all know water is a great source of salmonella,
2868 especially in peanut butter, as we know from the 2007 ConAgra
2869 outbreak.

2870 Ms. {Coward.} Yes, sir, and also if you will note in
2871 the letter, it also takes about packaging roasted product in
2872 a raw zone.

2873 Mr. {Stupak.} Correct. Okay. So we had three
2874 possibilities there identified in your letter there. Let me
2875 go next to Exhibit 40, just two back. That is dated February
2876 4, 2008. Now, at this point in time, because you are talking
2877 about a kill study and you are making suggestions as to a
2878 kill study, is that correct?

2879 Ms. {Coward.} Yes, sir, I believe they contacted our
2880 Edenton, North Carolina, facility to help them understand a
2881 kill step study for their roaster, and we were trying to
2882 understand how to go about doing that. That is not something
2883 that we had ever done before as a laboratory and so this was
2884 a new process for us and so we were trying to understand how
2885 to do that.

2886 Mr. {Stupak.} Okay. So between 2006 and 2008, is it
2887 fair you consulted, JLA was a consultant then to the Peanut
2888 Corporation of America?

2889 Ms. {Coward.} No, sir, we were not. These were--this
2890 was a moment in time in 2006, and I didn't have any follow-up
2891 with them after that.

2892 Mr. {Stupak.} Okay. So 2006, and you didn't have any
2893 follow-up with them until 2008, until this possible kill

2894 study, right?

2895 Ms. {Cowart.} Correct. They contacted us, and that is
2896 how it usually worked with PCA from JLA's perspective. We
2897 are an independent testing laboratory and we do microbiology
2898 testing. If they have a question, we will try to answer
2899 their question.

2900 Mr. {Stupak.} So between 2006 and then again in 2008,
2901 in 2006 you had salmonella. Did you have any indication in
2902 2008 at the time this memo was written, which is February 4,
2903 that they had other occurrences of salmonella at the Blakely
2904 plant?

2905 Ms. {Cowart.} No, sir, I was not aware of them, no,
2906 sir.

2907 Mr. {Stupak.} Okay. You indicate in here that, again
2908 the same document, February 4, on Monday you are using oven
2909 at three different temperatures, you are going to use these
2910 spore strips, which was something different. What is the
2911 cost of those spore strips?

2912 Ms. {Cowart.} I am sorry. Could you repeat that
2913 question?

2914 Mr. {Stupak.} Sure. The third paragraph from the
2915 bottom, it says, ``Monday I am starting a lab study using
2916 oven at three temperatures, 295, 300, 310 with duplicate BI
2917 spore strips exposed to the heat for varying times,' and you

2918 listed times. To do that, these spore strips, which is to
2919 help kill the salmonella spores, correct, if there is any in
2920 there, if you heat it up?

2921 Ms. {Coward.} Yes, sir, this is a lab study and so
2922 these spore strips, what they were trying to do is not to
2923 introduce a pathogen but a surrogate, yes, sir.

2924 Mr. {Stupak.} What would it cost to put these spore
2925 strips in with your production?

2926 Ms. {Coward.} I am not sure I know. I don't know that
2927 answer.

2928 Mr. {Stupak.} Let me ask you this. You support then,
2929 it has been suggested throughout today, that labs, food
2930 processors should be registered, should be certified, the
2931 people doing the testing, and that the results should be
2932 filed with the FDA on every test?

2933 Ms. {Coward.} Yes, sir, I think we agree with that. I
2934 mean, having heard what we have heard this week and in the
2935 papers, I think it is the right thing to do. I think we
2936 would want to be a part of the solution, absolutely, yes,
2937 sir.

2938 Mr. {Stupak.} Mr. Deibel, how about yourself? Do you
2939 think labs that do testing, labs should be certified by the
2940 FDA, that people doing the testing should be registered or
2941 make sure they have proper qualifications, and that the

2942 results of every test whether it is positive or negative be
2943 electronically submitted to the FDA?

2944 Mr. {Deibel.} In regards to laboratory accreditations,
2945 I mean certainly laboratories should be using the published
2946 methods. They should be using good practices in regards to
2947 laboratory. We call them GLPs, good laboratory practices.
2948 In regards to having a laboratory, mandating that the
2949 laboratory would submit those test results to government, I
2950 don't believe that would be a good practice.

2951 Mr. {Stupak.} How do you prevent lab shopping then, as
2952 has been alleged in this case?

2953 Mr. {Deibel.} That I don't know. The overriding
2954 concern of this, and I am a consumer, my laboratory does a
2955 lot of testing for food safety, we want to have safe food.
2956 The entire industry at large, if you look at all the foods
2957 that we consume on a daily basis, and I am not just talking
2958 the foods that we make but the ingredient companies that
2959 manufacture ingredients for those, you know, finished product
2960 manufacturers, it is an enormous industry, and on a day-to-
2961 day basis most of us eat safe foods and we don't have an
2962 illness, and I think based on the huge amount of food
2963 companies that are out there, generally, you know, there
2964 isn't--my concern, I guess, in reporting those positive
2965 results is that you would actually encourage those businesses

2966 to test less. There are different types of tests that are
2967 done all along the manufacturing process. A raw ingredient
2968 before you use it, you do process validation work. You test
2969 your environment. We want to encourage that. We want to
2970 encourage companies to find problems if they exist, and
2971 again, my overriding concern--

2972 Mr. {Stupak.} Then how do we ever know then if a
2973 company is having positive test results if they are not
2974 reporting it to anybody but themselves?

2975 Mr. {Deibel.} Every year millions of pounds of products
2976 feed landfills so companies find a positive result, destroy
2977 product, do not ship it--

2978 Mr. {Stupak.} In theory. In theory they do that,
2979 right? Because obviously here they didn't do it.

2980 Mr. {Deibel.} Correct. I guess a food company, it is a
2981 business, and they are not in business to manufacture a
2982 product that will get somebody sick and they are at their
2983 best when they can make safe, wholesome products that a
2984 consumer will buy, enjoy and buy again. If a company
2985 manufactures a product where somebody eats it, falls ill,
2986 they are likely not to be in business.

2987 Mr. {Stupak.} So it is just a cost of doing business
2988 then when people get sick?

2989 Mr. {Deibel.} Most food companies do spend, I would say

2990 in my experience, a lot of money and a lot of their efforts,
2991 their resources in making safe and wholesome foods, and we
2992 would want to have them be able to have the right to test as
2993 much as they can, find the problem--

2994 Mr. {Stupak.} Right, but this is our ninth hearing in 2
2995 years. If we don't get on this thing, if we don't require
2996 some kind of reporting, how are we ever going to end this? I
2997 mean, we can't be doing this every--let us see, nine times in
2998 2 years, every, what, 2 months, a new outbreak?

2999 Mr. {Deibel.} Testing though is just one aspect of the
3000 overall food safety program.

3001 Mr. {Stupak.} I agree.

3002 Mr. {Deibel.} And we really need to be focusing more on
3003 preventative strategies because even in testing, I mean, we
3004 see this with PCA. Even when several labs were involved
3005 testing, you always didn't find it, even though we knew it
3006 was there.

3007 Mr. {Stupak.} Because no one was reporting it.

3008 Mr. {Deibel.} It became known that it was--

3009 Mr. {Stupak.} Because nobody was reporting it. I agree
3010 with you, we should be proactive as opposed to reactive.
3011 Right now we are reactive. If we had reporting, mandatory,
3012 maybe we could be proactive.

3013 With that, I will turn to Mr. Walden for questions.

3014 Mr. {Walden.} Thank you, Mr. Chairman.

3015 I guess that a question I want to go to the FDA on.

3016 Wouldn't you benefit from knowing the lab results?

3017 Dr. {Sundlof.} Thank you, Congressman, yes. FDA like
3018 any other enforcement organization wants all the information
3019 we can get.

3020 Mr. {Walden.} And you don't get those lab results
3021 today, correct?

3022 Dr. {Sundlof.} That is correct.

3023 Mr. {Walden.} And would you be overwhelmed with the
3024 number of lab results you would get?

3025 Dr. {Sundlof.} It is hard to say, I mean, but certainly
3026 having that information available would be very helpful.

3027 Mr. {Walden.} Only if it is in a form that could be
3028 readily accessed and utilized. It seems to me like there
3029 ought to be in the modern era of computers a way where those
3030 lab results could go in and then flag if there is a facility
3031 that repeatedly tests positive for salmonella. It would help
3032 you identify where you need to go inspect, wouldn't it?

3033 Dr. {Sundlof.} I believe that is right.

3034 Mr. {Walden.} Now, let me go back to Mr. Deibel. I am
3035 troubled with this notion that those lab results shouldn't be
3036 shared with the FDA or the Georgia Department of Agriculture
3037 or whomever, and I don't disagree that I think they should be

3038 inspected. I think they should seek out, I think as a small
3039 businessperson I had nothing to do with food, but it seems to
3040 me in their best self-interest to make sure their product
3041 line works and is sanitary. In theory, most don't want to
3042 make somebody sick. So what is the harm in sharing those
3043 positive results with the regulators so that they are on
3044 notice there may be a problem here?

3045 Mr. {Deibel.} From a laboratory level, we always don't
3046 understand what types of samples are coming into our
3047 laboratories.

3048 Mr. {Walden.} Right.

3049 Mr. {Deibel.} So it could be part of environmental
3050 monitoring where product fell on the floor and they want to
3051 test that. It could be--

3052 Mr. {Walden.} Okay, but couldn't we--

3053 Mr. {Deibel.} --processed samples. They could be doing
3054 a new R&D project.

3055 Mr. {Walden.} Right, but--

3056 Mr. {Deibel.} We just don't know.

3057 Mr. {Walden.} Okay, but how hard would it be to have a
3058 row of boxes that says this is an R&D sample test, this is an
3059 off-the-floor sample, this is something that is going into
3060 the Austin crackers that some 3-year-old is going to eat? Is
3061 that that hard?

3062 Mr. {Deibel.} That wouldn't be hard, however, I don't
3063 know that that would happen.

3064 Mr. {Walden.} All right. So if the private lab doesn't
3065 collect the samples, how can you ensure the integrity of
3066 those samples? Can you, Ms. Cowart? They just send you
3067 whatever, right?

3068 Ms. {Cowart.} Correct. What happens with our company
3069 is, we receive samples into our laboratory with a request for
3070 analysis and we do the analysis that was written on the
3071 request form. We do not know where the samples came from.
3072 We don't know the history of them. And so our obligation as
3073 an independent laboratory is to run the test and to notify
3074 them with the accuracy and speed that we can to get them to
3075 them.

3076 Mr. {Walden.} And it sounds like you have a very
3077 thorough process to do that, which I commend you for, both e-
3078 mail and a voice process.

3079 Ms. {Cowart.} Thank you.

3080 Mr. {Walden.} So let me go back to this notification.
3081 We learned yesterday or sometime this week that there is this
3082 mystery peanut-processing plant in Texas that apparently has
3083 never been reviewed by the FDA, no regulators have been in
3084 there. Is that correct?

3085 Dr. {Sundlof.} No, sir. The FDA was in there in 2001

3086 inspecting but at that time they were not producing peanut
3087 butter or peanut paste.

3088 Mr. {Walden.} Have you been back since they have been
3089 producing peanut butter or paste?

3090 Dr. {Sundlof.} Yes. I am sorry. Which plant are we
3091 talking about?

3092 Mr. {Walden.} The one in Texas.

3093 Dr. {Sundlof.} Oh, the one in Texas. I am sorry. Let
3094 me retract that. No, we had not been in there.

3095 Mr. {Walden.} Were you aware it even existed?

3096 Dr. {Sundlof.} We were.

3097 Mr. {Walden.} You were aware? Some of the news
3098 accounts indicate nobody knew this thing was going on, it
3099 wasn't registered, wasn't inspected. Do you know if it had
3100 been inspected?

3101 Dr. {Sundlof.} I don't believe it had been inspected.

3102 Mr. {Walden.} So Mr. Deibel, if I understood you
3103 correctly, your company was actually doing tests from peanut
3104 product from that plant and discovered there was salmonella
3105 in some of that plant's product. Is that accurate?

3106 Mr. {Deibel.} The Texas facility?

3107 Mr. {Walden.} Yes, sir.

3108 Mr. {Deibel.} That is correct.

3109 Mr. {Walden.} So if you had had to report that to the

3110 FDA, then the FDA would have known there was salmonella in a
3111 plant they had never inspected?

3112 Mr. {Deibel.} We did report that.

3113 Mr. {Walden.} To the FDA?

3114 Mr. {Deibel.} We reported this to the subcommittee. I
3115 am unsure if we reported it to--

3116 Mr. {Walden.} Wait a minute. When did you do the
3117 salmonella test?

3118 Mr. {Deibel.} The result just came off this last
3119 Sunday.

3120 Mr. {Walden.} Okay. So you just found out about this?

3121 Mr. {Deibel.} Yes.

3122 Mr. {Walden.} But you didn't report that--I mean, you
3123 knew we were doing an investigation so you shared it with us
3124 in that context. You wouldn't normally have sent us just
3125 sort of randomly test results, right? Of course not. But
3126 had you reported test results to anybody before?

3127 Mr. {Deibel.} We report test results to our clients but
3128 there is no mechanism currently in place to--

3129 Mr. {Walden.} Right. And that is what we in the other
3130 context of the full are going to debate is, what is the
3131 mechanism that should be there. I mean, I am not an advocate
3132 of just sending enormous amounts of data to another
3133 government agency that will put it in boxes, it will go in a

3134 warehouse that will probably leak and we can produce peanuts
3135 there too. But, you know, it doesn't make sense so it has
3136 got to be something that is usable. And so had you done
3137 tests prior to the ones this week on that plant in Texas?

3138 Mr. {Deibel.} We have been doing results for them for a
3139 number of years.

3140 Mr. {Walden.} A number of years, and had you spotted
3141 salmonella in any of those tests?

3142 Mr. {Deibel.} No, everything was negative up to the
3143 point of the results on Sunday.

3144 Mr. {Walden.} Dr. Cowart, did your firm do any tests on
3145 that plant in Texas?

3146 Ms. {Cowart.} On the Texas facility, no, sir, we did no
3147 microbiology testing.

3148 Mr. {Walden.} And why do you think--I find it curious
3149 that your firm consistently found salmonella, you said six
3150 times in 2007 and four in 2008?

3151 Ms. {Cowart.} That is correct.

3152 Mr. {Walden.} And then it sounds like PCA decided we
3153 are going to go somewhere else. Is that your read of it?

3154 Ms. {Cowart.} After reviewing the documents and talking
3155 with our associates back at the laboratory, it appears that
3156 way, yes, sir.

3157 Mr. {Walden.} And then they sort of sent you one under

3158 the name of an internal operation just to, I guess, have you
3159 do that test.

3160 Ms. {Coward.} That is right, and again, not knowing the
3161 history of the samples, we just took the sample--

3162 Mr. {Walden.} You do the test.

3163 Ms. {Coward.} --and we did the test. That is correct,
3164 yes, sir.

3165 Mr. {Walden.} Did you know whether or not PCA went to
3166 any other labs?

3167 Ms. {Coward.} We were aware of, they were asking us
3168 about a high coliform count and an aerobic plate count and so
3169 in an effort to answer their question, we did ask them if
3170 they could send us the results of the aerobic plate count and
3171 the coliform count just to compare, because we obviously go
3172 into a diagnostic mode also.

3173 Mr. {Walden.} Sure.

3174 Ms. {Coward.} And so we did know that they had used
3175 another lab for that, yes.

3176 Mr. {Walden.} And then do you like check the
3177 calibration of your equipment and all of that to just see?

3178 Ms. {Coward.} Yes, sir, we do, and we also run
3179 quarterly proficiency sample tests so that we can be able to
3180 check against an unknown sample that would come in from a
3181 proficiency organization.

3182 Mr. {Walden.} All right. And Mr. Deibel, do you have
3183 any idea why your data would be different than JLA's data?

3184 Mr. {Deibel.} Just based on--

3185 Mr. {Walden.} How does that all work?

3186 Mr. {Deibel.} We are dealing with a dry commodity good,
3187 and as had been mentioned before, you know, water does play a
3188 role in these organisms, and so the results are not always
3189 going to be consistent within that sample and so you will get
3190 some degree of variability in those test results.

3191 Mr. {Walden.} I want to thank the witnesses for your
3192 testimony and for answering our questions. It is helpful in
3193 our efforts.

3194 Thank you, Mr. Chairman, for your indulgence.

3195 Mr. {Stupak.} Thank you.

3196 Mr. Braley for questions, please.

3197 Mr. {Braley.} Thank you.

3198 Dr. Sundlof, as I understand it, the FDA did not conduct
3199 inspections of the PCA plant in Blakely, Georgia, from 2001
3200 until January of 2009. Is that correct?

3201 Dr. {Sundlof.} That is correct. Now, we did again
3202 inspect in 2001 and at that time they were not producing
3203 peanut butter or peanut paste. In I think it was 2007, the
3204 State of Georgia inspected under contract from FDA, so in
3205 essence, that was an FDA inspection in 2007 and one in 2008.

3206 Mr. {Braley.} Well, after the recent salmonella
3207 outbreak was traced to peanut products in January of 2009,
3208 FDA conducted a detailed inspection of the PCA facility and
3209 issued an inspection report called a 483 report, and in that
3210 report you listed 12 occasions in 2007 and 2008 when private
3211 labs informed PCA that its products tested positive for
3212 salmonella. I want to ask you about one of those. According
3213 to the 483 report, in June of 2008 the company received a
3214 private lab test that was positive for salmonella, and
3215 according to your report, the lot was manufactured on June 9
3216 and the sample that tested positive was provided to the
3217 private lab on June 10. Is that correct?

3218 Dr. {Sundlof.} I believe that is correct.

3219 Mr. {Braley.} Dr. Sundlof, wasn't June 10 the same day
3220 the Georgia Department of Agriculture inspected the facility
3221 on your behalf?

3222 Dr. {Sundlof.} I would have to check my records.

3223 Mr. {Braley.} Well, if that is the case and that is
3224 what the records show, the day after the company produced
3225 peanut products with salmonella, your inspectors were inside
3226 this facility but they didn't detect salmonella because you
3227 didn't direct them to test for it. Isn't that true?

3228 Dr. {Sundlof.} That is true.

3229 Mr. {Braley.} And you had the legal authority to order

3230 those tests, didn't you?

3231 Dr. {Sundlof.} Yes.

3232 Mr. {Braley.} So why didn't you order salmonella
3233 testing that day?

3234 Dr. {Sundlof.} Well, first of all, we did not know of
3235 the test results at the time. We did not know those until
3236 January. Secondly, our policy had been that on routine
3237 inspections, and this is not for-cause inspections, in other
3238 words, where we don't suspect that there is a problem in the
3239 plant, we have not asked our inspectors in general whether it
3240 is the FDA inspectors or the inspectors under contract to
3241 collect samples or obtain environmental samples. We are
3242 changing that now as a result of this.

3243 Mr. {Braley.} Well, does your office and do your
3244 inspectors apply a heightened degree of suspicion when there
3245 are other things going on in the food production business
3246 that might alert you to potential problems?

3247 Dr. {Sundlof.} Yes, we do. I mean, we take the
3248 entirety of all of the findings into account to determine
3249 whether or not it raises us to the next level where we would
3250 issue an inspection report of action, that there would be
3251 required actions to be taken by the company. In this case, I
3252 think all of the inspections that were conducted indicated
3253 that there were some infractions, that they didn't

3254 immediately pose what appeared to be a risk to the safety of
3255 the food supply and that the company was correcting those
3256 deviations either while the inspector was in the plant or
3257 gave assurances that those would be corrected.

3258 Mr. {Braley.} Well, the reason I ask you that very
3259 specific question about a heightened index of suspicion is
3260 because in April of 2007 this subcommittee held a hearing on
3261 a salmonella outbreak at the ConAgra peanut butter plant in
3262 Sylvester, Georgia, which is only 75 miles from the PCA
3263 plant, and that outbreak resulted in over 400 illnesses in 44
3264 States. Wasn't that cause enough for FDA to order testing
3265 for salmonella at the PCA plant?

3266 Dr. {Sundlof.} After that outbreak of Peter Pan, we
3267 went back and did a lot of education for the peanut industry.
3268 There was a seminar that was given in Atlanta in which the
3269 entire peanut industry was invited. We had FDA people there.
3270 They had other people talking about the kinds of measures
3271 that should be put in place in order to prevent this from
3272 happening in the future. We looked back at our records and
3273 determined that four people from PCA were registered to
3274 attend that particular symposium.

3275 Mr. {Braley.} So then you would agree with me that in
3276 this geographic area, in your State, there was certainly a
3277 heightened degree of suspicion about the potential for

3278 salmonella outbreak at the time these inspections were
3279 performed?

3280 Dr. {Sundlof.} Yes.

3281 Mr. {Braley.} And are there any written standards that
3282 apply to determine when there is for cause to test for
3283 salmonella?

3284 Dr. {Sundlof.} I don't believe there is any written
3285 ones. I would ask Mike Chappell if he can comment on that.

3286 Mr. {Chappell.} Well, after the ConAgra series, we did
3287 indeed provide some additional guidance to our field staff,
3288 and as Dr. Sundlof just mentioned, the realization is that we
3289 probably need to depend more on environmental sampling than
3290 we have in the past, not just the for cause, which means the
3291 conditions in the plant suggest there are serious problems.

3292 Mr. {Braley.} Mr. Chairman, it seems to me that private
3293 labs detected salmonella at the PCA facility but since they
3294 only reported it to PCA, the public never found out about it
3295 and that is a difference that we can't afford to have in our
3296 food safety system, and I yield back.

3297 Mr. {Stupak.} I thank you, Mr. Braley.

3298 Mr. Deal for questions, please.

3299 Mr. {Deal.} Thank you, Mr. Chairman. My line of
3300 inquiry is in two areas. First of all, what are
3301 manufacturers required to do, and secondly, what are State

3302 and federal authorities allowed to do. Now, in that regard,
3303 I would ask first of all, has peanut butter been classified
3304 by FDA as a high-risk product?

3305 Dr. {Sundlof.} I don't believe it has. That may change
3306 in the near future.

3307 Mr. {Deal.} Do you think that would be an appropriate
3308 classification?

3309 Dr. {Sundlof.} I believe so.

3310 Mr. {Deal.} If it is so classified, what would change
3311 with regard to what the manufacturer must do and what the FDA
3312 and State authorities can do?

3313 Dr. {Sundlof.} Well, certainly considering it high
3314 risk, we would change the way that we inspect, and I think we
3315 just addressed that, that in the future we are in the process
3316 of writing all of our guidance to our inspectors that they
3317 will be taking samples of the product and the environment in
3318 the future and that will go a long way I think to detecting
3319 these problems earlier, but there is no--in terms of what is
3320 required under Good Manufacturing Practice standards, they
3321 are written rather broadly and they are written more for all
3322 foods than specific products, and as such they are not very
3323 prescriptive. You know, what will probably result from this
3324 is some stronger guidance that will be more specific about
3325 peanut butter as it pertains to the kind of manufacturing

3326 controls that need to be put in place and the kinds of
3327 inspections that we will do.

3328 Mr. {Deal.} Can anything that FDA does by way of
3329 classification or otherwise require a peanut butter
3330 manufacturer to do product sampling with a specified period
3331 of regularity?

3332 Dr. {Sundlof.} Currently, the Good Manufacturing
3333 Practice standards are not written that way.

3334 Mr. {Deal.} Do you think maybe they should be?

3335 Dr. {Sundlof.} Well, in my testimony I talked about
3336 putting more preventive controls, mandatory preventive
3337 controls in place in certain food facilities, and what we are
3338 talking about here, the term is the Hazard Analysis Critical
3339 Control Point, type of quality systems in which all of those
3340 kinds of things would be documented for any food process that
3341 falls under that kind of preventive control.

3342 Mr. {Deal.} In the absence of requiring things like
3343 sampling and testing of those samples, then sampling and
3344 testing is a voluntary action on the part of the
3345 manufacturer. Is that correct?

3346 Dr. {Sundlof.} Currently, that is correct.

3347 Mr. {Deal.} And the concern that some people have of
3348 requiring disclosure of those voluntary samples of disclosure
3349 of the results is that as long as it is voluntary, all that

3350 may very well do is to have less testing rather than more
3351 testing. Do you share that concern?

3352 Dr. {Sundlof.} Yes.

3353 Mr. {Deal.} I am sorry I don't have time for you to
3354 elaborate much on it. If you have that concern then, is that
3355 one of the things that your recommendations to Congress has
3356 included? Is that one of your recommendations?

3357 Dr. {Sundlof.} We will be working--we are more than
3358 happy to work with the Administration and the Congress to
3359 craft any new legislation authorities that we need. I mean,
3360 I think the concern with us is that we need to make sure that
3361 it doesn't discourage additional testing. In other words, if
3362 it is required, will companies actually do less testing
3363 because they know that the FDA will have access to those
3364 records. So it needs to be very carefully thought through
3365 how that process works.

3366 Mr. {Deal.} Now, one of the problems I understand
3367 existed was that you could not access internal records and
3368 only had to go under the bioterrorism statutory authority in
3369 order to be able to get those internal records. Have you
3370 recommended or would you recommend that that be changed in
3371 terms of what the FDA or State authorities acting under your
3372 jurisdiction have the right to access internal records?
3373 Should they have that right?

3374 Dr. {Sundlof.} Yes. That is the other--again, we are
3375 working with the Administration on that but certainly if we
3376 had greater authority to access those kinds of records
3377 outside of the threshold that is required under the
3378 Bioterrorism Act to access those records, we would get a lot
3379 more information in a timely manner.

3380 Mr. {Deal.} Mr. Garrison, I know that you act in
3381 conjunction with your contract authority with FDA to do
3382 inspections on their behalf that you are contracted to
3383 perform. Is that correct?

3384 Mr. {Garrison.} That is correct.

3385 Mr. {Deal.} And you have outlined the fact that money
3386 is a shortage factor and the number of inspectors are in
3387 short supply to do all that you undertake to do at the State
3388 level as well as in your contract capacity. Is that right?

3389 Mr. {Garrison.} Yes, sir. Currently, we receive
3390 funding of about \$123,000 through our FDA contract. The
3391 State funding for our food protection program is some \$6
3392 million.

3393 Mr. {Deal.} I would ask this of both you, Mr. Garrison,
3394 and you, Dr. Sundlof, and that is, especially in the area of
3395 the FDA, we have seen that one of the ways to augment and get
3396 better results is through a user-fee program in which the
3397 producer has an incentive to have the testing done and in

3398 effect pays for that extra cost. We see it in other areas
3399 under FDA's jurisdiction. Have you considered a user fee to
3400 fund the cost for additional inspections at the federal level
3401 and/or the State level?

3402 Dr. {Sundlof.} Thank you. We are responding to
3403 legislation proposed, the Food Globalization Act, in which
3404 user fees are part of that, and we will be submitting formal
3405 responses and technical assistance on that bill.

3406 Mr. {Deal.} At the State level, Mr. Garrison, are user
3407 fees contemplated?

3408 Mr. {Garrison.} I would have to say that would be a pay
3409 grade above myself. That would be something that
3410 Commissioner Irvin and the State legislature and the governor
3411 would have to take up.

3412 Mr. {Deal.} It is not in the current proposed
3413 legislation then?

3414 Mr. {Garrison.} Not that I am aware of, no, sir.

3415 Mr. {Deal.} Thank you for the extra time.

3416 Mr. {Stupak.} Ms. Christensen for questions. Oh, I am
3417 sorry, excuse me, Mr. Dingell for questions, please.

3418 Mr. {Dingell.} Well, Mr. Chairman, first I want to
3419 commend you. This is a continuation of the excellent
3420 hearings which you had in the last Congress, and I want to
3421 commend you for your vigor and your energy and your

3422 enthusiasm and for the success of your efforts. You are
3423 going to make possible major reform here and I want to
3424 commend you for that.

3425 These questions are all to Dr. Sundlof. Please, Doctor,
3426 answer yes or no because we have relatively little time in
3427 which to do this. Food processors should be made to notify
3428 the FDA when they begin producing products that have not
3429 previously been registered. Do you agree, Doctor, yes or no?

3430 Dr. {Sundlof.} I am sorry. Could you repeat the
3431 question?

3432 Mr. {Dingell.} Please pay attention because we do have
3433 limited time here. Food processors should have to notify FDA
3434 when they begin producing products that they had not
3435 previously registered. Do you agree?

3436 Dr. {Sundlof.} Yes.

3437 Mr. {Dingell.} In light of the current crisis with
3438 regard to Food and Drug and producers, should foreign and
3439 domestic food facilities be required to have safety plans in
3440 place to identify and to mitigate hazards?

3441 Dr. {Sundlof.} In some cases, yes.

3442 Mr. {Dingell.} Now, what should these plans, rather
3443 should these plans be subject to review by FDA inspectors?

3444 Dr. {Sundlof.} Yes.

3445 Mr. {Dingell.} Would increase in inspections by FDA

3446 have potentially prevented the salmonella outbreak?

3447 Dr. {Sundlof.} It is potentially possible, yes.

3448 Mr. {Dingell.} In other words, more frequent and more
3449 thorough inspections by Food and Drug would have done so. Is
3450 that right?

3451 Dr. {Sundlof.} Yes.

3452 Mr. {Dingell.} Now, if FDA had better traceback
3453 capabilities, would that have helped prevent this salmonella
3454 outbreak?

3455 Dr. {Sundlof.} It would have helped us recall product
3456 quicker.

3457 Mr. {Dingell.} Now, should testing done on food
3458 products be subject to certain safety requirements and be
3459 performed only by a laboratory accredited by FDA?

3460 Dr. {Sundlof.} I have no opinion on that at this time.

3461 Mr. {Dingell.} You will note that you had a number of
3462 laboratories which performed tests that either didn't reveal
3463 the presence of salmonella or that were not reported to FDA.
3464 If FDA had had reliable reports from reliable laboratories,
3465 would it not have been better able to protect the public?

3466 Dr. {Sundlof.} Yes. I want to just say about
3467 salmonella testing, you can test the same product several
3468 times and not find the salmonella and it can be still in
3469 there. We suspect that these were all good laboratories and

3470 that the failure to confirm a positive was not the
3471 laboratory's fault but the sampling.

3472 Mr. {Dingell.} I am driven to the unfortunate
3473 conclusion that if that statement is true, Food and Drug
3474 probably could have done without laboratory inspections at
3475 all because apparently the laboratory inspections either
3476 didn't get communicated to FDA or they didn't reveal the
3477 presence of salmonella, and how does Food and Drug do its job
3478 without proper assistance in identifying the presence of
3479 pathogens like salmonella?

3480 Dr. {Sundlof.} We rely heavily on States and private
3481 laboratories and others to help us in our mission.

3482 Mr. {Dingell.} It sounds like you are saying trust
3483 everybody. I would add to that my dad's abjuration that you
3484 should always cut the cards. Now, in light of the salmonella
3485 outbreak caused by PCA's products, could this crisis have
3486 been mitigated if testing laboratories were required to send
3487 their testing results to FDA?

3488 Dr. {Sundlof.} It would have alerted us a lot sooner,
3489 yes.

3490 Mr. {Dingell.} I am sorry?

3491 Dr. {Sundlof.} It would have alerted us sooner than
3492 that there was a problem.

3493 Mr. {Dingell.} So you need both qualified and competent

3494 laboratories and you need to have them registered and you
3495 need to have them send their results to Food and Drug so that
3496 you know what is going on, right?

3497 Dr. {Sundlof.} Again, we appreciate all the information
3498 that we can get.

3499 Mr. {Dingell.} Okay. Should FDA have authority to
3500 issue mandatory recalls of tainted foods?

3501 Dr. {Sundlof.} We are more than happy to discuss that.
3502 It depends, I believe, on how the law is written and what--

3503 Mr. {Dingell.} You do not have that authority now.

3504 Dr. {Sundlof.} We do not.

3505 Mr. {Dingell.} And you need it if you are to do your
3506 job effectively, do you not?

3507 Dr. {Sundlof.} It would be helpful, yes.

3508 Mr. {Dingell.} More than helpful, it is necessary.

3509 Isn't that so?

3510 Dr. {Sundlof.} I can tell you that almost in every case
3511 when we ask companies to recall product, they do it
3512 voluntarily.

3513 Mr. {Dingell.} Now, Food and Drug was not able to visit
3514 or inspect the Peanut Corporation of America for about 8
3515 years. Is that right? And then they turned the matter over
3516 to Georgia, which in 2 years is supposed to have visited PCA
3517 but they didn't find a thing. What caused the failure of FDA

3518 to be able to inspect the people who were subject to their
3519 jurisdiction? I am told that the Department of Agriculture
3520 can investigate and can visit and inspect dog food producers
3521 oftener than Food and Drug can inspect food producers. Do
3522 you need more resources at Food and Drug to carry out proper
3523 inspections or not?

3524 Dr. {Sundlof.} We would like to do more inspections,
3525 yes.

3526 Mr. {Dingell.} Well, you are not doing the inspections
3527 that need to be done so you are not able to protect the
3528 people. PCA tells us clearly that the consumers were not
3529 protected because tainted and unsafe salmonella-infected
3530 peanut products and peanut butter got on the market, and with
3531 more resources you could have done a better job of protecting
3532 the public. Is that not so?

3533 Dr. {Sundlof.} It is not clear in this case.

3534 Mr. {Dingell.} It is not clear?

3535 Dr. {Sundlof.} It is not clear--

3536 Mr. {Dingell.} In 8 years you couldn't investigate
3537 them. That is clear to me. Then Georgia investigated them
3538 and they couldn't do a good job. So that tells me that Food
3539 and Drug does not have either the resources--you are caught
3540 in a cleft stick here. Either you don't have the resources
3541 or you are incompetent to do the job you are supposed to do.

3542 Which conclusion am I to arrive at?

3543 Dr. {Sundlof.} I would hope the former.

3544 Mr. {Dingell.} That you don't have the resources? I am
3545 content to believe that you are incompetent but I have tried
3546 to defend you against that and point out that you need
3547 resources. What I get from you, however, is, a modified
3548 reluctance to have more resources, and I am distressed
3549 because I think that the only way Food and Drug is going to
3550 amount to a hill of beans is to have the resources that it
3551 needs and to have the statute that it needs and to have the
3552 leadership that it needs. I find the leadership lacking, I
3553 find the resources lacking, and you are driving me to the
3554 conclusion that perhaps maybe Food and Drug is not as
3555 diligent as it should be because it might have the resources.
3556 Now, what is your response to that?

3557 Dr. {Sundlof.} Well, obviously we need to be inspecting
3558 more frequently. In this particular case, we should have
3559 been taking environmental samples. That would have led us to
3560 find problems earlier. We should have been more directed to
3561 the State of Georgia in directing them to take environmental
3562 samples. Had they done that, we might have detected this
3563 sooner.

3564 Mr. {Dingell.} Mr. Chairman, my time has expired. You
3565 have been very gracious. I thank you.

3566 Mr. {Stupak.} Well, thank you, Mr. Dingell, and on
3567 behalf of all the members, when they were doing the tribute
3568 on the Floor on your resolution, we all would have liked to
3569 have been there but we were doing as you have taught us to
3570 do, oversight, so forgive us for not being there when they
3571 did the House resolution in tribute to your longevity on the
3572 Floor. I know some of us after hours tonight will be paying
3573 tribute to your length of service, but more than that, the
3574 quality of service you provided to the American people.

3575 Mr. Gingrey for questions, please.

3576 Mr. {Gingrey.} Mr. Chairman, thank you, and following
3577 up on the chairman emeritus's line of questioning, let me
3578 address my first question to Dr. Sundlof of the FDA. You
3579 know, I think as I read your testimony that FDA actually went
3580 into Blakely, Georgia, to inspect this PCA plant on January
3581 9, 2009, and this was based on the information that had been
3582 obtained by Minnesota Department of Public Health that
3583 clearly there was salmonella in an open container of this
3584 peanut butter product, and yet you go there and you find
3585 pretty quickly in going through the records of the company
3586 that some of the lab reports that were submitted by these two
3587 labs, these private labs, which by the way I don't feel are
3588 necessarily responsible for not notifying the FDA. I mean,
3589 their job is basically a contract with the company. It is

3590 just like if a physician does a blood sample on someone and
3591 sends it to a lab and it is a low hemoglobin, as an example.
3592 Well, the laboratory is going to report back to the doctor
3593 and maybe even flag that, particularly if it is a dangerously
3594 low number, but that is where their responsibility ends. I
3595 mean, they cannot run down every patient and interfere with a
3596 doctor-patient relationship. So it may be that that is
3597 something that we should change, and I will get to that
3598 question in just a minute. But my question to you is, FDA
3599 went in and knew on January 9 beyond a reasonable doubt that
3600 this was the source of the contamination and yet waited
3601 another 10 days or so to get some unopened can of peanut
3602 butter from somewhere in Connecticut to absolutely,
3603 unequivocally prove it. Couldn't you have had the ability to
3604 say to the company, cease and desist until we can prove this?
3605 If we disprove it, then, you know, you continue operations
3606 and maybe the Federal Government, the FDA mitigates any
3607 financial loss but when you just continue to get to the nth
3608 degree for another 10 days, I don't now how many more
3609 hundreds of people got sick or maybe even additional deaths
3610 because of that delay. Why couldn't you have issued a cease-
3611 and-desist order at that time?

3612 Dr. {Sundlof.} I believe we went in on the 9th. I
3613 believe that was a Friday. The company recalled on the

3614 following Monday. So we did move very quickly.

3615 Mr. {Gingrey.} Well, the company recalled a certain
3616 product that was produced and then it was later that they
3617 recalled it and then finally they had another recall that
3618 went all the way back to January 2007, but that probably
3619 should have been done immediately.

3620 Dr. {Sundlof.} We can only work with the information
3621 that we have at the time. At that time we only knew of the
3622 products, the King Nut products as being the source. We
3623 moved quickly. They quit producing on that date and quit
3624 marketing on that date, on the 9th of January, and started
3625 recall of the products that we knew were affected by the
3626 following Monday.

3627 Mr. {Gingrey.} Let me move on to Mr. Garrison with the
3628 Georgia Department of Agriculture. Do you feel like the
3629 Department under contract with the FDA had sufficient
3630 training? Were there any manuals in regard to the inspectors
3631 that work with the Department of Agriculture? Did you have
3632 enough training and guidance to properly inspect?

3633 Mr. {Garrison.} Training is always a continual issue
3634 when you are looking at the evolving food continuum that we
3635 see. There have been a lot of advances in food processing, a
3636 lot of new programs brought online, as Dr. Sundlof stated,
3637 Hazard Analysis Critical Control Point. Those inspections

3638 are now required in seafood processors and in juice
3639 processors. So where there is specific training required of
3640 an operator of a facility, then our inspectors are also
3641 provided with that training. We have taken the Good
3642 Manufacturing Practices from FDA. Those are adopted in the
3643 State regulations and those are also in our performance
3644 manual that--

3645 Mr. {Gingrey.} And Mr. Garrison, did the Department
3646 abide by the terms of the contract in regard to the frequency
3647 of inspections?

3648 Mr. {Garrison.} Yes, sir. The terms of the contract
3649 only lays out one inspection in the assigned facilities
3650 during a calendar year unless there is an indication by FDA
3651 that a follow-up would be necessary based on documentation.

3652 Mr. {Gingrey.} Let me real quickly ask our lab folks,
3653 if you will bear with me, Mr. Chairman. If you were required
3654 to submit a copy of your report, certainly a positive report,
3655 let us say, to the FDA, how much more expense or burden would
3656 that be for the laboratories? How much more would you have
3657 to charge the food processor that contracted with you to do
3658 the lab testing if you were required to submit a duplicate
3659 copy to the FDA?

3660 Ms. {Coward.} Mr. Gingrey, I can speak specifically for
3661 our company. All of our documents are e-mailable in a new

3662 system that we have put in place since August of 2007 so it
3663 would be very simple to e-mail to whoever in FDA would be the
3664 appropriate person.

3665 Mr. {Gingrey.} Mr. Deibel, would you agree with that?

3666 Mr. {Deibel.} Yes. We have a system where we can plug
3667 in on each client each client contact that would want a
3668 report. The system, once we go through our checks and
3669 balances to ensure that the result is accurate and
3670 authorized, once that is authorized, it is automatically
3671 either e-mailed or faxed to whomever.

3672 Mr. {Gingrey.} So easily done, not expensive and
3673 nothing you would object to if we decide that that should be
3674 done in the future?

3675 Mr. {Deibel.} If that was something that this body
3676 decided, it would not be a problem.

3677 Mr. {Gingrey.} Mr. Chairman, I will yield back. I know
3678 my time has expired.

3679 Mr. {Stupak.} Ms. Christensen for questions, please.

3680 Ms. {Christensen.} Thank you, Mr. Chairman.

3681 I would like to direct my first question to Dr. Sundlof
3682 also. I had a chance to look through some of the Senate
3683 testimony and the director of food safety for the Center for
3684 Science and Public Interest had what I am going to read to
3685 you in her testimony. She says that in April of 2008, Canada

3686 rejected a shipment of peanuts from PCA as unfit for food.
3687 PCA attempted to clear the peanuts for sale in the United
3688 States but FDA rejected its test results and eventually the
3689 peanuts were destroyed. During that period--well, wouldn't
3690 that have sent a red flag up to FDA and shouldn't that have
3691 caused FDA to require more inspections of PCA, given the fact
3692 that this is April of 2008? Because the testimony goes on to
3693 say that FDA did not follow up with inspection of the plant.

3694 Dr. {Sundlof.} That is not entirely true. The shipment
3695 was rejected because it was peanut granules and it was
3696 determined that it contained some metal fragments in there.
3697 It was returned back to PCA. FDA witnessed its destruction
3698 so that it did not move into commerce. At that time we also
3699 asked that the State of Georgia do an additional inspection
3700 in that facility. That was one of the two that was conducted
3701 under FDA contract and they went in there I think in May or
3702 June was when they went back in to inspect. I believe they
3703 determined what the source of the metal was and the firm took
3704 corrective action.

3705 Ms. {Christensen.} And Mr. Garrison, you are familiar
3706 with those inspections.

3707 Mr. {Garrison.} Yes, ma'am.

3708 Ms. {Christensen.} Was it your testimony that you found
3709 no evidence for any contamination in those inspections? Was

3710 it a complete inspection or was it just related to the metal?

3711 Mr. {Garrison.} What the e-mail that we received from
3712 FDA stated was, it was to be a contract inspection and
3713 focusing on GMPs, which is what the contract states, and also
3714 looking for any metal inclusion that may have occurred and to
3715 check out the metal detector. What we reported back to FDA
3716 was a couple of metal scrubbers, which we would call a brillo
3717 pad, that were inside the facility and also a scraper--

3718 Ms. {Christensen.} But that would not have precipitated
3719 any other inspections? Was it focused just on the metal?

3720 Mr. {Garrison.} No, ma'am. We actually had done a Good
3721 Manufacturing Practice inspection during that time.

3722 Ms. {Christensen.} And there was nothing to suspect
3723 that there would be any other contamination in those
3724 inspections?

3725 Mr. {Garrison.} Like I said, there was no red flags
3726 that would indicate an imminent health hazard inside that
3727 facility.

3728 Ms. {Christensen.} My understanding, Mr. Garrison, is
3729 that between 2007 and 2008, PCA had 12 positive salmonella
3730 tests reported to them, and in that time the Department
3731 tested 35 product samples from five Georgia facilities. How
3732 many of those were from the Blakely plant?

3733 Mr. {Garrison.} There were three samples taken from the

3734 Blakely plant in believe August of 2007.

3735 Ms. {Christensen.} And their first positive was in June
3736 of 2007, but you didn't find any in your three?

3737 Mr. {Garrison.} No, ma'am, we did not.

3738 Ms. {Christensen.} Since there has been a salmonella
3739 outbreak the year before that was in peanut butter, when this
3740 outbreak started to surface, did that not raise concern and
3741 should not that have precipitated some increased inspection
3742 at peanut butter plants, for either Dr. Sundlof or Mr.
3743 Garrison.

3744 Mr. {Garrison.} From the State perspective, when the
3745 outbreak began we worked closely with our department of
3746 Public Health and their epidemiologists were monitoring the
3747 CDC calls looking for potential causes and implicated foods
3748 and then they would bring those to us. You know, once the
3749 peanut butter was brought forward as a potential, then at
3750 that point the State along with FDA began looking at
3751 potential problems that may be associated with those
3752 facilities.

3753 Ms. {Christensen.} But nobody seemed to think back to
3754 March of 2007 to say well, this is salmonella, we had a
3755 salmonella outbreak a year before where the source was peanut
3756 butter?

3757 Mr. {Garrison.} From a State perspective, we are

3758 constantly shuffling resources. You know, when we can run 45
3759 samples through our laboratory, you know, coming into June we
3760 were dealing with imported jalapeno peppers that, you know,
3761 actually tainted our tomato industry in Georgia. We had
3762 melamine in products coming from China that the State was
3763 running tests on in October so, you know, with very limited
3764 lab resources, we are constantly moving around what we are
3765 testing and what we are looking for from a State standpoint.

3766 Ms. {Christensen.} If I can get just one more question,
3767 a quick question, to Mr. Deibel and Ms. Cowart. The fact
3768 that there was a negative follow-up test after a positive
3769 one, how many negative tests would you consider enough to
3770 convince you that the positive test result could be ignored?
3771 Can you ignore a positive test just because you get another
3772 follow-up?

3773 Mr. {Deibel.} Absolutely not. If you tested 50 samples
3774 for a given lot and 49 of those were negative and one was
3775 positive, that one positive must trump the 49 negatives. The
3776 49 negatives should never have more precedence over that one
3777 positive. You cannot retest away a positive result.

3778 Ms. {Cowart.} And I will agree with that statement
3779 wholeheartedly.

3780 Ms. {Christensen.} Thank you, Mr. Chairman.

3781 Mr. {Stupak.} Thank you.

3782 Ms. Schakowsky, questions, please.

3783 Ms. {Schakowsky.} Thank you, Mr. Chairman.

3784 Mr. Deibel, on April 28, 2008, your lab confirmed that a
3785 PCA sample tested positive for salmonella contamination. Is
3786 that correct?

3787 Mr. {Deibel.} I believe so. Yes.

3788 Ms. {Schakowsky.} I think you said before, what would
3789 you have expected a manufacturer to do with that information?

3790 Mr. {Deibel.} We do a lot of consulting services for
3791 our clients and most of what we try to get involved with is
3792 more on the front-end quality control procedures, working
3793 with clients to have--

3794 Ms. {Schakowsky.} What would you have expected that
3795 they would do?

3796 Mr. {Deibel.} In the event of a positive occurrence, we
3797 would expect that they would shut that line down or stop that
3798 production, quarantine that lot, try to figure out how that
3799 positive occurred in retesting.

3800 Ms. {Schakowsky.} Okay, but--

3801 Mr. {Deibel.} But ultimately throw it out.

3802 Ms. {Schakowsky.} But actually following that initial
3803 positive, PCA sent you additional samples from the same lot
3804 and they also went to Dr. Cowart's firm and provided an
3805 additional sample, and those tests came back negative for

3806 salmonella, right?

3807 Mr. {Deibel.} Correct. That is not unheard of.

3808 Ms. {Schakowsky.} Dr. Garrison, what is a company
3809 expected to do if there is a positive? And do you also agree
3810 that negatives don't erase the positive that has been found?

3811 Mr. {Garrison.} The State of Georgia Department of
3812 Agriculture would expect that company to immediately destroy
3813 the product. If it has been put in commerce, it would expect
3814 them to recall that. During our testing procedures, when we
3815 get what Ms. Cowart had referred to as a presumptive positive
3816 from a facility we regulate, we will notify industry at that
3817 point, and in most cases, as a matter of fact, in all cases
3818 from that presumptive positive, the processing facility will
3819 either hold the product if it hadn't went out or go ahead and
3820 issue a recall just based on that presumptive.

3821 Ms. {Schakowsky.} Okay. Now, between June of 2007 and
3822 September of 2008, private lab testing found salmonella on 12
3823 separate occasions. You inspected the plant on June 10,
3824 2008. Did you ask if there had been any laboratory tests?

3825 Mr. {Garrison.} There is no evidence on our inspection
3826 reports that we asked but that is something that the company
3827 does not have to supply to the State. That is the reason--

3828 Ms. {Schakowsky.} Do you ask though?

3829 Mr. {Garrison.} I can't say in this particular instance

3830 if we asked or not.

3831 Ms. {Schakowsky.} Is it on your report form to ask?

3832 Mr. {Garrison.} No, ma'am, it is not something that is
3833 required of--

3834 Ms. {Schakowsky.} I know it is not required. I am just
3835 wondering if you asked and if the company refused to tell you
3836 because they don't have to, would that not indicate that
3837 there might be some sort of a problem? I mean, I don't
3838 understand. If there has been test after test, I think
3839 everybody here agrees that a positive test should result in a
3840 product being taken away. I think we will change that. I
3841 hope we will change that so they do have to inform you, but I
3842 can't understand why that question wouldn't be asked. Can
3843 you explain that to me?

3844 Mr. {Garrison.} When companies are not required to give
3845 records, we don't even know if tests have been conducted.

3846 Ms. {Schakowsky.} Exactly.

3847 Mr. {Garrison.} And when you are dealing with the
3848 elements that we are dealing with in this case, if we think
3849 by simply asking they would tell us that they didn't have the
3850 results or that they were all negative, you know, we are
3851 dealing with a different element here. We are dealing with
3852 something that at this point appears to have intention based
3853 in it.

3854 Ms. {Schakowsky.} There is at tab 42 an e-mail from
3855 Stewart Parnell, the owner of PCA, and in these e-mails with
3856 the plant manager, Sam Lightsey, Mr. Parnell inquired about
3857 the results of a subsequent test from Deibel. Mr. Lightsey
3858 informed Mr. Parnell that the subsequent tests were in spec,
3859 meaning they came back negative for salmonella. Although Mr.
3860 Parnell knew that this lot previously received a confirmed
3861 positive for salmonella, Mr. Parnell instructed this plant
3862 manager, ``Okay, let's turn them loose then.'' Dr. Sundlof,
3863 is this the appropriate response to these two tests, to turn
3864 the product loose on American consumers?

3865 Dr. {Sundlof.} No, it is not, and I don't believe that
3866 is in any way the industry practice. I think this is a case
3867 in which one company has violated what I think all other
3868 companies know. It is well known within the peanut
3869 manufacturing community that testing, even finding a negative
3870 is not conclusive, that you have to take many tests, and that
3871 certainly once you find a positive test, that that product
3872 cannot be considered to be safe.

3873 Ms. {Schakowsky.} When you conduct tests as the FDA, do
3874 you ask if any tests have been conducted?

3875 Dr. {Sundlof.} I think we do but I am going to ask Mike
3876 Chappell to speak to that.

3877 Mr. {Chappell.} It certainly depends on the nature of

3878 the inspection. If you are asking whether it is a routine
3879 requirement for our investigators to ask for whatever
3880 testing, that is not our procedure, but we are changing that
3881 procedure to require that our investigators do ask what
3882 testing is being done and ask to have access to those
3883 records.

3884 Ms. {Schakowsky.} Well, hopefully, Mr. Chairman, we are
3885 going to require that those tests get reported back to the
3886 FDA. I just want to say that it is really unbelievable that
3887 Mr. Parnell knew that the food that he produced was
3888 contaminated. It escaped any inspections by the State. Even
3889 though the testing laboratory found that there was a
3890 positive, nothing happened, and rather than be responsible,
3891 destroying these tainted products, he chose to test the same
3892 lot over again until he got the result that he wanted and
3893 then released the product to the public. We have a
3894 responsibility to change that. Thank you. Thanks for the
3895 extra time.

3896 Mr. {Stupak.} That concludes all the questions of the
3897 members in this round. I am sure we are going to go a second
3898 round but we do have two members of the full committee who
3899 are not members of the subcommittee but they are allowed to
3900 ask questions under the rules of the subcommittee. So Mr.
3901 Barrow, I know you have been here all day. Would you like 5

3902 minutes of questions?

3903 Mr. {Barrow.} Yes, sir. Thank you, Mr. Chairman.

3904 I am not as good a cross-examiner as my hero, Mr.

3905 Dingell here, and I am not as good as Mr. Braley over there

3906 so I am going to throw you guys a softball. I want to ask

3907 you a wide-open-ended question, but listen to the conditions

3908 of it because it might not seem that way, especially you, Dr.

3909 Sundlof. If you believe that the integrity of testing cannot

3910 be separated from the integrity of sampling, and the sampling

3911 and testing are both things that have to have integrity, if

3912 you want to preserve the existing regime of voluntary

3913 inspections and confidential reporting with the testing

3914 community but you feel it is necessary to mandate and

3915 superimpose on that a mandatory sampling and testing regime,

3916 if you want to make sure that the sampling and testing that

3917 is done isn't too rigorous that you put folks out of business

3918 but isn't too lax to miss stuff you need to know, in other

3919 words, if you want to do everything you reasonably can to

3920 make sure first that the manufacturer knows what the

3921 manufacturer needs to know when the manufacturer needs to

3922 know it and you want to make sure that the regulator knows

3923 what the manufacturer knows, whatever it is, when they know

3924 it, how do we go about doing that? Dr. Sundlof, you go

3925 first, please.

3926 Dr. {Sundlof.} Thank you. One of the things that again
3927 we will be asking for more authority, and that is to issue
3928 preventive controls in plants. That is, they have to have a
3929 quality system in place that specifies where the critical
3930 control points are, where contaminants can be introduced--

3931 Mr. {Barrow.} Is a sampling and testing regime going to
3932 be a part of that?

3933 Dr. {Sundlof.} Absolutely.

3934 Mr. {Barrow.} Is there going to be goals or is it going
3935 to be quotas? Is it going to be something we think folks out
3936 to look at or is it going to be something folks are going to
3937 be required to do? Are you going to have different protocols
3938 for different sectors of the food-processing industry?

3939 Dr. {Sundlof.} Manufacturers will have to develop their
3940 own HACCP plan which is specific to their particular
3941 manufacturing facility.

3942 Mr. {Barrow.} Are you going to require sampling be done
3943 by folks who have an independent stake in their work, folks
3944 who don't work for just one person or work within the
3945 community but who have a whole bunch of clients who actually
3946 stand to lose a lot if they don't do their sampling and their
3947 testing in a credible manner?

3948 Dr. {Sundlof.} I mean, I can't speak about how the
3949 exact program would work but certainly there has to be these

3950 checks and balances in there that can be verified by the FDA.

3951 Mr. {Barrow.} You will agree with me that folks can't
3952 be allowed to sample and test themselves?

3953 Dr. {Sundlof.} I am not completely sure about that.

3954 Mr. {Barrow.} When I was a boy, I learned at my daddy's
3955 knee that no person can be the judge of his own case. Don't
3956 you all know that?

3957 Dr. {Sundlof.} There may be ways that we could ensure
3958 the integrity even if they sample their own product and test
3959 their own product.

3960 Mr. {Barrow.} I am not saying folks can't be allowed to
3961 do that. I am saying we need to have a sampling and a
3962 testing regime in place in addition to the powers of
3963 mandatory recall that folks have talked about. We need to
3964 have a system in place where the manufacturer really doesn't
3965 have the option of knowing what they need to know when they
3966 need to know it and they don't get to be the only ones who
3967 decide to act on that information. The public regulator
3968 needs to know what they know and when they know it. Don't
3969 you think that is necessary, that that is a goal we need to
3970 reach for?

3971 Dr. {Sundlof.} Yes, and that is what we are requesting.

3972 Mr. {Barrow.} Well, that remains to be seen. Thank
3973 you.

3974 Anybody else want to take a stab at any of that with a
3975 little time left? How about you, Mr. Deibel? I understand
3976 the point you are making but you realize the point I am
3977 making, don't you? I am not trying to drive people out of
3978 the business knowing more than they need to know but I want
3979 to make sure they know what they need to know and that we
3980 know what they know when we need to know it.

3981 Mr. {Deibel.} I think there are a lot of opportunities
3982 in the subcommittee and in the discussions that we are going
3983 to be having to really build stronger bridges between
3984 government and industry and agree upon best practices that we
3985 can all use. I hope those best practices include
3986 preventative approaches rather than reactive approaches--

3987 Mr. {Barrow.} Well, what I want to do is, I want to
3988 take you guys out of the situation of having to rat out a
3989 client, an existing regime where folks have the right to come
3990 to you and ask as a matter of entering into the contractual
3991 relationship with you that you will keep quiet but that puts
3992 you in an untenable position. That is unacceptable. I
3993 recognize your interests there. Nobody can go forward, no
3994 part of the existing system can go forward to start doing the
3995 right thing if everybody else is going to continue to be
3996 allowed to do the wrong thing. So I want to put in place
3997 something that doesn't let that happen.

3998 Ms. Cowart, do you have anything to add to that?

3999 Ms. {Cowart.} No, sir, I agree with that in terms of
4000 what you are talking about. I think the broader picture of
4001 how that gets done is something that we would really like to
4002 be a part of helping with the solution.

4003 Mr. {Barrow.} Well, get ready because I think you are
4004 going to have a chance to play a role in that.

4005 Ms. {Cowart.} Thank you.

4006 Mr. {Barrow.} Thank you, Mr. Chairman.

4007 Mr. {Stupak.} Mr. Pallone for questions. You are the
4008 chairman of the Health Subcommittee with our legislation and
4009 FDA globalization bill that we are trying to get through for
4010 food and drug safety, so glad to have you here.

4011 Mr. {Pallone.} Thank you, Mr. Chairman. I wanted to be
4012 here for the whole hearing but I had a hearing on offshore
4013 drilling in my other committee, and that is important in my
4014 district so that is why I couldn't come until now. But I did
4015 want to mention, you mentioned the comprehensive FDA bill
4016 that you and Mr. Dingell have introduced and I just wanted to
4017 say that I was pleased to see that we included some of the
4018 provisions in a food safety bill that I have been trying to
4019 push for a number of years that are now in that comprehensive
4020 bill, specifically preventative measures to ensure that food
4021 safety has been addressed.

4022 I wanted to ask Mr. Sundlof a question. In the case you
4023 are examining today, many more companies than just PCA have
4024 been involved. In fact, over 50 companies use PCA's peanuts
4025 in their finished products, and what worries me about the
4026 situation is that first PCA did nothing to prevent their
4027 contamination, and as others have highlighted, knowingly put
4028 contaminated products on the market, but second, none of
4029 those other companies conducted adequate tests on their food
4030 items to detect and stop the tainted peanut products from
4031 making their way to consumers, and under current law there is
4032 no requirement that the companies who are actually putting
4033 food into the hands of consumers audit or check up on their
4034 supplies to ensure the ingredients they are getting from
4035 these suppliers are safe. Now, I believe that we need to
4036 give the FDA the authority to require food manufacturers to
4037 establish food safety plans and these plans would require
4038 food companies to evaluate what food safety risks exist,
4039 determine how best to address and protect against those risks
4040 and establish processes and procedures to control those
4041 risks. Finally, these food safety plans would require
4042 companies to maintain records documenting that they have
4043 complied with those plans and those of course would be
4044 available to the FDA. You mentioned all this in your
4045 testimony but I just wanted to make it clear, you do agree

4046 that the FDA should have this authority to require these
4047 manufacturers to establish food safety plans?

4048 Dr. {Sundlof.} Yes, I do, and in fact, we do have two
4049 areas of food that do require these kinds of preventive
4050 control systems. One of them is seafood and the other one is
4051 juice. They have to produce them under a HACCP program.

4052 Mr. {Pallone.} Now, do you also agree that having these
4053 sorts of requirements in place would have gone a long way
4054 towards avoiding the kind of major catastrophe that occurred
4055 here?

4056 Dr. {Sundlof.} It is unclear because the company, it is
4057 not clear they would have kept adequate records in this case
4058 because they did get positive samples and those chose or they
4059 shipped product anyway. If we had gone in and inspected
4060 their records and had gotten access to those records before
4061 this outbreak, certainly that would have been a warning to us
4062 and we potentially could have prevented this.

4063 Mr. {Pallone.} I mean, just in a general sense, would
4064 you agree that each company in the chain of manufacturing has
4065 an obligation to ensure that the ingredients they are using
4066 as well as their final products are safe for Americans to
4067 consume?

4068 Dr. {Sundlof.} Yes, absolutely.

4069 Mr. {Pallone.} And then the second thing, Mr. Chairman,

4070 I wanted to ask was about the fines. Mr. Sundlof again, PCA
4071 knowingly put contaminated products on the market. They knew
4072 their ingredients were going to be used by many companies in
4073 their various products. They knew the risks of this disease
4074 and yet they did nothing, but the most alarming thing to me
4075 is the lack of repercussions for the behavior. Under current
4076 law, the more severe penalty available for committing a
4077 single prohibited act with respect to foods is a misdemeanor,
4078 which carries a potential sentence of imprisonment of up to 1
4079 year or a monetary fine. But the FDA to successfully
4080 prosecute these companies and impose a penalty has a lengthy
4081 investigation and has to coordinate with the Justice
4082 Department and it is highly intensive in terms of the
4083 resources of the FDA and Justice. I also question whether
4084 the threat of a misdemeanor conviction has any deterrent
4085 effect at all, especially in light of the situation. FDA now
4086 has the authority to levy civil monetary penalties for
4087 certain drug and medical device violations, an administrative
4088 authority that permits FDA to proceed without involving the
4089 Justice Department, and for certain drug violations FDA can
4090 impose a fine of up to \$1 million for all violations
4091 adjudicated in a single proceeding but FDA does not have that
4092 authority with respect to foods with the exception of illegal
4093 pesticides. In your opinion, are civil monetary penalties

4094 less burdensome for the agency to impose than criminal
4095 penalties, and do you agree that having the ability to impose
4096 an administrative monetary fund would be a useful enforcement
4097 tool for the FDA?

4098 Dr. {Sundlof.} Congressman, it is not something that I
4099 have had discussions with. Certainly it is something that we
4100 will be talking about in the wake of this salmonella outbreak
4101 but it is not something I have an opinion on at this point.

4102 Mr. {Pallone.} And you don't want to express an opinion
4103 at this point?

4104 Dr. {Sundlof.} I don't.

4105 Mr. {Pallone.} All right. I wish you would, but I
4106 can't force you.

4107 Thank you, Mr. Chairman.

4108 Mr. {Stupak.} Thank you, Mr. Pallone.

4109 Let us go for another round. I think we are going to
4110 have votes here soon but let us try to get a couple more
4111 questions in before we release this panel.

4112 Mr. Garrison, when I take a look at the document binder,
4113 it seems between Exhibits 15 to 37 are Georgia's inspections
4114 of this place, and if I am correct--by ``this place'' I mean
4115 PCA. That is about 22 different inspections, and it looked
4116 like early on, 2004, 2005, 2006, you did not only inspections
4117 but also scale inspections. Is that correct?

4118 Mr. {Garrison.} Yes, sir, that is correct.

4119 Mr. {Stupak.} Then why the drop-off after 2006? I
4120 think you had one in 2007 and one in 2008?

4121 Mr. {Garrison.} On the scale inspections or on the food
4122 inspections?

4123 Mr. {Stupak.} Both.

4124 Mr. {Garrison.} The scale inspections were conducted
4125 under another section of my division. On the food
4126 inspections, it was basically due to attrition throughout the
4127 department.

4128 Mr. {Stupak.} And budget cutbacks you spoke of?

4129 Mr. {Garrison.} Budgetary issues and those type of
4130 things.

4131 Mr. {Stupak.} So you never did any inspection of this
4132 plant, the Blakely, Georgia, plant, for salmonella then even
4133 though that was sort of the goal to do it once a year, right?

4134 Mr. {Garrison.} No, sir. We would have done an
4135 inspection at least twice per year during this period of
4136 time.

4137 Mr. {Stupak.} But let me ask you this. Had you ever
4138 had any knowledge, anyone in your department or agency, that
4139 they were having trouble with salmonella at this plant in
4140 Blakely, Georgia?

4141 Mr. {Garrison.} No, sir, it was never reported to any

4142 of our inspectors or even through our consumer complaint
4143 logs.

4144 Mr. {Stupak.} Okay. Your last inspection was October
4145 23, 2008, and when you take a look at it, it has a little bit
4146 of history of past problems that they had in this place,
4147 especially water. Water is sort of a red flag in peanut
4148 butter that there could be contamination or salmonella.
4149 Isn't that so?

4150 Mr. {Garrison.} You want to eliminate moisture from the
4151 peanut process.

4152 Mr. {Stupak.} And that is even one of the reasons why
4153 you roast peanuts and heat them up is to get rid of the
4154 salmonella? It has to be more than 170 degrees, if I
4155 remember correctly, correct?

4156 Mr. {Garrison.} The temperature would really depend on
4157 the roaster speed and the temperature there. It is a
4158 combination of the two during the roasting procedure.

4159 Mr. {Stupak.} Okay. On October 23, when you take a
4160 look at it, and I am looking at the FDA's report in January,
4161 they indicate even in October like they are missing dates as
4162 to the firm's temperature inadequate or just left off the
4163 reporting charts, and that was never noticed by your
4164 inspectors. Wouldn't they look for the temperatures for
4165 roasting peanuts if you are doing an inspection?

4166 Mr. {Garrison.} When our inspectors go in, they will
4167 look at the current temperatures are being observed at the
4168 time that they are inside.

4169 Mr. {Stupak.} They wouldn't look at past temperatures
4170 to see if they are being reported?

4171 Mr. {Garrison.} Those would be records that they would
4172 not have to supply us with.

4173 Mr. {Stupak.} I had asked Ms. Cowart, and it was
4174 Exhibit 38 there, when she did a walk-through when she was
4175 consulting with PCA and she found three reasons why there
4176 could be salmonella, number one, the Chinese product could
4177 have already been contaminated before it got there, but then
4178 after that it was in the production and packaging. If Ms.
4179 Cowart, if she just does a walk-through and notices these
4180 things in this plant, why wouldn't your inspectors notice
4181 them because they are looking for the same things, aren't
4182 they?

4183 Mr. {Garrison.} Ms. Cowart had knowledge that the
4184 facility had a problem with salmonella. That is something
4185 that the State didn't have and that is what we are pushing
4186 for is for these plants in Georgia if they have problems,
4187 they have to let us know. We have to have every tool
4188 available to us.

4189 Mr. {Stupak.} Sure, but as inspectors, salmonella,

4190 water, peanuts, bad combinations. I just think you would
4191 pick up on those things.

4192 Mr. {Garrison.} Exactly. You know, the inspections are
4193 a snapshot in time. What Ms. Cowart had seen during her
4194 inspections may not have necessarily been there when our
4195 inspectors went through.

4196 Mr. {Stupak.} Well, that is why you look at the
4197 temperature records and things like that, correct?

4198 Mr. {Garrison.} When they have to supply them to us.
4199 That is why we go back to the HACCP requirements that Dr.
4200 Sundlof spoke about with the juice HACCP and the seafood
4201 HACCP. They are required to maintain those records, to sign
4202 off on those records--

4203 Mr. {Stupak.} But there is no way you can get those
4204 records unless they voluntarily give them to you, right?

4205 Mr. {Garrison.} In these type facilities, that is
4206 correct.

4207 Mr. {Stupak.} Dr. Sundlof, I have been asking this
4208 question for 2 years and the answer has always been no. Go
4209 back to 2007, Peter Pan, you mentioned in your testimony here
4210 today, did you ever get those records for Peter Pan from
4211 ConAgra?

4212 Dr. {Sundlof.} I don't know the answer to that. I will
4213 ask Mike Chappell if he knows.

4214 Mr. {Stupak.} So 2 years and you don't have the records
4215 from 2007 and yet you continue to say you don't need subpoena
4216 power. Don't you think you subpoena power?

4217 Dr. {Sundlof.} Again, I don't know whether or not we do
4218 have the records, sir.

4219 Mr. {Stupak.} I have just been handed a report. Ohio
4220 officials now have linked a woman's death to nationwide
4221 salmonella outbreak, so I guess we are now up to nine deaths
4222 and growing.

4223 Let me ask you this, Dr. Sundlof. Go to tab 11 there,
4224 which is FDA's amended 483 report from January inspection. I
4225 would like to know about each of these violations. Should
4226 they be caught in a Good Manufacturing Practices inspection,
4227 and if you could do a yes or no, like observation number
4228 three on page five, this is about the temperature being not
4229 recorded. I mentioned in October six times it wasn't
4230 recorded, November 2008, 24 days you never recorded the
4231 temperature, in December and January, nothing was recorded.
4232 Should that have been caught by inspection, a GMP inspection?

4233 Dr. {Sundlof.} Yes.

4234 Mr. {Stupak.} All right. How about the pallets being
4235 three feet, observation number four, three feet from the
4236 finished product, and water stains running down in the
4237 cooling unit fans in the cooler. Should that have been

4238 observed by GMP inspection?

4239 Dr. {Sundlof.} I am going to have to ask Mike Chappell.

4240 Mr. {Stupak.} Mr. Chappell, should that have been

4241 caught, water stains, with the GMP?

4242 Mr. {Chappell.} Certainly one of the things that we do

4243 during inspection is look for environmental situations and a

4244 water stain is indication of a previously--

4245 Mr. {Stupak.} In observation number five, plant is not

4246 constructed in such a manner to allow ceilings to be kept in

4247 good repair. Should that have been caught in a GMP

4248 inspection?

4249 Mr. {Chappell.} One of the things that we look for to

4250 see the general condition of the building, and there are

4251 certain things that we look for, and if the building is

4252 properly constructed, it is easy to repair those, and if not,

4253 it is not.

4254 Mr. {Stupak.} So that is yes then, they should have

4255 caught that in the GMP?

4256 Mr. {Chappell.} Yes.

4257 Mr. {Stupak.} Okay. How about observation number six,

4258 design of equipment and utensils failed to preclude

4259 adulterated food with contaminants, specifically felt

4260 material is present on the final roller at the discharge.

4261 This material cannot be adequately cleaned or sanitized.

4262 Should that have been caught in a GMP inspection?

4263 Mr. {Chappell.} If indeed that particular equipment was
4264 in place and in use at that time, that would be an--

4265 Mr. {Stupak.} That would be a yes then. Okay. How
4266 about number seven, proper precautions to protect food and
4267 food contact surfaces from contamination with microorganisms
4268 cannot be taken because of deficiency in plant construction
4269 and design. So that would be there all the time. So that
4270 should have been caught by GMP, would it not?

4271 Mr. {Chappell.} I think plant design is certainly one
4272 of the things that we would look at, especially at it relates
4273 to product flow and segregation.

4274 Mr. {Stupak.} So that is a yes. How about number
4275 eight, specifically the sink located in the peanut butter
4276 room is used interchangeably as a point for cleaning hands
4277 and utensil tools and for washing out mops. That is not Good
4278 Manufacturing Practice, is it?

4279 Mr. {Chappell.} It is not, but again, though, if indeed
4280 the investigator was there at a time it was not being used
4281 for both things, they might not necessarily have pointed that
4282 out.

4283 Mr. {Stupak.} Right, but a sink shouldn't be in the
4284 final product area anyway, should it? Because that is water
4285 again, isn't it?

4286 Mr. {Chappell.} Yes.

4287 Mr. {Stupak.} Okay. How about number 10, besides the
4288 dead and live roaches, let me ask you this. The bumper pads
4289 were inadequate, openings of six inches or more were observed
4290 along sides and tops of trailers. These trailers contained
4291 raw and roasted products, can be left backed up for 7 to 5
4292 days leaving openings in the plant. Is that GMP? Is that
4293 Good Manufacturing Practice?

4294 Mr. {Chappell.} That should have been observed, yes.

4295 Mr. {Stupak.} These violations I have just listed here,
4296 all six or seven of them, all should have been caught in a
4297 normal GMP inspection. Then why weren't they in the prior
4298 inspections?

4299 Mr. {Chappell.} The prior inspection the FDA conducted
4300 was 2001, so I think it depends on the conditions at the
4301 time--

4302 Mr. {Stupak.} Well, there was a GMP inspection, there
4303 was an inspection for cause on the metal shavings, but some
4304 of these are just structural. You can see water stains,
4305 things like that. That should have been caught, should it
4306 not?

4307 Mr. {Chappell.} It certainly should be observed during
4308 the inspection.

4309 Mr. {Stupak.} All right. I guess my time is up. Mr.

4310 Deal?

4311 Mr. {Deal.} Thank you. First of all, let me clarify
4312 some things that I think may have been confused here. First
4313 of all, peanuts are not an inherently dangerous product. In
4314 fact, they are inherently safe. Some of us still eat them
4315 raw. Isn't that correct?

4316 Dr. {Sundlof.} Peanuts, because they lack water, do not
4317 support the growth of bacteria. What we have seen in the
4318 ConAgra case and in the recent case with PCA is that once
4319 salmonella is introduced into these peanut products, it
4320 doesn't die, it just stays there, and then when it becomes
4321 ingested, then the bacteria is able to reproduce and cause
4322 disease.

4323 Mr. {Deal.} But that is further in the process.
4324 Inherently they are a safe product unless you get the
4325 occasion for something like the Chinese organic and there you
4326 are talking about something in the organic area where the
4327 fertilizer, it contains salmonella in many instances and that
4328 is not the traditional method and not the traditional peanut
4329 product that comes to these plants. Am I correct?

4330 Dr. {Sundlof.} Just let say, you know, peanuts are
4331 grown in the dirt and in the dirt there are lots and lots of
4332 bacteria and salmonella can certainly be one of those.
4333 Generally the peanut processors require a roasting step--

4334 Mr. {Deal.} And that is the kill cycle?

4335 Dr. {Sundlof.} That is the kill cycle.

4336 Mr. {Deal.} So whatever might have been there, even
4337 though they are not inherently dangerous, a proper kill cycle
4338 would supposedly eliminate that?

4339 Dr. {Sundlof.} That is correct.

4340 Mr. {Deal.} And that is why the temperatures of the
4341 roasters, etc., are critical pieces of information?

4342 Dr. {Sundlof.} Yes.

4343 Mr. {Deal.} All right. Once you get through the kill
4344 cycle, then it should not have salmonella in the peanut?

4345 Dr. {Sundlof.} Right, and that is when the Good
4346 Manufacturing Practices have to make sure that salmonella is
4347 not reintroduced after the roasting process?

4348 Mr. {Deal.} And that is the reason you can get
4349 inconsistent samples one day versus the next day. Presumably
4350 if you get a bad sample and a bad report that the lab reports
4351 back to the manufacturer, their presumption, and I think
4352 anybody's commonsense presumption is that they not only would
4353 destroy the product that is bad but also that they would take
4354 the corrective action in cleaning up the facility, doing the
4355 other good management practices that would have caused the
4356 bad sample to occur. Am I not correct, Dr. Cowart?

4357 Ms. {Cowart.} Yes, sir. That insurance, yes, sir.

4358 Mr. {Deal.} So it is not then inconceivable or totally
4359 within reason that you might get a bad sample, somebody gets
4360 the results, they clean it up, they don't get a bad sample
4361 the next time somebody comes by or the next time an
4362 inspection takes place. But I think the thing we all are
4363 focusing on is the kinds of things that will be able to
4364 prevent the bad actors from coming along. We have a bad
4365 actor here. He did not respond in a way that would be a
4366 normal response that everybody had reasons to expect they
4367 would respond. So I guess the thing we are trying to do is
4368 to come up with ways and methods whereby we can try to
4369 prevent the bad actor from being able to slip through the
4370 holes, and that would be including maybe reporting of
4371 internal testing to outside agencies such as the State
4372 department of agriculture or perhaps even the FDA, the
4373 mandatory keeping of internal records that would be required
4374 to be disclosed to the inspectors when they come by so that
4375 they would know whether or not there had been periods where
4376 the kill cycle was not operating properly or they would know
4377 if they had gotten a bad test result back. I think those are
4378 the objectives that all of us have in mind. Is that not the
4379 general format, Dr. Sundlof, that we should be approaching
4380 this from?

4381 Dr. {Sundlof.} Certainly I think we need to have

4382 systems in place that are, number one, preventive, and number
4383 two, alert us early on when there is a problem.

4384 Mr. {Deal.} And I think we all agree with that, and the
4385 question is, how do we achieve that goal, and since we are in
4386 the middle of a vote, I am going to conclude, but let me
4387 conclude by having thanks to all of you for your
4388 participation here. You have enlightened us and we do
4389 appreciate your attendance at this hearing.

4390 Thank you, Mr. Chairman.

4391 Mr. {Stupak.} Thank you.

4392 Mr. Braley, any questions?

4393 Mr. {Braley.} Yes, thank you.

4394 Dr. Cowart, I would like to ask you about a document
4395 known as a certificate of analysis. As succinctly as
4396 possible, tell us what a certificate of analysis is.

4397 Ms. {Cowart.} A certificate of analysis for our
4398 laboratory is the final results that we have obtained through
4399 our testing program that is issued to the client for the
4400 sample they submitted.

4401 Mr. {Braley.} And what does a company do with a
4402 certificate of analysis?

4403 Ms. {Cowart.} With a certificate of analysis, they
4404 would look at their sample description and understand where
4405 that came from, and based on the results they need to take

4406 action, depending on the positive or negative results they
4407 get.

4408 Mr. {Braley.} And let me just show you why what we are
4409 talking about is so important. This is a list of the 1,900
4410 product recalls at the FDA as of February 10, 2009. So when
4411 you issue a certificate of analysis, you are issuing a
4412 certification from your company to be relied upon, which has
4413 legal consequences. Isn't that correct?

4414 Ms. {Coward.} I think for the company, it is their
4415 responsibility to do with it what they need to do so it is
4416 our result on the sample, yes, sir.

4417 Mr. {Braley.} And you have a contractual obligation to
4418 make a good-faith effort to perform that test to the best of
4419 your abilities because you know they are relying on your
4420 analysis for their business purposes and their regulatory
4421 compliance?

4422 Ms. {Coward.} When we issued our certificate of
4423 analysis, yes, sir, we believe they are relying on us to do
4424 that.

4425 Mr. {Braley.} So I would like you to take a look at a
4426 certificate generated by your company, JLA, which is at tab
4427 51, page 1, and we have got it up on the monitor so you can
4428 follow along. In this certificate of analysis, your company
4429 confirmed the product from Peanut Corporation of America

4430 tested positive for salmonella, and you can see the lot
4431 number is 8168-ABCD and it is dated June 23, 2008. Is that
4432 correct?

4433 Ms. {Coward.} Yes, sir.

4434 Mr. {Braley.} Mr. Deibel, let me show you another
4435 certificate of analysis on the same tab, 51, page 3. This is
4436 your private lab's analysis of the same lot number on the
4437 same date but your result shows that salmonella is negative.
4438 Is that correct?

4439 Mr. {Deibel.} That is correct.

4440 Mr. {Braley.} So just to understand, PCA sent two
4441 samples from the same lot to two private labs, JLA found
4442 salmonella and Deibel did not, so let us see what PCA did.
4443 PCA generated its own certificate of analysis. This is in
4444 the same tab, 51, on page 2, and PCA's report shows that its
4445 product tested negative for salmonella. This is a
4446 certificate of analysis that PCA prepared for its customers,
4447 correct? You will have to answer affirmatively.

4448 Mr. {Deibel.} Based on what we are looking at, yes.

4449 Mr. {Braley.} Dr. Sundlof, what is FDA's position on
4450 this? Isn't it true, Doctor, that is illegal for a company
4451 to report on a certificate of analysis a negative salmonella
4452 report when it knows that there is another lab test that
4453 shows a positive result?

4454 Dr. {Sundlof.} I cannot speak to the legality of that.
4455 That certificate of analysis is between the laboratory and
4456 the company. Certainly, you know, if we find that they did
4457 introduce contaminated food into the marketplace, then they
4458 are in violation of the Food, Drug and Cosmetic Act.

4459 Mr. {Braley.} Well, are you saying that you don't know
4460 or that it doesn't apply in this context whether that would
4461 be illegal for a company to do?

4462 Dr. {Sundlof.} I think that is part of the criminal
4463 investigation and I can't expand on that.

4464 Mr. {Braley.} Well, based on everything we have heard
4465 today, wouldn't you agree that if that is not in an illegal
4466 practice, it certainly should be?

4467 Dr. {Sundlof.} Certainly if they were supplying false
4468 information to the FDA, that would certainly be an illegal
4469 practice.

4470 Mr. {Braley.} Well, and we have heard testimony here
4471 that if any lot result tests positive, that takes precedent
4472 over any comparative negative test result, correct?

4473 Dr. {Sundlof.} That is not written anywhere in the law
4474 or the regulations but it is common knowledge within the
4475 industry that you can't test your way to negative.

4476 Mr. {Braley.} So if it is common knowledge within the
4477 industry, isn't it true that it would make sense to have that

4478 also be applicable in the statute and the regs?

4479 Dr. {Sundlof.} We would be happy to work with that.

4480 Mr. {Braley.} And can you tell us how can this practice
4481 be allowed, because it is not just egregious, it is really
4482 fraudulent to the American people, isn't it, the American
4483 consumers who purchase these products?

4484 Dr. {Sundlof.} If they are purchasing food that is
4485 purported to be something that it is not, absolutely.

4486 Mr. {Braley.} Thank you.

4487 Mr. {Stupak.} Mr. Walden has a question.

4488 Mr. {Walden.} Well, Mr. Chairman, I know we have to get
4489 to the Floor for a vote. I do have a couple of questions I
4490 would like to be able to submit in written form to the panel
4491 for your written response. Unfortunately, we have run out of
4492 time, but I would concur with my colleagues and thank you for
4493 your participation today. It has been helpful in our
4494 efforts, and obviously we have got some changes to make in
4495 the Federal Government to protect the food supply for all
4496 Americans, and we are going to do that, so thank you. Thank
4497 you, Mr. Chairman.

4498 Mr. {Stupak.} And that concludes all questioning. I
4499 know there are many other questions members have. I want to
4500 thank all of our witnesses for coming today and for your
4501 testimony.

4502 The committee rules provide that members have 10 days to
4503 submit additional questions for the record. I ask unanimous
4504 consent that the contents of our document binder be entered
4505 in to the record provided that the committee staff may redact
4506 any information as business proprietary, relates to privacy
4507 concerns or is a law enforcement-sensitive matter. Without
4508 objection, documents will be entered in the record.

4509 That concludes our hearing. This meeting of the
4510 subcommittee is adjourned. Thank you all again.

4511 [Whereupon, at 2:17 p.m., the subcommittee was
4512 adjourned.]