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3 HEARING ON ``REGULATION OF BOTTLED WATER''

4 WEDNESDAY, JULY 8, 2009

5 House of Representatives,

6 Subcommittee on Oversight and Investigation

7 Committee on Energy and Commerce

8 Washington, D.C.

9 The subcommittee met, pursuant to call, at 10:04 a.m.,
10 in Room 2123 of the Rayburn House Office Building, Hon. Bart
11 Stupak [Chairman of the Subcommittee] presiding.

12 Members present: Representatives Stupak, Christensen,
13 Walden, Burgess, Blackburn and Barton (ex officio).

14 Staff present: David Rapallo, General Counsel; Theodore
15 Chuang, Chief Oversight Counsel; Stacia Cardille, Counsel;
16 Anne Tindall, Counsel; Scott Schloegel, Investigator;
17 Jennifer Owens, Special Assistant; Ken Marty, HHS-OIG
18 Detailee; Lindsay Vidal, Special Assistant; and Jen

19 Berenholz, Deputy Clerk.

|
20 Mr. {Stupak.} This meeting will come to order.

21 Today we have a hearing titled ``Regulation of Bottled
22 Water.'' The chairman, the ranking member and the chairman
23 emeritus will be recognized for 5-minute opening statements.
24 Other members of the subcommittee will be recognized for 3-
25 minute opening statements. I will begin.

26 Food safety is an extremely important issue that this
27 committee has held nearly a dozen hearings on over the past 2
28 years. Time and again we hear from individuals who want more
29 information so they can make wise decisions about what they
30 eat and drink. My constituents are no exception. Today's
31 hearing on bottled water hits close to home. My vastly rural
32 district in northern Michigan contains more shoreline than
33 any other Congressional district except Alaska but we have a
34 keen awareness of water quality issues. Michigan is also
35 home to a large bottled water facility in Mecosta County that
36 has not been without controversy over the years.

37 In 2008, Americans consumed 8.6 billion gallons of
38 bottled water. Bottled water is a billion-dollar-a-year
39 industry with sales up more than 83 percent this decade.
40 Many Americans believe that the water they drink from a
41 bottle is healthier than the water that comes from their
42 faucets. The Water Research Foundation found that nearly 56

43 percent of bottled water drinkers cite health and safety as
44 the primary reason they choose bottled water over tap water.
45 As a result, Americans are willing to pay top dollar for
46 bottled water, which costs up to 1,900 times more than tap
47 water and uses up to 2,000 times more energy to produce and
48 deliver.

49 Over the past several years, however, bottled water has
50 been recalled due to contamination by arsenic, bromate,
51 cleaning compounds, mold and bacteria. In April, a dozen
52 students at a California junior high school reportedly were
53 sickened after drinking bottled water from a vending machine.
54 Consumers may not realize but many of the regulations that
55 apply to municipalities responsible for tap water do not
56 apply to companies that produce bottled water. I would like
57 to put up a chart that outlines some of these differences.

58 [Chart.]

59 For example, municipal tap water suppliers are required
60 to tell their consumers within 24 hours if they find
61 dangerous contaminants that exceed federal levels but this
62 requirement does not apply to bottled water companies.
63 Certified laboratories must be used to test tap water but
64 bottled water has no similar requirement. Tap water
65 suppliers provide their customers with annual consumer
66 confidence reports that detail the sources of their water,

67 any contamination found, the likely cause of contamination
68 and any potential health effects. Bottled water distributors
69 are not required to provide this report to consumers.
70 Instead, bottled water consumers rely on limited information
71 found on labels and in some cases on company websites.

72 Some companies exacerbate this problem by exaggerating
73 claims about the health benefits of their products. For
74 example, Poland Springs explains the history of its water by
75 saying, ``When Joseph Ricker was revived from his deathbed,
76 reputedly by drinking the spring's water and lived another 52
77 years, the water's health benefits became legendary.''
78 Mountain Valley Water Company provides similar accounts of
79 its water, stating ``Clinical tests at hospitals in New York,
80 St. Louis and Philadelphia demonstrated improvements in the
81 health of patients suffering from kidney and liver disorders
82 and rheumatism as a result of drinking Mountain Valley
83 Water.''
84 Aquamantra spring water explains that the words
85 written on its labels, mantras such as ``I am healthy'' and
86 ``I am loved'' permeate the liquid, influencing the taste and
87 beneficial properties of water. The company also claims that
88 Aquamantra uses the design of its label to affect the
89 molecular structure of the water.

89 Today the subcommittee will receive two new reports that
90 raise questions about why the regulations governing bottled

91 water are weaker than those governing tap water, as well as
92 widespread public perception that bottled water is healthier
93 than water from the tap. The first is a report by the
94 Government Accountability Office that was originally
95 requested by our former colleagues, Hilda Solis and Al Wynn.
96 In this report, GAO examines whether federal and State
97 authorities are adequately ensuring the safety of bottled
98 water and the accuracy of claims regarding its purity and
99 health benefits. The second report is by the Environmental
100 Working Group, which conducted an 18-month survey of bottled
101 water labels and websites and concluded that just two of the
102 188 bottled water companies surveyed provided consumers with
103 information on the source of their water, the manner in which
104 it is treated and any contaminants present. Given these
105 findings by GAO and Environmental Working Group, the
106 subcommittee is sending today to a dozen bottled water
107 companies letters requesting information on the source of
108 their water, their treatment methods and results of their
109 contaminant testing for the past 2 years.

110 Even when water is treated at municipal facilities and
111 then bottled, there still may be questions about contaminants
112 such as pharmaceuticals that may be present in the treated
113 water. Environmental Working Group reports an estimated 25
114 percent of bottled water brands that rely on tap water are

115 drawing from supplies that collectively contain 260
116 pollutants. According to Associated Press, drugs have been
117 found in municipal water samples across the country.
118 Officials in Philadelphia discovered 56 pharmaceuticals or
119 byproducts in treated drinking water. Anti-epileptic and
120 anti-anxiety medications were detected in the treated
121 drinking water for 18.5 million people in southern
122 California. And drinking water here in Washington, D.C., and
123 surrounding areas testified positive for six pharmaceuticals.
124 For these reasons, I have introduced H.R. 1359, the Secure
125 and Responsible Drug Disposal Act of 2009, which will provide
126 for proper disposal through drug take-back programs so
127 individuals are not simply flushing their medications down
128 the toilet into our water systems. I am also proud to be the
129 original cosponsor of the Food Safety Enhancement Act of
130 2009, which passed out of this committee last month and which
131 is again ready for Floor action, and which provides FDA with
132 much-needed authority to assessing testing records of food
133 and water supplies.

134 I look forward to today's hearing, and I ask for
135 unanimous consent that reports issued today and the other
136 documents in the binder prepared by staff be entered into the
137 official record. Without objection, they will be entered in
138 the record and will be used throughout the hearing.

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

140 ***** COMMITTEE INSERT *****

|
141 Mr. {Stupak.} I next would like to turn to my friend,
142 Mr. Walden from Oregon, for his opening statement, please.

143 Mr. {Walden.} Thank you, Mr. Stupak.

144 My home State of Oregon and the 2nd Congressional
145 district which I represent is home to a number of water
146 bottlers including those located in the small central Oregon
147 community of Culver, EARTH20, and the eastern Oregon town of
148 Cove with Artesian Blue, and in the northern portion of my
149 district in The Dalles, H2 Oregon. These successful
150 businesses are in many cases providing much-needed job
151 opportunities in areas of Oregon that have been hard hit by
152 today's weak economy. In fact, Mr. Chairman, our
153 unemployment rate is second only to yours in Michigan.

154 Today's hearing raises some valid questions regarding
155 the differences in regulation between the Food and Drug
156 Administration and the EPA regarding bottled water. However,
157 I should note, concern that with all of the life-threatening
158 health priorities facing the FDA including numerous foodborne
159 illness outbreaks, complications with acetaminophen and swine
160 flu pandemic, this issue does to me seem a little secondary
161 in terms of the FDA's overwhelming workload on other issues.

162 We should also put this hearing in context. The two
163 reports that are the focus of today's hearing point out a few

164 noteworthy findings but do not assess the safety of the
165 bottled water itself. Neither the Government Accountability
166 Office, GAO, nor the Environmental Working Group, EWG,
167 conducted any testing of the bottled water or the bottles
168 themselves while completing their reports. The regulations
169 for bottled water do differ from those promulgated for tap
170 water, mostly because bottled water is considered a food
171 product and is therefore regulated by the Food and Drug
172 Administration, whereas tap water is regulated by the
173 Environmental Protection Agency. However, FDA does require
174 that the standards of quality for bottled water must be no
175 less protective of public health than the EPA standard.
176 Under the FDA regulations, bottlers must follow current Good
177 Manufacturing Practices, also known as GMPs.

178 FDA actually requires more safeguards from water
179 bottlers than other food processors. The GMPs for bottled
180 water are commodity specific. Under these GMPs, bottlers
181 must, among other things, test their source of water once a
182 week for microbiological contaminants and test finished
183 bottled water weekly for microbiological contaminants. Now,
184 some of the water bottlers in my district follow a practice
185 of testing their water every hour in order to meet the
186 requirements of purchasers of their products, so they are
187 doing hourly water testing.

188 I do have a few questions for FDA. One discrepancy
189 between EPA and FDA is in the case of a chemical substance
190 called DEHP. This is a phthalate, a substance added to
191 plastics to change their physical characteristics, and I am
192 sure you are familiar with it. FDA has yet to establish a
193 standard for this contaminant in bottled water, even though
194 the EPA did over a decade ago. An FDA taskforce is
195 supposedly examining the information surrounding DEHP and I
196 want to ask the deputy commissioner when can we expect a
197 ruling from your agency. And the question that I will speak
198 to in a minute is about recycled bottles themselves. I have
199 some tell me that the use of recycled bottles perhaps
200 produces more leaching or whatever it is that comes out of
201 the plastic than first-time use, and I would be curious to
202 know if that is the case.

203 Conducting inspections is one way the FDA ensures the
204 bottlers are following GMPs. Concerns have been raised on
205 how frequently the plants are inspected and what access FDA
206 inspectors have to plant records regarding testing and other
207 important information during the inspection, and I would be
208 curious to know the legislation passed unanimously out of the
209 full committee that expands FDA's inspection process, if that
210 would apply in these cases and therefore you will get new
211 authority if the House and the Senate Act. I would like to

212 hear from the deputy commissioner as well on how the agency
213 can improve the inspection process and if you do need any
214 additional authorities. Congress needs to act. We need to
215 know exactly what the agency needs and why. Currently,
216 bottlers are not required to disclose the source of their
217 water, the treatment process used or the detection of any
218 contaminants. The question is, should they, and I look
219 forward to your response on that.

220 Mr. Chairman, I would conclude by thanking you for this
221 hearing but I would also like to raise the issue that July
222 8th has come and gone. A number of us on this side of the
223 aisle have raised questions of the Environmental Protection
224 Agency regarding bottled-up science, and we expect the EPA to
225 respond to our inquiries regarding Dr. Allen Garland and his
226 report that is not allowed to be considered in the
227 endangerment finding process, and if the EPA is unwilling to
228 respond in a timely manner, which may well be the case, I do
229 hope that our request of this subcommittee to have an
230 oversight hearing on what appears to be the bottling up of
231 science and debate on the whole carbon issue will be granted
232 an opportunity for a hearing and a full investigation. So we
233 will be coming back to you on that issue, and I thank you for
234 your time.

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

236 ***** COMMITTEE INSERT *****

|
237 Mr. {Stupak.} Thank you, Mr. Walden.

238 Ms. Blackburn, opening statement, please.

239 Mrs. {Blackburn.} Thank you, Mr. Chairman, and I do
240 want to welcome our witnesses and thank them for being with
241 us today.

242 As you have heard, we all are concerned about bottled
243 water, the product that is there. We are also concerned
244 about tap water and the work the EPA does there. And I will
245 submit a written statement. Mr. Chairman, I want to take my
246 time to just say I would prefer that we be spending this time
247 to look at other issues that are important to our
248 constituents that the FDA and EPA deal with. There are other
249 committee issues that we could be looking at such as the
250 options for reducing health care costs for our constituents
251 and looking at how you do that through patient-driven,
252 consumer-driven, patient-centered health care. We should be
253 looking at the Medicare trust fund and the pressures that are
254 on that trust fund, the ballooning costs of Medicaid if we
255 move to a public option as we move into health care reform or
256 even from my State, the lessons that should have been learned
257 from TennCare, which was the test case for Hillary Clinton
258 health care back in 1994. My State still has this. It is
259 the greatest public health care in the country. That would

260 be a great opportunity for us to look at what is affecting us
261 with health care. Certainly there are more pressing issues.
262 We are appreciative of your time to be before us today, and
263 while we all are concerned with leaching chemicals that come
264 from plastics into bottled water, we are indeed very
265 concerned with what we see as sequestering evidence from EPA
266 employees. We are concerned with what we see, health care
267 issues that are affecting all of our constituents and a lack
268 of willingness to address those in a patient-centered,
269 consumer-driven manner, and I yield back my time.

270 [The prepared statement of Mrs. Blackburn follows:]

271 ***** COMMITTEE INSERT *****

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272 Mr. {Stupak.} Thank you. Let me just respond that, you
273 know, we had a hearing just before we broke here not even 2
274 weeks ago on health insurance on rescissions where companies
275 rescind health care to people who have it, and next week is
276 scheduled all week in committee for the health care markup
277 bill, so I am sure we will have plenty of opportunities to
278 speak of health care.

279 Mr. Burgess for opening statement, please.

280 Mr. {Burgess.} Thank you, Mr. Chairman, and maybe I
281 should take a second to respond to your response, and isn't a
282 shame that we have a Subcommittee on Health within the
283 Committee on Energy and Commerce and we are to have no markup
284 on what is going to be the greatest change in the delivery of
285 health care in America since the institution of Medicare in
286 1965. Certainly the people who were in Congress in 1965
287 likely could have never foreseen what Medicare would become,
288 at least as far as the price of that federal program, and
289 wouldn't we all be in better shape today if perhaps a little
290 more care was taken back in 1965 and the object lesson for us
291 today is, we need to take good care and exercise due caution
292 as we structure this major fundamental change to American
293 health care.

294 We also could have had a hearing on medical devices in

295 this subcommittee, which I have asked for for some and has
296 yet been forthcoming, so there are ways we could have made
297 use of this time today, Mr. Chairman, but here we are and we
298 are going to talk about bottled water this morning, and that
299 is important. Normally I have a bottle of water here so that
300 if I get parched in the hour that I have to address the
301 committee, but now we are stuck with D.C. water which there
302 used to be a little sign in my office in the Longworth
303 Building that said do not drink the tap water. I don't know
304 if that has changed but I am a little reluctant to drink what
305 is before us today.

306 A pretty broad definition of food would be one that
307 included bottled water, and the tremendous breadth and depth
308 of the responsibility entrusted to our good friends at the
309 Food and Drug Administration is this \$11 billion industry
310 known as bottled water. The average American consumer is
311 unlikely to think that the FDA would be the primary regulator
312 of bottled water but it is. The regulatory responsibility of
313 bottled water is split between the Environmental Protection
314 Agency and the federal Food, Drug and Cosmetic Act with the
315 Food and Drug Administration overseeing the process of taking
316 public water in its natural form in the environment into a
317 convenient plastic container for sale to the American
318 consumer.

319 Now, as much I appreciate the collegiality, the
320 intelligence and the willingness of Dr. Sharfstein to appear
321 here today as a representative of the Food and Drug
322 Administration, it does seem odd to only have the Food and
323 Drug Administration here to answer tough questions and to not
324 have the Environmental Protection Agency to answer questions
325 that would fall into their jurisdiction about the standards
326 for municipal water versus bottled water. Currently, bottled
327 water requires a higher threshold of testing than municipal
328 water. Municipal water is required to be tested every 4
329 years, bottled water every year. In fact, bottled water is
330 currently one the few stand-alone industries with its own
331 Code of Federal Regulations regarding Good Manufacturing
332 Processes. From the definition of water to the testing and
333 sampling of products, from the length of time the records
334 must be kept, currently 2 years, and how they should be
335 available to the Food and Drug Administration as well as the
336 role of the Environmental Protection Agency, the State and
337 local government agencies in helping to ensure the safety and
338 sanitation and quality of water, this burgeoning industry has
339 seemingly existed in a compliance-oriented manufacturing
340 system rather, if ever, producing bad actors. It would seem
341 that this industry is an example of the ingenuity and
342 innovation of the marketplace to create a product which had,

343 if you will pardon the pun, an unquenchable need for a
344 convenient, transportable water and this good idea has been
345 met with significant market success.

346 We must ensure that the trust and faith of consumers and
347 that the government places in the bottled water industry are
348 not misguided. More Americans drink bottled water than milk
349 or beer combined, so if there is any step in this multilayer
350 process to deliver this food product where the trust and
351 faith is misallocated, then certainly I look forward to
352 having the science point to a solution. Furthermore, any
353 deficiencies in the regulation of bottled water, any
354 potential fraud in the process of producing bottled water and
355 any alleged environmental issues of draining of our natural
356 resources and the burdensome transportation costs of moving
357 the end product, we will certainly look forward to seeing
358 what is sure to be voluminous evidentiary proof.

359 Thank you, Mr. Chairman, for your indulgence. I will
360 yield back the balance of my time.

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

362 ***** COMMITTEE INSERT *****

|
363 Mr. {Stupak.} No problem. I didn't want you to get
364 parched. As you know, in the Health Subcommittee, you guys
365 did hold a hearing on medical devices last month and the 510K
366 approval process, so those hearings are being taken. This
367 hearing--

368 Mr. {Burgess.} But I would submit the investigatory
369 part of that has not been completed, as least to my
370 satisfaction, and I think this subcommittee would be the
371 appropriate place to have that. In addition, we have got the
372 whole question of biosimilars out there that would probably
373 just roll into this health care bill and we have not had the
374 FDA in to talk to us about the science of biosimilars. So
375 there is stuff we could be doing, is the point I am trying to
376 make.

377 Mr. {Stupak.} Absolutely, and this committee has been
378 very active, as you know, for the last 2 years and we hold
379 many, many hearings, and this one with the two reports being
380 released today, it really dovetails into everything we have
381 been doing for the last couple of years in food safety, and
382 whether it is BPA or the PET that we talked about here, or as
383 Mr. Walden brought up, the DEHP, why has it taken 15 years to
384 put out regulations for that, certify labs' test results, all
385 that is contained in this hearing so it is not just strictly

386 bottled water, false advertising. That is what this whole
387 thing is about, sort of wraps up everything we have been
388 doing for the last few years, and we do have these two
389 reports coming out today so we thought it was appropriate to
390 have the hearing today. Very good.

391 Mr. Barton, opening statement, please.

392 Mr. {Barton.} Thank you, Mr. Chairman. Let me say
393 before I give my prepared statement how much I personally
394 appreciate you, so don't take some of what I am about to say
395 too personally.

396 But I think it does say something, given the serious
397 issues which you have traditionally tackled as your
398 subcommittee chairmanship along with Ranking Member Walden
399 that today's hearing does not rank at the top of that list,
400 and it shows when you look on your side how much support
401 there is. They may all be here but they are disguised as
402 empty chairs, if they are.

403 Mr. {Stupak.} Well, you know, most of the committee is
404 down in the Consumer Protection because we are putting a new
405 administrator in there and that is where most of them are.
406 In fact, that is why we started a little late because I am
407 also on that subcommittee and I had to stop by there.

408 Mr. {Barton.} Well, Greg and I will take over if you
409 want to go down there.

410 Mr. {Walden.} Could we have a vote on that right now?

411 Mr. {Barton.} Anyway, Mr. Chairman, today's hearing
412 does examine several interesting questions surrounding the
413 differences between bottled water and tap water. These
414 differences arise in regulatory approaches as well as in
415 processing, treatment and public perception. Several of the
416 witnesses today including the Government Accountability
417 Office and the Food and Drug Administration will discuss and
418 possibly debate ways in which bottled water regulations
419 should be changed and possibly improved. Other witnesses
420 including the Environmental Working Group and the
421 International Bottled Water Association will discuss ways
422 industry can be more transparent and responsive to consumer
423 inquiries. I don't have a problem with transparency, in
424 fact, I am pushing transparency in the upcoming health care
425 debate, and as you well know, I am certainly pushing
426 transparency at the Environmental Protection Agency where Mr.
427 Walden and I have asked the EPA to release their documents
428 concerning their suppression of the EPA report within its own
429 agency debating whether there really is an endangerment
430 finding with regards to CO2.

431 So those of us on the minority are concerned whether
432 this particular hearing is the best use of our limited
433 oversight hearing times. We have confronted the issue of

434 swine flu pandemic. We have confronted safety of products
435 like Tylenol. As I said a minute ago, Mr. Chairman, this one
436 just doesn't seem to be up to that standard of excellence
437 which you have established for your oversight. I hope that
438 after this hearing you will consider supporting Mr. Walden
439 and myself on getting information about the EPA's suppression
440 of the document which we call Carbon Gate regarding the CO2
441 and the endangerment finding. We also hope that you will
442 work with us, as I talked with you yesterday informally about
443 doing more hearings and doing some action times on the
444 automobile dealer closure issue. I know that is something
445 that is very important to you personally. We await your
446 response and Mr. Waxman's response.

447 So Mr. Chairman, we always appreciate when you hold a
448 hearing. We always participate and we are looking forward to
449 going on to a little bit more intense issues in the future.
450 Again, thank you for holding this hearing.

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

452 ***** COMMITTEE INSERT *****

|
453 Mr. {Stupak.} Well, thanks, Mr. Barton. And, you know,
454 one of the reasons why we are having this hearing because I
455 think as have seen on your side a little bit, maybe we assume
456 because it is in a bottle like this it is healthy, it is
457 clean, it is pure, and that is an assumption I think we
458 erroneously are making, so we are doing a hearing to try to
459 get to the issues here because I don't think we have to wait
460 for a deadly outbreak of disease in bottled water like we
461 have seen in salmonella in peanut butter last year, and we
462 can't say there is zero risk here. Between 2002 and 2008,
463 there were 23 recalls of bottled water. Now, that is about
464 one every quarter. Most of them stemmed from an elevated
465 level of contaminants such as arsenic and bromate, both of
466 which cause cancer. Over the past 6 years the FDA has issued
467 three warning letters to bottled water companies for
468 violating safety regulations, and that is in addition to
469 dozens of other problems found in the EPA inspections at
470 water bottling facilities.

471 In 2007, the FDA issued a press release against drinking
472 mineral water imported from Armenia because the arsenic level
473 was 50 times greater than the federal standard. And then,
474 like I said, last month in southern California, we have girls
475 sick at a high school who were buying bottled water out of a

476 vending machine. So these are problems the FDA has uncovered
477 and they only have about two or three employees devoted to
478 it, and like I said earlier, I think just because it comes in
479 a bottle, we assume it is healthier for us. That is what
480 most Americans assume. We find that is not the case and that
481 is the reason for the hearing, and all the other things we
482 have done this year on salmonella, institutional review
483 boards, dual use, so we have got a lot going on here.

484 Mr. Walden, go ahead.

485 Mr. {Walden.} Well, Mr. Chairman, just two points, one
486 I didn't mention in my testimony but I know that water is
487 also an ingredient in many other drinks, and I guess the
488 question I would have for our panel is, well, just because it
489 is clear and in those bottles, how is that treated or
490 monitored versus if it is colored and sugared and perhaps
491 carbonated. Does somebody check the water that goes into
492 that as well? Are there different standards there? The
493 second point I would make on, I think it is Santa Clara, the
494 junior high students, my understanding is that the FBI may be
495 involved in investigation there so it might be more of a
496 tampering issue. Is that correct?

497 Mr. {Stupak.} They are involved but no one has reached
498 a conclusion whether it is tampering.

499 Mr. {Walden.} Right. I understand. I wasn't trying to

500 jump to a conclusion. Thank you, Mr. Chairman.

501 Mr. {Stupak.} Okay. You bet. That is a good segue
502 into our first panel. Let me introduce our first panel of
503 witnesses with Mr. Joseph Stephenson, who is director of
504 National Resources and the Environment at the government
505 Accountability Office. We have Dr. Joshua Sharfstein, who is
506 the principal deputy commissioner at the U.S. Food and Drug
507 Administration, Ms. Jane Houlihan, who is the senior vice
508 president for research at the Environmental Working Group,
509 and Mr. Joseph K. Doss, who is the president of the
510 International Bottled Water Association.

511 It is the policy of this subcommittee to take all
512 testimony under oath. Please be advised that you have the
513 right under the rules of the House to be advised by counsel
514 during your testimony. Do you wish to be represented by
515 counsel? Mr. Stephenson?

516 Mr. {Stephenson.} No.

517 Mr. {Stupak.} Dr. Sharfstein, Ms. Houlihan? No. Okay.
518 Then I am going to ask you to please rise and raise your
519 right hand to take the oath.

520 [Witnesses sworn.]

521 Mr. {Stupak.} Let the record reflect that the witnesses
522 have replied in the affirmative. You are now under oath. We
523 will now hear 5-minute opening statement from our witnesses.

524 You may submit a longer statement for the record and would be
525 included in today's hearing. Mr. Stephenson, we will start
526 with you.

|
527 ^TESTIMONY OF JOHN STEPHENSON, DIRECTOR, NATURAL RESOURCES
528 AND THE ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE; JOSHUA
529 M. SHARFSTEIN, DEPUTY COMMISSIONER, U.S. FOOD AND DRUG
530 ADMINISTRATION; JANE HOULIHAN, SENIOR VICE PRESIDENT FOR
531 RESEARCH, ENVIRONMENTAL WORKING GROUP; AND JOSEPH K. DOSS,
532 PRESIDENT, INTERNATIONAL BOTTLED WATER ASSOCIATION

|
533 ^TESTIMONY OF JOHN STEPHENSON

534 } Mr. {Stephenson.} Thank you, Mr. Chairman and Mr.
535 Walden. I am pleased to be here today to discuss the quality
536 and safety of bottled water and its environmental impacts.

537 Over the past decade, the per capita consumption of
538 bottled water in the United States has more than doubled from
539 13.4 gallons per person in 1997 to 29.3 gallons per person in
540 2007. That is over 200 bottles a year for every man, woman
541 and child and an \$11 billion plus market. With this increase
542 come several questions and concerns over bottled water's
543 quality and safety. My testimony is based upon the report
544 that we are issuing to the committee today which is going to
545 be publicly released.

546 In summary, we found that FDA's safety and consumer
547 protections are less stringent for bottled water than

548 comparable EPA protections for tap water. While FDA's
549 standards for bottled water generally mirror the standards
550 for nearly all of the 88 contaminants covered by EPA's
551 national primary drinking water regulations, there is one
552 notable exception, DEHP, which is a plasticizer used to
553 soften plastic, which has been linked to reproductive and
554 liver problems and increased cancer risk. It has been
555 regulated by the EPA in tap water since 1992 but FDA deferred
556 action on DEHP in a rule published in 1996 and has yet to
557 either adopt a standard or publish a reason for not doing so,
558 even though the statutory deadline for acting was more than
559 15 years ago. Since DEHP is used in food packaging as well
560 as bottled water, this is a broader issue that FDA is still
561 studying. Nevertheless, our report recommends that FDA
562 expeditiously promulgate a DEHP standard for bottled water.

563 More broadly, we found that FDA, unlike EPA, does not
564 have the statutory authority to require bottlers to use
565 certified laboratories for water quality tests or to report
566 test results, even if violations of the standards are found.
567 Most tests are done by the bottlers themselves. Several
568 states have requirements to safeguard bottled water that
569 exceed those of FDA but are still less comprehensive than for
570 tap water. In addition, while FDA bottled water labeling
571 requirements are similar to labeling requirements for other

572 foods, they provide consumers with far less information about
573 the source and quality of water than what EPA requires of
574 public water systems under the Safe Drinking Water Act. For
575 example, public water systems must annually provider consumer
576 confidence reports that summarize water quality information
577 about the water sources, detected contaminants and compliance
578 with national primary drinking water regulations as well as
579 information on the potential health effects of certain
580 contaminants. FDA does not require bottled water companies
581 to provide similar information. In a study mandated by the
582 1996 amendments to the Safe Drinking Water Act, FDA concluded
583 that it was feasible for the bottled water industry to
584 provide the same type of information to consumers that public
585 water systems must provide. However, the agency was not
586 required to act on its findings and has yet to do so.

587 A survey of 50 States and the District of Columbia
588 showed that consumers have misconceptions about bottled
589 water, believing that it is safer and healthier than tap
590 water. We also found that information comparable to what
591 public water systems are required to provide to consumers of
592 tap water was available for only a small percentage of the 83
593 bottled water labeled we examined, companies we contacted or
594 company websites we reviewed. We believe that consumers
595 would benefit from better information on the quality and

596 safety of bottled water, and our report also recommends that
597 FDA implement the results of this study to accomplish this.

598 In examining the environmental effects of bottled water,
599 we found that only about 25 percent of water bottles are
600 recycled and that the remaining 75 percent are discarded in
601 municipal landfills where they never decompose and
602 essentially remain forever. While this is over 900,000 tons
603 of plastic annually, it represents less than 1 percent of
604 municipal waste.

605 Another issue is the amount of energy used to
606 manufacture and transport bottled water. Another study
607 estimates the energy use at 5.8 megajoules per liter. At the
608 current rate of consumption, this is the equivalent of the
609 energy used by 4.7 million households for a year and is 1,000
610 to 2,000 times the energy used for tap water. We also found
611 that groundwater extraction for bottled water facilities in
612 selected areas and that Michigan and other States have passed
613 laws to minimize the impact of stream levels and wetlands.

614 Finally, I would note that some of our bottled water
615 findings are indicative of FDA'S overall food safety
616 oversight problems that led to GAO's designating it a high-
617 risk area in January 2007 and again in 2009 when we called
618 for a fundamental reexamination of the federal food safety
619 system. We believe that FDA's lack of authority and

620 resources to effectively regulate bottled water should be
621 part of that reexamination.

622 Mr. Chairman, that concludes the summary of my statement
623 and I will be happy to answer questions at the appropriate
624 time.

625 [The prepared statement of Mr. Stephenson follows:]

626 ***** INSERT 1 *****

|

627 Mr. {Stupak.} Thank you, Mr. Stephenson.

628 Dr. Sharfstein, would you like to make your opening

629 statement?

|
630 ^TESTIMONY OF JOSHUA M. SHARFSTEIN

631 } Dr. {Sharfstein.} Thank you very much. We appreciated
632 the GAO report, and I especially appreciate that he finished
633 with exactly 2 seconds left. I was watching. I have never
634 seen that before.

635 Good morning, Mr. Chairman and members of the
636 subcommittee. I am Dr. Joshua Sharfstein, the principal
637 deputy commissioner of the Food and Drug Administration of
638 the Department of Health and Human Services. I want to thank
639 the committee for your work on a wide range of health issues
640 and for the opportunity to discuss FDA's regulation of
641 bottled water today.

642 As has been mentioned, bottled water and tap water are
643 regulated by two separate agencies. FDA regulates bottled
644 water while the EPA regulates tap water, also referred to as
645 municipal water or public drinking water. EPA has
646 regulations on the production, distribution and quality of
647 public drinking water including source water protection,
648 operation of drinking water systems, contaminant levels and
649 reporting requirements.

650 The Food, Drug and Cosmetic Act provides FDA with
651 regulatory over food and as part of that, bottled water that

652 is introduced interstate commerce. Under the Food, Drug and
653 Cosmetic Act, manufacturers are responsible for producing
654 safe, wholesome and truthfully labeled food products. It is
655 a violation of the law to introduce into interstate commerce
656 adulterated or misbranded products.

657 FDA has established specific regulations for bottled
658 water in the Code of Federal Regulations. These regulations
659 include standard identity regulations that define different
660 types of bottled water such as spring water versus mineral
661 water and standard quality regulations that establish
662 allowable levels for chemical, physical, microbial and
663 radiological contaminants. FDA has established Good
664 Manufacturing Practice regulations for the processing and
665 bottling of bottled drinking water. Labeling and GMP
666 regulations for foods in general also apply to bottled water.
667 Federal law requires FDA to set similar standards for bottled
668 water as exist for municipal water or explain why they should
669 not apply. FDA has established such standards for more than
670 90 contaminants and in some cases such as for lead or copper,
671 the FDA limits are stricter for bottled water than for
672 municipal water. And another point to make in this regard is
673 that the way that the testing is done is different. For
674 example, take the lead standard. Any test that is high is
675 violative that is done on FDA-regulated bottled water, for

676 the municipal water only a percentage of the samples is above
677 a certain level. The municipal water supply failed that. So
678 they are allowed to have certain failures and not have it as
679 a failure for the municipal water supply. So it just
680 illustrates that there is a different approach that is taken
681 in a few contexts.

682 FDA monitors and inspects bottled water products and
683 processing plants as part of the general food safety program.
684 Inspections occur approximately once every 1 to 3 years. The
685 agency inspects violative firms more frequently, depending on
686 the number, significance and recurrence of violations. FDA's
687 field offices follow up on consumer and trade complaints and
688 other leads on potentially violative bottled water products.
689 As for other types of food, FDA periodically collects and
690 analyzes samples of bottled water. Samples of foreign
691 bottled water offered for entry may be collected and tested
692 to determine if they are in compliance with the laws and
693 regulations, and labs may test the water for microbial,
694 radiological or chemical contamination.

695 In recent years, FDA has promulgated a number of quality
696 standard for bottled water in conjunction with EPA. Most
697 recently, on May 29, 2009, FDA published a final rule to
698 require that bottled water manufacturers test source water
699 and finished bottled water products for total coliform

700 organisms and to prohibit distribution of products containing
701 any E. coli, an indicator of fecal contamination. FDA is
702 also requiring that before a bottler can use source water
703 from a source that has tested positive for E. coli, the
704 bottler must take appropriate measures to rectify or
705 eliminate the cause of the problem, and the bottler must keep
706 records of such actions.

707 In general, FDA's oversight of bottled water, I think
708 can be described as successful. The agency is aware of no
709 major outbreaks of illness or serious safety concerns
710 associated with bottled water over the past decade. FDA is
711 aware the GAO report released today highlights a number of
712 issues that the agency faces in regulating bottled water.
713 FDA has worked with GAO to provide information and assist
714 with their investigation.

715 Let me address some of the issues that GAO has raised,
716 and let me say that while I do believe that FDA's oversight
717 has been generally successful, I also believe that there is
718 room for improvement. First, GAO found that FDA has not yet
719 set a standard for the phthalate known as DEHP. This was
720 contemplated in 1996 but the Administration at the time did
721 not pursue this because of a legal issue we could discuss
722 further if you want known as prior sanction. We are now
723 revisiting this decision and intend to pursue a DEHP standard

724 as anticipated under the law.

725 Second, GAO found that FDA labeling regulations for
726 bottled water provided for less information about the sources
727 and quality of water than required by FDA for municipal
728 systems. FDA has found that it would be feasible for
729 manufacturers of bottled water to provide such information to
730 consumers. However, the Food, Drug and Cosmetic Act does not
731 provide a mechanism to require bottlers to make that
732 information available so Congress would have to take
733 additional action.

734 Third, GAO expressed concern that FDA cannot require the
735 submission of results to the agency on tests conducted by
736 bottled water manufacturers. This is a fair point and a part
737 of the oversight of water and food in general that should be
738 strengthened. In fact, it would be strengthened by the food
739 safety legislation that the committee is showing so much
740 leadership on.

741 Fourth, GAO has pointed out that FDA does not have
742 specific authority to mandate the use of certified
743 laboratories. This is also a reasonable point, and FDA does
744 require the use of methods that are at least as sensitive as
745 FDA's methods but the food safety legislation passed by the
746 committee would also be extremely helpful here.

747 I would also mention that the food safety legislation

748 provides for food safety plans, hazard analyzes and
749 preventive controls that will complement FDA's Good
750 Manufacturing Practices for bottled water facilities and
751 generally strengthen the system of oversight for bottled
752 water, and for foreign-produced bottled water, the Act would
753 require importers to register with FDA, comply with Good
754 Importer Practices and give FDA the authority to require
755 certification as a condition of importation.

756 So we will continue to work with this committee on the
757 legislation, which we think is very important, and I am
758 pleased to be here and look forward to your questions.

759 [The prepared statement of Dr. Sharfstein follows:]

760 ***** INSERT 2 *****

|

761 Mr. {Stupak.} Thank you, Doctor.

762 Ms. Houlihan, would you pull that mic over.

|
763 ^TESTIMONY OF JANE HOULIHAN

764 } Ms. {Houlihan.} Mr. Chairman and members of the
765 subcommittee, I am Jane Houlihan, senior vice president for
766 research at Environmental Working Group. We are a nonprofit
767 research and advocacy organization in Washington, D.C. Thank
768 you for holding this hearing.

769 Today we are releasing an 18-month survey of labels and
770 websites for 188 bottled waters. Here is what we found.
771 Consumers spent about 1,900 times more for bottled water than
772 for tap water yet they often have no way to learn essential
773 facts about what is actually in the bottle. Only two of 188
774 bottled waters make public three basic facts routinely
775 disclosed by local tap water utilities. These are the
776 specific name and location of the water source, purification
777 methods and chemical pollutants that remain in the water
778 after treatment. These two brands are Ozarka Drinking Water
779 and Penta Ultra-Purified Water, the only two of 188 doing so.

780 Bottled water companies are not required to make these
781 basic facts public, and here is the reason: they enjoy a
782 regulatory holiday under the federal Food, Drug and Cosmetic
783 Act with near-complete latitude on what, if any, information
784 to share with consumers. In contract, every one of the

785 Nation's 52,000 municipal water suppliers produces an annual
786 water quality report giving its water source and pollutant
787 testing results as required under the Safe Drinking Water
788 Act. EPA calls these reports the centerpiece of consumers'
789 right to know about water quality.

790 This double standard is unfair to consumers who have a
791 right to know what is in the water they buy. Surveys show
792 that over half of bottled water drinkers choose it because
793 they are worried about the safety of their tap water. They
794 believe it is free of contaminants. They do it for their
795 health. But in too many cases, consumers have no way to
796 check if the purity they are looking for is what they are
797 actually getting.

798 So where does the water come from? Our survey found
799 that 30 percent of bottled waters provide no information
800 whatsoever about their water source on the label but 37
801 percent fully divulge both the name and location of their
802 water source, and the remaining 33 percent give generic
803 information like spring or deep aquifer. If you could look
804 at figure 1 in your packet, please, this is a brand that is
805 doing the right thing. It is Great Value. It is called in
806 your figure a smaller brand. It is not in the top 10 but it
807 is actually distributed by Walmart. You will see on the
808 label the source clearly indicated municipal supply, Fort

809 Worth, Texas, so you know exactly where this water comes
810 from. You will also see the treatment method on this label,
811 reverse osmosis. Let us look at the next figure by way of
812 contrast. On the other end of the spectrum is Dasani. On
813 this label, you will see that the product is pure and it is
814 crisp and it has a fresh taste but nowhere on this label will
815 you find the source of that water. Dasani is one of 30
816 percent of the brands not giving any information on source
817 along with Whole Foods, Food Lion, CVS, Kroger store brands
818 and many other brands.

819 How is bottled water purified? Bottled water companies
820 are not required to disclose what, if any, methods they use
821 to purify their water. Municipal water suppliers aren't
822 required to disclose this information either but most of them
823 do. We found that 44 percent of bottled waters provide no
824 treatment information on labels. One-third provide no
825 information on labels or websites.

826 If you look at figure 2 in your packet, you will see a
827 label for Ozarka. This is a Nestle brand that is actually
828 doing the right thing. You will see on this label the water
829 comes from the Houston municipal water supply, but it doesn't
830 stop there. It is further treated by reverse osmosis, carbon
831 filtration, microfiltration and ozonation. Now, for
832 contrast, let me read to you what you will see on a Fiji

833 label. ``The purest water comes from the purest clouds. Our
834 rainfall is purified by trade winds as it travels across the
835 Pacific Ocean to the islands of Fiji,' and that is all the
836 information you will see on treatment on that label, and Fiji
837 is one of the 60 percent of bottled waters that print
838 marketing claims of purity from among those waters that don't
839 label their treatment methods. Consumers have no way to know
840 if the claims are true.

841 What pollutants are in bottled water? Every tap water
842 utility publishes an annual water quality report listing all
843 their results for the year but only 18 percent of bottled
844 waters do the same. Those that do include all eight domestic
845 Nestle brands. Those that don't include Aquafina, which is a
846 Pepsi brand, and figure 3 of your packet. Without data,
847 consumers are left with marketing claims, and these are
848 extensive. You have heard Poland Springs, a man who lived 52
849 additional years after drinking the water. Mountain Valley
850 Springs became known as a remedy for the treatment of gout,
851 rheumatism and other diseases. Evian claims its water is a
852 symbol of health, general well-being. Valdix water is
853 extremely pure but they don't publish a test report. And
854 finally, Aquamantra's water resonates with the energy and
855 frequency of well-being. When you pay a premium price for
856 bottled water, you deserve more than just claims. We

857 recommend that bottled water labels and websites disclose the
858 same information that the law requires of municipal water
859 utilities and that this disclosure be mandatory. Consumers
860 have a right to know where their bottled water comes from,
861 how or if it is treated and the pollutants it contains.

862 Thank you for your time.

863 [The prepared statement of Ms. Houlihan follows:]

864 ***** INSERT 3 *****

|

865 Mr. {Stupak.} Thank you.

866 Mr. Doss, your opening statement, please, sir.

|
867 ^TESTIMONY OF JOSEPH K. DOSS

868 } Mr. {Doss.} Chairman Stupak, Ranking Member Walden and
869 members of the subcommittee, my name is Joe Doss. I am
870 president and CEO of the International Bottled Water
871 Association. I appreciate very much this opportunity to
872 discuss the regulation of bottled water.

873 Bottled water, whether in retail-size packages or in
874 larger containers used in home and office water coolers, is a
875 safe, healthy, convenient beverage. It is comprehensively
876 regulated as a packaged food product at both the federal and
877 State level, and as with other packaged food and beverages,
878 bottled water must meet FDA's general food regulations which
879 include extensive labeling requirements for ingredients, the
880 name and place of business of the manufacturer, packer or
881 distributor, the product's net weight, and if required,
882 nutrition labeling. In addition, FDA has promulgated
883 separate standards, as we have heard, separate standards of
884 identity including labeling requirements that identify the
885 type of bottled water, standards of quality and good
886 manufacturing practices specifically for bottled water.
887 Federal law requires FDA bottled water regulations to be as
888 protective of the public health as EPA standards for public

889 drinking water systems, and to that end, FDA has established
890 bottled water standards for quality for more than 90
891 substances. Most FDA bottled water quality standards are the
892 same as EPA's maximum contaminant levels for public water
893 systems. The few differences in regulated substances are
894 because they are not found in bottled water or they are
895 regulated under another provision of law such as FDA's food
896 additive program.

897 If a container of bottled water has a contaminant that
898 exceeds an FDA standard, this fact must by law be disclosed
899 on the label. Failure of a bottled water container to meet
900 the standards of quality and to be properly labeled can
901 subject it to recall by the company and enforcement action by
902 FDA. If a bottled water product source is a public water
903 system and the finished bottled water product does not meet
904 the FDA standard of identity for purified or sterile water,
905 that product label must disclose the fact that it comes from
906 a public water source.

907 It is also important to note that the courts have held
908 that FDA' jurisdiction over food and beverages extends not
909 only to those products that move in interstate commerce but
910 to those products sold within a single State if they are
911 using packaging materials that have moved in interstate
912 commerce such as the bottle, the caps or the labels, and that

913 is the case for almost every bottled water sold in the United
914 States. In addition, Congress has created a statutory
915 presumption of interstate commerce for all FDA-regulated
916 products including bottled water.

917 Now, while the current laws regulating bottled water
918 products protect the public health, IBWA members and others
919 in the food industry have recently worked with the Energy and
920 Commerce Committee to update the food safety laws. IBWA
921 supports a risk-based inspection system that would require
922 inspections of all food facilities every 6 months to 3 years,
923 a requirement for all food manufacturers to conduct a hazard
924 analysis and establish and maintain preventive controls which
925 all IBWA members already do as a condition of membership in
926 granting FDA authority to mandate recall under circumstances
927 where a food product presents an imminent threat of serious
928 adverse health consequences or death.

929 IBWA supports a consumer's right to clear, accurate and
930 comprehensive information about the bottled water products
931 they purchase. As I mentioned, all packaged food and
932 beverages including bottled water are subject to extensive
933 FDA labeling requirements that provide consumers with a great
934 deal of product quality information. In addition, virtually
935 all bottled water products include a phone number on the
936 label that consumers can use to contact the company. In

937 fact, IBWA petitioned FDA in 2001 to require all bottled
938 water labels to include a phone number on the label. IBWA
939 believes that the most feasible way to consumers to obtain
940 information not already on the label is through a request to
941 the bottler. In addition, consumers can go to the IBWA
942 website to obtain contact information or water quality
943 information for all IBWA member brands.

944 Consumers have many options when choosing which bottled
945 water brand to drink. If a bottled water company does not
946 provide them with the information that they want, he or she
947 can choose another brand of bottled water. That is not the
948 case with tap water. Consumers cannot choose which public
949 water system is piped into their homes, and that is a
950 fundamental issue: consumer choice.

951 Unfortunately, many people want to make this out to be a
952 bottled water versus tap water issue. We just don't see it
953 that way. If people are drinking water, whether it is tap or
954 bottled, that is a good thing and consumers should be free to
955 choose. In fact, 75 percent of consumers who drink bottled
956 water also choose to drink tap water. IBWA supports
957 investments to improve the U.S. public drinking water system
958 in order to maintain the highest quality of water for all
959 citizens. And with the increase in diabetes, obesity and
960 heart disease rates in the United States, any actions that

961 would discourage consumers from drinking bottled water are
962 not in the public interest. Throughout the years, bottled
963 water companies have always responded to the need for clean,
964 safe drinking water after natural disasters such as
965 hurricanes, floods and forest fires, and in emergency
966 situations such as terrorist attacks and boil alerts.
967 However, the bottled water industry cannot exist only for
968 disaster response. The vast majority of bottled water
969 companies in the United States are primarily family owned and
970 operated small business that depend on a viable commercial
971 market to provide the resources necessary to respond in
972 emergency situations. In fact, 90 percent of IBWA's members
973 have gross sales of less than \$10 million a year.

974 In summary, bottled water is a safe, healthy, convenient
975 good product that is comprehensively regulated at the federal
976 and State level. IBWA stands ready to assist the
977 subcommittee as it considers this very important issue.
978 Thank you for considering our views.

979 [The prepared statement of Mr. Doss follows:]

980 ***** INSERT 4 *****

|
981 Mr. {Stupak.} Well, thanks. We will start with
982 questions, and thank you all for your comments.

983 Mr. Doss, let me ask you this. Is it true 80 percent of
984 the water bottlers are part of your organization, about 80
985 percent?

986 Mr. {Doss.} I am sorry?

987 Mr. {Stupak.} Water bottlers in this country, they
988 belong to your organization?

989 Mr. {Doss.} I would say we probably represent 75
990 percent of the actual facilities.

991 Mr. {Stupak.} Is Dasani, Coca-Cola, are they part of
992 your--

993 Mr. {Doss.} Dasani is not a member of the association.

994 Mr. {Stupak.} How about Nestle?

995 Mr. {Doss.} Nestle is a member.

996 Mr. {Stupak.} Okay. And how about Aquafina? That is
997 Pepsi, right?

998 Mr. {Doss.} That is not a member.

999 Mr. {Stupak.} So are those the three biggest, Coke,
1000 Pepsi and Nestle?

1001 Mr. {Doss.} The largest companies.

1002 Mr. {Stupak.} So two of the three are not part of your
1003 organization?

1004 Mr. {Doss.} That is correct.

1005 Mr. {Stupak.} Your standards, which track many of the
1006 things we recommended and GAO and the others, that is
1007 voluntary standards you try to have your member comply with?

1008 Mr. {Doss.} IBWA has always tried to, you know, have
1009 the highest possible safety standards so we have a mandatory
1010 requirement for our member, and if they don't meet those
1011 standards, then they cannot be a member of the International
1012 Bottled Water Association.

1013 Mr. {Stupak.} Do you do anything on the advertising
1014 then? I mean, we have seen these crazy--

1015 Mr. {Doss.} No, advertising is not an issue that we
1016 deal with. Obviously that is a case-by-case situation where
1017 there are State and federal laws that would allow companies
1018 to be--action to be brought against them for deceptive or
1019 misleading advertising, so we don't do anything in that
1020 regard.

1021 Mr. {Stupak.} Okay. So like Aquamantra about these
1022 mantras inherently penetrate the molecular structure of the
1023 water, you guys don't condone any of that?

1024 Mr. {Doss.} It is not something--the association does
1025 not deal with advertising issues. That is something that
1026 would be left to the State and federal authorities.

1027 Mr. {Stupak.} Well, the company went on to say that it

1028 consulted, and I use the word ``consulted'' because that is
1029 what it said on the website, with a Dr. Marura Emoto who
1030 wrote a book called Hidden Messages in Water, and the company
1031 said that he showed us the basic principles of quantum theory
1032 whereby the molecular structure of water was changed by a Zen
1033 Buddhist monk's thoughts. Based on this premise, Aquamantra
1034 uses the design on its labels to affect the molecular
1035 structure of California natural spring water to make it more
1036 refreshing and wholesome. Is there any water studies that a
1037 Zen monk can change the molecular structure of water?

1038 Mr. {Doss.} Well, I can't speak to what that company
1039 has found. I just can't speak to that. I don't know that
1040 they are a member of IBWA so I can't comment on what
1041 information they may have about what they say on their label
1042 or other materials.

1043 Mr. {Stupak.} Dr. Sharfstein, have you seen anything
1044 quite like this? Do you think those should be part of the
1045 labeling of bottled water, Zen Buddhist monks' thoughts that
1046 can change the structure of water?

1047 Dr. {Sharfstein.} I would be highly skeptical.

1048 Mr. {Stupak.} But, you know, we have seen it, and Ms.
1049 Houlihan pointed out and a couple others, these are just sort
1050 of like fantastical claims. Are they legal? Can they do it
1051 underneath your misbranding or false advertising?

1052 Dr. {Sharfstein.} Well, we will definitely look into
1053 this case. In general, misbranding pertains to whether
1054 people are claiming to treat disease. That is the big one.
1055 That is where we put our priority. If people are saying you
1056 drink this water and it cures your cancer, then people may
1057 not pursue cancer treatment.

1058 Mr. {Stupak.} So like Mr. Ricker of Poland Springs who
1059 had a miraculous recovery and lived nearly 52 years and it is
1060 good for liver and kidney diseases, is that--

1061 Dr. {Sharfstein.} Well, there were two that you--you
1062 know, the one with historical fable. I don't know if that is
1063 exactly--

1064 Mr. {Stupak.} That is Mr. Ricker.

1065 Dr. {Sharfstein.} But the other one where you said used
1066 in clinical--

1067 Mr. {Stupak.} Clinical tests, Philadelphia, St. Louis.

1068 Dr. {Sharfstein.} That one I think we would like to
1069 see. I mean, that to me strikes me as pretty, you know,
1070 worth our evaluating. I am not familiar with that. But I
1071 think that would definitely fall into something we would look
1072 closely at.

1073 Mr. {Stupak.} How about the other one? The makers of
1074 H2OM claim that they play music and sounds at their bottling
1075 facility that charge the water with special vibratory

1076 frequencies? Would that be misadvertising?

1077 Dr. {Sharfstein.} I am not a musician but I would still
1078 express skepticism about that one, and I think that, you
1079 know, we have--the misbranding provision is really about
1080 things that we focus on we really think are going to pose a
1081 public health threat, a claim like that, and you know, the
1082 issue about whether it treats kidney or liver disease, this
1083 really does raise that issue.

1084 Mr. {Stupak.} You know, in tab 13 is that chart again,
1085 and we might want to put it back up on the board there. And
1086 the two reports by GAO and Environmental Working Group talk
1087 about the regulations, and you mentioned a little bit in
1088 yours too. If the bottlers discovered dangerous contaminants
1089 of water, they don't have to alert the public. Unlike
1090 municipalities, bottlers don't have to use certified labs.
1091 Water bottlers generally are not required to provide
1092 information about test results, the source of their products.
1093 You know, take Dasani here. We mentioned them today, and I
1094 have this bottle that was put on the airplane when I fly back
1095 and forth so I grabbed it with me as I was reading my
1096 testimony. When I go through and read it, you know, their
1097 claims aren't too outrageous. It is enhanced with minerals
1098 for a pure, fresh test that can't be beat, and then you go to
1099 www.makeyourmouthwater.com. That is out there a little bit

1100 but it says bottled by CCDA Waters LLC, Millersburg,
1101 Pennsylvania, but then underneath it they have CT and then
1102 the symbol for number, 992, then they have NV 07354, NYSHD
1103 certificate 173 and then they have another one, L, but CT,
1104 would that be Connecticut? NV, would that be Nevada? New
1105 York State Health Department, I take it, would be New York.
1106 It doesn't say anything about sources or anything, so you
1107 don't know where this water really came from, Nevada,
1108 Connecticut, New York or Pennsylvania.

1109 Dr. {Sharfstein.} I could not decipher that for you.

1110 Mr. {Stupak.} Mr. Doss, can you help out on that, these
1111 markings?

1112 Mr. {Doss.} I can't say for sure because I obviously
1113 don't--I am not familiar with that brand but it may be that
1114 all of those states require the product to be registered like
1115 other food products do within the State. If you are going to
1116 sell products within a State, I think all food products tend
1117 to have those registration information on the bottles.

1118 Mr. {Stupak.} So you would have to figure out--the last
1119 one is probably a lot number. You would have to go through
1120 and figure out your lot number to try to figure out where it
1121 came from, right, and whether Nevada, Connecticut, New York
1122 or Pennsylvania, or Coca-Cola in Atlanta, Georgia, because
1123 that address is on there too. Really, a consumer has no way

1124 of knowing, and this is one of the big bottlers.

1125 Mr. {Doss.} Again, I can only tell you I think that is
1126 what that refers to.

1127 Mr. {Stupak.} Mr. Walden.

1128 Mr. {Walden.} Thank you very much, Mr. Chairman.

1129 Just like any food product regulated by the FDA, if
1130 dangerous contaminants are in the bottled water, it is
1131 considered adulterated by the FDA, correct, Doctor?

1132 Dr. {Sharfstein.} That is correct.

1133 Mr. {Walden.} And it violates the law if it is sold to
1134 consumers?

1135 Dr. {Sharfstein.} People can go to jail if they do it.

1136 Mr. {Walden.} And if we are worried about some of these
1137 claims on the label, isn't that really also under the
1138 jurisdiction of the FTC, the Federal Trade Commission, on
1139 false advertising and labeling?

1140 Dr. {Sharfstein.} You know, I will have to get back to
1141 you. I don't know if I can answer that. I think we do have
1142 certain jurisdiction there and I am not sure about the FTC.

1143 Mr. {Walden.} I would assume that they would but I
1144 don't know that for a fact but it is something we ought to
1145 look at because it would be helpful if they were here today
1146 and the EPA was here today and perhaps somebody from Coca-
1147 Cola as well since they are not represented on this panel but

1148 we are singling them out.

1149 Dr. {Sharfstein.} One thing I might want to mention is,
1150 in just a couple of months FDA is going to launch--

1151 Mr. {Walden.} Is your mic on, by the way?

1152 Dr. {Sharfstein.} Yes.

1153 Mr. {Walden.} Okay.

1154 Dr. {Sharfstein.} In just a couple months, FDA is going
1155 to launch the reportable food registry that was part of
1156 legislation that Congress passed, and when that happens, we
1157 are anticipating September, companies will have to notify FDA
1158 if there is a product release that could pose a serious risk
1159 to health. So some of the gap will be filled by that but we
1160 really think, you know, the passage of the food safety
1161 legislation is necessary to really close that.

1162 Mr. {Walden.} Yes, we are hopeful that that can be
1163 brought up on the--Mr. Chairman, has that been scheduled for
1164 House Floor consideration yet?

1165 Mr. {Stupak.} Not yet. We are still working on the
1166 final touches.

1167 Mr. {Walden.} Okay. In your testimony, Doctor, you
1168 discussed new FDA testing requirements for bottled water to
1169 include testing source water for total coliforms and
1170 establish a zero tolerance for E. coli. Does the EPA require
1171 testing for coliforms in tap water and did the EPA establish

1172 a zero tolerance level for E. coli?

1173 Dr. {Sharfstein.} Give me one second. I have some
1174 information on that right here. I was curious about that
1175 also.

1176 Mr. {Walden.} Because I think you made the case on
1177 lead, that you have zero tolerance for lead in bottled water
1178 but EPA allows a certain--

1179 Dr. {Sharfstein.} I think it illustrates the point that
1180 it is just a little different, the systems. My understanding
1181 is that public water systems are required to collect monthly
1182 total coliform samples throughout their distribution systems
1183 and that if they are positive they must be tested for E.
1184 coli. For a system collecting more than 40 samples per
1185 month, if more than 5 percent are positive, that triggers a
1186 violation. If it less than 40 samples per month, then one
1187 positive sample triggers a violation. So, you know, for FDA,
1188 bottled water, if there is any violation that kicks in for
1189 municipal, it has to be certain percentage of the tests
1190 violative for it to trigger a violation. So the standards
1191 are slightly different. I hope I was able to explain that
1192 clearly enough. They do a whole bunch of tests--

1193 Mr. {Walden.} Are they more stringent under your
1194 regulations or the EPA regulations?

1195 Dr. {Sharfstein.} It is--

1196 Mr. {Walden.} Or is it just different?

1197 Dr. {Sharfstein.} They are different. I mean, you
1198 know--

1199 Mr. {Walden.} Because I know here in the District of
1200 Columbia, I think I am correct in saying this, that we all
1201 went many years drinking the tap water believing it to be
1202 safe only to discover that they hadn't really fully disclosed
1203 the amount of lead that was coming into the water through the
1204 pipes, and so I don't know if you ran into that in Baltimore
1205 when you were health commissioner there, but as I recall you
1206 advocated to people to buy it and it would be safer to drink
1207 bottled water.

1208 Dr. {Sharfstein.} Well, not for the population of
1209 Baltimore because the municipal water supply in Baltimore we
1210 felt very comfortable with but--

1211 Mr. {Walden.} But for public school children?

1212 Dr. {Sharfstein.} Public school children. That is
1213 right. In fact, I advised the school superintendent to turn
1214 off all the drinking fountains in the Baltimore City public
1215 schools because of problems that they were having with lead.

1216 Mr. {Walden.} And to go to bottled water.

1217 Dr. {Sharfstein.} And to go to bottled water across the
1218 system. It turned out to be cheaper also, given the expense
1219 of testing the municipal water because of the old buildings

1220 and the problems they had with the pipes in the school. So,
1221 you know, I certainly as a health commissioner, I think there
1222 are certain scenarios where, for example, after certain types
1223 of disruptions of the water supply, the water can be unsafe
1224 for a period of time and we recommended that people buy
1225 bottled water or boil it.

1226 Mr. {Walden.} Thank you.

1227 Mr. Doss, a question about this notion that consumers
1228 are wanting to know what it is in their bottled water. While
1229 I want to know that it is safe when I drink it, I am not sure
1230 I am going to chase down what spring it came out of or well,
1231 as long as I know it is safe. How many inquiries do you get
1232 through your association of people who say I want to know the
1233 ingredients, I want to know--I mean, when I take water out of
1234 my place here in D.C., there is no label on the tap that
1235 tells me all this stuff. I wouldn't know where to go in the
1236 D.C. system to even find out, and frankly, as long as it is
1237 safe, I don't care. How much of this is the case? How many
1238 people are rushing to you and calling your folks saying hey,
1239 I demand to know where this water came from?

1240 Mr. {Doss.} At IBWA, the association has hardly gotten
1241 any comments, any questions from consumers. I have talked to
1242 some of my members including our large members and our small-
1243 and mid-sized members, and they get very few requests. Now,

1244 I will say--

1245 Mr. {Walden.} And how do they handle those requests?

1246 Mr. {Doss.} They provide them with the information.

1247 Mr. {Walden.} Do they disclose?

1248 Mr. {Doss.} If they want testing results, if they want
1249 source information, whatever they ask for, you know, in our
1250 opinion, that is what they should provide, and that is our
1251 bottom line is that if a consumer has a question, we believe
1252 they have the right to have that information. The real issue
1253 is how to best provide that information. I think that is the
1254 distinction here and that was related a minute ago. These
1255 are two different systems. Bottled water is a packaged food
1256 product in a very different distribution system than tap
1257 water. So there are necessarily some differences in the way
1258 you might want to provide the information, and as far as the
1259 overall safety is concerned, again, they both have to be
1260 safe. There are different ways that you get to that goal.

1261 Mr. {Walden.} Because I don't think in a soft drink
1262 bottle they disclose where the liquid source comes from,
1263 right? Because they put water in a cola beverage, right? Is
1264 that right, Doctor?

1265 Dr. {Sharfstein.} Yes.

1266 Mr. {Walden.} Isn't that the number one ingredient, is
1267 water, in these beverages we all drink? And the last time I

1268 checked, nobody is saying tell me where the water came from
1269 that is in there. It is not required to be on those labels,
1270 is it?

1271 Mr. {Doss.} And that is why--

1272 Mr. {Walden.} So you are kind of being singled out.

1273 Mr. {Doss.} Bottled water is a food product so we
1274 follow the rules that are in place.

1275 Mr. {Walden.} Is cola a food product?

1276 Dr. {Sharfstein.} Cola is a food product and it is not
1277 subject to the Good Manufacturing Practices that exist
1278 specifically for bottled water, so there is a--

1279 Mr. {Walden.} So is there less oversight on our soda
1280 drinks from the FDA's perspective?

1281 Dr. {Sharfstein.} Maybe I wouldn't use the word
1282 ``oversight'' but I would say there is definitely more
1283 regulations and--

1284 Mr. {Walden.} On which?

1285 Dr. {Sharfstein.} On bottled water.

1286 Mr. {Walden.} Than on cola products? And I am not
1287 picking on cola versus uncola versus, you know, the new cola
1288 versus whatever. I am just talking soft drinks.

1289 Dr. {Sharfstein.} That is correct.

1290 Mr. {Walden.} So there is less oversight--well, I will
1291 use the term ``oversight'' but in terms of food safety

1292 issues--

1293 Dr. {Sharfstein.} Right, and there are Good
1294 Manufacturing Practices that apply to foods generally that
1295 apply to colas, and someone will tap me if I am getting this
1296 totally wrong, but I understand that the bottled water has a
1297 whole set of regulations that are really just for bottled
1298 water, and it relates to the fact--

1299 Mr. {Walden.} Commodity-specific--

1300 Dr. {Sharfstein.} Right.

1301 Mr. {Walden.} --regulations which don't exist for soft
1302 drinks?

1303 Dr. {Sharfstein.} Right.

1304 Ms. {Houlihan.} Can I also say that one difference
1305 between bottled water and soda is also that people choose
1306 bottled water because they think it is healthier and safer
1307 than--

1308 Mr. {Walden.} Yes, but that is not--

1309 Ms. {Houlihan.} --in a lot of cases, and that is not
1310 the reason they are choosing colas. So I think that--

1311 Mr. {Walden.} Yes, but the question--whether they
1312 choose it or not, the question I thought you were getting at
1313 is, consumers have the right to know the source of the
1314 ingredients in the bottle, the labeling and all that. I
1315 mean, I want to know if--I may think a soda product is better

1316 than bottled water.

1317 Ms. {Houlihan.} Water is very different from other
1318 kinds of food products. It makes up more than half of our
1319 body and we are advised to drink at least eight--

1320 Mr. {Walden.} Right, because it helps remove toxins and
1321 everything else.

1322 Ms. {Houlihan.} Exactly, and so people are choosing
1323 bottled water in particular, not colas, because there is a
1324 perception that it is safer and healthier than tap water, and
1325 I think that is why it is being singled out here over other
1326 foods because of the special place that it holds in people's
1327 minds. Also, because it is almost 2,000 times more expensive
1328 than tap water and people--

1329 Mr. {Walden.} How much more expensive is a soda drink
1330 over tap water?

1331 Ms. {Houlihan.} Maybe a similar amount, but people are
1332 making really tough choices right now about their budgets and
1333 so bottled water is part of that.

1334 Mr. {Walden.} And I have almost doubled over my time.

1335 Mr. {Stupak.} No, that is all right. We will come back
1336 another time but I want to get to Ms. Christensen for
1337 questions.

1338 Mrs. {Christensen.} Thank you, Mr. Chairman. I just
1339 want to go over the contaminant disclosure issue again so I

1340 am clear. According to the new reports released today, it
1341 appears that consumers have access to a lot more information
1342 about contaminants in tap water than they do about
1343 contaminants in bottled water in answer to some of the
1344 questions previously asked.

1345 Mr. Stephenson, under current law, municipal water
1346 authorities have to notify the public within 24 hours when
1347 they detect contaminants such as E. coli above prescribed
1348 levels in tap water. Is that correct?

1349 Mr. {Stephenson.} That is right.

1350 Mrs. {Christensen.} And they have to send that notice
1351 over broadcast media or in warnings posted in conspicuous
1352 locations?

1353 Mr. {Stephenson.} Yes, there are very specific
1354 requirements on how you report those.

1355 Mrs. {Christensen.} But if a bottled water company ran
1356 the same tests on its water and found the same level of E.
1357 coli, a level that both EPA and FDA say is dangerous to human
1358 health, they don't have to tell the FDA or EPA or the public?

1359 Mr. {Stephenson.} Or the State. Well, some States
1360 require it but not the FDA.

1361 Mrs. {Christensen.} A few States require it but
1362 generally no?

1363 Mr. {Stephenson.} Excuse me?

1364 Mrs. {Christensen.} Generally they don't have to report
1365 it?

1366 Mr. {Stephenson.} Generally, they don't.

1367 Mrs. {Christensen.} Now, under current law, municipal
1368 water systems are also required to issue annual consumer
1369 confidence reports that disclose any contamination problems,
1370 the likely source of that contamination, potential health
1371 effects of that contamination and information about the
1372 system's susceptibility to future contamination, correct?

1373 Mr. {Stephenson.} Yes.

1374 Mrs. {Christensen.} But bottled water companies are not
1375 required to make similar disclosures to the public?

1376 Mr. {Stephenson.} That is true. We currently don't
1377 have the authorities to make that requirement.

1378 Mrs. {Christensen.} Dr. Sharfstein, this is a striking
1379 disparity in the information available to consumers. We
1380 learn about dangerous contaminants in our tap water through
1381 broad public announcements within 24 hours but we may never
1382 learn about the dangerous contaminants in bottled water. Did
1383 you say that you supported a requirement to have the bottled
1384 water companies disclose test results showing contamination
1385 above the federal levels?

1386 Dr. {Sharfstein.} Actually, starting in September, we
1387 think, that requirement will take effect for contamination

1388 that poses a risk to the public.

1389 Mrs. {Christensen.} Is it enough to have the companies
1390 report their lab reports or should there be certified labs
1391 and should the labs be required to tell FDA when a positive
1392 result is found? Isn't that more reliable?

1393 Dr. {Sharfstein.} I think it is a very important
1394 question. I think there are two questions there, the
1395 certified lab and then whether labs should be required to
1396 report.

1397 Mrs. {Christensen.} Right.

1398 Dr. {Sharfstein.} So for certified labs, I think FDA
1399 would like to have authority to require labs if we think that
1400 that is important for a particular product, and I think that
1401 because of the broad preventive authority that this new
1402 legislation that has been moving through the House would
1403 give, we would be able to do that.

1404 The second question of requiring labs to report to FDA
1405 is a little bit more complex because there are so many tests
1406 that are done.

1407 Mrs. {Christensen.} Just the positive ones.

1408 Dr. {Sharfstein.} Right. I understand. The concern
1409 that is expressed there is whether or not it inhibits the
1410 private sector from testing at all. If they have a good
1411 testing program in place where there are identifying and

1412 keeping things out of the system, you know, should they be
1413 reporting every single positive, which ones should get
1414 reported. Those are questions that are a little bit more
1415 complex because you could be drowning, and if you are
1416 thinking not just for water but all the different foods, all
1417 the different tests, we don't want to inhibit companies from
1418 doing their own testing if they have good preventive plans in
1419 place. We want to not be missing the forest for the trees in
1420 terms of all the information coming to us. So that question
1421 of how much to require, where to get it from is sort of more
1422 complex issue that we would probably look at, you know, in a
1423 particular industry, a particular situation like, you know,
1424 certain types of tests we probably would want to know because
1425 they would be so serious.

1426 Mrs. {Christensen.} And earlier this year, the
1427 subcommittee held two oversight hearings on salmonella
1428 poisoning in peanut products that caused multiple deaths and
1429 dozens of illnesses, and we learned that the Peanut
1430 Corporation of America received positive tests for salmonella
1431 and was not required to disclose them to anyone, and FDA
1432 didn't have the access to those results and couldn't access
1433 them until people fell ill by invoking another law, the
1434 bioterrorism law, and so the same legal loophole applies to
1435 bottled water companies. Although the municipal water

1436 authorities are required to disclose their test results, FDA
1437 cannot compel bottled water companies to disclose theirs.

1438 So Ms. Houlihan, if a bottled water company tests its
1439 water and finds dangerous levels of E. coli, as far as you
1440 understand, is that required to disclose those results to the
1441 public?

1442 Ms. {Houlihan.} As far as I understand, that is the
1443 case. We found a lot of bottled water brands that are
1444 posting, 18 percent of the brands that we looked at that are
1445 posting full water quality test reports online, and we think
1446 100 percent of companies should be doing that and letting
1447 people know right away about contamination.

1448 Mrs. {Christensen.} I am not really--even though I made
1449 a reference to peanut butter, I am not in any way suggesting
1450 that the water issue is similar. But one important lesson
1451 that we learned is that sometimes disreputable companies have
1452 warning signs long before major problems arise because the
1453 systems are faulty, and if federal or State officials had
1454 access to that testing data, they might be able to flag small
1455 problems before they become big ones.

1456 Mr. Doss, your organization represents, I think you said
1457 about 75 percent of the bottled water industry. Do you
1458 support a requirement that bottled water companies make their
1459 test records available to the FDA during routine inspections?

1460 Mr. {Doss.} We do.

1461 Mrs. {Christensen.} And I am sure Dr. Sharfstein

1462 already answered that question. I guess I am out of time

1463 right now and I will just hold for a second round.

1464 [The prepared statement of Mrs. Christensen follows:]

1465 ***** INSERT 5 *****

|
1466 Mr. {Stupak.} Thank you.

1467 Mr. Burgess for questions, 5 minutes.

1468 Mr. {Burgess.} Thank you, Mr. Chairman. I apologize
1469 for being gone during your testimony and the earlier
1470 questioning. Can anyone tell me, if bottled water has a
1471 certain standard, what about our cola drinks? Are those
1472 bottles held to the same standard as bottled water?

1473 Dr. {Sharfstein.} So cola drinks are considered food
1474 and there are food Good Manufacturing Practices that they are
1475 held to but cola drinks are not held to the bottled water
1476 Good Manufacturing Practices which are sort of in addition to
1477 the general Good Manufacturing Practices.

1478 Mr. {Burgess.} To the best of anyone's knowledge, there
1479 is no difference in the way any of these compounds would
1480 leach out of the plastic into liquid phase whether it be
1481 water or cola drinks. Is that correct?

1482 Dr. {Sharfstein.} Yeah, I don't know if I know enough
1483 to answer that question. I do think that the point that is
1484 there, you know, from a food safety perspective. You know,
1485 there is not a--from a food safety perspective, water has a
1486 whole additional set of regulations compared to cola. It
1487 really depends on--and, you know, public health, you are
1488 saying compared to what. If you compare bottled water to

1489 cola, it has got a whole additional set of regulations. If
1490 you compare bottled water to municipal water, then there are
1491 certain disclosure requirements of municipal water that don't
1492 apply to bottled water. So it is sort of just your vantage
1493 point, but from a food safety perspective, you know, there is
1494 a whole additional set of regulations that apply to bottled
1495 water compared to cola.

1496 Mr. {Burgess.} Well, what about the water that is
1497 manufactured and sold with caffeine added to the water? Does
1498 that fall under the foodstuff or is that a water?

1499 Dr. {Sharfstein.} That is not a water.

1500 Mr. {Burgess.} That is not a water?

1501 Dr. {Sharfstein.} Yeah, I think--and somebody is going
1502 to tap me if I get this wrong but I am pretty sure that it is
1503 not a water. It depends. I think some of those may be--
1504 people may be attempting to market them as dietary
1505 supplements and other things but what they are actually
1506 marketed as is a whole separate discussion, but I don't think
1507 they are considered a water if you put extra caffeine in.

1508 Mr. {Burgess.} It just really underscores the
1509 complexity of the process that you have to deal with.

1510 Now, let me ask the GAO, on the report that two people
1511 to inspect the \$11 billion water industry, and 4 years ago
1512 the FDA changed the risk assessment for bottled water from

1513 low risk to high risk, so the question then comes, how many
1514 inspectors should be required? If two are not enough, what
1515 is our limit? We will be doing the agriculture
1516 appropriations bill this afternoon which will have the
1517 funding for the Food and Drug Administration in it. How do
1518 we know that we have got the right number of inspectors so
1519 that we can then know that we have the right appropriation
1520 attached to the FDA?

1521 Mr. {Stephenson.} That is a good question, and we don't
1522 have a precise number just for this segment of FDA's overall
1523 responsibility. We have said designating food safety a high-
1524 risk area over the past 2 years that the resources are
1525 inadequate to do the job right now, and we have pointed out
1526 from a broader standpoint that food safety is spread over a
1527 number of different agencies and of those agencies, FDA seems
1528 to get the smallest proportion of the budget yet it has 80
1529 percent of the responsibility. So I don't know whether two
1530 is right or four is right or six is right just for bottled
1531 water. All we are just doing is stating a fact, that that is
1532 how many FTAs are currently dedicated to inspecting bottled
1533 water facilities.

1534 Mr. {Burgess.} And that in fact does not seem to be a
1535 sufficient number?

1536 Mr. {Stephenson.} It does not seem to be a sufficient

1537 number, given the number of bottled water facilities.

1538 Mr. {Burgess.} Also in your testimony, you note that
1539 three-quarters of the water bottles produced in the United
1540 States in 2006 were recycled. Do we know about the rates of
1541 recycle for other beverages?

1542 Mr. {Stephenson.} I think it is probably similar for
1543 all plastic bottles. With bottled water being a growing
1544 share of the market, there are more bottles dedicated to
1545 water than soda percentage-wise.

1546 Mr. {Burgess.} So numerically, there are more in the
1547 environment--

1548 Mr. {Stephenson.} Right, and this isn't a volume
1549 problem, as we noted. It is less than 1 percent of what is
1550 going into a landfill. Nevertheless, they never decompose
1551 and they stay there forever, and recycling is a good thing in
1552 general.

1553 Mr. {Burgess.} And I would agree with that.

1554 Dr. Sharfstein, in the GAO report it states that the FDA
1555 currently assigns two people yet 4 years ago the Food and
1556 Drug Administration changed the risk assessment from low to
1557 high risk, so again, I would ask the question, how many
1558 inspectors should now be assigned to oversee the Code of
1559 Federal Regulations as it relates to bottled water?

1560 Dr. {Sharfstein.} I am not sure that is right, that we

1561 changed it to high risk. I think that in general compared to
1562 other foods, we considered bottled water in the lower risk
1563 side. I think that there are two issues. One is the
1564 frequency of inspection and the other is all the things that
1565 go with inspections, and one of the key things we talked
1566 about is just knowing who is making bottled water, and we
1567 have a hard time under the current food safety laws really
1568 understanding that because by law, people can register on
1569 paper and the category is called soft drinks and waters, so
1570 everyone is sort of thrown in together so we don't have a
1571 very good idea--we don't have as good an idea as we would
1572 like to have or we should have exactly who is making it.
1573 That is sort of the first step to have, like, you know, a
1574 solid system. And then we would like the ability to require
1575 preventive plans and, you know, all the key basic steps
1576 there, and then you put inspections as part of that strategy.
1577 But just thinking of inspections alone with the rest of the
1578 way it is, it is probably going to leave some opportunities
1579 for strengthening the system off the table if you are just
1580 thinking of inspection alone which is why we would like the
1581 parts of the law giving us access to records, giving FDA the
1582 ability to require preventive plans, certified labs if we
1583 think necessary, other things like that.

1584 Mr. {Burgess.} Let me ask you a question in the time I

1585 don't have remaining, and it is not fair to ask you this but
1586 I will do it anyway. We are going to vote on the agriculture
1587 appropriations bill today or tomorrow. Is the number we have
1588 in the bill for the Food and Drug Administration, do we have
1589 the right number there?

1590 Dr. {Sharfstein.} Yeah. The President's budget and
1591 what came out of committee is a historic increase and I think
1592 there is no question the Administration responded very
1593 strongly to GAO's finding this would be a high risk and
1594 putting a lot more resources into food safety, and if we get
1595 that combined with additional authority, I think we will be
1596 able to strengthen the system considerably.

1597 Mr. {Burgess.} And just for the record, Mr. President,
1598 the beautiful campus that they occupy is actually part of the
1599 GSA budget so none of your food safety dollars are going to
1600 build that lovely campus which we are all so proud of. I
1601 will yield back.

1602 Mr. {Stupak.} Thanks, Mr. Burgess.

1603 Let us go another round of questions. Dr. Sharfstein,
1604 if we do testing and if they have to report their positive
1605 results, wouldn't after a while if you see a continued
1606 positive results for E. coli or something from a plant that
1607 indicates you have a problem, we have to get there or at
1608 least increase inspections, like the peanut butter one with

1609 the salmonella. We had report after report of problems but
1610 no one ever received a report and no one ever knew, at the
1611 FDA, at least, what was going on there.

1612 Dr. {Sharfstein.} I agree with you. FDA has to respond
1613 to problems very aggressively and has got to be able to
1614 follow up with manufacturers that aren't meeting standards
1615 and if necessary shut them down, and, you know, in recent
1616 weeks we have taken action against some firms--

1617 Mr. {Stupak.} But you wouldn't know unless you received
1618 positive results, I mean, unless you received the results.
1619 Somewhere, someone at the FDA has to receive results and look
1620 at them, right?

1621 Dr. {Sharfstein.} Well, it could be that we got a
1622 complaint and we investigated. It could be testing that FDA
1623 does, and FDA does do some testing. So we can find out
1624 problems. We could have somebody call us and say there is a
1625 problem with this company, and so that leads us to
1626 investigate. But once we find the problem, I think it is
1627 important to really follow up until that problem is clearly
1628 resolved.

1629 Mr. {Stupak.} Well, how about for those bottlers who
1630 use municipal water as their source? Wouldn't it make sense
1631 to require them to post a link to the required EPA testing
1632 results because they have to do it once a year? Wouldn't

1633 that make sense to require them to--25 percent, I think, Ms.
1634 Houlihan was in your report, 25 percent of the bottlers use
1635 tap water, so why wouldn't we just require them to post their
1636 website?

1637 Dr. {Sharfstein.} Right. I can totally understand why
1638 that would make sense, why consumers might be interested in
1639 that. But the thing for FDA is, the standard that we have
1640 for putting something on the label is that it would have to
1641 be misleading without it, and so we can't--you know, we use
1642 that to say that, you know, something has got to be there or
1643 it is misleading without it, and that is a hard thing to put
1644 that, you know, to kind of file that in that category. So
1645 that is not to say we wouldn't support it but whether we
1646 could do it under our misleading, you know, authority, that
1647 we think is questionable and that it might require a
1648 different authority.

1649 Mr. {Stupak.} It is misbranding authority that you
1650 have?

1651 Dr. {Sharfstein.} Yeah, the misbranding authority. The
1652 basic--if we were to do it, and this would--you know, what
1653 standard would we have to meet, and it would be that it is
1654 misleading without it, and, you know, we don't require it for
1655 other types of foods. You know, would it really be
1656 misleading consumers not to have that, and that is a hard

1657 standard for us to reach. There may be a better way for
1658 Congress to achieve that.

1659 Mr. {Stupak.} Mr. Stephenson, if I may, on page 22 of
1660 your report you referred to a poll conducted by Water
1661 Research Foundation that approximately 56 percent of bottled
1662 water drinkers cite safety and health as the primary reason
1663 they sought an alternative to tap water. So is it fair to
1664 say that the number one reason people are buying bottled
1665 water is because they think it is safer and healthier than
1666 tap water?

1667 Mr. {Stephenson.} Well, there is that poll and several
1668 other research studies that have concluded that, although
1669 convenience is a top reason as well.

1670 Mr. {Stupak.} Well, what bothers me about that is the
1671 perception that bottled water is healthier than tap water, in
1672 many instances, bottled water is nothing more than tap water.
1673 The Natural Resources Defense Council, they estimated, as I
1674 said, 25 percent of bottled water is just tap water in
1675 bottles. Sometimes it is treated, sometimes it is not. So I
1676 guess my question is, and Ms. Houlihan, I think you cited in
1677 your report, is that accurate that 25 percent of the bottled
1678 water is just tap water in a bottle?

1679 Ms. {Houlihan.} Those are the numbers that are publicly
1680 available, and I think it is a big question as to whether it

1681 is even more than that because in so many cases we just don't
1682 have the information on what the source actually is and we
1683 found almost a third of all bottled waters have no
1684 information on their label.

1685 Mr. {Stupak.} But if they take it from tap water and do
1686 something like reverse osmosis or something, then they don't
1687 have to claim it is tap water, right?

1688 Ms. {Houlihan.} That is right, and there is a provision
1689 that requires that bottled waters be labeled as from a
1690 municipal supply if they have not undergone any additional
1691 treatment, but any treatment that is, according to FDA,
1692 quote, suitable, allows that bottled water manufacturer not
1693 to use that label and just to call it this is a purified
1694 water without giving people information on what the treatment
1695 processes actually were.

1696 Mr. {Stupak.} Well, like I said, I got this on the
1697 airplane yesterday. Does Coca-Cola use municipal water for
1698 its Dasani bottled water?

1699 Ms. {Houlihan.} You can't tell from the label. There
1700 is no information at all on the water source for that
1701 product.

1702 Mr. {Stupak.} How about Pepsi there that Dr. Burgess is
1703 drinking, the Aquafina bottled water? Does that come from a
1704 municipal source?

1705 Ms. {Houlihan.} Aquafina, we have that label in one of
1706 the examples, if you could pull that up. So on the label, it
1707 is labeled as from a municipal supply for Aquafina. It
1708 doesn't name the municipal supply, which is what so many
1709 other bottled waters are choosing to do.

1710 Mr. {Stupak.} But do we know if they do any further
1711 treatment or anything of it? Would it have to be on there?

1712 Ms. {Houlihan.} It doesn't have to be labeled at all,
1713 and we found 44 percent of all labels don't provide any
1714 information on treatment.

1715 Mr. {Stupak.} Mr. Doss, if Aquafina was part of your
1716 organization, I understand it is not, but if it was, would
1717 the have to put on there whether they further treated or
1718 would they just put down municipal source?

1719 Mr. {Doss.} No, they wouldn't, and I think the issue
1720 here is one maybe of misunderstanding. Purified bottled
1721 water, which is what Dasani is and what Aquafina is, is not
1722 just tap water in a bottle.

1723 Mr. {Stupak.} Correct. Something else happens to it.

1724 Mr. {Doss.} When water comes in from a municipal
1725 source, it goes through reverse osmosis, it goes through UV
1726 light, it goes through ozonation and then in a sanitary
1727 condition is placed in a bottle. Now, those purified waters
1728 must meet the U.S. pharmacopoeia standard for purified or

1729 sterile water. If it dose not, then that label must disclose
1730 in that bottle that it comes from a municipal source. So in
1731 that case, that water because it doesn't list it as from a
1732 municipal source, meets the U.S. pharmacopoeia standard for
1733 purified or sterile water, and that is the big difference,
1734 and that goes to the sourcing of the water. It would be not-
1735 -to list that this source was the Dayton whatever county
1736 municipal water, that water is quite different once it gets
1737 in that bottle than when it started out, and that is the
1738 distinction here.

1739 Mr. {Stupak.} Okay, let me ask you this. Let us go
1740 back to Dasani then. And again, I am reading the label right
1741 here on what I got here. It says ``noncarbonated, crisp,
1742 fresh taste. Dasani is filtered through a state-of-the-art
1743 purification system and enhanced with minerals for a pure,
1744 fresh taste that can't be beat.'' And then if you go on the
1745 other side of the label, it says purified water, magnesium
1746 sulfate, potassium chloride, salt, and then it has as
1747 asterisk, ``adds a negligible amount of sodium,'' then it has
1748 a cross on it and it says ``minerals added for taste,
1749 purified by reverse osmosis.'' So to get that clean, crisp
1750 taste, are the chemicals they are adding then magnesium
1751 sulfate, potassium chloride, salt and sodium or is it other
1752 chemicals?

1753 Mr. {Doss.} I can't speak to Dasani specifically but
1754 what is done sometimes is that the water comes in from a
1755 municipal source, it is purified by reverse osmosis and other
1756 treatments and then minerals are added back for taste. That
1757 is what they are disclosing. Again, I can't speak to that
1758 specific label but in general that is oftentimes what
1759 happens.

1760 Mr. {Stupak.} Okay. I guess my time is up.

1761 Mr. Walden, questions?

1762 Mr. {Walden.} Thank you.

1763 First of all, what the chairman cited, are those
1764 chemicals or minerals?

1765 Mr. {Doss.} I believe they are minerals that have been
1766 added for taste, and that is why they disclose it on the
1767 label. They are meeting the labeling requirements. They are
1768 making sure that they are informing those who buy it that
1769 this is a purified water with minerals added back.

1770 Mr. {Walden.} And if they added other things into the
1771 water, would they have to disclose that?

1772 Mr. {Doss.} I believe they would. It then is a
1773 question of the standard of identity for bottled water, which
1774 we talked about which specifically says if you are spring
1775 water, you have to do this, if you are purified water, you
1776 have to do that. So what--

1777 Mr. {Walden.} So there are already rules that say that?

1778 Mr. {Doss.} There are rules that say exactly what you
1779 must do if you want to say you are a purified water, a spring
1780 water, an artesian water, well water.

1781 Mr. {Walden.} All right.

1782 Mr. {Doss.} If you then add something else to the
1783 water, then for labeling purposes you would probably--and
1784 this is where FDA--I will have to make sure we can get back
1785 to you on this specifically but I think in that case, FDA
1786 would say you need to then make sure you are saying this is
1787 purified water with minerals added back, and I think that is
1788 why they do it.

1789 Mr. {Walden.} Dr. Sharfstein, do you know or do your
1790 folks know if that is correct?

1791 Dr. {Sharfstein.} The question is, what you are allowed
1792 to put back in?

1793 Mr. {Walden.} Not what you are allowed to put back in
1794 but that which you put back in, do you have to disclose on
1795 the label?

1796 Dr. {Sharfstein.} I am getting a yes, it is required.

1797 Mr. {Walden.} So it is already required? If I am a
1798 bottler of water and if I go through reverse osmosis and the
1799 UV and all that and then I add things back in, I have to put
1800 that on the label?

1801 Dr. {Sharfstein.} That is what I am understanding.

1802 Mr. {Walden.} Okay. I want to ask about the DEHP
1803 issue. In your testimony, you state the FDA has decided to
1804 move forward on making a decision on DEHP. Can you elaborate
1805 on this and tell us when we can expect a ruling? That is
1806 actually what I hear. If I hear anything about bottled
1807 water, it is about this discussion about what is in the
1808 plastic.

1809 Dr. {Sharfstein.} This is where it gets a little bit
1810 confusing, but basically in the mid-1990s when this was
1811 originally done and this particular chemical was deferred.
1812 The reason it was deferred is because it had been marketed
1813 prior to 1958 and had a special grandfather-like provision as
1814 a food additive, and it was thought that it was in plastic
1815 and therefore this provision of the law that we are talking
1816 about conflicted with another provision of the law. Our
1817 understanding has changed since that time. In fact, we don't
1818 believe that it is being used in water bottles or water caps
1819 right now, and as a result of that, the concern that existed--
1820 --and I am a pediatrician and not a lawyer--basically the
1821 legal conflict that was of concern in the mid-1990s is not of
1822 concern now and that we can move forward and basically
1823 testing whether or not there is a reason to--there has to be
1824 an affirmative reason not to have the same standard as

1825 municipal water so, you know, my presumption would be that we
1826 will move forward with the standard for DEHP like we have for
1827 all the other contaminants. What held it up before was
1828 really the grandfather legal issue, and I think that that may
1829 not apply anymore and we can move forward.

1830 Mr. {Walden.} But I want to get to sort of the heart of
1831 the matters for the people I represent. You are telling me
1832 that plastic in the cap here don't have the phthalate?

1833 Dr. {Sharfstein.} In our communications with industry,
1834 as I understand, we do not believe that this is regularly
1835 used in--

1836 Mr. {Walden.} Mr. Doss, can you speak to this issue?

1837 Mr. {Doss.} I can. It is my understanding that none of
1838 the plastic containers used for bottled water contain DEHP at
1839 all, not the PET, not the polycarbonate, not the HDPE. So
1840 none of the bottled water containers contain any DEHP.
1841 However, the International Bottled Water Association for
1842 purposes of parity several years ago, we have a standard in
1843 our model code that is exactly the same as the EPA, more for
1844 parity reasons, but none of the plastic containers used for
1845 bottled water contain DEHP.

1846 Mr. {Walden.} From your knowledge, does that apply also
1847 to Dr. Burgess's Pepsi bottle there and other bottles used
1848 for sodas?

1849 Mr. {Doss.} If they are using PET, which I believe most
1850 are, if they are using polycarbonate or HDPE, which are the
1851 three primary uses for all beverage products, then there is
1852 no DEHP in them.

1853 Dr. {Sharfstein.} So the DEHP issue is really, is it in
1854 the water separately just because it is in the environment
1855 and, you know, that--

1856 Mr. {Stupak.} Is there a number that you use for DEHP
1857 like PET has a number 1 on it, and that is what this one is
1858 here. But there is usually a symbol. Is there a symbol that
1859 if you use DEHP in a plastic--

1860 Dr. {Sharfstein.} I will have to get back to you on
1861 that.

1862 Ms. {Houlihan.} Can I also add--

1863 Mr. {Walden.} Go ahead. I actually have another
1864 question, though, I want to get to.

1865 Ms. {Houlihan.} The food contact notifications that EPA
1866 has approved show at least 100 different other kinds of
1867 plastic additives that could leach into the water, so this is
1868 a problem that is much bigger than DEHP.

1869 Mr. {Stupak.} Go ahead, Mr. Walden.

1870 Mr. {Walden.} I just wanted to get to another point
1871 because we are so focused, and I realize that is the focus of
1872 the hearing is on bottled water and where that water comes

1873 from and all of that, but I am sitting here thinking, if I
1874 buy orange juice in a carton that is made from concentrate,
1875 what percent of that is water? It has to be a huge percent,
1876 right? Because we are adding water in and then the
1877 concentrate. And if the issue here is the quality of the
1878 water and the source of the water going into what we consume,
1879 then it seems to me we are kind of myopic here just looking
1880 at bottled water because somebody doesn't like bottled water
1881 or presumes that it has a higher sort of threshold in our
1882 minds about purity. I would suggest that a lot of us drink
1883 orange juice thinking that is better than perhaps bottled
1884 water because you get other--no offense, but you get other
1885 things with it, and yet I am thinking 80 percent, 90 percent
1886 of what I am getting in the carton of orange juice unless it
1887 is, you know, fresh squeezed only, not from concentrate, is
1888 probably water. And so from the FDA's standpoint, do you
1889 look at the water that goes into that?

1890 Dr. {Sharfstein.} That is part of what makes food safe
1891 is the water and they need to meet food safety requirements,
1892 and--

1893 Mr. {Walden.} And that is the same thing you apply to
1894 the bottled water, right?

1895 Dr. {Sharfstein.} It is more we apply to the bottled
1896 water because we--

1897 Mr. {Walden.} Okay.

1898 Dr. {Sharfstein.} So as I was saying before, a lot of
1899 this is compared to what--if you are comparing bottled water
1900 to other foods or other foods that contain water, there are
1901 additional regulations that apply. If you are comparing it
1902 to municipal water, then there is more disclosure on
1903 municipal water than there is on bottled water.

1904 Mr. {Walden.} Well, I--

1905 Dr. {Sharfstein.} It is just your point of comparison.

1906 Mr. {Walden.} Yes, but I guess the question would be,
1907 where is that disclosure? I mean, I have never even--at
1908 least there is something on this label. In my hometown of
1909 Hood River, we have it out of a spring but I don't get a
1910 notice on my tap or on my water bill, or here in the District
1911 of Columbia, for heaven's sake, I mean, what it runs through
1912 to come out of my tap is scary. That is why I put a filter
1913 on the end and then refilter it in another deal and, you
1914 know, all of that. So anyway, I am over my time. I am done.
1915 Thank you.

1916 Mr. {Stupak.} So you get from a municipal water supply
1917 and you don't get a notice every year? We get a letter,
1918 seriously.

1919 Mr. {Walden.} Probably. And I rush out to my mailbox
1920 to read it.

1921 Mr. {Stupak.} Okay.

1922 Mr. {Walden.} And, you know, it is like the sewer
1923 notice I get here. It tells me that when it rains they
1924 inflate these inflatable things to keep the sewage from
1925 rushing out into the Potomac unless it rains too much and
1926 then they deflate them because they cause too much problems.
1927 But that is a whole other issue.

1928 Mr. {Stupak.} No, we don't want them releasing
1929 untreated sewage in our waters, that is for sure.

1930 Ms. Christensen.

1931 Mrs. {Christensen.} Thank you, Mr. Chairman.

1932 Mr. Stephenson, I note that in your report the surveys
1933 were done in the 50 States and the District of Columbia. Any
1934 reason why the territories are not included or are they
1935 generally not included in surveys done by GAO?

1936 Mr. {Stephenson.} No, no particular reason, just the
1937 methodology we chose.

1938 Mrs. {Christensen.} But they are not generally excluded
1939 just--

1940 Mr. {Stephenson.} No.

1941 Mrs. {Christensen.} --that in this particular--

1942 Mr. {Stephenson.} No, a limited amount of time, a
1943 limited amount of resources dictated 50 States and the
1944 District of Columbia.

1945 Mrs. {Christensen.} And Dr. Sharfstein, in your
1946 testimony you say that FDA has broad authority over food that
1947 is introduced or delivered in interstate commerce. So if it
1948 is just within a state or within a territory, FDA doesn't
1949 have any jurisdiction or do you work with the States then and
1950 the territories?

1951 Dr. {Sharfstein.} That actually is a pretty broad
1952 statement because if the bottle comes from outside the State
1953 or the cap comes from outside the State, even if it is just
1954 sold within the State, it counts as interstate, and there is
1955 a presumption, I understand, that it would be interstate, but
1956 in theory there might be products that could be challenged,
1957 our authority over them, although I am not aware that we
1958 heard about a problem that we haven't been able to get to
1959 either directly or through the State.

1960 Mrs. {Christensen.} Mr. Stephenson, we have talked a
1961 lot about whether bottled water is safer and healthier and
1962 there is disagreement on that but there is no disagreement on
1963 the fact that bottled water uses more energy to produce and
1964 deliver. On page 26 of your report, there is a quite amazing
1965 statistic where you refer to a study by the Pacific Institute
1966 which examined how much energy it takes to bring bottled
1967 water from different locations throughout the world to L.A.,
1968 and in your report this is what it says. ``The Institute

1969 estimated that the total energy required to bring a typical
1970 one-liter bottle of water weighing about 38 grams to a
1971 consumer in Los Angeles would typically range from about
1972 1,100 to 2,000 times the energy cost of producing tap water.

1973 Mr. {Stephenson.} That is true.

1974 Mrs. {Christensen.} So if I drink a single bottle of
1975 Evian or Fiji or some other bottled water, which I may not
1976 ever drink again, from overseas, I could be using up to 2,000
1977 times more energy than if I just walked over to my sink and
1978 filled up a glass?

1979 Mr. {Stephenson.} That is true. The import bottled
1980 water accounts for a very small percentage of the total
1981 bottled water but that is true.

1982 Mrs. {Christensen.} I see. Okay. The study cited in
1983 the GAO report also describes how transporting these bottles
1984 can be the single biggest cost. According to that study,
1985 transportation energy costs can be as high as 57 percent of
1986 the total energy costs for spring water bottled in France,
1987 transported overseas by cargo ship and transported by rail
1988 from the eastern United States to Los Angeles.

1989 Mr. {Stephenson.} That is correct.

1990 Mrs. {Christensen.} Your report also has some other
1991 findings related. For example, you concluded that most
1992 plastic water bottles are discarded rather than recycled.

1993 Mr. {Stephenson.} Yes, we estimate 25 percent are
1994 recycled, so 75 percent are discarded.

1995 Mrs. {Christensen.} So Ms. Houlihan, how did we get
1996 here? Why do consumers pay so much, hundreds of times more
1997 for bottled water, taking thousands of times more energy to
1998 produce?

1999 Ms. {Houlihan.} You heard some of the marketing claims
2000 that are used by the industry and I think a lot of people are
2001 under a misperception that bottled water must be safer than
2002 tap water. A lot of people believe that it is free of
2003 contaminants. In fact by law, it is not required to be any
2004 safer than tap water. When we tested 10 major brands of
2005 bottled water, we found 38 different pollutants, everything
2006 from disinfection byproducts to radioactive isotopes, even
2007 traces of Tylenol and fertilizer residues. So one thing that
2008 we need when it comes to the bottled water industry is just
2009 more daylight, information for consumers on where that water
2010 comes from, how it is treated and what is in it.

2011 Mrs. {Christensen.} I think it is really important for
2012 the information to be there so that people can make
2013 knowledgeable judgment.

2014 I certainly understand that bottles are convenient, but
2015 if we are going to use them, isn't there a better way than
2016 going into the landfill. This bottle of water is bottled in

2017 Virginia and is transported just a few miles from here to the
2018 Capitol and it is biodegradable. Mr. Doss, you represent the
2019 bottled water companies. How many of them are using
2020 biodegradable bottles?

2021 Mr. {Doss.} I am not sure exactly how many are using
2022 biodegradable bottles but I will say that as a general
2023 statement that bottled water companies like other food
2024 industry companies are trying to do whatever they can to
2025 reduce their environmental footprint. Obviously, going to
2026 bottles such as those is one way of doing it. We have made
2027 significant efforts to lightweight the bottled water
2028 containers. Anyone who drinks bottled water knows these days
2029 they are much lighter weight which uses less plastic. We
2030 also have some of our companies that are using recycled
2031 content, less virgin materials. So bottled water is trying
2032 to do what it can to reduce the environmental footprint, but
2033 I think it is important to recognize that bottled water is
2034 just one of thousands of food products on the market in
2035 plastic, and in fact, we are only one-third of 1 percent, as
2036 reported in the GAO report, of the entire waste stream in the
2037 United States so I think that any efforts to reduce the
2038 environmental impact of packaging has to focus more broadly
2039 on all consumer goods.

2040 Mrs. {Christensen.} Absolutely. Thank you for your

2041 answers.

2042 Mr. {Stupak.} Thank you.

2043 Mr. Burgess, let us get 5 minutes in before we have to
2044 go for votes.

2045 Mr. {Burgess.} Great. Thank you.

2046 Dr. Sharfstein, just to follow up a little bit on what
2047 Mr. Walden was talking about on the lawsuit with the
2048 phthalate DEHP that has been held up. I think Mr. Stupak
2049 referenced it has been 15 years in the making. You are now
2050 prepared to issue a ruling in September. Do I understand
2051 that correctly, on DEHP? The FDA is prepared to go ahead
2052 with that ruling now or is that--

2053 Dr. {Sharfstein.} So there is questions whether we set a
2054 standard for bottled water, and our intent is to proceed with
2055 setting a standard for bottled water. That is just a matter
2056 of preparing the standard, getting it going. If we come
2057 across some reason why this doesn't apply to bottled water at
2058 all, we are permitted to make the statement that it doesn't
2059 apply to bottled water at all but it is not obvious to us
2060 there is such a compelling reason at this point, so we would
2061 anticipate then going forward and setting a standard. So at
2062 that point is just as long as it takes to do. What is in the
2063 law, and this gets, you know, there is a 180-day standard in
2064 the law which is that if EPA sets the standard, FDA needs to

2065 set a standard at least 180 days before so that it can take
2066 effect at the same time as the EPA standard. But with this
2067 one where they waited so long because of this legal thing,
2068 that is sort of out the window. It doesn't really apply
2069 because the EPA's standard went into effect so long ago. So
2070 really, we would just like to do it in a reasonable time
2071 frame.

2072 Mr. {Burgess.} And at this point, any preview, any look
2073 ahead as to what that standard may be?

2074 Dr. {Sharfstein.} Sure. It would just be the--if we
2075 were to do it, it would be the same standard that EPA has
2076 unless we had a really good reason otherwise, but that would
2077 be the assumption, just like we have done for almost all the
2078 other contaminants, the same standard as EPA.

2079 Mr. {Burgess.} Mr. Chairman, on the issue of the high
2080 risk, low risk, apparently there was a ruling issued by the
2081 FDA in 2005 in the risk assessment, and I have a copy of
2082 that. With your permission, we will make that available to
2083 the committee for its consideration and adding it to the
2084 record.

2085 And then finally, let me just ask a question about
2086 recycling, and really this is for everyone on the panel,
2087 about the compounds leaching out of the plastic in greater
2088 amounts in recycled materials than native or first-run

2089 materials. So is that a real concern for us to have? Are
2090 there going to be different standards for the recycled
2091 bottles or should there be different standards? Do consumers
2092 need to be aware of any difference between a recycled bottle
2093 and a first-run bottle?

2094 Ms. {Houlihan.} We looked at FDA reviews of additives
2095 in plastic and found that there are over different compounds
2096 that could leach out of plastic, so the question you have
2097 raised is a very important question and we think not only do
2098 recycled bottles need to be more closely inspected and tested
2099 with regard to that but also new bottles, what is coming out
2100 of the plastic into waters, and that kind of testing is not
2101 required. We fully support the greater rates of recycling in
2102 industry. That is just a smart move overall.

2103 Mr. {Burgess.} Is there another secondary use for the
2104 recycled plastic water bottle other than re-creating another
2105 plastic water bottle? Can they be used in building materials
2106 or is there any other use for these bottles?

2107 Ms. {Houlihan.} That is a fabulous question, and I
2108 think we are creative enough in this country to come up with
2109 other uses that don't involve direct contact with water.

2110 Mr. {Burgess.} Mr. Doss, do you have an opinion?

2111 Mr. {Doss.} I don't know anything specifically about
2112 the issue you just raised but I do know that FDA has to clear

2113 all contact packaging materials. So if FDA clears it, then
2114 the manufacturer is able to use it and they have made the
2115 determination that they are safe to use.

2116 Mr. {Burgess.} So we come to Dr. Sharfstein.

2117 Dr. {Sharfstein.} There has got to be a standard of
2118 safety. Whether it is recycled or not recycled, there has
2119 got to be a standard of safety, and so that is what FDA
2120 enforces, and understanding in light of, you know, new
2121 evidence that comes out about the particular substances and
2122 the latest science and the different concerns people have,
2123 FDA's job is to weigh that, but at the end of the day, it has
2124 to be a standard of safety and it has got to apply no matter
2125 what is in the package.

2126 Mr. {Burgess.} So where are we right now with the issue
2127 of recycling? Should consumers be concerned about buying
2128 bottled water in a recycled product? Are you testing these
2129 products currently, or even are there any available?

2130 Dr. {Sharfstein.} Well, we test the water, you know.
2131 When we test water, it could be from a recycled bottle or
2132 not, but I am not aware of any special concerns for recycled
2133 plastic but I think if there are concerns people have they
2134 should share them with the agency.

2135 Mr. {Burgess.} And I guess I don't really even know
2136 enough to know whether these recycled materials are then

2137 broken down and reconstituted or do we just simply wash out
2138 the bottle and put a new cap on it. But, I mean, obviously
2139 the push is to recycle so we are going to be seeing more of
2140 these products on our shelves and in our stores.

2141 Dr. {Sharfstein.} I think you are illustrating why the
2142 job is so challenging because products change and FDA has to
2143 be up on them so we can enforce the same basic safety
2144 standards.

2145 Mr. {Burgess.} Thank you, Mr. Chairman.

2146 Mr. {Stupak.} Thanks, Mr. Burgess.

2147 Just one last question and we will close the hearing.
2148 Mr. Stephenson, in your GAO report that we talked about today
2149 about consumer confidence reports, and in 1996 Congress
2150 directed the FDA to assess the feasibility of providing
2151 bottled water to consumers with the functional equivalent of
2152 a consumer confidence report, and according to your GAO
2153 report that is released today, on August 25, 2000, FDA
2154 concluded that it would be feasible to provide consumers with
2155 some of the information contained in the consumer confidence
2156 report directly on a bottle label and access the remaining
2157 information through an address or phone number, and that is
2158 tab number 3 there in the document. Is that correct?

2159 Mr. {Stephenson.} Yes, that is right.

2160 Mr. {Stupak.} So Mr. Doss, any reason why your

2161 organization would object to that or do you think we should
2162 have a consumer confidence report for bottled water?

2163 Mr. {Doss.} Well, as I think was reported in their
2164 study, they did say it was feasible. They didn't exactly say
2165 what was feasible to put on the label. I think they were
2166 quite skeptical of putting some of the contaminants, et
2167 cetera on the label because it would just clutter the label.
2168 Now, as I said before, I think that the bottom line for us
2169 that consumers ought to be able to get information and we
2170 think that a telephone number, call the company and request
2171 that information is the best way to do it and almost all
2172 bottled waters currently as well as other food products have
2173 a phone number at least that a consumer could call the
2174 company and say could you send me the information and that
2175 information should be sent, and if it isn't, I would say go
2176 find another product to buy.

2177 Mr. {Stupak.} So you don't mind the phone number but
2178 you don't want any other information?

2179 Mr. {Doss.} We don't.

2180 Mr. {Stephenson.} Mr. Chairman, I think there needs to
2181 be some specificity in what is going to be required in those
2182 confidence reports. When were checking labels and websites,
2183 it was very difficult to get the kind of information we were--
2184 -

2185 Mr. {Stupak.} Sure. Your report didn't say put the
2186 whole report on the bottle.

2187 Mr. {Stephenson.} It doesn't have to be on the label.

2188 Mr. {Stupak.} Just that some information should be on
2189 there and there should at least a phone number to back it up
2190 if you want further information.

2191 Mr. {Stephenson.} That is right.

2192 Mr. {Stupak.} Well, that concludes all of our
2193 questioning. I want to thank all of our witnesses for coming
2194 today and for your testimony.

2195 The committee rules provide that members have 10 days to
2196 submit additional questions for the record. That concludes
2197 our hearing. This meeting of the subcommittee is adjourned.

2198 [Whereupon, at 12:00 p.m., the subcommittee was
2199 adjourned.]