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2 HIF336.140

3 HEARING ON ``BREAST CANCER SCREENING RECOMMENDATIONS''

4 WEDNESDAY, DECEMBER 2, 2009

5 House of Representatives,

6 Subcommittee on Health

7 Committee on Energy and Commerce

8 Washington, D.C.

9 The subcommittee met, pursuant to call, at 10:07 a.m.,
10 in Room 2123 of the Rayburn House Office Building, Hon. Frank
11 Pallone, Jr. [Chairman of the Subcommittee] presiding.

12 Members present: Representatives Pallone, Dingell,
13 Eshoo, Green, DeGette, Capps, Schakowsky, Baldwin, Matheson,
14 Christensen, Castor, Sarbanes, Space, Sutton, Braley, Waxman
15 (ex officio), Shimkus, Shadegg, Blunt, Pitts, Rogers, Wilkins
16 Myrick, Burgess, Blackburn, Gingrey and Barton (ex officio).

17 Staff present: Ruth Katz, Chief Public Health Counsel;
18 Purvee Kempf, Health Counsel; Sarah Despres, Health Counsel;

19 Jack Ebeler, Health Advisor; Stephen Cha, Professional Staff;
20 Anne Morris, Professional Staff; Bobby Clark, Professional
21 Staff; Alvin Banks, Special Assistant; Elana Leventhal,
22 Professional Staff; Katie Campbell, Professional Staff;
23 Virgil Miller, Professional Staff; Andy Bindman, Robert Wood
24 Johnson Fellow; Ryan Long, Minority Chief Health Counsel;
25 Brandon Clark, Minority Professional Staff; and Chad Grant,
26 Minority Legislative Analyst.

|
27 Mr. {Pallone.} The subcommittee is called to order, and
28 I will first recognize myself.

29 The subcommittee is meeting today to review the new
30 breast cancer screening recommendations issued by the U.S.
31 Preventive Services Task Force just a few weeks ago. By now,
32 I am sure everyone in this room is familiar with the new
33 guidelines or at least we are familiar with the controversy
34 surrounding them. From what I have heard from my
35 constituents, friends, family members and academic
36 institutions in my district, there are a lot of questions,
37 frustration and confusion around these new recommendations.
38 The controversy that was ignited by the report may be
39 eclipsing what the report actually says, and this is the
40 reason why I am holding this hearing today. It is time for
41 all of our questions to be answered. We want a clear
42 understanding of what the report did and didn't say and what
43 others have to say about the report.

44 We also want to understand the process used by the task
45 force. Should they operate, for example, with more
46 transparency? Do they get sufficient input from stakeholder
47 groups? Do they consider different opinions? And I have
48 invited the U.S. Preventive Services Task Force to speak
49 directly about their work. It is my hope that we will all

50 walk out of this room later today with a better understanding
51 of how these recommendations came about, how they should be
52 viewed and what exactly they mean. We want to get these
53 answers. We want to know as much as we can because women and
54 their doctors deserve to know what is best.

55 I also want to hear from organizations, advocacy groups
56 and medical experts. We don't want the task force's report
57 to stand alone if there are different opinions. I know that
58 some of the frustration is due to the fact that this
59 recommendation was seemingly made with little input from
60 these groups. That may be a problem with process as well as
61 a problem with the substance of the report, and they will
62 have a platform and a voice today.

63 The United States is at the forefront of medical
64 research and innovation. Investment in science has led to
65 the development of early detection methods for certain
66 cancers. It has led to treatments and cures for diseases
67 once considered a death sentence, and it is important that
68 all of this new medical information is used to empower
69 physicians and their patients when making medical decisions.
70 This information should be used to help patients and their
71 doctors. It should not be used, and I stress, it should not
72 be used as an excuse to deny needed care. Scientific studies
73 enable patients and their physicians to make more-informed

74 decisions about what is best for them in any given situation.
75 These studies should be one of many tools. Patients and
76 their doctors should have access to as much information as
77 available. They should have informed conversations. But the
78 decisions about mammography for women in their 40s should
79 remain with women and their doctors.

80 There is a lot of disagreement in the medical community
81 about when exactly to begin using mammography screening for
82 breast cancer. Studies have shown that mammograms save lives
83 while at the same time others have highlighted the risks
84 associated with the test. For example, an article published
85 in the New York Times just yesterday cites a new study that
86 indicated that the risks associated with yearly mammograms
87 can actually put high-risk women at an even greater risk to
88 develop breast cancer in their lifetime, though at the same
89 time the study also cautions that more research is needed to
90 make a more conclusive recommendation. And it appears to me
91 that the takeaway message from all this is that more research
92 is needed and there is already quite a bit of disagreement
93 within the community as to what is best for the patient. But
94 remember, our goal is to provide the best ways of preventing,
95 detecting and treating breast cancer. All the studies,
96 reports and recommendations should be used with that goal in
97 mind. And I also believe that we do not want this study or

98 any other study to be used as an excuse by insurance
99 companies or others to deny mammograms or treatment that
100 would help women. And again, the decision should be between
101 the women and their doctors, not with the insurance
102 companies. Essentially we want stakeholders today and the
103 task force and all groups to be heard. We want people to
104 understand whatever recommendations are made and what the
105 implications are from these recommendations.

106 So I want to thank the witnesses that are here today for
107 coming on relatively short notice.

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

109 ***** COMMITTEE INSERT *****

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110 Mr. {Pallone.} At this time I would recognize our
111 ranking member, our temporary ranking member, I guess, the
112 gentleman from Missouri, Mr. Blunt.

113 Mr. {Blunt.} Well, I thank you, Mr. Chairman, and Mr.
114 Deal will be here at some point during the hearing. I am
115 glad to substitute for him in this chair for a little while
116 today. I certainly thank you for holding this hearing on the
117 recent recommendations on breast cancer screening. I think
118 there will be large agreement from the committee and concern
119 about those recommendations.

120 These new guidelines or these new proposed guidelines
121 have caused a great deal of confusion for women and their
122 families. The U.S. Preventive Services Task Force no longer
123 recommends routine mammograms for women between the ages
124 of 40 and 49 yet this group accounts for about one out of six
125 instances of breast cancer. I believe it is a huge mistake
126 to send a message to women and their families and health care
127 providers that an early alert system is not beneficial or may
128 not be beneficial. As a cancer survivor myself, I am very
129 interested in hearing from members of the task force on why
130 these recommendations were formalized, how they were
131 finalized and then communicated to the public because I know
132 how important screening was for me on two different cancers

133 on two different occasions as part of my annual physical.

134 As we all know, health care reform has been a hot topic
135 for this Congress. In a time when we have been talking about
136 encouraging more prevention in the health care arena, these
137 recommendations run counter to almost every other discussion
138 that we are having. I am also concerned about how these
139 recommendations could be interpreted should the House-passed
140 health care bill become law. I find it unlikely, or at least
141 questionable that the government-run health benefits advisory
142 committee would propose including services in the central
143 benefits package that another government-appointed board has
144 recommended are not necessary.

145 Mr. Chairman, I think this is an important hearing. I
146 congratulate you for holding it. I look forward to working
147 with you and our ranking member, Mr. Deal from Georgia, on
148 the subcommittee as we work to figure out how and why these
149 confusing recommendations were made.

150 [The prepared statement of Mr. Blunt follows:]

151 ***** COMMITTEE INSERT *****

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152 Mr. {Pallone.} Thank you, Mr. Blunt.

153 Next is our chairman, Mr. Waxman, the gentleman from
154 California.

155 The {Chairman.} Thank you, Chairman Pallone, for
156 holding this important hearing.

157 Today we are going to talk about an issue about which
158 people have strong views: which women should be routinely
159 screened for breast cancer and when. It is a question that
160 resonates with every person in this room. We all know
161 someone, a family member or friend, who has received a breast
162 cancer diagnosis. In some instances, this may be a younger
163 woman in the prime of her life. Indeed, just a few weeks
164 ago, this subcommittee heard powerful testimony from a member
165 of our own Congressional family, Representative Wasserman
166 Schultz, about her diagnosis and treatment for breast cancer
167 at age 40.

168 The new guidelines for breast cancer screening that were
169 recently issued by the U.S. Preventive Services Task Force
170 have placed this issue front and center again. I emphasize
171 the word ``again'' because this is not the first time
172 recommendations about the use of mammography and breast self-
173 exams have been revisited by the task force or NIH or any
174 number of cancer-related research or advocacy groups. Just

175 as we have seen with prostate cancer screening, immunization
176 schedules and even last week cervical cancer screening as
177 well as numerous other services, new information or new
178 interpretations of old information often result in a change
179 in what the experts tell us works at all or works most
180 effectively at all, and this is how it is supposed to be. As
181 the science of medicine evolves, so too should the
182 recommendations on the best use of that science. I believe
183 that is what the U.S. Preventive Services Task Force set out
184 to do in making a review of its 2002 mammography guidelines:
185 to take a fresh look at what has been learned over the last
186 several years and based upon that body of work to provide its
187 best professional judgment on what doctors and their patients
188 should consider when they are making decisions about breast
189 cancer screening. While that judgment may be contentious, I
190 have no doubt it was driven by science and by the
191 interpretation of science and not by cost or insurance
192 coverage or the ongoing health care reform debate. I am also
193 confident that these recommendations are just that--
194 recommendations, and that the task force would not expect
195 them to be used to take the place of a considered opinion of
196 a physician and a patient.

197 As we will hear shortly, there is a deep divide about
198 these guidelines among other experts that I believe together

199 with the task force share the primary goal of ensuring the
200 best possible care for women. We want to learn more about
201 those differing views today and understand better exactly
202 what the task force has proposed and why, but in the end,
203 what must prevail is a set of recommendations that is
204 evidence based, backed by science and supported by experts in
205 the field. American women and their doctors deserve and are
206 entitled to nothing less to inform their decisions, not to
207 make them but simply but to inform them. I hope that will be
208 our sole focus here today.

209 I look forward to hearing from all of our witnesses and
210 thank them in advance for their testimony. Thank you, Mr.
211 Chairman.

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

213 ***** COMMITTEE INSERT *****

|
214 Mr. {Pallone.} Thank you, Chairman Waxman.

215 Next is the gentleman from Illinois, Mr. Shimkus.

216 Mr. {Shimkus.} Thank you, Mr. Chairman, and I hate to
217 disappoint Mr. Waxman but this will not be our sole focus
218 today because this is the canary in the coalmine. This is
219 what we get when we have government intervention starting to
220 dictate health care policy decisions and this will not be
221 taken outside the context of H.R. 3962, which will then set
222 up a government system and will eventually ration care, and
223 when you have government commissions setting policy instead
224 of a doctor and a patient relationship, you get this. So
225 don't be surprised if we do not focus on how this is just one
226 small example of how health care will be delivered in this
227 country pretty soon, 2013, and definitely in 10 or 15 years.
228 We will be able to point out in H.R. 3962 the ratings of A
229 and B in the essential benefits package and the highest
230 rating of C, women would not receive access to regular
231 mammograms until the age of 50. One estimate finds rationing
232 of care like this would result in 50,000 preventable deaths
233 from women who go undiagnosed. H.R. 3962 does give the
234 Secretary the ability to add benefits but only after getting
235 approval to do so from a new bureaucracy that is created
236 called the Health Benefits Advisory Council. Will the new

237 Health Benefits Advisory Committee take into account cost
238 when making decisions? Will the committee make
239 recommendations another government board like the task force
240 has said shouldn't be covered? When mammograms and other
241 services aren't covered by government, where will people
242 turn? In Canada, we know those people can turn to the United
243 States market. In the U.K., they are allowed to purchase
244 their own private plan, this creating a two-tiered system.

245 Under H.R. 3962, we create the same tiered system for
246 the rich, one for the rich and one for the poor. The
247 Secretary can approve additional benefits to be covered or
248 enhanced and a premium plan is to be offered in the exchange.
249 These plans will cost more money and in 2013, 2014, anyone
250 receiving subsidies to help them afford insurance can only
251 purchase a basic plan. How will these people receive
252 coverage? So here is proof the government will have the
253 ability to come between you and your doctor and that we won't
254 need a single payer to get there. The government-run public
255 option will allow them the same ability to ration care, and I
256 yield back my time.

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

258 ***** COMMITTEE INSERT *****

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259 Mr. {Pallone.} The gentlewoman from California, Ms.
260 Eshoo.

261 Ms. {Eshoo.} Thank you, Mr. Chairman, for holding this
262 very important hearing today. I want to welcome the
263 witnesses, the members of the task force, the National Breast
264 Cancer Coalition, the American Cancer Society and the Susan
265 Komen Foundation here today as well, and to thank you all for
266 your work.

267 I will place a full statement in the record, but there
268 are a couple of points that I would like to make at this
269 moment, and that is, number one, I think that if we wander
270 away from science, from evidence-based science in our
271 country, then it will be a march to folly. Sometimes we
272 debate, and we should, and question the scientists and how
273 they arrived at the conclusion that they have come to, but
274 science is something that has been honored by the American
275 people for a very, very long time. We have come through a
276 period of time where science was not honored by the Congress.
277 It was political science that drove it, and scientists within
278 the government were muzzled and we paid a big price for it.
279 Certainly the task force and coming out with their
280 information, I wish there were maybe a better communications
281 plan. I think a lot of people were simply not prepared all

282 of a sudden to be hearing what the task force came out with.
283 But now is the sober and the prudent time to examine what the
284 task force has come out with and why and where that may take
285 us.

286 Now, on the issue of national health insurance, of
287 course our Republican friends are going to try and drag this
288 into that but I remember too many times where they were too
289 slow to take up the call to reform, to bring services to
290 women, especially poor women, in the fight against breast
291 cancer. So today is a most important hearing and we need to
292 remain, I think, devoted and dedicated to solid science in
293 our country and to pay heed to that, and I think that that
294 really drives to the core of what we are here today for and
295 God help us if we don't. This is not about anybody's
296 political science as much as members are tempted to drag that
297 into it, and I might say that insurance companies, private
298 insurance companies have long made decisions about who they
299 want to insure and what they will cover, and women and their
300 complicated bodies have been left out of so many of those
301 decisions and not covered by them and that is why we have
302 engaged in a whole new debate and hopefully we will be
303 successful with our efforts to remain all of that.

304 So, Mr. Chairman, thank you. Thank you for having the
305 scientists, the experts that are here today for us to query,

306 to understand better and their recommendations and that with
307 that we will be far more confident about the discussion and
308 the debate that they brought forward, so thank you.

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

310 ***** COMMITTEE INSERT *****

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311 Mr. {Pallone.} I want to thank the gentlewoman.

312 The gentleman from Texas, Mr. Burgess.

313 Dr. {Burgess.} Thank you, Mr. Chairman.

314 I agree with the gentlelady's previous statement that
315 the fight against cancer knows no ideological or partisan
316 lines, and I am certain the doctors who will be testifying
317 before us today would agree with that. Cancer is a disease
318 that all Americans fear and one that is all too often very,
319 very close to home. We have learned in this committee that
320 cancer is a complex disease, still has no cure but efforts
321 geared towards prevention, early detection and treatment have
322 made significant gains. We start there because as we embark
323 upon this hearing, we must remember not to embrace policies
324 that would undo the successes that we have enjoyed. I agree,
325 we should not make this partisan but the 2,000-page gorilla
326 in the room is the bill that this House passed 2 weeks ago,
327 and if things were just to stay as they are now, then the
328 task force recommendations would be just that,
329 recommendations. Doctors would be free to accept them or
330 reject them. But what we have written in the legislative
331 language may take some of that freedom away from doctors and
332 may take some of that freedom away from patients as well.
333 Cancer strikes roughly one-third of all women in the

334 United States and 13,000 Texans are expected to be diagnosed
335 with breast cancer this year, so we come to these new
336 recommendations made by the United States Preventive Services
337 Task Force and they have made some pretty dramatic statements
338 regarding breast cancer screening. Now, the whole concept of
339 not participating in a monthly self-exam, well, okay, maybe
340 that is a good thing but I cannot tell you as a physician
341 practicing obstetrics and gynecology for 25 years in north
342 Texas the number of new cancers that were brought to my
343 attention by the patient herself who found something on exam.
344 In fact, the young OB/GYN physician learns very early in
345 their course not to question the patient's clinical judgment
346 when they come in and tell you something is wrong because
347 very likely something is wrong. We are all happy when the
348 tests show that in fact there was no problem but more often
349 than not there is going to be something there that does
350 deserve further scrutiny.

351 Now, we had these task force recommendations come up 2
352 weeks ago and I went home to Texas, and on my desk waiting
353 for me was a periodical called OB/GYN News, not necessarily a
354 peer-reviewed scientific journal but articles of the day
355 which are of interest to practicing OB/GYNs are discussed and
356 they had a story that ironically was the day before the task
357 force recommendation came out that said headline, breast

358 cancer deaths higher without routine screening, and this was
359 from a report given to the American Cancer Society out in San
360 Francisco and a rather startling statistic that Dr. Katie
361 reported to this group that 345 breast cancer deaths, which
362 was nearly three-fourths of the total, were in women who were
363 not regularly screened. Women who were regularly screened
364 had 25 percent of the cancer deaths. Women who did not have
365 regular screening, 75 percent of the cancer deaths. I think
366 that is trying to tell us something and I think again the
367 2,000-page gorilla in the room is this new brave new world of
368 health care which Congress is going to dictate how things are
369 happening and the recommendations of the United States
370 Preventive Task Force now carry the weight of law, if you
371 will, under the auspices of the Secretary of Health and Human
372 Services or whoever the health care commissar is that they
373 designate.

374 So I thank you for having this hearing. I think it is
375 extremely important. I think it is extremely timely. I look
376 forward to the testimony of our witnesses. Dr. Brawley,
377 always good to see you. And I will yield back the balance of
378 my time.

379 [The prepared statement of Dr. Burgess follows:]

380 ***** COMMITTEE INSERT *****

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381 Mr. {Pallone.} Thank you, Mr. Burgess.

382 The gentlewoman from California, Ms. Capps.

383 Mrs. {Capps.} Thank you, Chairman Pallone, for holding
384 this hearing.

385 I am so pleased that you and we all have responded
386 quickly to the release of the task force's recommendation
387 because there has been a lot of confusion underscoring the
388 value of having hearings like this in our House of
389 Representatives. I have just returned, as we all have, from
390 our Thanksgiving break and I was with my family, and in fact
391 as an aside, received my own annual mammogram during that
392 time. I can assure you that the message is out there but I
393 am afraid it is not necessarily the accurate one. So I am
394 looking forward to hearing in great detail today how the task
395 force arrived at its conclusions and what the recommendations
396 really mean in a practical sense.

397 Unfortunately, there are people who have completely
398 twisted what the task force is, what the task force does and
399 what its recommendations mean. The scare tactics I have
400 witnessed since the release of the recommendations have been
401 deplorable, quite frankly. The recommendations are based on
402 scientific findings. This is so important to underscore.
403 Now, we know there is not always consensus within the

404 scientific community or within the advocacy community, both
405 groups so important to us in setting public policy, but we in
406 Congress owe it to our constituents and the public to listen
407 to what a reputable group of experts in evidence-based
408 medicine and prevention have to say.

409 Furthermore, we owe it to them to refrain from engaging
410 in partisan rhetoric about what these recommendations mean.
411 The United States Preventive Services Task Force issues
412 guidelines for a whole range of preventive services. They do
413 not make coverage determinations for insurance companies,
414 public or private, and ultimately all decisions should be
415 made between patients and their health care professionals.
416 The task force's website affirms that their purpose is to
417 present health care providers with information about the
418 evidence behind each recommendation, allowing clinicians to
419 make informed decisions about implementation. At the end of
420 the day, this is information that clinicians should use to
421 make decisions in consultation with their patients and
422 nothing more.

423 So I look forward to hearing in greater detail what the
424 task force concluded and how they arrived at these
425 conclusions, and I hope we can stop with the false
426 accusations.

427 Before I yield back, Mr. Chairman, I ask unanimous

428 consent to enter a letter from the Partnership for Prevention
429 into the record. The partnership is a group of reputable
430 organizations, the American Academy of Family Physicians,
431 nurse practitioners, physicians assistants and on and on,
432 there is about 10 of them, and they are calling attention to
433 our committee on the three most common misstatements that
434 have appeared in the media, one being that that the task
435 force recommends that women age 40 to 49 not receive
436 mammograms, this is nowhere in the report, that the intention
437 of the task force was to reduce cost, this is nowhere in
438 their analysis, and that they are not qualified. These are
439 some of the misstatements out in the public that this task
440 force is not qualified to make recommendations or that they
441 have other agendas in play, and I ask that the letter be made
442 part of the record, and I yield back.

443 [The prepared statement of Mrs. Capps follows:]

444 ***** COMMITTEE INSERT *****

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445 Mr. {Pallone.} Without objection so ordered. Thank
446 you, Ms. Capps.

447 [The information follows:]

448 ***** COMMITTEE INSERT *****

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449 Mr. {Pallone.} Next is the gentleman from Georgia, Mr.
450 Gingrey.

451 Dr. {Gingrey.} Mr. Chairman, I thank you.

452 We have heard already some comments from the Democratic
453 side regarding the danger of ignoring science if we go down
454 that road. I don't think we are talking about Newton's third
455 law here, by the way. We are not talking about exact
456 science. We are talking, I think, about an opinion, a
457 judgment that is made by the United States Preventive
458 Services Task Force, 15 or so members, based on looking at
459 alt of studies. I will tell you as a practicing OB/GYN
460 physician, like my colleague from Texas, Dr. Burgess, I have
461 spent 26 years practicing medicine. In that specialty, I am
462 a very proud member of the American College of Obstetrics and
463 gynecology and a board-certified fellow, and we take our
464 recommendations from that organization and from the standard
465 of care in the community, my community, the greater Atlanta
466 area, of what is best practices, and the American public and
467 particularly the American women, they know who the American
468 Cancer Society is. They know who the Susan G. Komen for the
469 Cure organization is. So many of them help raise money for
470 that organization but very few of them have ever heard of the
471 United States Preventive Services Task Force or in what

472 department they are embedded and how much power they have and
473 how much authority they have, Mr. Chairman. They will find
474 out pretty darn soon, and I would refer them to pages in both
475 the House and the Senate bill, the Senate bill of course
476 pending, the House bill 3962, and let them just connect the
477 dots and to see the power that this organization, this U.S.
478 Preventive Services Task Force, no matter what they call it,
479 to tell physicians basically that this is not an A or B
480 recommendation, this is a C recommendation. Well, Mr.
481 Chairman, if the President had followed through, if the
482 Congress had followed through on the President's
483 recommendation of having meaningful medical liability reform
484 in these pending health care bills, then maybe physicians
485 like myself would not have to worry too much if we decide to
486 follow the United States Preventive Services Task Force
487 guideline and not order a mammogram for our patients between
488 the ages of 40 and 49 or not recommend it to them that they
489 do breast self-examination, and we miss a diagnosis of cancer
490 and they died from that disease. Or on the other hand, if we
491 decided to ignore the recommendation and we did the mammogram
492 and a lump was detected or a suspicious marking on the
493 mammogram, the patient had a needle biopsy, it turned out to
494 be benign, but unfortunately, she developed a breast abscess
495 and then the physician gets sued for not following the

496 recommendations and doing something that is, quote,
497 unnecessary. So you put doctors in an untenable position and
498 you put their patients at risk of death.

499 So I can't wait to hear from Susan G. Komen and from the
500 American Cancer Society and obviously from the Preventive
501 Services Task Force and the others on the panel. Mr.
502 Chairman, with that, I will yield back.

503 [The prepared statement of Dr. Gingrey follows:]

504 ***** COMMITTEE INSERT *****

|
505 Mr. {Pallone.} Thank you.

506 The gentlewoman from the Virgin Islands, Ms.

507 Christensen.

508 Mrs. {Christensen.} Thank you, Chairman Pallone.

509 Given the confusion and the uncertainty the updated
510 recommendations on screening for breast cancer by the U.S.
511 Preventive Services Task Force has elicited, this hearing I
512 hope will bring some clarity which I feel is needed on both
513 sides, and I thank you for holding it.

514 I have only read the executive summary but I have
515 several questions like why now. Did the task force not
516 foresee the reaction that has occurred, and why was it just
517 released as an article as important as it is and now in a
518 briefing with press and stakeholder organizations. As an
519 African American woman who has had friends and family
520 diagnosed in their 20s, their 30s and 40s, many with no known
521 risk factors, some with good outcomes and others who died
522 because of the aggressive of their disease, and as a
523 physician who knows the pain of caring for women who came
524 with very late stage carcinomas like the 24 black women who
525 are going to be reported on shortly diagnosed in this city by
526 Dr. Wayne Frederick, the head of the cancer center at Howard,
527 in a recent 18-month period, 24. I am not pleased to say the

528 least with the report not specifically addressing those of
529 who die most often from this disease.

530 Mammograms are not perfect and perhaps least so in the
531 40 to 49 age group, but as part of the full armamentarium, it
532 is the best we have today. We have never told women that
533 mammograms are all that there is. As Dr. Frederick of Howard
534 said, and Ms. Luray and Dr. Brawley will attest, in
535 prevention, our main concern ought to be the gaps in outcomes
536 and the lack of access of many women to mammograms, exams and
537 other screening and diagnostic modalities, and while is most
538 evident in the uninsured, copays create almost equal barriers
539 to women with insurance, and neither is the federal
540 government doing enough. As an example, the Virgin Islands
541 scored very high on the breast and cervical cancer grant
542 application but was never funded. There is inadequate
543 funding to meet the need.

544 Until every woman has access, you can well imagine that
545 we will not welcome, I will not welcome, anyway, these kinds
546 of narrow recommendations. What is next? Colonoscopy
547 screening for cancer screening? It probably saved my life,
548 and not having one has caused me to lose too many friends.
549 The task force is independent, which I consider a good thing.
550 It is also very important to base decisions and
551 recommendations like these on science, but the task force is

552 not as diverse as it needs to be to adequately and
553 appropriately address the health care needs of all Americans.
554 The recommendations may have been very different or at least
555 more expansive if some of the recommendations that the
556 American Cancer Society offered had been accepted. They are
557 similar to ones that we recommended for H.R. 3962.

558 But I welcome all of the panelists today and I look
559 forward to the testimony.

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

561 ***** COMMITTEE INSERT *****

|
562 Mr. {Pallone.} I thank the gentlewoman.

563 The gentleman from Pennsylvania, Mr. Pitts.

564 Mr. {Pitts.} Thank you, Mr. Chairman, for convening
565 this hearing.

566 On November 16, the U.S. Preventive Services Task Force
567 released its updated breast cancer screening recommendations
568 for women in the general population. Several of the
569 recommendations have since caused widespread confusion and
570 concern, primarily its recommendations for women age 40 to
571 49. The task force recommended against routine screening
572 mammography in women age 40 to 49 but did say that certain
573 patients in this age range based on individual factors should
574 be screened. This is a change from the task force's 2002
575 recommendation that all women age 40 and older receive
576 screening mammography every 1 to 2 years.

577 The U.S. Preventive Services Task Force was first
578 convened by the Public Health Service in 1984 and since 1998
579 it has been sponsored by the Agency for Health Care Research
580 and Quality, a division of the Department of Health and Human
581 Services. It is instructive, therefore, to pay attention to
582 what the Secretary of Health and Human Services had to say
583 about the task force recommendations. On November 19,
584 Secretary Kathleen Sebelius said, ``My message to women is

585 simple: mammograms have always been an important lifesaving
586 tool in the fight against breast cancer and they still are
587 today. Keep doing what you have been doing for years. Talk
588 to your doctor about your individual history, ask questions
589 and make a decision that is right for you.' ' Basically she
590 told women to ignore the task force recommendations. The
591 good news for women age 40 to 49 is that they can talk to
592 their doctors and determine whether or not routine mammograms
593 are best for them. The bad news is that if the House-passed
594 health reform bill, H.R. 3962, becomes law, a woman in that
595 age range may not be allowed to have a mammogram. The House-
596 passed reform bill renames the U.S. Preventive Services Task
597 Force the Task Force on Clinical Preventive Services. As
598 part of the bill's essential benefits package, preventive
599 services including those services recommended with a grade of
600 A or B by the Task Force on Clinical Preventive Services must
601 be covered, but according to the task force's just-released
602 recommendations, routine mammograms for women age 40 to 49
603 received only a grade C. Should the health reform bill
604 become law, the new task force will make recommendations to
605 the Health Benefit Advisory Committee which will determine
606 what is and is not covered in the essential benefits package.
607 I think we should ask ourselves how likely it is that one
608 government board, the Health Benefits Advisory Committee,

609 will recommend including services in the essential benefits
610 package that another government board, the task force, has
611 recommended not be covered.

612 It is important to note that all private plans in the
613 exchange will have to meet the essential benefits package but
614 they cannot exceed it. A private insurer cannot add
615 additional benefits above and beyond what the government
616 requires in the essential benefits package except to premium
617 plus plans and then only if the added benefit is approved by
618 the health benefits commission. So, for example, if the
619 essential benefits package did not coverage routine
620 mammograms for women age 40 to 49, insurance plans would be
621 forbidden from covering them. My State of Pennsylvania
622 requires that all plans cover mammograms for women age 40 to
623 49. If this bill were to become law and the Secretary were
624 to adopt these breast cancer screening recommendations as is
625 as part of the essential benefits package, Pennsylvania would
626 either have to change its benefit mandate law or reimburse
627 the government for the added cost of screening this
628 population. These recommendations should be a wake-up call
629 that government-run health care will come between patients
630 and their doctors.

631 I look forward to hearing our distinguished witnesses.
632 Thank you, and I yield back my time.

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

634 ***** COMMITTEE INSERT *****

|
635 Mr. {Pallone.} Thank you, Mr. Pitts.

636 The gentlewoman from Florida, Ms. Castor.

637 Ms. {Castor.} Thank you, Mr. Chairman, very much for
638 the hearing today because it not only gives us an opportunity
639 to further understand the recommendations as to breast cancer
640 screening but it affords us an opportunity to raise awareness
641 about the real issue involving women's health in America and
642 that is access to care, plain and simple.

643 For women in America, access to care, affordable health
644 care, including screenings of all kinds, eclipses the debate
645 over what age women and their doctors should begin routine
646 mammograms. For millions of women across America, this
647 debate has no application whatsoever. They are not receiving
648 screenings at age 50, they are not receiving screenings at
649 age 60. They simply do not have access to affordable health
650 care because our health care system in this country is
651 broken.

652 It is very basic. We know that if you do not have
653 affordable health care you are less likely to receive the
654 vital preventative screenings that women with insurance have.
655 The American Cancer Society reports that in my home State of
656 Florida, if you don't have health insurance, you are simply
657 not going to receive any screening whatsoever. Women in this

658 country just do not have access to affordable care. Maybe
659 one-quarter of women in the State of Florida that do not have
660 health insurance will receive some mammogram during age 40 to
661 60, and it is much worse if you are African American or
662 Latina. The disparities in screenings, diagnosis and
663 treatment exist and I think this is the critical issue that
664 Donna Christensen has raised that really deserves a great
665 deal of attention and debate and it is the proper place for
666 our outrage over women's health in America because regardless
667 of your insurance status, if you are African American, you
668 are 1.9 times more likely to be diagnosed with an advanced
669 stage of breast cancer than white women and Hispanic women
670 are almost 1-1/2 times more likely to be diagnosed than white
671 women.

672 So the real concern here and the proper place for our
673 outrage is access to care in and of itself. Our broken
674 system prevents millions of women in America from even being
675 part of this debate over screening. Fortunately, due to the
676 efforts of many over the past year, we are on the road to
677 correcting this problem, and I hope that we can focus on the
678 true issues of our broken health care system in America that
679 affects, yes, breast cancer screening but really is the heart
680 of the problem in our fight to making America a healthier
681 country. Thank you.

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

683 ***** COMMITTEE INSERT *****

|
684 Mr. {Pallone.} I thank the gentlewoman.

685 Next is the gentleman from Michigan, Mr. Rogers.

686 Mr. {Rogers.} Thank you, Mr. Chairman.

687 You know, science is a whole host of disciplines and
688 math is one of them, and when you look at what the task force
689 recommendations have done, it is absolutely disingenuous to
690 say cost didn't play a role in it. Let me quote you from the
691 American Cancer Society: "The task force says that screening
692 1,339 women in their 50s to save one life makes screening
693 worthwhile at that age yet the task force also says that
694 screening 1,904 women ages 40 to 49 in order to save one life
695 is not worthwhile.'" When you look at their executive
696 summary, clinical breast examination specifically talks about
697 costs. The principal cost of a CBE is the opportunity cost
698 incurred by clinicians and the patient encounter. Clearly,
699 cost is a consideration. They did it with digital
700 mammography. Digital mammography is more expensive than film
701 mammography and talks about the cost-benefit analysis of that
702 as they work their way through. Magnetic resonance imagine--
703 magnetic resonance imaging is much more expensive than either
704 film or digital mammography. To say that cost was not a
705 factor in this is not being honest. It is just not. It
706 clearly was the reason, and to say, well, they don't have any

707 authority. Wait until that insurance company comes out and
708 says well, we based it on this task force, a government task
709 force recommendation says I don't have to pay for mammography
710 for a woman between the ages of 40 and 49. That is where we
711 are going.

712 As a matter of fact, in your 2,000-page bill, that is
713 exactly what you do. The Health Benefit Advisory Committee
714 is created to do exactly that. And how do we know that?
715 Because the National Institute of Clinical Effectiveness, the
716 NICE board in Great Britain, is the very organization that
717 limits things like Pap smears. They raised it from 23 to 25
718 for young women. Why? Why did they do it? Because science
719 told them? No, to save money. And what the math part of
720 your science equation is, we think that we are willing to
721 accept that more women will be diagnosed later on in later
722 stages of cancer. We are willing to accept a higher
723 mortality rate to save money. That is what this report says
724 and that is what we are getting ready to foist on the
725 American people. That is not a scare tactic. That is
726 reality, and it happens in Great Britain and it happens in
727 Canada and it happens in France, and what we are saying is,
728 we can and should do better.

729 I am a cancer survivor because of early screening. I
730 know Mr. Blunt is a cancer survivor because of early

731 screening. Why we would foist this kind of an ugly system
732 and hide behind the fact that we will have more deaths, more
733 mortality because of cancer because of it is beyond me. What
734 we are saying is, this 2,000-page bill and its 118 new
735 boards, commissions and other government agencies that will
736 dictate your health care policy is wrong and we can and we
737 should by these women in their 40s do much better, and I
738 would yield back the remainder of my time, Mr. Chairman.

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

740 ***** COMMITTEE INSERT *****

|
741 Mr. {Pallone.} Thank you, Mr. Rogers.

742 Next is--I am having a hard time seeing who is here.

743 The gentlewoman from Illinois, Ms. Schakowsky.

744 Ms. {Schakowsky.} Thank you, Mr. Chairman, for moving
745 so quickly to convene a hearing on the recommendations of the
746 U.S. Preventive Services Task Force. I appreciate it.

747 This committee has talked a lot about the need for
748 evidence-based science over the last year but it is
749 important, particularly when it comes to something as
750 critical as breast cancer screenings that we do look
751 carefully into the justification for these recommendations
752 and their ramifications for individual women. Many of my
753 constituents have questions, as do I, and I look forward to
754 asking them. But I do want to say right now that this is not
755 something that should become a political football or, in my
756 view, an attack on the need for health reform that guarantees
757 access to comprehensive health care for women. We all want
758 to insure women, especially women threatened with life-
759 threatening diseases like breast cancer and make sure that
760 they have access to the health care that they need without
761 preexisting-condition exclusions, gender rating denials that
762 exist today.

763 But among the questions that have been asked is, how do

764 we reduce the number of unnecessary screens while ensuring
765 that we do not provide disincentives for mammograms that will
766 save women's lives? How do we empower women to ask for a
767 screening when they suspect a problem? How do we build on
768 what we know today to ensure that are getting the research
769 and science around breast cancer prevention and treatment
770 right? What improvements are needed to obtain more accurate
771 screens? How do the grades provided by the task force mesh
772 with its recommendation that doctors and their patients be
773 allowed to make individual choices, particularly when it
774 comes to high-risk women? And how do we make adequate
775 insurance coverage or high cost sharing don't prevent
776 barriers to screening and all appropriate follow-up care?
777 Women across the country are concerned about getting access
778 to mammograms and other essential services, and women's
779 groups across the Nation have endorsed comprehensive health
780 reform for this very reason: because they know that millions
781 of women's lives depend on it.

782 I am eager to hear from our witnesses and discuss the
783 task force's recommendation and again, Mr. Chairman, thank
784 you for having this hearing. I yield back.

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

786 ***** COMMITTEE INSERT *****

|
787 Mr. {Pallone.} Thank you.

788 The gentleman from Arizona, Mr. Shadegg.

789 Mr. {Shadegg.} Thank you, Mr. Chairman, and I want to
790 also thank you for holding this hearing so quickly on this
791 important topic. I believe I have mentioned to this
792 committee before that my older sister is a 20-year breast
793 cancer survivor so I have a keen interest in this topic.

794 The breast cancer treatment guidelines released on
795 November 16th by the U.S. Preventive Services Task Force have
796 created a firestorm across the country, giving rise to
797 concerns about women's access to lifesaving screening. Some
798 have commented that these recommendations are merely
799 guidelines for insurance companies and government officials
800 trying to assess the relative value of mammography, clinical
801 breast exams and breast self-exams. In a written statement,
802 Health and Human Services Secretary Kathleen Sebelius said
803 the guidelines had caused a great deal of confusion and worry
804 among women and their families across this country and
805 stressed that they were issued by ``an outside, independent
806 panel of doctors and scientists who do not set federal policy
807 and don't determine what services are covered by the federal
808 government. I am here to tell you today and to tell every
809 women in America that under this bill, H.R. 3962, which has

810 already passed this Congress, that statement will not be
811 true. Indeed, under this bill, the recommendation of this
812 task force would become binding law, and if so, it would be
813 devastating to access to mammograms and nothing short of
814 catastrophic for women's health in this country.

815 In their recent report, mammograms for women age 40 to
816 49 were given a grade of C. Under this bill, any procedure
817 given a grade of less than A or B cannot be covered by the
818 public plan. So the women that my colleague worried about
819 who have no access to care today for mammograms could not
820 legally get mammograms once this bill becomes law. The panel
821 also found insufficient evidence to determine it is worth
822 screening over the age of 74. Again, because the grade was
823 neither an A nor a B, it was an I, insufficient, under this
824 bill those women could not get mammogram screening legally
825 under any public plan.

826 But it is important to understand precisely how far this
827 bill goes. Because it does not just prohibit mammogram
828 screening if this were the finding of this same task force
829 after H.R. 3962 becomes law, it would prohibit private
830 insurers, make it illegal for private insurers to provide
831 mammogram coverage to women in these age groups. That is
832 what the law says. Let me explain. Under the House bill,
833 private insurers can offer four plans: one, a basic plan;

834 two, an enhanced plan; three, a premium plan; and four, a
835 premium plus plan. Under section 303 of H.R. 3962, women
836 purchasing insurance under the first three categories, basic,
837 enhanced or premium, would not be allowed to purchase because
838 the insurance company would not be allowed to offer a policy
839 covering mammogram services. That is right, it would be
840 illegal for a private insurance company in any one of those
841 first three categories, basic, enhanced or premium, to offer
842 coverage for mammograms because mammograms were not given
843 either an A or a B rating.

844 With regard to the top category, premium plus, an
845 insurance company could offer coverage for mammograms but if
846 and only if the health choices commissioner specifically
847 allowed the policy to cover mammograms. Now, I don't suspect
848 that many of my colleagues on the other side of the aisle
849 understand that aspect of this bill and I hope that before
850 this bill or anything like it were to become law, they would
851 study it closely and recognize what is wrong with it.
852 Certainly having the government prohibit people who choose to
853 be able to buy mammogram coverage is not what was intended by
854 the authors of this legislation but in fact that is what the
855 bill does. The government would prohibit millions of women
856 from buying coverage for mammograms. The government would
857 forbid private plans from offering mammogram coverage to

858 millions of women. Poor and middle-class Americans by force
859 of law would be prohibited from getting mammogram coverage
860 under the insurance exchange--

861 Mr. {Pallone.} The gentleman is 2 minutes over.

862 Mr. {Shadegg.} --created in this bill.

863 I thank the gentleman for his indulgence and hadn't
864 realized I had gone over time. Thank you.

865 [The prepared statement of Mr. Shadegg follows:]

866 ***** COMMITTEE INSERT *****

|
867 Mr. {Pallone.} Thank you.

868 The gentleman from Maryland, Mr. Sarbanes.

869 Mr. {Sarbanes.} Thank you very much, Mr. Chairman, for
870 holding this hearing. I expect we are going to hear a lot
871 about rationing today from the other side. To me, the
872 discussion today isn't about rationing, it is about being
873 rational in looking at all of the evidence that is available
874 to us and making smart decisions about what kind of treatment
875 we should deploy and what kind of coverage there should be,
876 and I think the jury is out on this. That is why we are
877 having the hearing. There have been recommendations that
878 have been put forward. They appear to me to be based on very
879 extensive studies, research and science, and I think we ought
880 to approach them with an open mind.

881 I am glad we are having this hearing. I think this is
882 exactly the kind of thing we should be doing, and the fact of
883 the matter is that as science advances, it causes us to
884 revisit treatment, and that is a good thing. Now, there may
885 be other considerations at play here. One of them is clearly
886 the high attention that there is to mammography screening and
887 the education effort that has gone on with women across this
888 country to make them more sensitive to this as a screening
889 tool, so all of those considerations ought to be fed into the

890 mix and I would expect that the Secretary of HHS will be
891 considering all of those things going forward. But to put
892 our head in the sand and not look at the science, it seems to
893 me would be a serious mistake. So we ought to review these
894 recommendations with a sober and dispassionate consideration.
895 I think that is what we are called upon to do. I would
896 assume that that is what the Health Benefits Advisory
897 Committee would do in receiving recommendations from any
898 other government body. The notion that one--we have this
899 theme again as well today, the notion that one government
900 body will accept without any kind of independent judgment or
901 review the recommendations of another government body, I
902 don't think makes any sense. I think the Health Benefits
903 Advisory Committee will look at all the factors in
904 determining what ought to be the policy when it comes to
905 treatment.

906 So I think that this is a good conversation to be having
907 and I thank the commission for putting the recommendations
908 forward, for basing them on science, and now we are going to
909 have to consider those in the light of many, many factors in
910 judging how to move forward. So I look forward to the
911 testimony of the witnesses and I yield back my time. Thank
912 you.

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

914 ***** COMMITTEE INSERT *****

|
915 Mr. {Pallone.} I thank the gentleman.

916 The gentlewoman from Tennessee, Ms. Blackburn.

917 Mrs. {Blackburn.} Thank you, Mr. Chairman, and I want
918 to say thank you so much to our witnesses for being here. I
919 am really appreciate of the opportunity for us to have this
920 hearing today and I have a formal statement I will submit for
921 the record, but I do want to make a few comments as we begin
922 this.

923 This is an issue of tremendous concern to me. I think
924 that all of us are concerned about the welfare and the health
925 of women. We are concerned about what you all as the task
926 force brought forward. Sure, we are concerned about the
927 science, and I want to discuss with you that science, where
928 you drew that from and your process. I also want to explore
929 with you your task force structure and look at the linkages
930 that you bear and what would happen if H.R. 3962 were to be
931 passed and read into law. You all have a portfolio of 105
932 topics. That gets to the heart of the issue because when you
933 start reading on H.R. 3962 on page 1,296 in Title 3 and you
934 look at section 2301 of this bill, the decisions you make do
935 end up having the weight of the law placed behind them, and
936 when you read specifically on pages 1,317 and 1,318, you see
937 exactly what is going to happen with your recommendations.

938 And then you go in and you look at how it becomes the
939 standard of the law, so I encourage everyone to take this
940 bill then and read it and read that title. Look at section
941 3101. Look at section 2301. Go back and look on pages 110
942 to 112 at how what you do and how you give priority and
943 preference to certain treatments and certain categories is
944 going to carry the weight of law.

945 Now, it is concern to me when I hear statements made by
946 Members of Congress that we are going to deploy certain
947 treatments or certain health care. That ability should rest
948 with the patient and their physician. We do need a
949 bureaucrat in that exam room. And yes, indeed, when you read
950 this bill, we do have concerns that it will lead to rationing
951 because the decisions appear that they are being made on cost
952 and not on health care.

953 So I welcome you all. I appreciate your time. We are
954 going to have a lengthy number of questions. And Mr.
955 Chairman, I yield the balance of my time.

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

957 ***** COMMITTEE INSERT *****

|
958 Mr. {Pallone.} I thank the gentlewoman.

959 Chairman Dingell, the gentleman from Michigan.

960 Mr. {Dingell.} I flew back this morning from Michigan
961 hoping to have a rather informed hearing on a very important
962 point. I find that I have come back to listen to some fairy
963 tales coming from the other side of the aisle and I find
964 myself offended by the lack of attention that my Republican
965 colleagues have given to the health bill and I find myself
966 very much offended to listen to the kind of distorted logic
967 and reasoning with which I am being afflicted as I enter this
968 room. I have great affection and respect for my friends on
969 the other side of the aisle and I am willing to assume that
970 their behavior this morning in making the comments I am
971 hearing about these recommendations and how they will play
972 with the bill is bottomed on a lack of attention, study,
973 knowledge or diligence in understanding either the bill or
974 the recommendations of the U.S. Preventive Services Task
975 Force.

976 It has been a little bit like listening to the fairy
977 tales of the Brothers Grimm, but to set the record straight,
978 I want my colleagues to understand the bill does not in its
979 provisions behave as my Republican colleagues would have us
980 believe. It does not use these kinds of recommendations to

981 suppress treatment or interfere with the relationship between
982 the patients and the doctors. This is the kind of scare
983 tactics that I have heard from that side of the aisle always
984 with great personal offense. They talked about how we are
985 going to pull the plug on Grandma, how we are going to push
986 euthanasia forward, how we are going to deny health care to
987 deserving people because of this legislation. These
988 recommendations that we are going into this morning are
989 recommendations, nothing more, and to say anything different
990 than that is either to transmit the grossest kind of
991 carelessness or, and I hope this is not the case, just plain
992 outright deceit.

993 It is time for us to look at these recommendations are
994 they are: the recommendations of a scientific panel created
995 to make advice on what is the best medical practice and how
996 we can see to it that we best protect our women with regard
997 to things like Pap smears and mammograms.

998 Now, I will yield to no one on either subject because
999 this committee and the Oversight Subcommittee when I was
1000 chairman of each were responsible for seeing to it that both
1001 mammograms and Pap smears were made in the safest way for the
1002 benefit of patients. I lost my mother to cervical cancer and
1003 I lost lots of friends to breast cancer and other things, and
1004 I am grossly affronted by the statements that I have heard

1005 coming from the other side in which they tell us how these
1006 recommendations and the health bill on which we are working
1007 so hard are going to deny women mammograms, proper
1008 mammography and Pap smear and other needed services. That is
1009 offensive. It is just plain wrong. It is absolutely false.
1010 And I would urge my friends on the other side to take a look
1011 at the bill, to read it carefully, and if they need any
1012 assistance in understanding what the bill does, I will be
1013 happy to volunteer to provide time so that they may come to
1014 have a better understanding of what the bill does and they
1015 may then make more-informed statements on these matters.

1016 We need to deal with our health problems in a
1017 responsible way. We need to see to it that we address the
1018 honest defects which are in the bill but not to manufacture a
1019 lot of fears and faults which do not exist. I am affronted,
1020 Mr. Chairman, and I hope that this record and this hearing
1021 will correct some of the unfortunate misapprehensions and
1022 misstatements that have been flowing thickly from the other
1023 side of the aisle this morning. I ask unanimous consent to
1024 revise and extend my remarks.

1025 [The prepared statement of Mr. Dingell follows:]

1026 ***** COMMITTEE INSERT *****

|
1027 Mr. {Pallone.} So ordered. Thank you, Mr. Chairman.

1028 Our ranking member, the gentleman from Texas, Mr.

1029 Barton.

1030 Mr. {Barton.} Thank you, Chairman Pallone, for holding

1031 this hearing.

1032 I listened with great affection and with great interest

1033 to my good friend from Michigan, former Chairman and current

1034 Chairman Emeritus Dingell's opening statement. I think it

1035 goes without saying the personal esteem and professional

1036 respect that I have for him. Having said that, there are no

1037 fairy tales being told on this side of the aisle this

1038 morning. Here is the bill that passed the House. In this

1039 bill on page 1,762, the U.S. Preventive Services Task Force

1040 is given the authority, and I quote ``to determine the

1041 frequency, the population to be served and the procedure or

1042 technology to be used for breast cancer screenings covered

1043 under the Indian Health Service.'' Section 303 of the

1044 legislation states, and I quote, ``The commissioner shall

1045 specify the benefits to be made available under the exchange

1046 participating health plans.'' In plain English, Mr.

1047 Chairman, what this means is, the new health choices

1048 commissioner will determine what preventive services

1049 including mammography are covered under the health insurance

1050 that is in this bill.

1051 Now, we also know that the U.S. Preventive Services Task
1052 Force is an outside independent counsel of doctors and
1053 scientists who make recommendations. They do not set federal
1054 policy and they don't determine what services are to be
1055 covered by the bill but their recommendations are going to be
1056 seriously listened to.

1057 Now, I have an aunt who passed away in her early 50s as
1058 a consequence of breast cancer. I have a sister who was
1059 diagnosed with breast cancer in her 30s, luckily received
1060 proper treatment, had a mastectomy and so far in the last 10
1061 years is cancer-free. I have a wife, beautiful wife who is
1062 under the age of 50 and she has annual mammograms every year.
1063 I have a good friend who was just diagnosed with breast
1064 cancer who is in her mid 40s. Again, she's undergoing
1065 treatment. Hopefully she is going to have a good outcome.

1066 To have a task force make the recommendation that has
1067 been made and to have in this bill the authority that is
1068 given to various unelected bureaucrats to make health care
1069 decisions including coverage and frequency in my opinion is
1070 wrong. Now, on a bipartisan basis, this subcommittee and the
1071 full committee repeatedly has passed bills increasing and
1072 supporting the early detection of breast cancer, the
1073 prevention, the research. I mean, we do it almost every

1074 Congress. So we are starting down a path in my opinion of
1075 socialization of medicine in this country with the passage of
1076 this bill out of this committee, with its passage on the
1077 House floor, it is waiting approval in the Senate. This is
1078 an excellent time to hold this hearing. I appreciate the
1079 subcommittee chairman and the full chairman chairman's
1080 personal attendance, but let us don't talk about fairy tales.
1081 Let us talk about the facts, the plain English of these
1082 bills. And if we continue to agree rhetorically, then we
1083 need to begin to make substantive changes in the legislation
1084 to prevent what we all say we oppose. We don't want
1085 rationing of health care in America, we don't want to
1086 intervene between the doctor-patient relationship, we don't
1087 want young women or for that matter more mature women over
1088 the age of 74 developing breast cancer they are not allowed a
1089 mammogram. My good friend to my right, Mr. Rogers of
1090 Michigan, had an amendment that was passed at committee that
1091 explicitly prevented the rationing of care and it
1092 mysteriously disappeared in the bill that got reported out of
1093 the Rules Committee. In the dark of the night some staffer
1094 on the Majority side or maybe a Member, I don't know, decided
1095 that the will of the committee didn't mean anything. It
1096 disappeared. Maybe we need to put that back in. I don't
1097 know.

1098 So I have great respect for this committee. I have
1099 great respect for the leadership on the committee. But let
1100 us don't talk about fairy tales when we can read these bills.
1101 Now, I am not saying the bill is a fairy tale but I will say
1102 the bill is not reflective of the policy that members on both
1103 sides of the aisle say they support.

1104 With that, Mr. Chairman, I yield back.

1105 [The prepared statement of Mr. Barton follows:]

1106 ***** COMMITTEE INSERT *****

|
1107 Mr. {Pallone.} Thank you.

1108 Next is the gentleman from Texas, Mr. Green.

1109 Mr. {Green.} Thank you, Mr. Chairman, and I appreciate
1110 the opportunity you have in so quickly dealing with this.

1111 First of all, I want to thank the chairman emeritus for
1112 his offer, Chairman Dingell willing to conduct a class on
1113 remedial health care comprehension, and my only question is,
1114 is it going to be mandatory or permissive. And hearing my
1115 colleagues on the other side talk about unelected
1116 bureaucrats, unelected insurance companies do this every day
1117 right now, and I will give you an example. When I moved to
1118 be a Member of Congress, my wife had been getting annual
1119 mammograms and yet our new insurance in Congress refused that
1120 after the first year, and she was a survivor. Her mom was a
1121 40-year survivor of breast cancer and she so fit the
1122 exception, and it took me as a Member of Congress I can't
1123 practice law, but believe me, I will file suit against our
1124 carrier if they continue to pay for those mammograms. You
1125 have to fight for the care that you want. And to say that
1126 the House bill that passed would set up this unelected group
1127 to do it, it all rests on our shoulders and I think that
1128 decision ought to be made by elected officials.

1129 Now, this group will take recommendations from everyone

1130 but ultimately it is going to be our decision and we will
1131 continue to provide legislation to have minimum benefits, and
1132 the statement I have, in 2002 the task force changed their
1133 breast cancer screening to a grade B to recommend mammograms
1134 every 1 to 2 years for women 40 to 75. That was only 7 years
1135 ago. And yet now the task force is making a change. Two
1136 weeks ago they revised it and made a grade C, and that's the
1137 issue I think that my colleagues are talking about, that
1138 women at the age of 40 would not be automatic but should not
1139 be denied. And again, it does go back to the doctor and the
1140 patient's decision. And I have in fact doctors on both
1141 sides. I have doctors tell me all the time that they have
1142 battles with insurance companies saying we need to do this
1143 and the insurance company won't allow it, and they are the
1144 ones that are practicing medicine and that is a battle that
1145 has to be fought every day no matter what happens if we pass
1146 a national health care bill. But to use this opportunity to
1147 pick at the national health care bill I think is interesting
1148 because the task force will be given the opportunity to
1149 clarify their statements and I am glad we have the testimony
1150 here today.

1151 The adverse reactions to the poor wording of the task
1152 force recommendations obviously have not gone unnoticed by
1153 our committee and the members of the committee. In fact, I

1154 have been contacted by a number of constituents in my
1155 district including M.D. Anderson Cancer Center in Houston
1156 about the recommendations. They were very public. They are
1157 opposed to the task force recommendations. They will
1158 continue to recommend it along with many, many other groups.
1159 And luckily the State of Texas has a mandate that all private
1160 insurers must cover annual breast cancer screenings beginning
1161 at the age of 40 but these new screening recommendations will
1162 cause some access problems for women.

1163 The topic is also especially sensitive because the
1164 reform bill 3962 states that the U.S. Preventive Services
1165 Task Force recommendations A and B are mandated benefits and
1166 the bill also includes report language saying A and B
1167 recommendations are a floor for benefits, not a ceiling. The
1168 A and B are a floor. So the task force recommendation will
1169 be considered that but the decision could be made still no
1170 matter what the task force says. So that is what we are here
1171 today to talk about. I have concerns about jeopardizing
1172 access to preventive screenings for women, especially since I
1173 represent a majority Latino district that is medically
1174 underserved, and I worked for years in Congress to expand the
1175 coverage of mammograms in our community for primary and
1176 preventive care services. I like the fact that the task
1177 force is an independent commission and is designed to keep

1178 politics out of medical recommendations because I can be an
1179 expert for 30 seconds on anything but I do depend on the
1180 experts to be able to make those decisions.

1181 Again, I look forward to the testimony, Mr. Chairman,
1182 and I ask unanimous consent that my full statement be placed
1183 into the record.

1184 [The prepared statement of Mr. Green follows:]

1185 ***** COMMITTEE INSERT *****

|
1186 Mr. {Pallone.} Without objection, so ordered. Thank
1187 you, Mr. Green.

1188 Next is the gentlewoman from North Carolina, Ms. Myrick.

1189 Mrs. {Myrick.} Thank you, Mr. Chairman. Thank you for
1190 holding the hearing today.

1191 I understand that scientifically and statistically this
1192 report information is not new, and I know that mammography is
1193 not perfect by any stretch of the imagination, but I want to
1194 talk to this whole report from the preventive side because to
1195 me it is sending the wrong message to women. It is saying
1196 you don't have to be vigilant, you don't have to take care of
1197 yourself, you don' have to do preventive care, and the reason
1198 that concerns me is, I am a 10-year breast cancer survivor.
1199 I am one of those who persevered literally to find, you know,
1200 my own cancer because I knew something was wrong with my body
1201 and I had good doctors who helped me. But because of that, I
1202 am here today, and we all know that earlier detection means
1203 longer survival. I mean, that is a no brainer. So many
1204 women really say to me I don't want to get a mammogram, it
1205 hurts, you know, or whatever, I just don't want to do it. I
1206 heard that over and over again ever since I started to get
1207 active on this issue. And then a lot of women have told me I
1208 don't want to know, you know, I really don't want to know if

1209 I have cancer. Well, my point whole in this is, you know,
1210 you better find out sooner rather than later because of what
1211 I said before.

1212 So I am very concerned that we are saying hey, you don't
1213 have to take care of yourself. Women look for an excuse not
1214 to do this anyway and not to do self-exams, and especially,
1215 you know, younger women today. There are so many younger
1216 women in my area that are in their 20s and 30s getting breast
1217 cancer, they have their own support group and that never used
1218 to happen. So when we talk about what we need to do, I hope
1219 that we will very seriously consider, you know--and I am glad
1220 the panel is going to be here to explain why they did what
1221 they did. But I know that some of the groups are going to
1222 continue to recommend they do the same thing and with digital
1223 mammography now, things have changed, especially with younger
1224 women.

1225 So, Mr. Chairman, I appreciate this opportunity very
1226 much and just look forward to hearing the recommendations
1227 from the panel.

1228 [The prepared statement of Mrs. Myrick follows:]

1229 ***** COMMITTEE INSERT *****

|
1230 Mr. {Pallone.} Thank you.

1231 The gentlewoman from Wisconsin, Ms. Baldwin.

1232 Ms. {Baldwin.} Thank you, Mr. Chairman. I appreciate
1233 your calling this hearing of the Health Subcommittee to
1234 discuss what is both a deeply personal and deeply political
1235 issue for myself and as you have heard many of our colleagues
1236 in this room.

1237 The U.S. Preventive Services Task Force was authorized
1238 by Congress to deliver recommendations regarding the efficacy
1239 of clinical preventive services. Ideally, these
1240 recommendations will be used to inform primary medical care.
1241 On November 16, the task force delivered new recommendations
1242 regarding breast cancer screenings incorporating the most
1243 extensive scientific evidence available. Among their more
1244 controversial findings were the grade C recommendation for
1245 mammography in women over 40, which means that because the
1246 science does not point to any significant harm or tremendous
1247 benefit, that the provision of the services should be a
1248 decision between an individual and her doctor. An
1249 independent, rigorous examination of the science behind
1250 clinical preventive services is an essential part of
1251 delivering effective health care. The task force was doing
1252 its job. And as they may admit today, they could have done

1253 much more around such a sensitive topic by educating and
1254 explaining their recommendations to women across the country.
1255 They could have engaged community and advocacy groups to be
1256 messengers of this information rather than combatants.
1257 Moving forward with additional recommendations in sensitive
1258 areas, I would encourage them to do just that.

1259 I came away from this report and the surrounding
1260 controversy with two additional thoughts that I would like to
1261 quickly share. First, we clearly need better screening and
1262 diagnostic tools. Mammography is not a precise enough tool.
1263 We need advancements in technology that can help us
1264 understand what conditions require further tests, what
1265 requires treatment and how we can best help women live long
1266 and healthy lives. Some of these advancements in technology
1267 are being developed in my home State of Wisconsin, tools to
1268 help us identify types of issue with more precision,
1269 improving the efficacy of an X-ray screening for breast
1270 cancer.

1271 My second point is that we urgently and desperately need
1272 health care reform. We must ensure that every woman and
1273 every American has access to a regular source of care. If
1274 the best approach is to discuss the option of mammography or
1275 other screening with your doctor, you have to have a doctor.
1276 The villain here is the lack of coverage and access to care.

1277 Otherwise women who are shut out of the health care system
1278 whether by stigma or lack of resources or even abusive and
1279 discriminatory insurance industry practices, these women have
1280 the potential of dying of breast cancer or other conditions
1281 before we even have a chance to intervene.

1282 Again, Mr. Chairman, thank you for allowing us this
1283 venue to discuss and clarify this critical topic. It has
1284 bearing not only on the health of women but the health of all
1285 Americans.

1286 [The prepared statement of Ms. Baldwin follows:]

1287 ***** COMMITTEE INSERT *****

1288 Mr. {Pallone.} Thank you.

1289 The gentlewoman from Colorado, Ms. DeGette.

1290 Ms. {DeGette.} Thank you very much, Mr. Chairman. I
1291 will submit my full statement for the record.

1292 I just want to say that as Mr. Sarbanes said, we have
1293 got to look at science here and we have got to look at the
1294 recommendations based on science which, you know, sometimes I
1295 feel revolutionary in Congress saying that, but that is what
1296 we need to look at. All of this excitement on the other side
1297 of the aisle about how these recommendations are going to be
1298 implemented, first of all, Mr. Green said, it is not a
1299 ceiling, it is just a floor, but secondly, even if they were
1300 implemented, most of them probably we wouldn't object to.
1301 The recommendations say, number one, the decision to initiate
1302 regular screening mammography in women age 40 to 49 years
1303 should be an individual one accounting for patient context
1304 and values rather than a population-wide recommendation for
1305 routine screening. That makes sense to me. Number two,
1306 biannual screening mammography for women age 50 to 74 years.
1307 Number three, insufficient evidence to assess the additional
1308 benefits and harms of screening in women over 75 years or
1309 old, and then the others.

1310 So really, if you actually look at the recommendations,

1311 they probably do make some sense from a scientific standpoint
1312 but I have got to say, it is no wonder why the women of
1313 America are unbelievably confused as to what these
1314 recommendations are saying because what they are saying is,
1315 most women need to talk to their care provider and they need
1316 to figure out for themselves based on their health and their
1317 family history what is appropriate for them. It is not a
1318 one-size-fits-all testing. That makes sense to me. But if
1319 you look at the 24-hour news cycle, that is not what is being
1320 said to people. They are scared, they are confused. And
1321 when you add the misinformation that we hear from some of my
1322 friends on the other side, they are triply confused and
1323 scared because they think now when we have a health care plan
1324 that applies to everybody, suddenly they are going to be told
1325 that they can't have tests that they need, and that is simply
1326 not the case.

1327 So, Mr. Chairman, that is why I came down and sat
1328 through all the opening statements and am looking forward to
1329 the testimony because I think we really need to clear it up.
1330 What is it that we are saying should be done with mammography
1331 and testing for women and what is it that women need to be
1332 talking to their physicians about. Ultimately it is going to
1333 be the decision of the physician and the woman what they need
1334 and they need to figure that out and then they need to feel

1335 secure that they are getting the level of testing that they
1336 need. Thank you, Mr. Chairman.

1337 [The prepared statement of Ms. DeGette follows:]

1338 ***** COMMITTEE INSERT *****

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1339 Mr. {Pallone.} I thank the gentlewoman.

1340 Next is the gentleman from Ohio, Mr. Space.

1341 Mr. {Space.} Thank you, Mr. Chairman, for taking the
1342 time to hold the hearing on this very important issue.

1343 Cancer is a terrifying specter for all Americans and
1344 almost all of us have had a loved one or a friend who has
1345 been affected by it. It certainly is a disease that strikes
1346 fear in the heart of all of us, and I want to preface my
1347 remarks by saying that I have heard some things from the
1348 other side of the aisle that have made a lot of sense, and I
1349 specifically point to Congresswoman Myrick's comments, and I
1350 find them very consistent with those just provided by my
1351 colleague from Colorado, Congresswoman DeGette. But we have
1352 heard some things from the other side of the aisle today that
1353 I think cause us or certainly cause me considerable concern.
1354 I think that it is wrong to use that fear that we all share
1355 of cancer to intimidate the people of this country into fear
1356 of comprehensive legislation that as some of our witnesses
1357 will testify today is good for people with cancer.

1358 In following up with some of the remarks made by
1359 Chairman Dingell, there are some things this bill does not do
1360 that need to be clarified. These task force recommendations
1361 will not lead to rationing care. That is simply not true.

1362 You know, I think it is tactics like these that weaken the
1363 faith of the American people not in any one particular party
1364 but in the institution of Congress. Nothing in this
1365 legislation prohibits insurers from covering mammograms. In
1366 fact, the legislation gives the Secretary leeway to add to
1367 the minimum benefits package as needed. I think it is
1368 disingenuous to on the one hand defend the status quo which
1369 sees the insurance industry every day making decisions about
1370 the lives of their insureds based on strictly financial
1371 considerations and then on the other hand condemn a system
1372 because you speculate that these kinds of recommendations
1373 will lead to the rationing of care.

1374 Second, what this bill does do is, it provides the
1375 benefit of insurance to millions of Americans that don't have
1376 it and then following on what Dr. Christensen mentioned
1377 earlier, it is not just those Americans that don't have
1378 insurance that would benefit from this bill when it comes to
1379 preventive care and access to mammograms, it is those who
1380 have insurance but can't afford the copayments, specifically
1381 those who are indigent or middle-class Americans. That makes
1382 a difference for them. This bill makes preventive care a
1383 basic and fundamental right for every American. That means
1384 again that my constituents, the 65,000 of them that have no
1385 access to coverage right now and tens of thousands more who

1386 can't afford copays will now have access to things like
1387 mammograms when they wouldn't have otherwise had that.

1388 These are questions that we all should be asking: what
1389 is the net benefit of this legislation to our constituents.
1390 Rather than jumping to irrational conclusions, adding
1391 confusion to the public and politicizing an issue which
1392 should transcend politics, we should be asking these rational
1393 questions, again as my colleague from Maryland indicates,
1394 based on reason and science.

1395 With that, Mr. Chairman, I thank you once again for
1396 calling this hearing and yield back.

1397 [The prepared statement of Mr. Space follows:]

1398 ***** COMMITTEE INSERT *****

1399 Mr. {Pallone.} Thank you.

1400 The gentlewoman from Ohio, Ms. Sutton.

1401 Ms. {Sutton.} Thank you, Mr. Chairman, for holding this
1402 extremely important hearing on the recommendations from the
1403 U.S. Preventive Services Task Force on mammograms for women
1404 in their 40s.

1405 As we have all heard and has been discussed here, the
1406 task force is no longer recommending routine mammograms for
1407 women in their 40s, and as someone who cares deeply about
1408 women's health, I like others was surprised by this change.
1409 Breast cancer is, to say the least, a terrible disease. It
1410 is the leading cause of death for women between ages 20 and
1411 59. We all know people who have been touched by breast
1412 cancer, people that we love and care about, and we all know
1413 people who have benefited from early detection.

1414 So this is such an important hearing and I look forward
1415 to hearing the discussion of the panel, and what the
1416 recommendations basically are is that a woman should talk to
1417 her doctor and make decisions accordingly for their care but
1418 many women as has been pointed out don't have doctors and
1419 many women don't have access to health care and women who
1420 should get mammograms either under the old recommendations or
1421 the new recommendations do not get the mammogram. In 2007,

1422 only 70 percent of the women in the country who should have
1423 been screened for breast cancer were screened for breast
1424 cancer, and part of the reason women, whether they are 40 or
1425 they are 60, are not screened is because they do not have
1426 insurance and because they don't have insurance they don't
1427 have access to the care that they need when they need it
1428 including preventive care.

1429 So let us be clear, that providing access to health
1430 insurance means providing access to preventive care which
1431 means saving lives. So what is important is that patients
1432 and doctors are able to consult and access the care that that
1433 patient needs when that patient needs it and that the
1434 patients and doctors together will decide the best course of
1435 care whether that includes a mammogram but in order to do
1436 that, people have to have access to doctors. Women of all
1437 ages under the health care bill that has been passed by this
1438 House will have improved access to coverage. That should not
1439 be lost and it certainly should not discussions otherwise
1440 representations otherwise should not be used as we debate and
1441 discuss this very important issue to derail efforts to give
1442 women access to the health care that they need in this
1443 country. I don't think that that serves women well. I don't
1444 think that serves our country well, and frankly, I find it
1445 outrageous, and I yield back.

1446 [The prepared statement of Ms. Sutton follows:]

1447 ***** COMMITTEE INSERT *****

|
1448 Mr. {Pallone.} Thank you.

1449 The gentleman from Iowa, Mr. Braley.

1450 Mr. {Braley.} Thank you, Mr. Chairman, and thank you
1451 for holding this important hearing.

1452 I also want to commend my colleague, the gentlewoman
1453 from North Carolina, for her eloquent and thoughtful
1454 statement on a very important topic, and while I disagreed
1455 with what some of my colleague from Georgia said, I have
1456 great respect for his real-world experience on women's health
1457 issues and appreciate the concern he brought to this hearing.

1458 But I also want to talk about the comments that were
1459 made by the chairman emeritus and others on this committee.
1460 If people don't believe that rationing takes place right now
1461 in our private insurance system every day and every State in
1462 every Congressional district, they are sorely misguided. It
1463 does happen every day under the current system, which is
1464 failing to meet the needs of the American people. I will
1465 give you a good example of a friend of mine who was diagnosed
1466 with prostate cancer and conferred with his physician on
1467 treatment options and agreed that proton beam therapy was the
1468 best choice of treatment for him, and he went to his private
1469 insurance company, which also is the Medicare administrator
1470 in my State of Iowa, and his treatment was denied on the

1471 basis that it was experimental. Well, guess what? Under the
1472 Medicare plan that that same private insurance company
1473 administered, it was considered non-experimental, and even
1474 though he was eligible for Medicare because of his age he was
1475 still covered by a private plan through his employer and was
1476 denied coverage for the same treatment he would have gotten
1477 if he had been a member of Medicare. That is what is wrong
1478 with our broken health care delivery system and that is why
1479 comparative effectiveness research is such a critical part of
1480 a rational discussion about health care policymaking.

1481 In an earlier hearing in this same subcommittee, I
1482 talked about a hearing that took place in this very room
1483 years ago when a researcher advocating high-dose chemotherapy
1484 with bone marrow transplant for metastatic breast cancer
1485 patients was the only path to cure for those women, even
1486 though it had not been tested by rigorous academic research.
1487 Then years after that, we came to the realization that many
1488 women were actually harmed and died because of being
1489 subjected to that treatment.

1490 And that is why, by the way, it is so important that the
1491 plain language amendment that I put in the health care bill
1492 be implemented in people dealing with health care issues. I
1493 think that in its position paper, the U.S. Preventive
1494 Services Task Force highlights why that is so important.

1495 They indicate on one page of their statement that the problem
1496 was a matter of communications because they did not say what
1497 the task force meant to say that the communication of the
1498 mammography screening recommendations was poor. Well, I
1499 agree with that, and all you have to look at is the next two
1500 sentences to find out why. This is what two of the sentences
1501 say, ``The we said is that screening starting at age 40
1502 should not be automatic nor should it be denied.'' That
1503 doesn't make sense. The next sentence says, ``What we are
1504 saying is that a decision to have a mammogram for women in
1505 their 40s should be based on a discussion between a women,
1506 her doctor.''

1507 If you don't communicate for your intended audience in
1508 language that they can comprehend easily, these barriers of
1509 communication between highly technical scientific and medical
1510 information will be a problem but the debate we are having is
1511 a healthy debate and what the most effective use and
1512 treatment for breast cancer patients is and that is what we
1513 need to focus on going forward, and I yield back my time.

1514 [The prepared statement of Mr. Braley follows:]

1515 ***** COMMITTEE INSERT *****

|
1516 Mr. {Pallone.} I thank the gentleman.

1517 Next is the gentleman from Utah, Mr. Matheson.

1518 Mr. {Matheson.} Thank you, Mr. Chairman. I will be
1519 brief because I am looking forward to hearing from our two
1520 panels on this topic.

1521 In my State of Utah, the incidence of breast cancer is
1522 lower than most States, however, our mortality rate is high
1523 because women in Utah are diagnosed in cancer's later stages.
1524 As a witness on our panel notes in his testimony, the recent
1525 recommendations provided by the U.S. Preventive Services Task
1526 Force November 16th have sparked concern and disagreement
1527 among providers, patients, families as well as sparked a
1528 public discourse that has led to further confusion and
1529 anxiety. As we can see from the testimony before this
1530 committee, there is not consensus on screening protocols but
1531 there does seem to be consensus that any screening and
1532 treatment discussion is an individual one between a provider
1533 and a patient.

1534 So I hope today's hearing can provide concrete
1535 information on the evidence-based decision-making processes
1536 of the task force but I am also interested to hear from the
1537 cancer community and medical providers on their next steps
1538 for outreach and patient education on the benefits and

1539 limitations of mammography screening.

1540 Thank you, Mr. Chairman. I yield back my time.

1541 [The prepared statement of Mr. Matheson follows:]

1542 ***** COMMITTEE INSERT *****

|
1543 Mr. {Pallone.} Thank you.

1544 I believe that concludes the opening statements by
1545 members of the subcommittee, so we will now turn to our
1546 witnesses, and if our first panel would come forward, I would
1547 appreciate it. Thank you.

1548 We have two witnesses both from the U.S. Preventive
1549 Services Task Force. To my left is Dr. Ned Calonge, who is
1550 chair of the U.S. Preventive Services Task Force, and next to
1551 him is Dr. Diana Petitti, who is vice chair of the U.S.
1552 Preventive Services Task Force. Now, I will just mention as
1553 I think you know that we have 5-minute opening statements
1554 from you. They become part of the record, and each of you
1555 may in the discretion of the committee submit additional
1556 statements in writing for inclusion in the record, and I
1557 would now recognize first Dr. Calonge.

|
1558 ^STATEMENTS OF NED CALONGE, M.D., M.P.H., CHAIR, U.S.
1559 PREVENTIVE SERVICES TASK FORCE; AND DIANA B. PETITTI, M.D.,
1560 M.P.H., VICE CHAIR, U.S. PREVENTIVE SERVICES TASK FORCE

|
1561 ^STATEMENT OF NED CALONGE

1562 } Dr. {Calonge.} Good morning, Mr. Chairman and
1563 distinguished members of the committee. On behalf of our
1564 fellow task force members, we thank you for the opportunity
1565 to discuss the task force and our work.

1566 Our recently published recommendations on breast cancer
1567 screening have drawn a remarkable amount of attention. We
1568 recognize the communication of what the recommendations say
1569 was poor and the timing of the release was unfortunate. We
1570 wish to explain the process and timeline for creating these
1571 recommendations and to clarify what we intended to say to
1572 clinicians and women.

1573 The health care clinician scientists on the task force
1574 fully understand, most through personal experience, the
1575 impact of breast cancer on the lives of women and their
1576 families. Our job, though, is to rigorously review
1577 scientific evidence. Politics play no part in our processes.
1578 Costs were never considered in our considerations. We voted

1579 on these recommendations long before the last Presidential
1580 election. The timing of the release of the findings last
1581 month was determined not by us but both the publication
1582 schedule of the medical research journal which peer reviewed
1583 our work.

1584 The current task force was created by Congressional
1585 mandate as an independent body with the mission of reviewing
1586 the scientific evidence for clinical preventive services and
1587 developing evidence-based recommendations for the health care
1588 community. Our primary audience for recommendations remains
1589 primary care clinicians. The task force has 16 volunteer
1590 termed members representing a diverse array of expertise in
1591 primary care and preventive health-related disciplines
1592 including adult, child preventive and behavioral medicine,
1593 women's health, nursing and research methods. The AHRQ
1594 director appoints members from the chair's recommendations
1595 developed from a public nomination process. Given the scope
1596 of topics covered, subspecialists who consult on or care for
1597 those identified through screening by primary care clinicians
1598 may not necessarily be recruited as members but instead are
1599 consulted to review and comment on our work at critical
1600 points in the process.

1601 Our current portfolio includes a broad array of 105
1602 clinical preventive services that are listed on our website.

1603 We strive to update topics every 5 years, which is what
1604 prompted the new breast cancer recommendations. To address a
1605 topic, designated task force work group members and
1606 scientists at an evidence-based practice center
1607 collaboratively develop an analytic framework and pertinent
1608 key questions. A structured, systematic review of evidence
1609 for each key question is conducted and a draft evidence
1610 report is created with working group consultation. Based on
1611 the evidence review and explicit methodology, the work group
1612 drafts a recommendation statement and at an in-person meeting
1613 the evidence and the draft statement are presented and
1614 discussed and the task force votes on the recommendation.

1615 There is careful attention to conflicts of interest such
1616 that members with potential conflicts are recused from
1617 discussion and vote or otherwise restricted in participation.
1618 Representatives of 24 partner organizations including all
1619 primary care specialties, key federal agencies and other key
1620 stakeholders specified in our written testimony and on our
1621 website are invited to participate in the discussion. At
1622 three key points in the process, work products are sent for
1623 review and comment by the partner organizations by
1624 subspecialty expert consults from the relevant disease area
1625 such as oncologists and by other stakeholders such as
1626 subspecialty professional organizations and advocacy groups.

1627 These products include the analytic framework and key
1628 questions, the draft systematic evidence review and the draft
1629 recommendation statement as voted on. All comments are
1630 considered in creating the final products. Final
1631 recommendation statements and evidence reviews are published
1632 in peer-reviewed medical journals.

1633 Recommendations are expressed as letter grades based on
1634 two factors only: the magnitude of net benefit or balance of
1635 benefits and harms of providing the service and the
1636 scientific certainty about whether the service works. Cost
1637 and cost-effectiveness are not addressed in our deliberations
1638 and making a recommendation. Over the past several years we
1639 have discussed whether cost should ever influence a
1640 recommendation and we have repeatedly said no.

1641 For A and B recommendations, they are sufficient net
1642 health benefits such as that primary care clinicians are
1643 recommended to provide these services for all appropriate
1644 patients. If there is no net benefit or there is net harm,
1645 we assign a D recommendation indicating to not provide the
1646 service. If gaps in the evidence prevent net benefit from
1647 being determined, we assign an I statement reflecting
1648 insufficient evidence, indicating that more research is
1649 needed.

1650 Finally, a C recommendation is assigned when there is a

1651 small net benefit. For C recommendations, we recommend the
1652 patient be informed about the potential benefits and harms
1653 and then be supported in making his or her own informed
1654 choice about being tested. The specific C language that we
1655 recommend against routine provision was intended for
1656 consideration by primary care clinicians, but unfortunately
1657 as played out in unintended ways in the public interpretation
1658 of the breast cancer recommendation.

1659 Congress through Public Law section 915 mandates that
1660 AHRQ convene the task force to address our mission. The role
1661 of AHRQ in the process is to support our activities and
1662 processes of AHRQ staff and the director of AHRQ do not vote
1663 or otherwise influence our decisions.

1664 I will have to admit to the committee that breast cancer
1665 is of particular concern to me. I lost both my mother-in-law
1666 to breast cancer and my sister is currently undergoing
1667 therapy. I fully understand this issue and have to rely on
1668 the science as we provide our recommendations.

1669 With that, I would like to turn testimony over to Dr.
1670 Petitti to testify specifically about the breast cancer
1671 screening recommendation.

1672 [The prepared statement of Dr. Calonge follows:]

1673 ***** INSERT 1 *****

|

1674 Mr. {Pallone.} I am sorry. I just wanted to thank Dr.

1675 Calonge and now ask Dr. Petitti to begin.

|
1676 ^STATEMENT OF DIANE B. PETITTI

1677 } Dr. {Petitti.} I am Diana Petitti. I am the vice chair
1678 of the U.S. Preventive Services Task Force. I am a physician
1679 and an epidemiologist. I have spent my entire 32-year career
1680 as a scientist working on issues of women's health. I
1681 published on the topic of mammography screening. I served as
1682 vice chair of the National Cancer Policy Board and I have
1683 expert in evidence synthesis, systematic review and med
1684 analysis. I participated in this process from the very
1685 beginning. I would not sign off on any recommendation that I
1686 did not believe reflected the best possible use of evidence
1687 for the benefit of women.

1688 I appreciate the opportunity to clarify for members of
1689 this subcommittee the task force recommendations and the
1690 evidence and weighing of the evidence that led to these
1691 recommendations. In specific, the task force recommends the
1692 following: women age 50 through 74 should have mammography
1693 every other year. The decision to start regular, biannual
1694 screening mammography before the age of 50 should be an
1695 individual one and take the patient context into account
1696 including the patient's values regarding specific benefits
1697 and harms. That is, the task force is saying that screening

1698 starting at 40 should not be automatic nor should it be
1699 denied. Many doctors and many women, perhaps even most
1700 women, will decide to have mammography screening starting at
1701 age 40. The task force supports those decisions.

1702 The task force acknowledges that the language used to
1703 describe its C grade recommendation about breast cancer
1704 screening for women 40 to 49 did not say what the task force
1705 meant to say. The task force communication was poor. The
1706 task force is committed, really committed to improving its
1707 communication.

1708 The task force first addressed the screening mammography
1709 topic in 1989. At that time the task force recommended
1710 screening women 50 through 75 every 1 to 2 years. With
1711 regard to screening younger women, the task force stated it
1712 may be prudent to begin screening at an earlier age for women
1713 at high risk of breast cancer. In its 1996 guide, the task
1714 force recommendation was in favor of screening women 50 to 59
1715 every 1 to 2 years. Mammography screening for women 40 to 49
1716 was given a C grade. At that time the C grade recommendation
1717 meant insufficient evidence. In 2002, the task force
1718 recommended screening women 40 to 69 every 1 to 2 years,
1719 stating that the benefits were smaller and took longer to
1720 emerge for women who were first screened in their 50s.

1721 On November 16th, as this committee knows, the task

1722 force issued its updated recommendations on breast cancer
1723 services. I wish for us to clarify that the timing of
1724 issuance of these recommendations. In late 2006, discussion
1725 of a plan for updating recommendations began. The breast
1726 cancer topic came up for review at the regularly scheduled
1727 time. Work on the topic started in 2007. When the
1728 recommendation statements came up for a vote in November
1729 2007, the members could not come to agreement about what to
1730 recommend because agreement about what to say about the
1731 balance of benefits and harms. In this context, the task
1732 force asked for additional evidence from its evidence-based
1733 practice center. The task force considered this evidence at
1734 its July 14-15 meeting.

1735 In making its final recommendation, the task force
1736 considered evidence identified in a systematic review of
1737 evidence for six key questions, the results of an analysis
1738 from the breast cancer screening consortiums and the results
1739 of a study commissioned by the task force and conducted by
1740 the cancer intervention and surveillance modeling network.
1741 The systematic review identified almost 3,000 studies, and
1742 550 of these were used to make the recommendation. The final
1743 recommendations were made based on a weighing of the benefits
1744 and harms of screening mammography. The task force concluded
1745 from the evidence that screening mammography for women 40 to

1746 64 has a benefit in reducing death due to breast cancer. The
1747 benefit is larger in older women than in younger women, and I
1748 would like to speak specifically to the issue of harms in
1749 this net benefit equation.

1750 Preventive services are provided to asymptomatic
1751 individuals for the sole purpose of preventing or delaying
1752 morbidity, delaying functional decline or postponing death.
1753 The promise of service delivery is net benefit, benefit minus
1754 harms. The benefits of mammography have been easy to
1755 communicate. The harms and potential harms have been
1756 difficult to communicate. The easily identifiable and
1757 commonly used definition of harm is physical injury. These
1758 physical injury direct harms are very, very small but the
1759 task force considers the harms of a screening test not just
1760 physical harms but psychological harms.

1761 A great deal of the controversy has centered on the task
1762 force use of consideration of anxiety and psychological
1763 distress as a harm of a false positive test. In particular,
1764 the psychological distress has been ridiculed. To understand
1765 the consequences of false positive tests, it is necessary to
1766 consider how women enter the screening cycle, what happens
1767 and what might happen to a woman who has a positive test. No
1768 matter how hard the concept of screening is explained, a
1769 positive mammogram screening test means cancer until cancer

1770 is proven not to exist. For some women who have a positive
1771 test, the time between a positive test and a statement there
1772 is no cancer is mercifully short. For other women, the
1773 follow-up involves more than one additional test, perhaps a
1774 clinical breast examination along with a test, a trip to a
1775 surgeon over a period of time that is not always short and
1776 over a period of time it is unpredictable and not within the
1777 control of the woman. Some women eventually need a biopsy.
1778 Cancer is a terrifying prospect. It carries special
1779 emotional weight because of the consequences of the diagnosis
1780 have in the past involve not only death but the prospect of
1781 mutilating surgery. Anxiety and psychological distress in
1782 women who have had positive screening tests is amply
1783 documented in the evidence. The task force wants only that
1784 screening mammograms be done with full knowledge of these
1785 potential harms, the frequencies of these harms and what is
1786 to be gained by being screened at an earlier compared with a
1787 later age. False positive tests are more frequent in younger
1788 than in older women.

1789 Other harms of mammography include ones that are less
1790 well documented. Some women are diagnosed in their 40s with
1791 cancer that could have been treated just as well if diagnosed
1792 later. These women may have unnecessarily been exposed to
1793 the harms of treatment including surgery, chemotherapy--

1794 Mr. {Pallone.} Doctor, I didn't want to stop because it
1795 is so important, but you are 2 minutes over, so keep going
1796 but--

1797 Dr. {Petitti.} I am going to say that--my final
1798 statement. Mammography starting at 40 should not be
1799 automatic. The task force recommends that women in their 40s
1800 decide on an age to begin screening that is based on a
1801 conversation with their doctor and is individual, and I
1802 apologize for going over.

1803 [The prepared statement of Dr. Petitti follows:]

1804 ***** COMMITTEE INSERT *****

|
1805 Mr. {Pallone.} I am going to apologize for trying to
1806 stop you because it is so important that you clarify a lot of
1807 these things, and I appreciate that.

1808 Our procedure now is that we have questions from the
1809 members of the panel--I mean from the Members of Congress,
1810 and I will start with myself.

1811 Let me say that you have actually clarified some of the
1812 questions I was going to ask very well but I still want to
1813 kind of review this if I could in my own mind, and if I say
1814 anything you disagree with, tell me, but I do want to ask you
1815 some questions as well. There are a lot of myths out there
1816 that have been spread both today and certainly in the last
1817 few weeks since you came out with your recommendations, and
1818 the way I understand it, the current task force uses these A,
1819 B, C ratings. These are the same kind of ratings that would
1820 be used under the different task force that is in the
1821 legislation, the larger health care reform legislation that
1822 we passed. In other words, you are the U.S. Preventive
1823 Services Task Force. The new task force in the bill that we
1824 pass has a different name, Clinical Preventive Services, but
1825 the A, B and the C ratings are the same or similar.

1826 But right now these A, B and C ratings have no force.
1827 They are just recommendations. And what some of my

1828 colleagues have said is that these insurance companies now
1829 don't have to cover A, B or C, they don't have to cover
1830 anything, and in fact what we are getting is that a lot of
1831 insurance companies right now don't prefer to cover any
1832 screenings because if you do a screening and they have to pay
1833 for treatment, it costs them money, which they try to avoid.
1834 And so what I see right now is that in some cases, States
1835 have required certain screening like my own State, but on the
1836 other hand we heard the gentleman from Utah talk about Utah
1837 where my understanding is, they don't require any screenings.

1838 So the point I am trying to make is that the big
1839 advantage of the health care reform bill that we pass is that
1840 H.R. 3962 will for the first time create minimum standards
1841 for requiring preventive benefits. So private insurers would
1842 be required under that bill to cover services with a grade A
1843 or B recommendation. Right now they don't have to cover
1844 anything. What we're doing in the bill is basically saying
1845 that at a minimum if you or your successor task force says
1846 that this is an A or B, it has to be required, which it is
1847 not now. The other thing that we do in the bill is that we
1848 say that the Secretary could require a C rating also be
1849 covered under both a public option or private insurance
1850 plans. In fact, my understanding is that the new task force--
1851 -I mean the Secretary under the bill could even require a C

1852 rating under the basic benefit package. Now, that is
1853 contrary to what some of my colleagues have been saying on
1854 the other side of the aisle, and my whole point here is to
1855 say that the truth is that if enacted into law, H.R. 3962
1856 would result in a lot of people who are not getting
1857 mammograms, Pap smears, colonoscopies, a lot of people don't
1858 get that at all now because insurance companies basically
1859 don't have to do it unless the State requires it. Now under
1860 this bill, they would have to do anything that you rate as an
1861 A or B and the Secretary could even require the C either in
1862 the public option or in the private plan under the basic
1863 benefit package.

1864 Now, I mention this because the bottom line is that
1865 women's ability to continue to obtain mammograms increases in
1866 these House and Senate bills that are being passed, and when
1867 I look at the Republican bill on the other side, it sets no
1868 floor whatsoever. There would be no minimum required
1869 benefits for insurance to provide under the Republican bill.
1870 Essentially it would just like the status quo that we have
1871 now. So I listen to the debate that we have had today and
1872 the bottom line is that the bill that we passed in this House
1873 provides a lot more coverage, has a lot more guarantees. The
1874 status quo doesn't provide any guarantees at the federal
1875 level nor would the Republican alternative that we have been

1876 given on the other side.

1877 Now, my question is, again, you mention that when you
1878 recommend a C, it says that it has a small net benefit and
1879 women are supposed to make their own decisions so you made it
1880 quite clear today that even if it is a C, there is some net
1881 benefit and the Secretary could decide under the new bill to
1882 say okay, that is going to be required as well. So you are
1883 not in any way with the C recommendation saying that this
1884 screening is not a good thing. In fact, you are actually
1885 saying there is a net benefit but you would like individual
1886 women to make that decision with their doctor because it is
1887 only a small net benefit. Is that accurate?

1888 Dr. {Petitti.} Mr. Chairman, I am going to speak to the
1889 science.

1890 Mr. {Pallone.} Absolutely.

1891 Dr. {Petitti.} And the science is that a C
1892 recommendation does mean a small net benefit, and we map that
1893 C recommendation through advice that women make the decision
1894 with their doctors about whether or not to undergo screening.
1895 I think this committee is dealing with incredibly complicated
1896 issues about health reform and coverage but the task force is
1897 not a coverage and health care reform and policy committee;
1898 we are scientists.

1899 Mr. {Pallone.} But the bottom line is--and I will end

1900 with this--is that even when you recommend a C you are saying
1901 there is a small net benefit, so again, let us not talk about
1902 today but let us talk about if the bill that we passed in
1903 this committee becomes law. Even then, you know, the
1904 Secretary could say okay, there is a small net benefit and so
1905 we do want to require this as a basic benefit, or, you know,
1906 you basically leave it up to the insurance companies to
1907 decide the way they do today. But, you know, the
1908 misinformation out there I think is that even under the bill
1909 that we passed, for once there is going to be a requirement
1910 that some of these screenings occur. If you rate it as an A,
1911 it has to be done. If you rate it as a B, it has to be done.
1912 If you rate it as a C, the Secretary can say it has to be
1913 done. Right now there is nothing, nothing at all, and the
1914 Republicans in their alternative would continue the status
1915 quo that says you don't have to cover anything, and I just
1916 appreciate it because I think you have helped me clarify.

1917 I yield now to the gentleman from Illinois, Mr. Shimkus.

1918 Mr. {Shimkus.} Thank you, Mr. Chairman, because what we
1919 need in this country is a continued debate on the failed
1920 health care bill that we passed on the Floor of the House.
1921 That is what we really need to do and that is what we are
1922 doing today, and we are using obviously what happened through
1923 your process to make the claim, the short-term concern of a

1924 public option, which many of my colleagues on the other side
1925 have said is the gateway to a one-payer system. So when the
1926 government controls all the health care decisions in this
1927 country, they will eventually default to control costs
1928 through rationed care.

1929 Now, the process, the scientific process that you have
1930 just admitted to said there is a small net benefit. When
1931 there is decreased revenue available, the default will be
1932 based upon 3962 just what you say on your website. Your
1933 website recommends against routine screening mammography in
1934 women age 40 to 49. Do you think that this statement would
1935 be perceived by women younger than 50 that they should not
1936 get a mammogram on your website?

1937 Dr. {Petitti.} We have communicated very poorly about
1938 the C recommendation. It is clear that many women, many
1939 physicians and certainly the media interpreted that language
1940 as if we were recommending against women in their 40s ever
1941 having a mammogram. That was not our intention.

1942 Mr. {Shimkus.} I understand, but we are concerned of
1943 commissions. We are concerned of bureaucracy. We are
1944 concerned of rationed care. We are concerned about
1945 bureaucrats saying there is no real net benefit, and then--
1946 yeah, it is right. It is exactly what we are concerned about
1947 and that is why we are having this debate. In the bill, and

1948 Chairman Pallone pretty adequately talked about the
1949 differences--we know that services with a rating of A and B
1950 must be included in essential benefit package. In this case
1951 with the highest rating of C, women would not receive--
1952 currently if this was law, as is today, women in the C
1953 category would not receive this as a covered benefit under
1954 3962, and that is part of our concern and this does segue
1955 into the full health care debate. The commissioner on part
1956 of the bill, and I don't have the whole 2,000 pages, I just
1957 pulled out excerpts. The commissioner shall specify the
1958 benefits to be made available under exchange participating
1959 health benefits plans during each year, and then you can go
1960 further on. Basic, enhanced and premium, and then the
1961 premium plus, A, approved by the commissioner, and then you
1962 can go to the C section, which is again highlighted, and we
1963 continue to have preventive services including those services
1964 recommended with a grade A or B by the task force on clinical
1965 preventive services.

1966 So this is again for a lot of us an important debate.
1967 Do any of you know an individual who has been diagnosed for
1968 cancer between the ages of 40 and 49 personally?

1969 Dr. {Petitti.} Oh, I know many individuals who have
1970 been diagnosed with cancer--

1971 Mr. {Shimkus.} Dr. Calonge?

1972 Dr. {Petitti.} --between the ages of 40 and 49.

1973 Dr. {Calonge.} Yes.

1974 Mr. {Shimkus.} And then the other question, what about
1975 over the age of 74? Anyone who has been diagnosed with--

1976 Dr. {Petitti.} Yes.

1977 Mr. {Shimkus.} Because although we are focusing on 40
1978 to 49, in your report over 74 has the I category, and we
1979 don't even know if it is. So what are saying to those over
1980 the age of 74?

1981 Dr. {Petitti.} I speak to the evidence and to the
1982 mapping of the evidence to the task force recommendations.

1983 Mr. {Shimkus.} And I appreciate that, and I only got 38
1984 seconds and I am going to be punctual on my time. Part of
1985 this concern with H.R. 3962 is as we said, the public option,
1986 the gateway to a one-payer system, eventually rationed care,
1987 and then a decision based upon the financial ability of the
1988 country to fund care across the spectrum but also our seniors
1989 in our country, and again, this incomplete aspect for 74, it
1990 speaks to the concern that if you are elderly in this country
1991 and we get to a one-payer system, there will be decisions
1992 made not based upon health care but on cost, and I yield back
1993 my time.

1994 Mr. {Pallone.} Thank you.

1995 Chairman Waxman.

1996 The {Chairman.} Thank you, Mr. Chairman.

1997 The health care bill that the Republicans are
1998 complaining about is not law yet your agency, the Preventive
1999 Task Force, is an operation. Is it set up under law?

2000 Dr. {Calonge.} Yes.

2001 The {Chairman.} And your job isn't to make
2002 recommendations to insurance companies, is it?

2003 Dr. {Calonge.} That is correct.

2004 The {Chairman.} Your job is to make recommendations on
2005 preventive services so that the latest science and
2006 information about the science is communicated to clinical
2007 practitioners. Isn't that your job?

2008 Dr. {Calonge.} That is correct.

2009 The {Chairman.} And this is very useful information.
2010 Now, we are focused on the breast cancer issue, but that is
2011 not the only area where you have made recommendations. Isn't
2012 that true?

2013 Dr. {Calonge.} That is correct.

2014 The {Chairman.} How many other areas has the task force
2015 made recommendations in the last couple of years, let us say?

2016 Dr. {Calonge.} Well, our current portfolio is 105 total
2017 and we take up around 15 new or updated topics annually.

2018 The {Chairman.} You have recommended that teenagers be
2019 screened for mental illness?

2020 Dr. {Calonge.} Yes, that was a new recommendation this
2021 year, Congressman, that we just came out with, so this is new
2022 services that have not been recommended prior.

2023 The {Chairman.} And there was a breast feeding
2024 behavioral intervention recommendation?

2025 Dr. {Calonge.} That is correct.

2026 The {Chairman.} And you have had a recommendation that
2027 aspirin for the prevention of cardiovascular disease be a way
2028 to prevent the disease. Is that right?

2029 Dr. {Calonge.} That is correct.

2030 The {Chairman.} So you have had a whole range. You say
2031 how many, 103?

2032 Dr. {Calonge.} A hundred and five total.

2033 The {Chairman.} A hundred and five total. I am
2034 assuming that none of the others have been as controversial
2035 as this particular one.

2036 Dr. {Calonge.} That is correct.

2037 The {Chairman.} So we have a controversial issue
2038 because it challenges the accepted notion about the frequency
2039 of breast cancer screening and we are going to hear a lot
2040 more about that from the next panel. But I want to have us
2041 look at the challenges being raised by some of the
2042 Republicans, which I think is all political. They are acting
2043 as if your recommendations based on bringing the scientists

2044 who have the expertise which are directed at clinical people
2045 will be used to ration care. That is their argument: we are
2046 going to ration care. And then they say well, that is
2047 because there is going to be a health care bill that will
2048 provide a requirement for minimum benefits. Now, there will
2049 be minimum benefits in that it should have access to
2050 hospitals, it should have access to doctors, have access to
2051 pharmaceuticals. Your area is in the preventive area and
2052 nothing could be more important to me than having the latest
2053 science on how to prevent diseases, because if we can prevent
2054 illnesses, we won't have to treat them later. Your task
2055 force will continue in operation. You will convene the
2056 scientists who are experts in different areas of prevention.

2057 Now, I guess the question, I am not raising this to you
2058 but the question is, how will your recommendations affect the
2059 minimum benefits that will be required for health care
2060 insurers? Health care insurers could be a public insurance,
2061 if that survives in this legislation process. It certainly
2062 would be private insurance. Right now private insurance
2063 doesn't have to abide by your recommendations. Isn't that
2064 true?

2065 Dr. {Calonge.} That is correct.

2066 The {Chairman.} And some of them cover these preventive
2067 services and some of them don't. Isn't that true?

2068 Dr. {Calonge.} That is correct as well.

2069 The {Chairman.} It is their decision. But if we are
2070 going to provide subsidies for people to get insurance and we
2071 are going to try to get a market where insurance companies
2072 compete against each other based on price and quality, we
2073 ought to make sure that all of them provide at least a
2074 minimum set of benefits. One of the star issues for
2075 Republicans is to have a lot of insurance plans that don't
2076 provide any minimum benefit at all. They can be cheaper if
2077 they don't provide minimum benefits. Well, I find that
2078 troubling. But let us say we are going to have minimum
2079 benefits and you make a recommendation. Is your
2080 recommendation under the proposed bill automatically going to
2081 be in effect for all insurance? Do you know whether that to
2082 be the case?

2083 Dr. {Calonge.} Congressman, I am not well--

2084 The {Chairman.} You are not an expert on the bill.

2085 Dr. {Calonge.} That is correct.

2086 The {Chairman.} But let me explain what the bill will
2087 do. The new bill will take your recommendations. They will
2088 go to the Secretary. The Secretary will review them. The
2089 Secretary will have a notice of rule and comment and a public
2090 process and then decide whether that is a minimum benefit.
2091 Now, a minimum benefit is a minimum benefit. It is not a

2092 maximum benefit. So if there is a recommendation as you
2093 proposed on breast cancer screening, that will be not a
2094 requirement of insurance to do no more than that, it will be
2095 a recommendation that will require insurance companies to do
2096 that as a floor, not a ceiling. I just wanted to set this
2097 out because I think some people watching this hearing may get
2098 confused when they hear stories about bureaucrats or
2099 rationing care or the health care bill being a gateway to
2100 single payer. We expect a bill with competition and people
2101 to make choices between insurance plans but we don't want the
2102 choices between insurance plans to be those that cover breast
2103 cancer screening and those who don't, but those are at least
2104 a minimum of preventive services that we can hope will
2105 prevent diseases and need for paying for care for those
2106 diseases.

2107 Thank you, Mr. Chairman.

2108 Mr. {Pallone.} Thank you, Chairman Waxman.

2109 Next is the gentleman from Texas, Mr. Burgess.

2110 Dr. {Burgess.} Thank you, Mr. Chairman.

2111 Let me ask you a question. I have got the clinical
2112 guidelines, and I guess this is a reprint from the Annals of
2113 Internal Medicine, the last page of which is an appendix
2114 which lists the members of the U.S. Preventive Services Task
2115 Force, and a number of individuals are listed there. Their

2116 specialties are not. Is anyone on the list there a board-
2117 certified OB/GYN?

2118 Dr. {Petitti.} Yes, there are two board-certified
2119 OB/GYNs on the task force, and that is a usual--we usually
2120 have two.

2121 Dr. {Burgess.} Which are those two that are on the list
2122 that I have in front of me?

2123 Dr. {Petitti.} Kimberly Gregory and Wanda Nicholson.

2124 Dr. {Burgess.} And they both participated in this
2125 decision?

2126 Dr. {Petitti.} Kimberly Gregory was on the task force
2127 when this decision was voted; Wanda was not. There was
2128 another OB/GYN on the task force when this topic was voted.
2129 That was George Siwaya, who is a professor of OB/GYN at
2130 University of California-San Francisco.

2131 Dr. {Burgess.} Were these unanimous votes?

2132 Dr. {Petitti.} No, the votes were not unanimous.

2133 Dr. {Burgess.} Do we know how the individuals voted?

2134 Dr. {Petitti.} I can't recall. That is in the record,
2135 and we could make that information available to the committee
2136 if that is important.

2137 Dr. {Burgess.} I would like to see it. I don't know if
2138 the committee will deem it as important, but I would
2139 certainly appreciate the opportunity to see it.

2140 Now, is there a radiologist in this group?

2141 Dr. {Petitti.} No, there is no radiologist in this
2142 group.

2143 Dr. {Burgess.} Is that a problem?

2144 Dr. {Petitti.} The expertise of this panel has been
2145 called into question. The experts are individuals who have
2146 experience in screening science and prevention. Radiologists
2147 were consulted and reviewed the documents and the
2148 recommendations and provided input.

2149 Dr. {Burgess.} On this task force, the majority of
2150 these individuals were primary care doctors. Was there a
2151 general surgeon on the task force?

2152 Dr. {Petitti.} Well, again, the experts are experts in
2153 primary care and prevention, and yes, there were, and I would
2154 have to count them, four primary care physicians on the task
2155 force currently and four at the time that these were voted.

2156 Dr. {Burgess.} But was there a general surgeon who
2157 specializes in--

2158 Dr. {Petitti.} No, there was no--

2159 Dr. {Burgess.} --needle localization and breast biopsy?

2160 Dr. {Petitti.} No, there wasn't. They were consulted.

2161 Dr. {Burgess.} They were consulted. All right. And I
2162 apologize for being in and out but we are doing nine
2163 simultaneous hearings today and the financial services

2164 makeover requires some attention and thought as well. On the
2165 issue, though of talking about--you said you factored in the
2166 psychological events surrounding a callback on a positive
2167 mammogram. You factored in the psychological cost, if you
2168 will, to the patient in that exchange. Do I understand that
2169 correctly?

2170 Dr. {Petitti.} Well, the issue was a qualitative
2171 assessment. Anxiety, psychological distress, inconvenience
2172 are all considered to be harms and potential harms, and
2173 again, it is a part of the net benefit equation.

2174 Dr. {Burgess.} When I was in school back in the 1970s, I
2175 realize it was a long time ago, but mammographic screening
2176 was not, at least in the area that I went to school, that was
2177 not something that was done. You sent someone for a
2178 mammogram, it was kind of a big deal because you felt
2179 something, but it wasn't done as just part of a routine
2180 screening. In fact, I don't think, as I recall looking back,
2181 it was probably the mid-1980s when that became a standardized
2182 screening test, and in fact in Texas, I don't know whether
2183 this is true nationwide but in Texas I know women can self-
2184 refer for mammography. When that all happened, that
2185 psychological cost was one of the arguments that was used by
2186 people who felt that routine screening would not be a good
2187 idea. So how is it that we have come to the point now where

2188 we rejected it back in the 1980s but now in 2009 this is a
2189 factor again that is worthy of our consideration?

2190 Dr. {Petitti.} Again, this is not determinative. It is
2191 information that we want women to know about. We want them
2192 to know how common it is. Again, the false positive rate is
2193 much lower as women get older and that is part of the net
2194 risk benefit equation. We would not want women to be afraid
2195 of having mammography. This is again one piece of
2196 information that women and their physicians should discuss
2197 when decided when to start screening.

2198 Dr. {Burgess.} And does that same rationale apply to
2199 self-examination?

2200 Dr. {Petitti.} The task force recommended against
2201 clinicians teaching women breast self-examination. They did
2202 not recommend that women not pay attention to their bodies,
2203 that they ignore lumps or that they ignore problems that
2204 might come up when they find a lump. Again, the task force
2205 recommendation was against doctors teaching women breast
2206 self-examination.

2207 Dr. {Burgess.} Well, how are women supposed to get that
2208 knowledge? If they can't just get it by intuition, someone
2209 along the line has got to provide them some guidelines on
2210 proper time to do the exam and how to do it and what to be
2211 concerned about and what not to be concerned about. As I

2212 recall, and I may be wrong on this but I don't ever recall
2213 coding and being compensated for teaching breast self-exams
2214 so it is not a--I mean, I wasn't a cost center for you. I
2215 wasn't a cost driver. My only inference from that could be
2216 that you are worried that people will find things that then
2217 lead to procedures and we are better off if we don't ask,
2218 don't tell.

2219 Dr. {Petitti.} Again, the evidence--there have been two
2220 very well-conducted randomized clinical trials in which women
2221 were taught how to do breast self-examination and both of
2222 those trials found no overall benefit in terms of reducing
2223 mortality from breast cancer. Again, we go to the evidence.

2224 Dr. {Burgess.} Well, and I will say anecdotally--

2225 Mr. {Pallone.} The gentleman's time has expired.

2226 Dr. {Burgess.} --as I said in my opening statement, it
2227 does strike me--

2228 Mr. {Pallone.} Mr. Burgess, you are 2 minutes over.

2229 Dr. {Burgess.} It does strike me that the amount of
2230 disease--

2231 Mr. {Pallone.} Mr. Burgess.

2232 Dr. {Burgess.} --the amount of disease that was brought
2233 to my attention by the patient herself, and again--

2234 Mr. {Pallone.} Dr. Burgess, your time has expired.

2235 Dr. {Burgess.} I will just be interested in what some

2236 of the other clinicians tell us when they get their chance to
2237 testify. Thank you, Chairman.

2238 Mr. {Pallone.} Dr. Burgess, you are almost 3 minutes
2239 over and we are about to vote.

2240 I think we have time for one more set of questions and
2241 then we are going to vote. We have five votes. We will take
2242 one more set of questions and then we will adjourn and come
2243 back after the five votes. Next is--Chairman Dingell, did
2244 you want to proceed now?

2245 Mr. {Dingell.} I think I can proceed rather quickly,
2246 Mr. Chairman. Yes, please.

2247 I would like to welcome you both to the committee and
2248 tell you how helpful it is to have you here. From the things
2249 I have heard said on the other side of the aisle about you
2250 folks at the agency, I was afraid you would appear with
2251 horns, tail, fangs and in a red suit breathing fire demanding
2252 that we immediately terminate all health benefits for the
2253 unfortunate, sick, weak, poor and especially with regard to
2254 mammograms and Pap smears. So I am very much comforted and I
2255 want to welcome you to the committee this morning.

2256 I just have really one question that I think is
2257 important. I find it curious that the task force has
2258 repeatedly over the years voted to leave costs out of its
2259 deliberations on whether to provide or not approved

2260 preventive service. Why?

2261 Dr. {Calonge.} Thank you, Congressman. I think this is
2262 a key question. The task force believes its major charge
2263 from Congress and responsibility to primary care clinicians
2264 and patients is that we set the evidence-based stake in the
2265 ground immune from how much it costs to achieve the benefits
2266 associated with a given effective preventive service. So--

2267 Mr. {Dingell.} So your short answer is, that you are
2268 recommending the needed services, the needed tests, the
2269 needed treatments as opposed to looking at the cost. Is that
2270 it?

2271 Dr. {Calonge.} That is correct.

2272 Mr. {Dingell.} Okay. Now, to assist my colleagues on
2273 the other side of the aisle, and I do this out of great
2274 affection and respect and charity, you address this question
2275 in your statement and you say here, and I will read this for
2276 the benefit of my colleagues on the other side, you say,
2277 ``Task force recommendations are based on consideration of
2278 the health benefits and health harms of providing the
2279 preventive service and on the scientific certainty of whether
2280 the preventive service works. Cost effectiveness of specific
2281 prevention services are not addressed by the task force in
2282 its deliberation.'' Then you say this: ``The task force
2283 only--'' and that is underlined ``considers scientific

2284 evidence of health benefits and health harms. The task force
2285 has specifically discussed whether cost should influence a
2286 recommendation and has repeatedly voted to leave costs out of
2287 deliberations on whether or not to provide a preventive
2288 service.' ' Is that right?

2289 Dr. {Calonge.} That is correct.

2290 Mr. {Dingell.} Now, when your recommendations are made,
2291 are they used to put a ceiling on benefits or are they used
2292 to describe a minimum level of benefits that people should
2293 get?

2294 Dr. {Calonge.} Congressman, I must admit that it is
2295 outside of the scope of our recommendations how they are used
2296 by other entities.

2297 Mr. {Dingell.} Okay. Now, your recommendations are not
2298 expected to be substituted for the need of the patient or the
2299 concerns and expertise of the doctor, and they are not
2300 intended to intrude into the doctor-patient relationship. Am
2301 I correct in that interpretation or am I wrong?

2302 Dr. {Calonge.} That is correct. In fact, if you read
2303 our statement that is published in the annals, it says, ``The
2304 task force recognizes the clinical or policy decisions
2305 involve more considerations than this body of evidence alone.
2306 Clinicians should understand the evidence and individualized
2307 decision-making to the specific patient or situation.' ' This

2308 actually precedes all recommendations. It is a
2309 recommendation statement that we expect clinicians to do what
2310 they are trained to do in order to address the needs of the
2311 individual patient for his or her best interest.

2312 Mr. {Dingell.} Now, you do permit as the task force
2313 goes about its business to have different agencies and
2314 persons of concern present in the deliberations. Is that not
2315 so?

2316 Dr. {Calonge.} That is correct.

2317 Mr. {Dingell.} And your deliberations are public?

2318 Dr. {Calonge.} At this point, the deliberations of a
2319 task force vote are by invitation only.

2320 Mr. {Dingell.} By invitation, but you don't gag the
2321 people who come in to listen. They can go out and say what
2322 is going on and they also are permitted to make comments to
2323 you on the task force. Is that not so?

2324 Dr. {Calonge.} We actually invite comments from our
2325 partners to help us do our job better and to take into
2326 consideration different viewpoints and different issues.

2327 Mr. {Dingell.} And you allow citizen input?

2328 Dr. {Calonge.} The task force is currently moving
2329 towards increased private-citizen input with the resource we
2330 have available to consider and identify those. We have prior
2331 to this time done more with input through specific groups

2332 that we invite to comment because we think they are important
2333 stakeholders. This is an issue that the task force believes
2334 that in the interests of enhanced transparency and
2335 responsibility to the American public and the patients whose
2336 physicians may consider our recommendation needs to be
2337 improved.

2338 Mr. {Dingell.} Thank you, Mr. Chairman.

2339 Mr. {Pallone.} Thank you, Chairman Dingell.

2340 We have five votes, I would say about an hour, but when
2341 they are done we will come back and reconvene. The committee
2342 stands in recess.

2343 [Recess.]

2344 Mr. {Pallone.} Thank you both for being here. We now
2345 go to a Republican member, Mr. Gingrey.

2346 Dr. {Gingrey.} Mr. Chairman, thank you, and I thank the
2347 witnesses.

2348 My first question kind of pertains to what Dr. Burgess,
2349 Dr. Petitti, was asking you a little bit earlier about how
2350 many OB/GYNs there currently are on the task force. I wanted
2351 to specifically ask you though how many GYN oncologists serve
2352 as members of the task force when the recommendations were
2353 promulgated--GYN cancer specialists.

2354 Dr. {Petitti.} There are no GYN cancer specialists on
2355 the U.S. Preventive Services Task Force.

2356 Dr. {Gingrey.} Well, let me read to you from testimony
2357 that we are going to hear from the second panel, in fact, the
2358 president of the National Breast Cancer Coalition, Fran
2359 Visco, Attorney Fran Visco, where she states in her
2360 testimony, ``We want to note that the attacks against the
2361 makeup of the task force are misplaced. Screening is an
2362 issue of primary care. It is a health intervention for a
2363 healthy population. The experts in this area, those with the
2364 scientific training and objectivity to do the necessary
2365 analyses are primary care health professionals and
2366 methodologists such as epidemiologists and biostatisticians,
2367 not radiologists or medical oncologists.'' And I am quoting
2368 directly from her statement, which we will hear later. What
2369 is your opinion on that?

2370 Dr. {Petitti.} The task force expertise in this area
2371 was sufficient to weight the evidence that led to its
2372 recommendations. The recommendations are made by the task
2373 force with the input of a variety of other specialty groups.
2374 They are not made in a vacuum. In this case, they were
2375 submitted to, I can't remember the number of partner
2376 organizations but it was at least 10. Each of these partner
2377 organizations sent them out to experts. Those experts
2378 provided written opinions.

2379 Dr. {Gingrey.} And some of those experts then would be

2380 cancer specialists?

2381 Dr. {Petitti.} Yes.

2382 Dr. {Gingrey.} Female-cancer specialists?

2383 Dr. {Petitti.} There was--

2384 Dr. {Gingrey.} So by that response, I guess you would
2385 take exception to the comments by Ms. Visco, but we will hear
2386 from her later.

2387 Let me ask you another question. On your website--and
2388 either you or Dr. Calonge--on the USPSTF website, it clearly
2389 states that the United States Preventive Services Task Force
2390 recommends against routine screening mammography in women age
2391 40 to 49 years. Do you think that this statement could be
2392 perceived by women younger than 50 that they should not get a
2393 mammogram?

2394 Dr. {Petitti.} We need to immediately figure out how to
2395 get that statement off the website. I think it could be
2396 misconstrued. It has been misconstrued and we need to fix
2397 our website.

2398 Dr. {Gingrey.} Dr. Petitti, I thank you for that
2399 response, and I hope that you will do that. I think it is
2400 very important. I agree with you.

2401 I want to ask you, Dr. Calonge, are you aware that the
2402 Senate version of health care reform, specifically section
2403 4004, I think it is on page 1,150, that requires the

2404 Secretary of HHS to create a national prevention awareness
2405 campaign based on all of your task force recommendations,
2406 both those that you favor, the A's and B's, and those you
2407 recommend against, the C's and D's? Do you think that this
2408 national awareness campaign could be perceived by women
2409 younger than 50 that they should not get a mammogram or
2410 perform a breast self-examination?

2411 Dr. {Calonge.} I wonder, Congressman, if it would be
2412 okay if you restate your question, because the first part of
2413 it and the second part I didn't--

2414 Dr. {Gingrey.} Well, what I am saying is, in the Senate
2415 bill, if it becomes law, if that prevails, the Senate
2416 language in the conference report, it becomes law, and it
2417 specifically says, and I named the page and section, that the
2418 Secretary would require the creation of a national prevention
2419 awareness campaign, television ads, TV spots based on all the
2420 task force recommendations both those that you in favor of
2421 and those you recommend against. Don't you think or do you
2422 think this national awareness campaign could be perceived by
2423 women younger than 50 that they should not get a mammogram
2424 nor should they perform breast self-examination?

2425 Dr. {Calonge.} Thank you for the clarification,
2426 Congressman. So I can't speak specifically to the bill or to
2427 the policy. I will speak to the communication of the

2428 recommendation which we believe needs to focus on the
2429 decision to start regular biannual screening before the age
2430 of 50 should be an individual one and take patient context
2431 into account including the patient's values regarding
2432 specific benefits and harms, and so that message which I
2433 realize is preceded by the ``recommends against'' statement
2434 is one we feel communication needs to be improved and that
2435 clear message of what the task force intended needs to lead
2436 that, not follow.

2437 Dr. {Gingrey.} Thank you, Doctor.

2438 Mr. Chairman, if you will bear with me just for maybe 15
2439 seconds, I had one other point I wanted to make. The United
2440 States Preventive Services Task Force concludes that the
2441 current evidence is insufficient to assess the additional
2442 benefits and harms of clinical breast examination beyond
2443 screening mammography in women 40 years or older. That is
2444 saying that you don't recommend that the clinician, a
2445 physician, primary care physician, OB/GYN specialist, should
2446 routinely do a breast examination as part of a complete
2447 physical in her or her patients, that that has no value?

2448 Dr. {Petitti.} The evidence does not provide support
2449 for a clinician doing a clinical breast examination.

2450 Dr. {Gingrey.} Well, I thank you for that response and
2451 your honesty.

2452 Mr. Chairman, I know I have gone beyond my time. I
2453 appreciate your patience. I think that is terrible and
2454 something needs to be done about that.

2455 Mr. {Pallone.} Next is our vice chair, the gentlewoman
2456 from California, Ms. Capps.

2457 Mrs. {Capps.} Thank you, Mr. Chairman.

2458 I just want to say thank you to both of you for being
2459 here, for your excellent testimony and being among the few on
2460 Capitol Hill who apologize occasionally, and it is not a
2461 habit that we do very well so the fact that you--I wouldn't
2462 call it an apology as much as acknowledging the communication
2463 glitches that occurred perhaps, and for me, I think it was a
2464 lot of was timing, but I don't take it as a negative thing.
2465 I think we are seen as a very positive overall experience
2466 happening in our country, not to minimize the confusion that
2467 many women experience, but I think we can use it as a
2468 teachable moment. Let us put it that way. The timing of the
2469 release of the report and the debate on health care reform
2470 has been seized by many who want to detract really from the
2471 health care legislation to use your testimony in widely
2472 misconstrued ways, and I want to take a minute of my time to
2473 mention one very important distinction but it is also an
2474 important point of what the health care reform bill is, which
2475 actually will be augmenting a lot of the preventive work that

2476 you are doing because women will be able to have occasion to
2477 understand more about cancer prevention in its wider forms
2478 and their behaviors and their body changes, which are all
2479 essential. But the essential benefits package in the
2480 exchange consists of 11 benefit categories including
2481 inpatient hospital services as examples, outpatient services,
2482 maternity care, prescription drugs as well as preventive
2483 services. But with regard to preventive services, the bill
2484 says that the recommended items and services with a grade of
2485 A or B from U.S. Preventive Services Task Force shall be
2486 covered as part of the essential benefits package, a rightful
2487 designation of the importance of your studies and your
2488 recommendations, but not a conclusive piece of it, and they
2489 said this be something which we highly recommend that there
2490 be no cost sharing for this grade A and B of your
2491 recommendations. The benefits advisory committee, part of
2492 the health reform, will be able to recommend through its
2493 public standard-setting process that additional preventive
2494 services such as mammograms for women under 40 or between 40
2495 and 49 be covered without cost sharing. I mean, there is an
2496 additional recommendation that can come as part of the bcc
2497 bill. The Secretary may also approve such coverage. The
2498 essential thing here is that the benefits package, the
2499 essential benefits package is a floor, not a ceiling, and

2500 that really is important. I want the record to state that
2501 very clearly. Once the exchange goes into effect and there
2502 is real competition between private insurance plans, they may
2503 wish to offer more-attractive packages to win more, you know,
2504 coverage so it may be understood more fully as we go along
2505 this. I just wanted to make sure that is in the record.

2506 But I wanted to give you even more opportunity, both of
2507 you or one of you, to talk about what the future could hold.
2508 You see, I think this is an opportunity, a ``wow'' moment, as
2509 one of the advocate groups put it, and I want to commend all
2510 of the breast cancer advocacy groups who have brought us to a
2511 level in this country where when a set of recommendations
2512 like yours comes out, that there is a more intelligent
2513 audience receiving it, able to understand it and able to use
2514 it and to advocate even more in a wide range of ways which I
2515 think is very healthy for our country to be a part of. I am
2516 only giving you about a minute but I would like you to
2517 elaborate further on ways that your task force can
2518 communicate in the future in ways that maybe we can access
2519 and use more efficiently.

2520 Dr. {Petitti.} Well, what I thought would happen with
2521 these recommendations is that it would move the discussion
2522 more towards the notion of individualized decision making and
2523 risk stratification. What I thought is, it might initiate a

2524 dialog where we decided to work harder at finding out who
2525 really is at higher risk so we could make more tailored
2526 recommendations for screening, and among those groups that we
2527 really have ignored are African American women who--

2528 Mrs. {Capps.} Absolutely.

2529 Dr. {Petitti.} --are younger and women of Ashkenazi
2530 Jewish background, some of whom have a very high risk based
2531 strictly on their membership in this group. Again, what I
2532 thought would happen would be a move towards individualized,
2533 tailored, risk-stratified decision making and not this sort
2534 of rehashing of a bunch of old data.

2535 Mrs. {Capps.} Dr. Calonge, would you like to add
2536 anything to that? And I know I am squeezing a few more
2537 seconds. I think this is really important.

2538 Dr. {Calonge.} I want to echo the issue about
2539 individualized decision making. We hear a lot about
2540 personalized medicine and I think the basis of personalized
2541 medicine can be and should be individual based decision
2542 making, and it is really what we were hoping the language for
2543 the younger age group would start engendering, this issue
2544 about, you know, we as consumers of health care should kind
2545 of understand that every test we have and every treatment we
2546 have has both inherent risks and benefits and we should make
2547 our decisions based on understanding those and then what is

2548 important to us.

2549 Mrs. {Capps.} And that underscores the value of the
2550 work that you do in this topic and in every other topic and
2551 the importance of having educated in the area of health a
2552 population that can seize the material as well as primary
2553 care providers and others doctors, you know, use your
2554 information every single day to make the kind of informed
2555 decisions that they and their patients need to have before
2556 them. So I hope this can be the beginning.

2557 I again want to thank our chairman. This is the kind of
2558 setting, this hearing setting that is so important for us to
2559 take advantage of and use your expertise and your research
2560 and have this kind of debate, if you will, but discussion.
2561 So I thank you again for being here.

2562 Mr. {Pallone.} Thank you.

2563 Mr. Rogers.

2564 Mr. {Rogers.} Thank you for being here, and I have some
2565 quick yes or no questions if I may just to get through it.
2566 Were you familiar with the references to your task force in
2567 the bill as it was introduced in July?

2568 Dr. {Petitti.} No.

2569 Mr. {Rogers.} So you knew nothing about the over a
2570 dozen references to your task force in this bill?

2571 Dr. {Petitti.} You know, I hate to say, but I was busy

2572 preparing a course in biostatistics, and the answer is
2573 honestly no.

2574 Mr. {Rogers.} And is that consistent through the whole
2575 task force or any of its representatives or administration
2576 thereof?

2577 Dr. {Calonge.} I hesitate to have the two of us
2578 represent the opinions of all the task force.

2579 Mr. {Rogers.} But it wasn't part of your discussions?

2580 Dr. {Calonge.} In July? Absolutely not.

2581 Mr. {Rogers.} Are you aware that in this particular
2582 bill, and I think maybe our Health Committee chairman was
2583 mistaken and I think the chairman emeritus was mistaken.
2584 This is not necessarily a new committee. They may create a
2585 new name but in the bill--and I will just read right from the
2586 bill. ``The preventive services task force convened under
2587 section 915A of the Public Health Service Act and the Task
2588 Force on Community Preventive Services, and then in quotation
2589 marks ''as such section task forces were in existence the day
2590 before the day of the enactment of this Act shall be
2591 transferred to the Task Force on Clinical Preventive Services
2592 and the Task Force on Community Preventive Services,
2593 respectively, established under these sections,'' And then
2594 it goes on to say that whatever your recommendations were
2595 prior to that enactment are in effect. Are you aware of

2596 that, sir or ma'am?

2597 Dr. {Petitti.} Well, certainly--

2598 Mr. {Rogers.} Yes or no. I am sorry.

2599 Dr. {Petitti.} Yes, I am now aware of it.

2600 Mr. {Rogers.} But were you aware of that during your
2601 deliberations?

2602 Dr. {Petitti.} No.

2603 Mr. {Rogers.} Would that have changed your
2604 deliberations at all?

2605 Dr. {Petitti.} I can't speculate on what might have
2606 happened.

2607 Mr. {Rogers.} Interesting. So what you are saying is
2608 that according to the law of which this committee wants to
2609 enact you have now taken ages 40 to 49 and made them a
2610 category C which means they will not be paid for under this
2611 committee. That is interesting.

2612 Now, let me ask you this. You say you didn't consider
2613 cost. Is every appendix that is attached to your task force
2614 recommendation, is that something that would have been
2615 reviewed by the individuals who made the determination? Is
2616 that something of value? That is why you attached it as an
2617 appendix, I imagine?

2618 Dr. {Petitti.} Yes, all the material and evidence is
2619 germane to the--

2620 Mr. {Rogers.} Thank you very much. Are you familiar
2621 with appendix C1 where the question is, what is the cost
2622 effectiveness of screening, that assigns a dollar value by
2623 quality of years of life? Are you familiar with this? This
2624 clearly is a cost-effectiveness portion of your study.
2625 Clearly you cannot in good conscience tell this committee you
2626 didn't consider cost. You just told me that every piece of
2627 information according to your study is considered. This is a
2628 dollar value per quality of life and it is done on
2629 mammography screenings.

2630 Dr. {Petitti.} The committee--

2631 Mr. {Rogers.} Will you remove this from your task force
2632 study as well as your recommendation that said--

2633 Dr. {Petitti.} I am sorry but I am trying to see what
2634 you are pointing at, and I--

2635 Mr. {Rogers.} It is appendix C1 of your own task force
2636 recommendation that clearly, clearly considers cost just by
2637 your own testimony, and again, you can see why women of
2638 America and those of us who are very concerned about
2639 bureaucracies interacting between health care. On your
2640 website again you say that you recommend against routine
2641 screening. You say that are going to take that off. That is
2642 great. You say that gee, we didn't consider cost but on your
2643 own report it says you considered costs. You can see why

2644 after we are creating 118 brand-new commissions just like
2645 yours all of your authority will now be enacted into law
2646 according to their own bill by the reference I have just
2647 read. I mean, it is pretty serious.

2648 And let me ask you another question. As a part of
2649 this, it says, and I am going to read this again from the
2650 bill because I think some of my members on the other side
2651 maybe either haven't read the bill or maybe misunderstand
2652 their own language, but even under the--this is the Indian
2653 health care section, section 206, I would encourage you to
2654 read it, under mammography and other cancer screening, ``The
2655 Secretary shall ensure that screening provided for under this
2656 paragraph complies,`` meaning you have got to do it ``with
2657 the recommendations of the task force with respect to, A,
2658 frequency, B, the population to be served, and C, the
2659 procedure or technology to be used,`` all of which is
2660 referenced in your report. Imagine that when this passes
2661 your report now becomes a matter of law according to their
2662 own language in this bill right here. Would that change your
2663 consideration as a scientist knowing by your own testimony it
2664 did not pass unanimously? You say science and evidence but
2665 clearly people equally learned as both of you believe that
2666 that was the wrong answer? Is this something you should
2667 reconsider?

2668 Mr. {Pallone.} Mr. Rogers--

2669 Mr. {Rogers.} I would like an answer to my question.

2670 Mr. {Pallone.} No, I know, but I am going to ask you to
2671 go beyond that. I mean, you used your 5 minutes. Take what
2672 time is necessary to respond because I am not sure you even
2673 know what the questions are, but please take your time.

2674 Dr. {Petitti.} I was going to say that.

2675 Mr. {Roger.} I got my yes and no's.

2676 Dr. {Petitti.} There were a number of different
2677 questions and I am not sure which one to respond to. What I
2678 would like to say, and I want to say it again on the record,
2679 that when we voted for the recommendations for mammography
2680 screening A, B and C, we voted them without regard to cost or
2681 cost-effectiveness analysis. I can say honestly, absolutely,
2682 the word ``cost'' was not in the room. It was not mentioned.
2683 It was not uttered and it did not in any way determine--

2684 Mr. {Rogers.} But it was part of your study, was it
2685 not? Was it not part of your study? You just told me that
2686 everything that was in your study was considered. Appendix
2687 C1 considers cost. How could you--

2688 Mr. {Pallone.} Mr. Rogers' time is up, but you can
2689 respond and say what you want but we have got to move on.

2690 Mr. {Rogers.} I have more questions, Mr. Chairman, if
2691 you would like.

2692 Dr. {Petitti.} I have nothing more to say.

2693 Mr. {Pallone.} Mr. Rogers, I am just trying to make
2694 sure she is able to respond, but I think we should move on
2695 because we are a minute over now and she doesn't want to say
2696 anything else.

2697 Mr. {Rogers.} Well, Mr. Chairman, my only caution here
2698 is that--and I--

2699 Mr. {Pallone.} I understand what you are--

2700 Mr. {Rogers.} No, I do believe the intention of the
2701 other side is real. I do believe that. But the language of
2702 the bill of which I believe that most Members of Congress
2703 have not read--

2704 Mr. {Pallone.} But she has repeatedly said that the
2705 bill--she didn't even know what was in the bill and their
2706 deliberations were done under the previous Administration
2707 before President Obama was even President of the United
2708 States, so--

2709 Mr. {Rogers.} But, Mr. Chairman, the point here is that
2710 she did say that cost wasn't part of their voting but it
2711 certainly was part of their report. That is very important
2712 knowledge for all of us to know when we raise questions about
2713 adding--when you--

2714 Mr. {Pallone.} You made your statement. She responded
2715 to it. Let us move on. I can't help but repeat that their

2716 deliberations, as I said, even preceded the current
2717 Administration. But whatever, let us move on.

2718 Next on the Democratic side is the gentlewoman from the
2719 Virgin Islands, Ms. Christensen.

2720 Mrs. {Christensen.} Thank you for your presentations
2721 and your answers thus far. I want to go back to the issue of
2722 African American women. Some years ago, many of us worked to
2723 ensure that mammograms be recommended and covered for women
2724 of African descent under age 40, and given that even though
2725 we may have a lower breast cancer incidence, we are more than
2726 likely to be diagnosed at later stages and have a higher
2727 mortality rate, and even in younger women, we find that
2728 younger African American women are more likely to be
2729 diagnosed with breast cancer. So in the recommendations, why
2730 wouldn't the task force single out this particular group and
2731 maybe give them a different recommendation rather than
2732 lumping all women between 40 and 49 or younger under C or I?

2733 Dr. {Petitti.} You make an excellent point, and I think
2734 again what I expected to happen with these recommendations is
2735 that we would begin to focus on how to make more stratified
2736 and nuanced recommendations that would identify those groups
2737 who are unrecognized as being at higher risk of consequences
2738 of breast cancer when diagnosed at a young age.

2739 Mrs. {Christensen.} So even though the bill says in the

2740 Indian Health Service that your recommendations would be
2741 applied, you might look at the Native American population as
2742 a group and decide maybe a different grade for different age
2743 groups in that particular age group and make that
2744 recommendation. Might that not happen?

2745 Dr. {Petitti.} Yes. I think that the accompanying
2746 editorial to our recommendations pointed the direction that
2747 we thought we would be going, you know, not in Congress
2748 trying to defend them but moving to the point where we have
2749 more individualized risk, and I would say that based on my
2750 understanding of the science, which I follow very closely,
2751 that breast cancer in young African American women is a topic
2752 which is not widely appreciated as being one which perhaps
2753 needs a different kind of recommendation. Again, we need to
2754 do better at the risk stratification and individualized risk.
2755 I can't say the task force will immediately be able to go
2756 back and--

2757 Mrs. {Christensen.} I understand, but you recognize it,
2758 and this is not the final answer?

2759 Dr. {Petitti.} This is definitely not the final answer.
2760 I think people would have wished that we would have not even
2761 ever opened this topic again after 2002.

2762 Mrs. {Christensen.} Especially not right now.

2763 Dr. {Petitti.} That was an accident.

2764 Mrs. {Christensen.} But given what occurred in response
2765 to the article and the press taking it up and how it has been
2766 interpreted, have you looked at other ways of presenting
2767 recommendations that might be controversial? I have never
2768 really liked the fact that the press really gets these
2769 advance notices and they start to tell us what is coming up
2770 in the medical journal because they don't really understand
2771 it.

2772 Dr. {Petitti.} Well, we communicated very poorly. We
2773 should have spent more time talking with our stakeholder
2774 groups. We should have had a formal communication plan both
2775 to consumers and physicians.

2776 Mrs. {Christensen.} I agree. Can you explain how the
2777 overdiagnosis--it is a bit confusing but can you explain how
2778 overdiagnosis occurs when DCIS or early-stage lesions,
2779 especially in younger individuals is diagnosed and treated?
2780 Because my understanding on the DCIS is that it is likely a
2781 precursor to invasive cancer, so is the task force that it
2782 might be better to not diagnose it or if you think it is
2783 there to leave it alone and not do further investigation or
2784 remove it? Because I would think--anxiety is one of the
2785 issues that you raised. I would think it would be more
2786 anxiety provoking to think that I had a CA in situ or early-
2787 stage cancer and sit and wait on it rather than to have it

2788 biopsied and removed.

2789 Dr. {Petitti.} Well, here we are definitely getting way
2790 out of my range of expertise. This is a topic which I would
2791 want to have addressed by a medical oncologist and those who
2792 are now working so hard to try to understand better how we
2793 separate and differentiate those tumors that are going to
2794 progress rapidly and those tumors that aren't going to
2795 progress, but this is outside my area of expertise.

2796 Mrs. {Christensen.} Well, speaking to surgical
2797 oncologists actually yesterday, they feel that DCIS is many
2798 times a precursor to invasive cancer and I am surprised that
2799 it is listed as one of those things that maybe we are
2800 overdiagnosing or overtreating, but I think my time is up, so
2801 thank you for your answers.

2802 Mr. {Pallone.} The gentleman from Arizona, Mr. Shadegg.

2803 Mr. {Shadegg.} I thank you, Mr. Chairman.

2804 First, I have to express some sympathy for you. You
2805 have stepped into a controversy which has been made much
2806 larger as a result of the overall health care reform that is
2807 going forward, and I think that to a certain degree you have
2808 been sucked into a much larger battle than your own efforts
2809 to try to make recommendations would have otherwise merited.

2810 As I understand your recommendation, you base it on
2811 science and you say look, here is what we have concluded

2812 based on that science, it shouldn't be automatic, it ought to
2813 be something you think through and here is our
2814 recommendations. That makes a lot of sense to me. I presume
2815 from that you believe that it should be a decision between
2816 the patient and her doctor and that, for example, if a
2817 particular patient had a history of cancer or breast cancer,
2818 then you might get screening at a younger age, or in some of
2819 the categories where you didn't feel it should be automatic
2820 but under those circumstances it should occur. Is that
2821 correct?

2822 Dr. {Petitti.} Yes, that is correct.

2823 Mr. {Shadegg.} Okay. You would then agree with me that
2824 if the government were to prohibit an insurance plan from
2825 providing coverage for someone who after consulting with
2826 their doctor or looking at their family history thought she
2827 needed it, that would make that at least not an insurable
2828 event, correct?

2829 Dr. {Petitti.} I am not here to get involved in the
2830 coverage and health care reform coverage issue.

2831 Mr. {Shadegg.} Fair enough. I will just then state for
2832 the record that in my view, the government should never
2833 prohibit someone and the government should never able to
2834 prohibit someone from offering mammogram coverage or as an
2835 insurance company or a public plan nor should it be able to

2836 prohibit an individual women or her family from deciding they
2837 want to purchase mammogram coverage, and I am deeply troubled
2838 that this bill, which seems to be the larger context into
2839 which your work has been reported, does precisely that.

2840 I do want to say that it is important, Mr. Chairman,
2841 that facts be abided by and unfortunately, in a piece of
2842 legislation this size, it is subject to interpretation and it
2843 is subject to quick review without people being very precise
2844 in their language. I want to make it very clear, I mean no
2845 personal offense by this by there have been things stated in
2846 this room today that are flat untrue. For example, the
2847 chairman said that if a C option--you have your A and your B
2848 and now a C--is determined by the Secretary to be covered, it
2849 is to be covered. That is in fact flat not true. The only
2850 way a C option can be covered under the language of this bill
2851 is for two things to happen. First, the Health Benefits
2852 Advisory Committee has to say contrary to what the bill says
2853 we think it should be covered, and then the Secretary has to
2854 say it. So it not a single decision by the Secretary.

2855 Second, and I am sorry he is not here but the chairman
2856 of the full committee came and made an adamant argument,
2857 which has been repeated several times here today, that the
2858 bill prescribes minimum benefits and therefore to say that
2859 coverage of mammograms is not prohibited is untrue, that all

2860 the bill does is prescribe minimums. That also is flat not
2861 true. If you go to page 169 of the bill passed by the
2862 Congress, you will discover, as I mentioned earlier, that
2863 there are four levels of plans. There is a basic plan, an
2864 enhanced plan, a premium plan and a premium plus plan. The
2865 basic plan can only cover A's and B's, the things you
2866 recommend be an A or a B. It could cover a C if the two
2867 exceptions I just pointed out were to occur. But the basic
2868 plan absent those things happening does not cover anything
2869 but A's and B's, but more important than that, the definition
2870 of enhanced plan and the definition of premium plan both
2871 prohibit any additional benefits. They say you can have an
2872 enhanced plan and you can have lower cost sharing. You can
2873 have a premium plan and it can have lower cost sharing but it
2874 can only cover the basic services. So all three of the first
2875 levels of plans are prohibited from covering any service
2876 other than an A or a B. Only until you get the definition of
2877 a premium plus plan, and I would point the chairman of the
2878 full committee to page 169, lines 20 through 25, does it say
2879 a premium plus plan is a premium plan that also provides
2880 additional benefits. That is the only plan that can provide
2881 a benefit beyond the basic plan, and therefore the first
2882 three levels of plans are prohibited from covering mammograms
2883 by law whether they are offered by the government or offered

2884 by a private insurance company. Whether they are in the
2885 public plan or in a private plan, they are prohibited, and
2886 that may not be the intent. As the ranking member, Mr.
2887 Barton, made very clear, we need to deal not with what the--
2888 we need to deal with what the bill says and if it does not
2889 reflect our intent, and I would hope in this case it doesn't,
2890 because I don't think the government ought to be in the
2891 business of telling people you cannot buy coverage for
2892 mammograms. Then we need to fix the language of the bill or
2893 at least talk truthfully about it, and the chairman of the
2894 full committee was wrong when he said that this sets only
2895 minimums. There are words at the beginning of the bill which
2896 refer to minimums but the words of the bill specifically say
2897 it can only cover those items with the exception of when both
2898 the Secretary and the Health Benefits Advisory Committee
2899 decide to cover a C, and I appreciate the opportunity to put
2900 that into the record. Thank you, Mr. Chairman.

2901 Mr. {Pallone.} Thank you. I don't want to keep
2902 belaboring the point but the reason I responded to your
2903 statement and said that there were situations where the
2904 Secretary, and now you are saying advisory commission could
2905 add it to a basic benefit package was because when you made
2906 your opening statement you suggested that it couldn't be done
2907 that way, that they couldn't include it. So I don't want to

2908 belabor the point. I don't disagree with you but you are
2909 disagreeing with yourself because you initially said that
2910 they couldn't add it as a basic benefit, and now you are
2911 saying they can.

2912 Mr. {Shadegg.} If the gentleman would yield?

2913 Mr. {Pallone.} Sure.

2914 Mr. {Shadegg.} I actually didn't say they couldn't add
2915 it. I didn't discuss whether they could add it. I said that
2916 the basic plan cannot offer it, and it cannot offer it absent
2917 extraordinary circumstances, which are two other things.

2918 Mr. {Pallone.} See, I think--

2919 Mr. {Shadegg.} And I think what we are--

2920 Mr. {Pallone.} I think the problem is, we are saying
2921 the same thing but I am not going to get into it. I don't
2922 think there is any difference between what you said and what
2923 I said.

2924 Mr. {Shadegg.} Let us agree on that, but let us agree
2925 to fix it so that the bill doesn't say that someone cannot
2926 choose to buy a plan--for that matter, let us allow people
2927 who get a public plan to get mammogram coverage.

2928 Mr. {Pallone.} I am not going to continue to belabor it
2929 because I think that we are not necessarily disagreeing on
2930 whether it could or could not be included.

2931 The next person is the gentlewoman from Florida, Ms.

2932 Castor.

2933 Ms. {Castor.} Thank you, Mr. Chairman, and thank you
2934 very much for your testimony today. I believe the larger
2935 issue is the lack of access to any screening or health
2936 service for millions of American women of all ages, and I
2937 would like you to comment upon the implications of your
2938 latest recommendations on the millions of women who are not
2939 being screened at all. What do you say to them no matter
2940 their age?

2941 Dr. {Petitti.} You know, again, the task force can't
2942 fix these problems. I am here as a member of the task force
2943 speaking to mammography guidelines and speaking to the
2944 evidence we used to make them. There are clearly huge issues
2945 facing this country about health care and health insurance
2946 and health policy but I am not an expert in that area.

2947 Dr. {Calonge.} If I could just add to the point that it
2948 is clear that the provision of mammography and screening for
2949 breast cancer extends life, and so that is the service that
2950 we recommend, and I think everyone in the room knows that and
2951 needs to keep in mind that if the idea is to maximize health
2952 and extend life, then the services that are recommended
2953 should be considered for provision.

2954 Ms. {Castor.} I mean, your recommendations talk about
2955 how, for example, the age 40 to 49, how it is important for

2956 women and their doctors to have a personalized plan with
2957 their trusted physician but there are many, many women out
2958 there who don't have a trusted physician, they don't have--
2959 they are not receiving their checkups. Certainly you all
2960 have something to say to women all across America no matter
2961 their age on being as proactive as they can in taking
2962 personal responsibility, finding--you must have something to
2963 say on higher risk groups to help us communicate in a better
2964 way. You have already acknowledged that you did not do the
2965 job in communication but here is your chance today to bring
2966 all of your expertise and to provide a message to women on
2967 the importance of taking personal responsibility and getting
2968 their screenings. They may not have access to care but there
2969 are wonderful nonprofit groups where they provide some
2970 services in communities. Can you at least go that far and
2971 provide a proactive message to women in this country on the
2972 importance of taking care of themselves and seeking out these
2973 screenings?

2974 Dr. {Petitti.} Well, again, I feel uncomfortable in
2975 being asked to put on a personal hat rather than my task
2976 force hat. I would be remiss if I didn't encourage women to
2977 be interested in their health, to take care of themselves,
2978 but I am here as a member of task force to speak to the
2979 mammography guideline recommendations and not to go beyond my

2980 expertise. I have friends who have no insurance. My
2981 daughter is uninsured. I know women who are uninsured who
2982 can't get surgeries they need. But that is not my role here.
2983 My role here is to speak to the mammography guidelines.

2984 Ms. {Castor.} You are familiar with the huge
2985 disparities in screening, diagnosis and treatment among
2986 various income levels and if you are African American, you
2987 are a Latina, correct?

2988 Dr. {Petitti.} There are disparities in health care
2989 throughout all services.

2990 Ms. {Castor.} If you could go back or will you go back
2991 and review your recommendations along the lines of higher
2992 risk groups, what we know in disparities of screening,
2993 diagnosis and treatment? Don't you think you could have done
2994 a better job in fleshing out some of those recommendations?

2995 Dr. {Petitti.} I think on many levels we know we could
2996 do a better job and among them is communication. We need to-
2997 -we have tried for a number of years to make our
2998 recommendations more risk stratified. For breast cancer,
2999 this has been perhaps a little more difficult than for some
3000 other topics like osteoporosis, but again, what I thought
3001 would happen with these recommendations is we would start
3002 having exactly this kind of discussion: how do we find women
3003 who are extremely high risk, how do we communicate with them

3004 effectively, how do we make screening mammography something
3005 that is more individualized and tailored.

3006 Ms. {Castor.} Thank you.

3007 Dr. {Calonge.} I would only add to that a plea for
3008 consideration of research of preventive services in the
3009 specific populations who are underrepresented in screening
3010 and other prevention studies. We often fail in this area,
3011 and I will inform the committee that we had a discussion
3012 about health disparities associated with nearly every
3013 recommendation vote, and the frustration on our part is the
3014 lack of evidence of efficacy in a specific trial aimed at
3015 high-risk populations. So I think this is a consideration of
3016 the task force, and as we are evidence based, this is a real
3017 plea on our part for researchers and funders of research to
3018 consider adequate studies that include disparate groups for
3019 where we are concerned there may be differences and require
3020 different recommendations.

3021 Ms. {Castor.} Thank you.

3022 Mr. {Pallone.} Is the gentlewoman complete? All right.
3023 Thanks.

3024 The gentlewoman from Tennessee, Ms. Blackburn.

3025 Mrs. {Blackburn.} Thank you, Mr. Chairman. I guess you
3026 are not used to women speaking a little more quickly and
3027 being a bit more succinct and so maybe that is why we have

3028 time left many times.

3029 I want to thank you all for your patience and your
3030 endurance today and I really want to thank you for being
3031 here. This is an issue that is of tremendous concern to us,
3032 and as we look at what your findings were and as we look at
3033 the language of the bills that are before us, I think what we
3034 want to make certain we do is, if there is offending language
3035 in the bill, we want to get it out, and of course we want to
3036 make certain that we have a clear understanding of what you
3037 brought forward and of your intent, and I am going to try to
3038 be succinct on this because I do know you are ready to move
3039 on and we have another panel. Dr. Burgess asked that you
3040 submit the vote from your committee as you arrived at your
3041 finding and your guidance that you made public, and as you
3042 submit that vote, who voted and how, one thing I would like
3043 for you to do for the record is also submit to us your
3044 science or evidence upon which you based these
3045 recommendations, what was reviewed, what studies, what
3046 findings, what groups. If we can have that as a part of the
3047 record so that we can look at it, I think that would be very
3048 instructive to us as we decide how to best move forward. So
3049 I would like to ask you all to do that.

3050 I would also like to know what period of time, how long
3051 did you spend on this? How long was this up for discussion

3052 and under review? What was the thought process and the
3053 matrix that you worked from to come to this decision? Let us
3054 see a little bit about what you went through and how you went
3055 through it and how you worked, what your process is, how you
3056 arrived at those decisions. I do honestly believe that will
3057 be helpful to us with an understanding. I will have to say I
3058 agree with some of my colleagues, you have probably stepped
3059 into a bit of a quagmire that you did not expect as you
3060 released these findings, and I would like to ask you, were
3061 you all aware of how the H.R. 3962, how it would affect you,
3062 how your task force would be drawn into that bill, that the
3063 language of 3962 actually pulls you in, renames you and then
3064 gives credence to these findings through statute?

3065 Dr. {Petitti.} Well, as unbelievable as it may seem to
3066 those who are so caught up in Washington, I was writing my
3067 biostatistics lecture and have been actually woefully and
3068 naively oblivious of what has been going on in the health
3069 care reform arena. Certainly from the point of view of
3070 specific statutory language in now what I know is a 2,000-
3071 page bill, you know, I knew nothing, and quite honestly when
3072 I found out that these recommendations were being released
3073 the week of the vote, the big vote, I was sort of stunned and
3074 then also terrified, and I think my being terrified was
3075 actually exactly the right reaction.

3076 Mrs. {Blackburn.} Dr. Calonge?

3077 Dr. {Calonge.} I would like to add again speaking
3078 specifically to the timeline for the consideration of this
3079 recommendation that it was completed prior to any sense that
3080 the role of the task force might change under upcoming health
3081 care reform. I will say that earlier this year we became
3082 aware of language in the House bill regarding the
3083 recommendations of the task force. However, this
3084 recommendation was considered and voted on with our explicit
3085 scientific methods well before that.

3086 Mrs. {Blackburn.} I appreciate that, and I do thank you
3087 all for your sensitivity to this. I think the linkage that
3088 exists with the language of changing your title and then
3089 giving credence in the force of law basically to the priority
3090 assignments that you would make is of concern to us and to
3091 our constituents. I thank you all. And I am only going to
3092 yield back 18 seconds but I yield it back, Mr. Chairman.

3093 Mr. {Pallone.} Thank you.

3094 Oh, I am sorry. The gentleman from Ohio, Mr. Space.

3095 Mr. {Space.} Thank you, Mr. Chairman.

3096 Just so I understand this correctly, the task force has
3097 been charged with developing a scientifically determined
3098 floor for preventive services in this bill. Is that your
3099 understanding of your role?

3100 Dr. {Petitti.} You know, I am realizing that I really
3101 don't understand the bill. I shouldn't speak to the bill. I
3102 have learned a lot about the bill here.

3103 Mr. {Space.} Well, the bill itself does in fact vest
3104 that kind of power with the task force to develop a
3105 scientifically determined floor, in other words, a minimum
3106 threshold under the basic coverage. Those recommendations
3107 then follow to the benefits advisory committee. Your
3108 recommendations will establish a floor under which the
3109 benefits advisory committee cannot go. They can go higher,
3110 however. Once the benefits advisory committee--and by the
3111 way, the benefits advisory committee consists of private
3112 medical doctors, patients, employers, insurance experts, a
3113 dentist and representatives of relevant government agencies.
3114 It is chaired by the surgeon general. Once it issues its
3115 recommendations, the Secretary--those recommendations then
3116 are the floor. The Secretary then has the discretion to
3117 increase or enhance the coverage available in the basic
3118 essential benefits package. Once that has been established,
3119 private insurers have the additional option of offering more
3120 coverage. So the suggestion that because your task force has
3121 issued the recommendations that it has, no insurance policies
3122 will cover mammograms for women in these categories, even the
3123 suggestion that the essential benefits package as established

3124 by this bill will not cover them is preposterous. There is
3125 no truth in it.

3126 I do have a specific question I would like to ask you
3127 regarding some confusion that your findings have created back
3128 home in my district. There was a recent letter to the editor
3129 that was very widely distributed regarding your findings that
3130 have created some confusion, and I'd ask that you try to
3131 clear this up for us. The author of this letter writes, this
3132 is a quote, ``What is most troubling about the federal
3133 panel's recommendations is that they are based mainly on cost
3134 saving.'' She also expresses concern that the
3135 recommendations are ``cost-saving measures.'' Can you tell
3136 us today in no uncertain terms what the role of cost of
3137 mammograms played in your investigation and findings?

3138 Dr. {Petitti.} This is an easy question. Cost played
3139 no role in our recommendations. Again, and I said it
3140 publicly in other settings and I will say it again here, I
3141 think I have said it three times here, cost was not a
3142 consideration in the voting of our recommendations.

3143 Mr. {Space.} Thank you. And finally, the author of
3144 that same letter pointed out that the task force contains
3145 ``no cancer specialists.'' This is obviously a point that
3146 would be disconcerting to many. Is it true that no member of
3147 the preventive task force have any experience in working with

3148 cancer?

3149 Dr. {Petitti.} That is incorrect. Members of the task
3150 force consist of myself. I was the vice chair of the
3151 National Cancer Policy Board. One member is a member of the
3152 National Cancer Institute Board of Scientific Counselors.
3153 Another member, current member is a professor of--he is the
3154 associate director of population sciences for the Dartmouth
3155 Hitchcock Comprehensive Cancer Center and an endowed chair of
3156 oncology. Again, the members of the task force have the
3157 expertise that permits them to make the kinds of
3158 recommendations they make within the arena of screening and
3159 preventive services.

3160 Mr. {Space.} Thank you, Doctor.

3161 I yield back my time.

3162 Mr. {Pallone.} Thank you.

3163 The gentleman from Texas, Mr. Green.

3164 Mr. {Green.} Thank you, Mr. Chairman, and I will be as
3165 quick as I can.

3166 I want to welcome our doctors. I guess having served on
3167 this subcommittee for 12 years now and the release from the
3168 USPSTF probably got more coverage than anything our
3169 subcommittee has done except the health care bill, and there
3170 was a lot of misinformation about it. But in your testimony
3171 you say that the individuals representing the views of the

3172 American College of Obstetricians and Gynecologists and the
3173 American Academy of Family Physicians weighed in on your
3174 recommendations and the obstetricians and gynecologists
3175 expressed concerns with the wording of the recommendations.
3176 Do you believe in the future it would be a good idea for the
3177 task force to actually have individual organizations such as
3178 these as actual reviewers instead of commenters?

3179 Dr. {Petitti.} Well, I want to clarify that they were
3180 official reviewers. First of all, as I pointed out, there
3181 were two members of the American College of Obstetrics and
3182 Gynecology on the panel. The ACOG reviewers were official
3183 reviewers. They made a number of comments. One of their
3184 comments which was the most substantive comment in retrospect
3185 was about their anticipation of misperception of our C
3186 recommendation, and they were right. And we should have
3187 listened more carefully to them and I am sure we will listen
3188 more carefully in the future.

3189 Mr. {Green.} And I think there was information I guess
3190 on the self-exam, and from your testimony earlier was that,
3191 you know, physicians need to be able to provide the expertise
3192 so women can do the self-exam, that it is not perfect. If
3193 there a question, then they ought to talk to their physician
3194 and that is where it goes from there. So that is why I don't
3195 understand the fear of the self-exam.

3196 My last question is, a major concern I have is the lack
3197 of transparency of the process within the USPSTF for deciding
3198 whether or not to change or create new screening
3199 recommendations, and depending on what happens with the
3200 health care bill, your initial decision could make a big
3201 difference. How could the task force be more open to outside
3202 input and feedback and what changes would you make in the
3203 future after what you have learned from this experience?

3204 Dr. {Calonge.} Thank you for this question. The task
3205 force understands the criticisms regarding transparency. As
3206 our profile has been increased during the discussion of
3207 health care reform, we believe it is incumbent upon us to
3208 increase our transparency in such a way that people
3209 understand as the previous Congresswoman asked how we get to
3210 the decisions that we get to. The task force is already
3211 working on new transparency approaches including allowing
3212 Internet-based public comment on different work products. We
3213 think that is a good step. We are cautiously trying to
3214 expand into areas of transparency to include potentially
3215 public commentary during meetings and other approaches that
3216 we believe meet the intent and the requirement for
3217 transparency so that the decisions are made in such a way
3218 that we are not spending time in front of the public trying
3219 to help people understand the processes. So we understand

3220 this criticism. We actually started working on enhancing
3221 transparency about a year and a half ago and I will only tell
3222 the Congressman that our slow working has to do with
3223 understanding the resource impact of becoming more
3224 transparent but we absolutely believe we need to do it and we
3225 are working towards that end.

3226 Mr. {Green.} Thank you.

3227 Thank you. Mr. Chairman.

3228 Mr. {Pallone.} Thank you, and I think that concludes
3229 our questions, but let me just thank both of you really. I
3230 think that you did a tremendous job today of clearing up a
3231 lot of misunderstandings, and as someone who has been in
3232 politics I guess I could say my entire life, I think it is
3233 kind of refreshing to find out that, you know, you really
3234 were very independent and not at all aware of what we were
3235 doing. I think we gives ourselves too much importance. We
3236 all think we are all so important, that everybody is paying
3237 so much attention to everything we do. It is kind of
3238 refreshing to know that you were not. Thank you.

3239 I will ask the next panel to come forward. Let me
3240 welcome our second panel and introduce the panel beginning on
3241 my left is Dr. Otis Webb Brawley, who is chief medical
3242 officer for the American Cancer Society, and next is Jennifer
3243 Luray, who is president of the Susan G. Komen for the Cure

3244 Advocacy Alliance, and then we have Dr. Donna Sweet, who is a
3245 member of the American College of Physicians' Clinical
3246 Assessment Efficacy Subcommittee, and finally, Fran Visco,
3247 who is president of the National Breast Cancer Coalition. I
3248 know some of you have been here before and thank you for
3249 being here. I won't repeat that we ask you each to keep your
3250 comments if you can to 5 minutes. They become part of the
3251 record. And if you want to, you can submit additional
3252 written comments later.

3253 Let us start with Dr. Brawley. Thank you.

|
3254 ^STATEMENTS OF OTIS WEBB BRAWLEY, M.D., CHIEF MEDICAL
3255 OFFICER, AMERICAN CANCER SOCIETY; JENNIFER LURAY, PRESIDENT,
3256 SUSAN G. KOMEN FOR THE CURE ADVOCACY ALLIANCE; DONNA SWEET,
3257 M.D., M.A.C.P., MEMBER, AMERICAN COLLEGE OF PHYSICIANS'
3258 CLINICAL ASSESSMENT EFFICACY SUBCOMMITTEE; AND FRAN VISCO,
3259 PRESIDENT, NATIONAL BREAST CANCER COALITION

|
3260 ^STATEMENT OF OTIS WEBB BRAWLEY

3261 } Dr. {Brawley.} Good afternoon, Mr. Chairman and
3262 distinguished members of the committee. I am Otis Brawley,
3263 the chief medical officer of the American Cancer Society. On
3264 behalf of the 11 million patients and survivors in America
3265 today, the Society thanks you for your continued leadership
3266 in the fight against your cancer and your commitment to
3267 enacting comprehensive health care reform legislation this
3268 year. I appreciate the opportunity to testify today about
3269 the important role mammograms play in combating breast cancer
3270 deaths.

3271 As a medical oncologist who actually treats breast
3272 cancer patients, I have treated hundreds of breast cancer
3273 patients in my career. Indeed, I have observed firsthand the
3274 heartbreak this disease has on women and their families.

3275 Over the years I have also witnessed the advances we have
3276 made in breast cancer early detection and treatment, advances
3277 that led to fewer women suffering and ultimately dying from
3278 this dreaded disease. I can't help but note that in our
3279 current system our society prohibits a large number of women,
3280 30 to 40 percent of those who should be getting mammograms,
3281 from actually getting mammograms. I also have to note that
3282 in my own research published and cited before this committee
3283 before has shown that uninsured women of the same stage have
3284 poorer survival compared to insured women of the same stage.
3285 That is to say that even when early detected, insurance is a
3286 prognostic factor in breast cancer.

3287 Mr. Chairman, as you know, the Society in recent weeks
3288 has publicly disagreed with the recommendations of the U.S.
3289 Preventive Services Task Force with respect to mammography.
3290 Let me say right now that I have tremendous respect for the
3291 task force. As an academic physician, I look forward to
3292 virtually everything that the task force has published over
3293 the last 20 years regarding cancer. I also want to say that
3294 reasonable experts can look at the science and disagree.
3295 There is useful screening that should be done and useless
3296 screening that actually can be harmful, and that is something
3297 that the task force I think should be looking at in an
3298 objective fashion and actually has generally done a very good

3299 job of doing.

3300 With respect to mammography, the scientific evidence
3301 supporting its value in reducing deaths from breast cancer is
3302 quite strong. In looking at the evidence, the Society along
3303 with other medical groups believes that screening mammography
3304 offers an identifiable and important survival benefit to
3305 women in the age group 40 to 49 and indeed women age 40 and
3306 above. More specifically, the Society believes that the
3307 reduction in mortality and less-invasive treatments
3308 associated with early detection of breast cancer using
3309 mammography continues to warrant a recommendation of annual
3310 screening for all women beginning at the age of 40. We do
3311 agree with the task force that women should be informed of
3312 the potential risks as well as the potential benefits of the
3313 procedure.

3314 The data and literature examined by the task force in
3315 the lead-up to its November announcement on mammography is
3316 essentially the same data reviewed by an expert panel of
3317 breast cancer researchers, clinicians and epidemiologists
3318 convened by the American Cancer Society in 2003. However, in
3319 that earlier review the Society's panel considered the
3320 additional findings of a population-based study of modern
3321 mammography which showed much stronger benefits from
3322 screening compared with the more limited data examined by the

3323 task force. Translated, we actually think there is a greater
3324 benefit to the mammography screening that does the task
3325 force.

3326 In addition, since that time, a number of advancements
3327 have emerged that have shown to increase the effectiveness of
3328 mammography for women age 40 to 49. There have been
3329 improvements in the quality of mammograms resulting from the
3330 Mammography Quality Standards Act, or MQSA. There has been a
3331 shift to using digital mammograms over film mammograms, which
3332 research indicates may be more effective in screening younger
3333 women with denser breasts. The introduction of new
3334 technologies such as magnetic resonance imaging has also
3335 proven to be a particularly effective tool in high-risk
3336 women.

3337 Let me very clear on the next point. We understand
3338 acknowledge that mammography screening is not a perfect test.
3339 Indeed, it is an imperfect test but we also believe that this
3340 imperfect test is the only good test other than awareness of
3341 one's breasts to help save lives at this time. We can and we
3342 must invest in research to find better tools for detecting
3343 and treating breast cancer. Women deserve a better test than
3344 mammography. Indeed, one of the great problems right now is,
3345 there is a certain complacency or satisfaction with the use
3346 of mammography in women of all ages. We need a better test.

3347 The essential fact right now is, mammography is one of the
3348 two ways that we can use to save lives.

3349 I have to note that there has been a lot of talk about
3350 breast self-exam, and as a medical oncologist and
3351 epidemiologist who is involved in screening and reads the
3352 screening literature and a doctor who treats, let me say that
3353 we have been talking past ourselves when we talk about breast
3354 self-exam today. Breast self-exam has shown in the medical
3355 literature and as spoken against by the task force is a woman
3356 doing a specific regimen and exam once a month. It actually
3357 would take about 20 to 30 minutes for a woman to do. What
3358 most of us including the American Cancer Society have done is
3359 moved away from that regimented breast self-exam, which was
3360 advocated 20 to 30 years ago, toward something which is a
3361 little bit different, which is women being aware of their
3362 breasts and essentially being aware of their breasts and
3363 looking for differences in their breasts on an almost daily
3364 basis. This is called breast awareness. Most women indeed
3365 find their breast cancer through breast awareness, not breast
3366 self-exam. There are two randomized clinical trials that
3367 show that breast awareness and breast self-exam are
3368 equivalent in terms of mortality reduction but breast self-
3369 exam actually increases the number of unnecessary biopsies
3370 done versus breast awareness, so I prefer to advocate breast

3371 awareness.

3372 I will note also that approximately 30 to 40 percent of
3373 American women age 40 and up are currently not getting
3374 regular mammograms. In the United States, about half of all
3375 women diagnosed with breast cancer actually are diagnosed
3376 through this breast awareness and not through mammography.
3377 For many of the women who cannot get mammography, this is the
3378 only way that they can actually have any type of early
3379 detection.

3380 In summing up, we know we can do better and with your
3381 help, Mr. Chairman, we are heading in the right direction.
3382 The Affordable Health Care for America Act, recently passed
3383 by the House, will improve health care and it provides a
3384 significant investment in cancer prevention and early
3385 detection by requiring first dollar coverage for prevention
3386 in both public and private plans with little or no cost to
3387 patients. The Society and its affiliate, the American Cancer
3388 Society--

3389 Mr. {Pallone.} Doctor, I think you are concluding but I
3390 know you are 2-1/2 minutes over.

3391 Dr. {Brawley.} I am sorry. We strong support the
3392 changes you have made in the legislation that will help the
3393 task force improve the transparency and inclusiveness of its
3394 operations.

3395 Let me just stop at that point and say thank you for
3396 asking me to appear here.

3397 [The prepared statement of Dr. Brawley follows:]

3398 ***** INSERT 2 *****

|

3399 Mr. {Pallone.} Thank you.

3400 Ms. Luray.

|
3401 ^STATEMENT OF JENNIFER LURAY

3402 } Ms. {Luray.} Thank you, Mr. Chairman, Mr. Ranking
3403 Member and members of the committee. Thank you for the
3404 opportunity to testify about the recommendations of the U.S.
3405 Preventive Services Task Force. My name is Jennifer Luray
3406 and I am president of the Susan G. Komen for the Cure
3407 Advocacy Alliance, and on behalf of the patients, survivors,
3408 scientists, clinicians and advocates of the Komen family, we
3409 thank you for holding this hearing, and I also want to thank
3410 the previous task force witnesses for their honesty in
3411 discussing how this was communicated to the public.

3412 Let me begin by stating that breast cancer experts agree
3413 far more than they disagree. This is a point that we have
3414 stressed since the task force recommendations were first
3415 released. There is no debate that mammography reduces the
3416 risk of dying from breast cancer, only debate over the timing
3417 and frequency of mammography. We don't want women to react
3418 to this latest controversy as a reason not to get screened.

3419 Komen in consultation with our scientific advisory board
3420 is not changing our screening recommendations at this time.
3421 We continue to recommend that women be aware of their breast
3422 health, understand their risks and continue to follow

3423 existing screening recommendations including mammography
3424 beginning at age 40 for women of average risk and earlier for
3425 women with known risks of breast cancer. As you can imagine,
3426 Komen affiliates have been inundated with concerns that the
3427 task force recommendations could led to impediments to
3428 mammography. Many comments have come from breast cancer
3429 survivors who are diagnosed before the age of 50. This is a
3430 very typical one: ``I was 46 years old when I went in for my
3431 annual mammogram. Like so many other women, there is no
3432 history of breast cancer in my family. I was stage II, and
3433 if not for the mammogram, I would have had much more advanced
3434 cancer.''

3435 We know that mammography is an imperfect tool, but
3436 instead of stepping away from it, we must close the
3437 technology gap and come up with better methods. That is why
3438 Komen is funding promising screening research. We must work
3439 together, government, private industry, doctors and patient
3440 advocates to deliver screening technology that is more
3441 predictive and personalized but less expensive. Next year,
3442 Komen will host a national technology summit and we asked NIH
3443 to help us prepare by reporting on investments that they have
3444 made in screening technology. But let us also redouble our
3445 efforts on behalf of the one-third of women, some 23 million
3446 American women, who are not being screened due to lack of

3447 access, education or awareness.

3448 We partner closely with the CDC's National Breast and
3449 Cervical Cancer Early Detection Program to fund free clinics
3450 and mobile vans yet the GAO found that over half of eligible
3451 women for this program do not receive screening. That is a
3452 disturbing funding that underscores the need for access to
3453 affordable insurance to eliminate health disparities. And
3454 that is why Komen supports the valuable patient protections
3455 in H.R. 3962 that would increase access to affordable health
3456 insurance, prevent insurance companies from denying coverage
3457 due to preexisting conditions, protect patients from high
3458 out-of-pocket costs and increase access to mammography
3459 screening.

3460 In light of the new task force recommendations, however,
3461 we must ensure that women ages 40 to 49 will have access to
3462 the same coverage and cost-sharing benefits as women age 50
3463 and older. Even a relatively small copayment reduces
3464 mammography rates. We do understand that H.R. 3962 will
3465 create a new entity which would not be bound by the task
3466 force's guidelines and that the bill does not exclude from
3467 the minimum benefits package services that are not rated A
3468 and B, i.e., we understand that the task force
3469 recommendations are a floor, not a ceiling. But our bottom
3470 line is that women in the 40 to 49 age group may after

3471 consulting with their doctor choose to forego a mammogram but
3472 those who do choose to have one must have access to it on the
3473 same terms as women age 50 and older. The Komen Advocacy
3474 Alliance is pleased that H.R. 3962 includes patient
3475 representatives as advisors to the task force on clinical
3476 preventive services. We believe that patient advocates can
3477 help to develop and deliver effective messages about
3478 prevention and screening.

3479 We hope that these past few weeks of confusion will
3480 ultimately result in women taking more interest in their
3481 breast health, that many more underserved women will be
3482 screened and that an intensive effort to make breakthroughs
3483 in screening technology will begin anew. Thank you, Mr.
3484 Chairman.

3485 [The prepared statement of Ms. Luray follows:]

3486 ***** INSERT 3 *****

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3487 Mr. {Pallone.} Thank you.

3488 Dr. Sweet.

|
3489 ^STATEMENT OF DONNA SWEET

3490 } Dr. {Sweet.} Good afternoon, and thank you, Chairman,
3491 for this opportunity. I am Donna Sweet, a general internist,
3492 and I am pleased to present the testimony of the American
3493 College of Physicians. I am a member of the ACP's clinical
3494 efficacy assessment subcommittee, which oversees the
3495 development of ACP's evidence-based guidelines, and I provide
3496 also comprehensive medical care to hundreds of patients in
3497 the State of Kansas.

3498 Because ACP does not comment on the guidelines issued by
3499 other organizations, I am unable to express an ACP opinion of
3500 the task force recommendations but I can speak to the
3501 College's own guideline on screening mammography in women
3502 between ages 40 to 49 years which was published actually in
3503 2007. We recommend that clinicians should perform
3504 individualized assessment of risk for breast cancer to help
3505 guide decisions about screening mammography, inform women
3506 about the potential benefits and harms of mammography, and
3507 base screening mammography decisions on benefits and harms of
3508 screening as well as a women's preferences and her own breast
3509 cancer risk profile. The purpose of ACP's clinical
3510 guidelines is to facilitate an informed and educated

3511 discussion between the patient and her trusted clinician so
3512 that together they can decide on a personalized plan of
3513 screening, diagnosis and treatment.

3514 Not all women between 40 and 49 have the same risk for
3515 breast cancer. Factors that increase the risk include older
3516 age, family history of breast cancer, older age at the time
3517 of first birth, younger age at menarche, and history of
3518 breast biopsy. In my own practice I use ACP's guidelines to
3519 engage my female patients in a discussion. I explain that
3520 mammography, although a potentially valuable tool to screen
3521 for breast cancer, is an imperfect one. For some patients, I
3522 will detect cancer at a more treatable stage. It can also
3523 lead to false positives, which can lead to biopsies, scarring
3524 and potential infection. It can lead to false negatives,
3525 that is, mammography does miss cancers. It may result in
3526 aggressive treatment of cancers that may never have become
3527 life threatening.

3528 Just in the past 3 days, I have had three different
3529 patients coming to see me who have been extremely confused
3530 over this whole issue. I was able to speak to each woman's
3531 risk profile and discuss with them the benefits and possible
3532 harms of getting a mammogram. One was a 66-year-old patient
3533 enrolled in Medicare who had come in for her routine visit
3534 for hypertension and clearly misunderstood most of the

3535 debate. She has a history of a sister with breast cancer.
3536 We have been doing yearly mammograms, and she was worried
3537 that I was not going to let her get a yearly mammogram
3538 because of these new recommendations. Another 71-year-old
3539 came in and she wanted to get her mammogram, which was
3540 scheduled in February, before January 1st--why she picked
3541 that date, I don't know--because she believed that the
3542 government would soon stop her from being able to get a
3543 mammogram and she didn't want that to happen. I was able to
3544 reassure her that I did not think mammograms would be
3545 rationed. The third, however, was a very good discussion, a
3546 46-year-old woman whose mother had breast cancer. She wanted
3547 to discuss her own risk and actually was wondering if she had
3548 to have yearly mammograms. I was able to communicate to each
3549 of them that in them they did need yearly mammograms, that we
3550 did not do things from a cookie cutter. Women should not be
3551 treated all alike. And in all three cases, as I said, they
3552 did and will get their yearly mammograms but based on their
3553 individual risk factors and a discussion of why.

3554 The controversy over the breast cancer screening
3555 guidelines gives physicians the opportunity to educate their
3556 patients on the importance of evidence-based guidelines to
3557 help them make the best choice for them. It also has
3558 important lessons for policymakers. One is that the public

3559 is ill served when assessments of clinical effectiveness are
3560 politicized. The U.S. Preventive Services Task Force is a
3561 highly regarded, credible and independent group of experts.
3562 Differences of opinion on the task force recommendations
3563 should be openly discussed but it is not constructive to
3564 undermine public confidence by making ill-founded attacks on
3565 the integrity, credibility, motivations and expertise of the
3566 clinicians and scientists on the task force. Such
3567 politicization if left unchallenged could result in future
3568 assessments being influenced by political or stakeholder
3569 interest instead of by science.

3570 Second, the ACP is concerned that the public is misled
3571 by some into believing that cost was behind the task force
3572 recommendations. According to ARC, the task force does not
3573 consider economic costs in making recommendations.

3574 Third, the public needs to understand that when health
3575 plans make decisions on covered benefits, they consider many
3576 different issues of which the evidence-based guidelines are
3577 just one. Under the bill passed by the House, health plans
3578 generally will be required to cover preventive measures for
3579 which a new constituted task force on clinical preventive
3580 services have given an A or a B. No limits are placed,
3581 though, on health plans' ability to provide benefits for
3582 other preventive services and to consult with other sources

3583 in making such determinations. Rather than limiting access
3584 to prevention, my patients will benefit from having a floor,
3585 not a limit on preventive services all health insurers will
3586 be required to cover usually with no out-of-pocket cost to
3587 them. And perhaps even more importantly as has been said
3588 here today many times, millions of women who have no access
3589 to health insurance will now have coverage and the ability to
3590 actually get screening mammograms.

3591 Fourth, we need to communicate information to the public
3592 in a way that facilitates an understanding of how evidence-
3593 based effectiveness reviews support, not supplant, individual
3594 decision making by patients and their clinicians. They
3595 should be informed that they have the right to know about the
3596 current best evidence on the benefits and risks of different
3597 treatments and interventions. My patients have the right to
3598 know that physicians will offer intervention shown to
3599 positively impact health and patient outcomes and they have a
3600 right to know that we will not recommend intervention shown
3601 not to provide any benefit and possibly cause harm. Patients
3602 have the right to be treated as individuals with their own
3603 unique values and personal risk characteristics instead of
3604 being asked to follow one-size-fits-all treatment protocols.
3605 And they have to know that the evidence comes from respected,
3606 independent and credible clinicians and other scientists

3607 protected from political and other stakeholder pressure.

3608 I thank you for this opportunity.

3609 [The prepared statement of Dr. Sweet follows:]

3610 ***** INSERTS 4, 5 *****

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3611 Mr. {Pallone.} Thank you, Doctor.

3612 Ms. Visco.

|
3613 ^STATEMENT OF FRAN VISCO

3614 } Ms. {Visco.} Thank you. I am Fran Visco, president of
3615 the National Breast Cancer Coalition and a 22-year breast
3616 cancer survivor.

3617 As you know, NBCC is a coalition of hundreds of groups
3618 from around the country dedicated to our mission to end
3619 breast cancer. One of our roles is to train advocates to
3620 understand the process, concepts and language of scientific
3621 research. We analyze scientific information for our members
3622 and the public from the perspective of lay advocates.

3623 Our number one priority for many years has been
3624 guaranteeing access to quality health care to everyone. We
3625 believe we cannot achieve our mission without it. We have
3626 been working with Congress and the Administration on this
3627 goal based on our framework for access to quality health care
3628 developed over a number of years of hard work by our grass
3629 roots leadership and a key component of that framework is
3630 making certain that trained consumers have a seat at every
3631 table where decisions are made on health care policy.

3632 We believe in evidence-based approaches to health care
3633 as a key to quality care. So what is the evidence behind
3634 mammography screening? As we are all well aware and as many

3635 people have said, mammography has significant limitations and
3636 there has been much controversy over the years about
3637 screening programs: at what age are they effective, how do
3638 we balance risk and benefits, how can we communicate the very
3639 real limitations of screening and the harms associated with
3640 it. In 1997, an NIH consensus conference recommended against
3641 routine screening of women under the age of 50, but political
3642 and outside organizational pushback, not evidence, torpedoed
3643 that recommendation. So in fact, we have known the issues
3644 with screening for decades.

3645 We also know that 40,000 women will die of breast cancer
3646 this year. Tens of millions of people in this country are
3647 uninsured. Many, many millions lack access to quality care.
3648 We know we have a great deal of work to do to fix this
3649 situation. We know that breast cancer is a complex disease,
3650 that while we have learned more about the biology of the
3651 disease, in the 4 decades since mammography screening
3652 programs have been instituted, we have not yet learned how to
3653 detect life-threatening breast cancer at a point where we can
3654 make a difference how to cure it for every woman, how to
3655 prevent it.

3656 Given all of this, we were frankly stunned at the
3657 reaction of the media and many in the cancer community and in
3658 government to the task force recommendations. The task force

3659 is a body of the right experts who looked carefully at
3660 updated evidence and objectively made recommendations not
3661 that different from their prior recommendations. Given all
3662 of this, the amount of time and attention given to these
3663 revised recommendations seems just a bit unseemly.

3664 The public has increasingly put their faith in screening
3665 and early detection, even though we have never had good
3666 evidence that this would have a significant impact, but too
3667 many did not want to highlight the known limitations of
3668 mammography. They wanted simple messages: once a year for a
3669 lifetime, early detection saves lives. The overemphasis on
3670 the importance of screening caused some people to state over
3671 and over again that mammograms prevent breast cancer, and
3672 please, let us be very clear, mammograms do not prevent
3673 breast cancer.

3674 We had hoped that the task force recommendations would
3675 cause all of us to stop and think about screening, take the
3676 time to look carefully at the evidence and put screening and
3677 its limitations into proper perspective, and that can still
3678 happen. It is important also to put this in the context of a
3679 population where screening programs are for a healthy
3680 population for the millions and millions of women, the vast
3681 majority of whom will never get breast cancer. The question
3682 then is how we devise a screening program that appropriately

3683 balances risks and benefits for these healthy women.

3684 So what did the task force actually say? To women in
3685 their 40s, they said there are benefits and harms from
3686 mammography screening that you should know about and you
3687 should make an individual decision at what age you will begin
3688 a screening program. So the task force actually recommends
3689 giving women control over their own health care decisions.
3690 On self-examination, Dr. Brawley pointed out that the self-
3691 examination touched on by the task force was that routine,
3692 regimented monthly search for cancer. It has been
3693 represented as saying that women shouldn't know their bodies.
3694 Of course they should. This isn't about that.

3695 Some are concerned that the new guidelines will prevent
3696 underserved women from entering the medical system at all,
3697 and we would counter that the solution to that is to enact
3698 universal access to health care for all, not to depend on a
3699 faulty test that exposes women to radiation and the risks of
3700 false positives in order to get them to a doctor.
3701 Disadvantaged women deserve the same access as all other
3702 women to quality evidence-based care and the right
3703 information. We do need to move forward because none of this
3704 is good enough for women.

3705 We can use this and we should have used this an
3706 opportunity to educate the public about science, about

3707 evidence-based care to help alleviate the unwarranted fear,
3708 not to feed it. Some argue that public health messages need
3709 to be simple and changing guidelines will confuse women. We
3710 would argue that while messages need to be simple, they need
3711 to be truthful. Women deserve the facts.

3712 We have all heard from women over the past month who are
3713 outraged and who believe that a mammogram saved their life.
3714 These anecdotes are not evidence. They may be compelling
3715 sound bites, great media stories but they are not evidence on
3716 which we should base this Nation's public health agenda.
3717 That should be based on the type of scientific work done by
3718 the task force. We can't believe in science only when we
3719 like the answers it produces.

3720 I want to end with an anecdote. Carolina Hinestrosa was
3721 the executive vice president of the National Breast Cancer
3722 Coalition, and her breast cancer was detected early in her
3723 late 30s, probably was not life threatening and she had
3724 treatment. She died this past June as a result of her
3725 treatment. Her story and all of the anecdotes just tell us
3726 how little we know about breast cancer, how we need to be so
3727 very careful about evidence and push for the right answers no
3728 matter how unhappy we are with what those answers are. Let
3729 us save our outrage for the reality that we know too little
3730 and women deserve so much more. Thank you.

3731 [The prepared statement of Ms. Visco follows:]

3732 ***** INSERT 6 *****

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3733 Mr. {Pallone.} Thank you, and we will try to get this
3734 done before the votes. I don't know if that is possible. I
3735 will start with myself.

3736 You know, I really want to apologize to you maybe on
3737 behalf of Congress, if I could that, because I was listening
3738 to what Dr. Sweet said, and you are absolutely right, that
3739 this has been totally politicized and I guess, you know, the
3740 problem is that Congress is political and maybe this isn't
3741 the vehicle for it. I mean, it is sort of interesting to see
3742 that in the first panel most of the members were here and
3743 most of the media were here and now we are on the second
3744 panel, which is not the political panel, and the situation is
3745 reversed, you know. And Ms. Visco talked about how
3746 essentially--and I don't want to put words in your mouth but,
3747 you know, after listening today, I can't help but say I am
3748 not sure there really was that much of a difference between
3749 what the task force said now versus what the recommendation
3750 was a few years ago or even between what you are saying and
3751 the previous panel said. It is just amazing how these
3752 differences, if there are any, have been exaggerated and
3753 politicized. I guess that is just the nature of the process
3754 around here so I don't know what we can do about it or make
3755 it any different, and I say that out of sadness, really.

3756 Let me ask you just a couple questions because I know
3757 the time is running out here. I will start with Dr. Brawley
3758 and also Ms. Luray. A few days after the task force
3759 recommendations, the Cancer Society issued a statement urging
3760 that health care reform create a transparent and evidence-
3761 based process for making task force recommendations, and I
3762 guess Komen echoed those concerns. But your statement, Dr.
3763 Brawley, listed a number of changes you would like to see in
3764 health reform and you discussed the importance of
3765 transparency and the task force's process of arriving at its
3766 recommendations. Now, I believe that the bill H.R. 3962
3767 actually addresses those concerns, so I wanted you to really,
3768 you know, answer that. I mean, the importance of stakeholder
3769 input and those recommendations you made about that, does the
3770 bill H.R. 3962 address those concerns?

3771 Dr. {Brawley.} Well, sir, I believe that it does. I
3772 think the most important thing is that the task force
3773 continue to provide objective evidence but also provide the
3774 objective evidence in an open arena where people can actually
3775 see the process.

3776 Mr. {Pallone.} And then Ms. Luray, from Komen's
3777 perspective, do you agree that the provisions in H.R. 3962
3778 would improve the task force recommendations process? I
3779 mean, you don't have to just say yes or no, but go ahead.

3780 Ms. {Luray.} Sir, actually yes. I mean, H.R. 3962 has
3781 a stakeholder panel that would advise the new clinical
3782 services task force and we think that makes a lot of sense.
3783 Such a panel I think could have helped to really communicate
3784 the findings of this task force, and even though people might
3785 not--there still may have been disagreement within the
3786 scientific community, I think the message could have been
3787 delivered in a way that was much more helpful to women and
3788 their providers.

3789 Mr. {Pallone.} I was just trying to make the point
3790 really that the issues that the American Cancer Society and
3791 Komen raised months ago well before these task force
3792 recommendations emerged, you know, that we felt on the House
3793 side we were listening to, and I am trying to point out that
3794 as a result of your efforts and this collaboration that the
3795 bill contains the changes to the task force necessary to
3796 improve the process. That was my only point.

3797 And then the second one, and I am going to ask all of
3798 you this quickly, and that is, as you know, my colleagues on
3799 the Republican side have repeatedly raised concerns about the
3800 House-passed health reform bill in light of the task force
3801 recommendations, and they have repeatedly asserted that H.R.
3802 3962 somehow--well, I don't want to put words in their mouth
3803 but I think there is a suggestion that somehow the bill, you

3804 know, is a step backward on the issue of breast cancer or
3805 breast cancer screening, so I just want to ask each of you on
3806 the whole, do you think the House-passed health reform bill,
3807 H.R. 3962, is actually more helpful, is a step forward or a
3808 step backward with regard to women with breast cancer and
3809 these screening issues? And I will just ask each of you to
3810 comment on that briefly.

3811 Dr. {Brawley.} Mr. Chairman, if I can just say there
3812 are thousands of American women who die today because of lack
3813 of access. There are thousands of women who die today
3814 because they are detected early but they don't have insurance
3815 to get access to reasonable and good care. Any effort that
3816 gets those people reasonable and good care is a good effort
3817 that is going to save lives. We have been talking about the
3818 number of lives that would be lost due to this recommendation
3819 of, maybe it was a recommendation not to get screened for
3820 women in their 40s, maybe it wasn't, but the number of lives
3821 that we could just fix, that we could just save through a
3822 logistical fix is tremendous. Just get them access to care.

3823 Mr. {Pallone.} Ms. Luray?

3824 Ms. {Luray.} I would add in addition to the universal
3825 access that Dr. Brawley mentioned, also the limitations on
3826 preexisting conditions and out-of-pocket costs are currently
3827 a huge burden for breast cancer patients and one of the main

3828 items that our advocacy community throughout the country asks
3829 that we followed very closely in health care reform, and
3830 those protections are included in H.R. 3962.

3831 Mr. {Pallone.} Thank you.

3832 Dr. Sweet?

3833 Dr. {Sweet.} Absolutely. This bill will help the
3834 health of American women with and without breast cancer.
3835 There are a number who do manage to get diagnosed and then
3836 have no access to reasonable care, as Dr. Brawley said. The
3837 number of women even in my own practice that are locked into
3838 jobs that they would rather not stay in, they can't move
3839 because of lack of health insurability. They know if they
3840 leave their job and leave that health insurance, when they
3841 try to get the next one they are going to be uninsurable, and
3842 I think the fact that this bill addresses getting rid of
3843 preexisting conditions and guaranteeing health insurance to
3844 all at a reasonable cost is extremely important.

3845 And then the third thing is, the bill does address some
3846 of the health care workforce issues. Access means having a
3847 trusted clinician, as the woman from Florida said, and there
3848 are not enough of the primary care people out there anymore
3849 to be trusted clinicians for all the people we are going to
3850 give access to, and your bill does put in provisions to have
3851 an improved, I think, primary care workforce by improving

3852 payment and other things. So I think this bill is an
3853 absolute improvement. The millions of lives that we lose
3854 because of true lack of health insurance is much, much
3855 greater than what we are going to lose by a few women who
3856 decide not to have screening once they think about it.

3857 Mr. {Pallone.} Thank you.

3858 Ms. Visco?

3859 Ms. {Visco.} Well, as you know, Mr. Chairman, the
3860 National Breast Cancer Coalition has endorsed the House bill
3861 and we completely support it. We believe it is an incredibly
3862 important tool in eradicating breast cancer. We think it
3863 will move us forward tremendously in getting everyone access
3864 to health care and helping save lives from breast cancer, and
3865 I hope that this controversy does not cause the Congress to
3866 interfere in any way with the independence and objectivity of
3867 the task force. We cannot allow that to happen. We need
3868 evidence-based quality care. And I also truly wanted to ask
3869 the question that if the bill was changed to mandate C-level
3870 recommendations in a basic benefit package if everyone who
3871 spoke to that issue today would then support the bill. I
3872 tend to doubt that. So I really think that if we want to
3873 save lives, if we want to move forward, if we want to end
3874 breast cancer, we need guaranteed access to health care
3875 reform and the House bill is very important to achieving that

3876 end.

3877 Mr. {Pallone.} Thank you.

3878 Let me mention, I was under the impression we had votes.

3879 In fact, we are in recess on the Floor so there is actually

3880 not any real time constraints here.

3881 Chairman Dingell.

3882 Mr. {Dingell.} I want to thank the panel and

3883 congratulate them for their very fine presentation. I am

3884 going to begin by reading something which appeared, and you

3885 will recognize this, in the statement of Dr. Sweet. ``Under

3886 Affordable Health Care for America Act, H.R. 3962, passed by

3887 the House of Representatives, a new task force on clinical

3888 preventive services would be created which would take on many

3889 of the responsibilities of the current U.S. Preventive

3890 Services Task Force. This new entity will have an important

3891 role in making evidence-based recognitions on preventive

3892 services that insurers would be required to cover but the

3893 only binding effect the recommendations of the task force

3894 will have on health plans is a requirement that preventive

3895 measures for which the task force has been given an A or B

3896 rating must be covered. The bill does not give the task

3897 force and the federal government itself any authority to put

3898 limits on coverage, ration care or require that insurers deny

3899 coverage. Health plans could offer additional preventive and

3900 other benefits of their choosing and no restrictions would be
3901 placed on their ability to consider recommendations from
3902 sources other than the task force in making such coverage
3903 recommendations. And now, if you please, starting with you,
3904 Dr. Brawley, do you agree with that statement?

3905 Dr. {Brawley.} Well, sir, I am not a policy person, I
3906 am just a simple doctor.

3907 Mr. {Dingell.} Well, just yes or no.

3908 Dr. {Brawley.} But I do agree with your statement.

3909 Mr. {Dingell.} Thank you. I am not trying to lay traps
3910 here. I want that clear.

3911 Ms. Luray?

3912 Ms. {Luray.} Yes, Congressman. As I said in my
3913 testimony, we also see the role of the task force as creating
3914 more of a floor than a ceiling, so in that sense, I would
3915 agree with you.

3916 Mr. {Dingell.} Obviously, Dr. Sweet, you agree.

3917 Mr. {Sweet.} Yes, I do, and I have some very good
3918 policy people behind me that agree. That is important too.

3919 Mr. {Dingell.} I am just trying to lay to rest some of
3920 the nasty untruths that are being circulated about this
3921 legislation.

3922 Ms. Visco?

3923 Ms. {Visco.} Yes, I agree.

3924 Mr. {Dingell.} Now, each of your organizations has
3925 supported the legislation, H.R. 3962. Do you have any
3926 apprehension that the provisions that we are discussing today
3927 or any other part of this legislation will trigger a nasty
3928 program of rationing health care?

3929 Dr. {Brawley.} No, sir.

3930 Mr. {Dingell.} Ma'am?

3931 Ms. {Luray.} No, sir.

3932 Dr. {Sweet.} No.

3933 Mr. {Dingell.} Ms. Visco?

3934 Ms. {Visco.} No.

3935 Mr. {Dingell.} Mr. Chair, I guess that is all the
3936 questions I have got. I think we have laid to rest some of
3937 the unfortunate misapprehensions of our colleagues and I can
3938 only express my great regret that they are not here to
3939 participate and to learn from the wisdom of our witnesses.
3940 Thank you, Mr. Chairman.

3941 Mr. {Pallone.} Thank you, Chairman Dingell.

3942 Mr. Green.

3943 Mr. {Green.} Thank you, Mr. Chairman. I apologize for
3944 being in and out but we have both Secretary Gates, Secretary
3945 Clinton and the Joint Chiefs of Staff and the Foreign Affairs
3946 Committee talking about Afghanistan, although this is such an
3947 important issue for the district I represent.

3948 I represent a majority Hispanic district that is also a
3949 federally medically underserved area, and we face many, many
3950 issues to encourage women to see primary and preventive care
3951 services. We rely on our Harris County Hospital District and
3952 our community-based health clinics to provide the services
3953 and screening for our constituents. I worry that the revised
3954 recommendations will discourage the safety-net providers from
3955 aggressively educating and screening for breast cancer in
3956 these underserved populations. I often say we have one of
3957 the premier medical centers in the world including M.D.
3958 Anderson Cancer Center located in our backyard but my
3959 constituents can see the medical center, it is just hard for
3960 them to get there because they are substantially uninsured.
3961 And unfortunately, most do not have the access to the medical
3962 services. Could you briefly speak about the current access
3963 barriers for breast cancer screening minority in those
3964 residing in medically underserved districts face and what
3965 impact these recommendations may have on these populations?
3966 Dr. Brawley?

3967 Dr. {Brawley.} Well, Congressman, I hope the
3968 recommendations of the task force will have very little
3969 effect on your constituents with the exception that perhaps
3970 the discussions that we have in the news over the last few
3971 weeks will bring breast cancer much more to the forefront. I

3972 have some hope. I said in my testimony about half of all
3973 women in their 40s and 50s who are diagnosed with breast
3974 cancer are actually diagnosed not through a traditional
3975 breast self-exam but through what we prefer to call breast
3976 awareness; they notice when they're getting dressed or when
3977 they in the shower, that sort of thing. Perhaps people will
3978 hear this national conversation we have had and actually be a
3979 little bit freer to come forth and get evaluated by a doctor
3980 should they find an abnormality. I also hope that people
3981 will continue listening to the other organizations like the
3982 American Cancer Society that have said that women age 40 and
3983 above should continue getting mammography on an annual basis
3984 but also I think it is important to realize that there is
3985 controversy about how good mammography is. And I will just
3986 leave you with one last statement. Mammography is imperfect
3987 but right now it is the best technical tool that we have
3988 other than awareness for early detection.

3989 Mr. {Green.} Mammography is much more valid than the
3990 PSA test is for males.

3991 Dr. {Brawley.} Oh, yes, absolutely. You are absolutely
3992 correct. There are nine studies in the literature that show
3993 that mammography saves lives. There are two randomized
3994 trials on PSA, one that shows it saves lives and another that
3995 fails to confirm that first finding.

3996 Mr. {Green.} Ms. Luray?

3997 Ms. {Luray.} Congressman, I would like to comment on
3998 that as well. As you know, we partner closely with the CDC
3999 and other providers to support free clinics and mobile vans
4000 in districts such as yours, and so we are very familiar with
4001 the kinds of constituents you have and really a very fragile
4002 relationship they have with the health care system, many of
4003 whom are uninsured, and so we have been working very hard in
4004 these last few weeks to make sure that the hullabaloo around
4005 the release of these recommendations doesn't cause women who
4006 really already have that fragile relationship who may just be
4007 coming into mammography clinics for the first time in their
4008 lives to say well, gee, maybe I don't need to come at all.
4009 So we are working very hard to ensure that that message
4010 doesn't get twisted around and be taken as a sign that
4011 mammography can't provide help to them.

4012 Dr. {Sweet.} And I would hope as a clinician doing
4013 this, just as in my practice, women will come in talking
4014 about it. There is nothing more likely to get a patient to
4015 bring something up than to see it on CNN or in the
4016 controversial position and maybe it will sort of nudge many
4017 of our clinicians who perhaps haven't taken the time to have
4018 that discussion to actually make it an individualized,
4019 personalized discussion with that woman about what she needs

4020 along with the fact, as we said earlier, that many, many of
4021 those women if health care reform can occur and we do have
4022 access to health insurance for the poor and the people who
4023 need it the most, we will be able to offer screening to some
4024 of these women in a clinical situation that have never had
4025 that available. So I truly see this as a critical time, and
4026 the hullabaloo, it is a political sort of system and there is
4027 a lot of things out there that just aren't true, I think, but
4028 it does bring women to discuss it, and once they bring it up,
4029 then the doctor, the clinician has to follow through.

4030 Mr. {Green.} Thank you.

4031 Ms. Visco?

4032 Ms. {Visco.} Yes, we are working very, very hard on
4033 making certain that everyone in this country has guaranteed
4034 access to quality health care, and that will certainly solve
4035 the problem. We are spending the majority of our resources
4036 on that issue. There are also a number of studies out there
4037 looking at what are the barriers to access for underserved
4038 population, why do they not access the health care system,
4039 and of course, one of the reasons is, because they don't have
4040 coverage for treatment. That is why the National Breast
4041 Cancer Coalition a number of years ago worked very hard to
4042 get enacted into law the CDC Breast and Cervical Cancer
4043 Treatment Act we knew that screening even if you do get a

4044 mammogram, you have to have access to treatment if you want
4045 to save a life. And so that is our number one concern and
4046 that is where we focus most of our work.

4047 Mr. {Green.} Thank you, Mr. Chairman. I know I am out
4048 of time. My concern about the furor over this is that women
4049 will make that decision not to, and again, early detection is
4050 still the answer, and particularly in underserved
4051 communities. Thank you, Mr. Chairman.

4052 Mr. {Pallone.} Thank you, and I think that concludes
4053 our questions. I just want to thank all of you again. Once
4054 again, I said to the previous panel, you certainly cleared up
4055 a lot of the misconceptions. I just hope we can get that
4056 message out to the media, which is often difficult.

4057 Some of the members may submit written questions, and we
4058 try to get those to you within the next 10 days, so you might
4059 get some additional questions. Of course, the clerk would
4060 notify you of that and the time period to get back to us.
4061 But I do want to thank you again.

4062 Without objection, this meeting of the subcommittee is
4063 adjourned. Thanks.

4064 [Whereupon, at 3:05 p.m., the subcommittee was
4065 adjourned.]